

User Manual

EM-KW-SW-IFU | Revision: 12.1

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Introduction

Purpose of this Manual

This manual provides instructions for use and describes the various functions and the features of the KUDUwave. It also describes how all the technologies involved in the KUDUwave's function work in conjunction.

This manual is not intended as a method to train KUDUwave operators to be healthcare professionals or to act as such. An operator may not act as a professional unless qualified to do so.

Medical Purpose

The medical purpose of the KUDUwave is to assist in testing the behavioral auditory responses of a patient and to determine hearing thresholds which will assist in diagnosis of hearing impairments.

Patient Populations

The KUDUwave is suitable for testing all patient populations, regardless of gender, age, weight, general health or ethnicity other than the following:

- very young children (suitable for ages 3+)
- patients with physical or mental disabilities that prevent them from signaling a response to a test audio tone presented to them.

During testing, patients should be calm and comfortable and free from distraction.

Device Description and Application

The KUDUwave is a mobile audiometer which provides compliant testing outside a certified sound room. The KUDUwave uses built-in sound attenuation and active noise monitoring to achieve this while including all the functions found in a typical audiometer.

The KUDUwave is suitable for open air testing in areas free from excessive noise. It must be kept dry and free from dust for reliable, safe operation. The KUDUwave is a highly sensitive and technically complex device that should be treated with care. We highly recommend that you use the robust, shock-absorbing, carry case to transport your device. Mark the package as FRAGILE when it is in transit.

Frequent Usage

The KUDUwave is suitable for continuous, regular use. Analysis of all its functions confirms that there is no risk to either the operator or patient. These functions are detailed within this document and include measures to minimise any potential risk.

Applied Parts Details



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

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



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

Operator Training Requirements

Basic Requirements

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

Training and Certification Requirements

eMoyo provides online training for both facilitators and operators of the KUDUwave. Visit the link below to view the online KUDUwave Academy. The operator will receive a certificate of completion after successfully completing their training.

https://sites.google.com/emoyo.net/kuduwave-academy/home

Description of Symbols

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

Symbol	Description
	Manufacturer, eMoyoDotNet (Pty) Ltd, 179 Beyers Naude Drive, Johannesburg, South Africa
EC REP	EC Authorised Representative, PSF Medical BV, Marten Messweg 8, 3068AV Rotterdam, The Netherlands
C E 0086	Symbol for CE Mark with Notified Body Number. Conforms to Medical Device Directive 93/42/EEC.
*	Symbol designating Type B Applied Parts according BS EN 60601-1.
▲ or ▲	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
cr 🚱	Consult instructions for use. Indicates the need for the user to consult the instructions for use.
2	Single use only.
SN	Serial number.
LOT	Batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.
IP20	Ingress protection.
Ť	Keep Dry. Indicates that the medical device needs to be protected from moisture
1	Temperature limit. Indicates the temperature limits to which the medical device can be exposed safely.
) L	Humidity limit. Indicates the range of humidity to which the medical device can be safely exposed.
Ţ	Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully.

Getting Started

Get to know your KUDUwave[™]

All KUDUwave devices have the following capabilities:

- Pure Tone Air Conduction Testing
- Active Noise Monitoring
- Automated and Manual Testing
- Testing Protocols
- Patient Management and Medical Record Suite
- Telemedicine Enabled

Your KUDUwave can be one of the following configurations, which determines what tests it can perform and extra features it may have.

KUDUwave [™] Prime	KUDUwave™ Plus	KUDUwave [™] Pro
Screening	Screening	Screening
-	Diagnostic (Bone VIbrator Included)	Diagnostic (Bone VIbrator Included)
-	-	Monitoring of Ototoxicity
-	-	Extended High Frequency (up to 16kHz)

KUDUwave[™] Serial Number

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

Unpacking the KUDUwave[™] Hardware

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

Adjustable Headband Fits all sizes

Bone Conductor

Sound Blocking Ear Cup

Active Noise Monitoring Real-time automatic detection and action against peak noise levels

Talk Forward Patient communication with the headset in place

LED Indicators

Circumaural Ear Seal Secure, comfortable fit

Dual Audiometers One per side



Packaging Checklist

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

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

Software Installation

If your KUDUwave controller PC was professionally configured by eMoyo, all the necessary software will already be installed. Should this not be the case, or should you wish to install the software on more than one computer, please visit the KUDUwave website (<u>www.kuduwave.com</u>). Click on the software link either on the top bar or on the tab in the right hand corner.





Complete the form, download the software from the provided link and run the the install file.

Use the chat function in the bottom right hand corner of your screen to chat to us live if you need help.

Software Launch



You should find this KUDUwave 5 shortcut on your PCs desktop. Alternatively you can find KUDUwave 5 under programs in your start menu. Click the icon to launch.

Warning: The KUDUwave 5 software must be launched with administrator rights in Windows 7, 8 and 10. To do this right click on the KUDUwave 5 icon and select "Run as administrator".

Software Language

The software is currently available in English, Spanish, French, Portuguese, Bahasa and Dutch.

Preparing the Test Environment

It is essential that the test environment is as quiet as possible in order to ensure test compliance and that the patient is not disturbed. The KUDUwave software will indicate if ambient noise is too loud and is disrupting the test. The test environment should be free from any distractions that may disturb either the operator or the patient as these may result in incorrect test results.

Preparing and Positioning the Patient

The patient should be seated in the test environment near to the test computer but should not be able to view the the computer screen. Care should be taken to ensure the patient is comfortable so as to minimise distractions.

If the patient is 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 calmed and reassured before testing.

Preparing the KUDUwave[™] Equipment

Connecting the KUDUwave™

Plug the larger USB plugs into the USB ports of the PC. Plug the smaller plugs into the corresponding ports of the KUDUwave headset.



The KUDUwave will indicate the right side with a red light and the left side with a blue light when powered. You will now be able to begin testing. If the device is not plugged in, it will not be possible to proceed to testing until the device is properly connected.

Ensure that the cables are positioned out of the way so that they are not tripped over or tangled. For safe storage and to extend the lifespan, please wind the USB cables in large loops when returning to the case for storage.

Device Drivers

KUDUwave is a plug and play device and all drivers will automatically begin installing when KUDUwave's USB cables are plugged into a PC. If the device is plugged into a different USB port on the same computer for the first time, then some drivers will be installed again. Please wait until Windows notifies you that the drivers have been installed successfully.

Warning: If you launch the KUDUwave software before the drivers were installed, the KUDUwave software will prompt you that it could not find the device, even though the device is plugged in. Contact Support should the drivers still not find the device.

Ear Inserts

Ear tips must be firmly attached to the plastic tubes using the brass couplers. Ear tips are intended for single use and should be disposed of as medical waste after testing. eMoyo will not be held liable for any complications if eartips are reused.

USB Patient Response Button

Connect the USB cable of the response button to the Left ear cup USB port, or into a third USB port in the PC. A light will pulse (come on and switch off again) if connected correctly.

Positioning the KUDUwave[™] Headset

When not in use, place the headset on a stable surface. Cleaning and disinfection can be done with cleaning wipes which are intended for cleaning plastics, that comply with EN1276.

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

Step 1: Initial Position

Gently place the KUDUwave headset on the patient's head, resting just above both ears. Ensure the headset is positioned correctly i.e. the left ear cup must be on the patient's left hand side and vice versa.

Step 2 Squee: and inc

2

Step 2: Insert Eartips

Squeeze and roll the foam tip down to its smallest diameter using your thumb and index finger. Pull the ear by the pinna (up and back in adults and down in children) and insert the foam tip into the ear canal. Ensure that the ear tip is fully inserted. Hold the ear tip in position while the memory foam expands to fill the ear canal. This will ensure that the eartip sits firmly in place. A loosely fitted ear tip or shallow insertion will result in testing inaccuracy.





Yellow eartip inserts are intended for most ear canal sizes while beige eartip inserts are intended for very small ear canals (i.e. children).

Warning: Improper selection or insertion of eartips may affect test results.



Step 3: Final Position



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

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

Step 4: Bone Vibrator Positioning



If the bone vibrator is to be used, the metal headband must be adjusted and placed over the patient's head. Ensure that it is positioned carefully on the patient's forehead, in line with the middle partition between the eyebrows or in line with the centre between their eyes.

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

Step 5: Patient Response Button

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

Remote Testing

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

To test remotely:

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

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

Getting Started with the KUDUwave[™] Software

Practitioner Details



Run the KUDUwave 5.0 application by double clicking on the **second** icon on your desktop or start bar, and enter your details to continue. These details will appear on all reports and audiograms. You

bar, and enter your details to continue. These details will appear on all reports and audiograms. You can also select your language of choice. Press enter or click the "Go" button.

KUDU	vave™
Details to appear o	n reports
Full name	
Name of professional as:	sociation
Registration number	
Go	English

Home Page

Your Portal to Patient Management

The home page appears as below with 3 main sections.

Folders	AVC [®] <u>Ple</u> Hi eMoyo	ease help us to make this so	oftware the best by	giving us feedback Check for a new version
Records Records 0 → 2013 -→ 2014 -→ 2015 -→ 2015 -→ 2017 0 → 2017 0 → 2017 0 → 2018 -→ A	Let's get s Scan patier QR code	tarted	×-check	Support
- 술 B - 술 C 8-술 Company 8-술 Company - 술 Company - 술 Company	#1 Recent #2 #3 #4	patients]	Search
1 2	2	3		
X-check				
🗱 Settings				

1. System Menu

Here you have access to:

- Home (return to the home page)
- Records (return back to the folder you were busy with)
- X-check (built in automated calibration verification tool)
- Settings (backup data, personalise your reports and more)

2. Folder Management Pane

Folders can be created and managed here. Organise your patient files and make record retrieval quick and easy.

It is recommended to organise patients either under alphabetical folders, organisation / company names or according to the date (month/year) they were tested.

3. Data View Pane

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A series of quick links are made available for your convenience.

- Scan QR codes (for quick retrieval of patient data)
 - Add new folders (which in turn gives access to add new patients)
- X-Check (built in automated calibration verification tool)
 - Support (navigates to our website to contact the support technicians)
 - Search (filter through your recent patients listed below the search tool)

Give us your feedback

Help us improve the KUDUwave by giving us your feedback.

In the software is a link to a short 5 min survey, where you can let us know how you are experiencing your mobile audiometer and its accompanying software. We'd appreciate your feedback so we can improve your KUDUwave experience.

KUDUwave

Please help us to make this software the best by giving us feedback Check for a new version

Or contact us through our website : www.kuduwave.com.

Working with Folders

Management of folders is done within the Folder Management Pane

Creating Folders and Subfolders

To create a folder click:



Add main folder

Enter the name of your folder and select "OK" to save.

Patient details will only be displayed if the folder they fall under is selected. Once a folder is selected, a subfolder can be created by clicking the + icon next to its name.



Accessing Folders

Access a folder by clicking on the folder name. Double click on the folder name or click on the + icon to view subfolders. To hide subfolders, double click again on the folder icon or click on the - icon. Selecting a folder or subfolder will display its contents in the right hand pane.

	2	2018					Smart fold	l <u>ers</u> I 7 industrial healt	B5449A1C-413ADE Icare hearing conservation progr	F6 ams
Folders +===== 2013	P	atients			+ Add patient	Import	Export	Move	Find	
-======================================		Name	Surname	Date of Birth	Sex	ID/SS	P	assport	QR code	^
-== 2015		steve	NoSumame	1899/12/30	Unknown				2937A8A06E964D19	
-== 2010	Г	test	NoSumame	1899/12/30	Unknown				B3398DCE89E546D1	
e- ≅ 2018 (00									

Smart Folders

The KUDUwave uses multiple criteria (OSHA, SANS, WHO etc.) to develop testing protocols and assistive interpretations of results. The KUDUwave also uses these criteria to separate which test protocols are most needed and used by a particular industry.

To streamline the process of choosing which tests need to be done with which patients, you can change the default settings of the folder. Change the smart folder type by selecting the folder and click on "Smart folders" in the top right hand corner.

		Example		\sim	Smart fold Default folder	ers	B5449A1C-5C3206D0
Home	Folders ⊕	Patients	+ Add patient	Import	Export	Move	Find

Under the "Smart folder type" there are six available smart folder configurations, each with their own user interfaces and pre-selected tests for all patients in this folder. Select one option.

		KUDUVAVC Mining out of houring Smart folder settings	
Home Records	Folders ⇒ 2013 ⇒ 2014 ⇒ 2015 ⇒ 2016 ⇒ 2017 ⇒ 2017 ⇒ 2017 ⇒ 2017 ⇒ 2018 ⇒ 4 ⇒ 6 ⇒ 2018 ⇒ 2018 ⇒ 2018 ⇒ 2018 ⇒ 2019 ⇒ 2019 ⇒ 2017 ⇒	Smart folder type Required fields and tabs Significance items to show Users and security Smart folder type Default folder type Default folder type Occupational / industrial healthcare hearing conservation programs Hearing screening for schools (W.H.O.) Ototoxicity monitoring program for MDR-TB Hearing screening for humanatarian outreach projects Hearing conservation screening for SAPPI Hearing conservation screening for SAPPI	

Under "Required fields and tabs", you can customise the selected smart folder type by selecting which details you want to make required fields.

KUDU\vav	Smart fold	er settings	
Smart folder type	Required fields and tabs	Significance items to show	Users and security
Required field	ds that must be filled f Birth)	in for all patients in thi	s folder
Company		~	
Department	:/Ward	~	
Job title		~	
Number		~	
Show tabs fo	r all patients in this f essaging n	older	

Under "Significance items to show", you can select the labels which are available to use for the tests generated in this folder.

Required fields and tabs	Significance items to show	
	Significance items to show	Users and security
following "Note / te	st" significance option	s
e (Previous) a (Current) e (Deleted) ison ng titc ist isstone		
I/Milestone up eline iitoring LH		
	e following "Note / te e (Previous) e (Current) e (Deleted) ision disc to to to to to to to to to to	e following "Note / test" significance option (Previous) (Current) e (Deletad) sion s

Under "Users and security", you can contact eMoyo by completing the online form, to setup folder

security providing restricted access to particular folders.



Click the save icon to save changes. The folder type will be displayed at the top right hand corner of your screen.

Smart folders	B5449A1C-5C3206D0
Occupational / industrial he	althcare hearing conservation programs

How to use the MDR-TB Screening Smart Folder

This folder specifically caters for the MDR-TB set-up in South Africa, but can be applied to other projects across the world.

Which tests can I perform in this folder type?

- Extended high frequencies with the KUDUwave Pro[™].
- Incorporates questionnaires for the patient, including records of which medication the patient is currently receiving.
- Automatically continues with the test after the questionnaire is completed.
- Assistive Interpretation done after testing and any indication of ototoxicity is highlighted in a report.

How do I start testing?

- 1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
- 2. This next menu will appear for you to select the relevant test you want to perform. (Baseline/Initial, Monitoring or Exit, depending on the patient and where they are in the program stages) You can return to the normal interface by clicking on the button "Select a new Test / Note / Interpretation / Notification" in the top left corner. Once you click on a button, the automatic testing sequence will begin:
 - Questionnaire / Form
 - o Test
 - Assistive Interpretation

- 3. At any point during the test you can manually take over by clicking on pause.
- 4. Save after each step.



- As a patient enters the MDR-TB monitoring program (i.e. it is their first visit to the clinic), an initial / baseline form, test and assistive interpretation must be recorded.
- If the patient has already completed their baseline test (for example he was first tested a year ago), manually enter these results into the KUDUwave database by clicking: Enter baseline / initial test.

NOTE: You cannot perform a Monitoring or Exit test until the patient's full history is manually entered into the system.

- Once the manually recorded results are saved in the database, you can continue on to the monitoring test.
- When the patient arrives for their next follow-up visit, complete the monitoring form, test and interpretation.
- Once the patient is ready to exit the program, complete the exit form, test and interpretation.

How to use the Occupational (Industrial) Healthcare smart folder

Using this smart folder type simplifies the method of testing to identify early hearing loss and to calculate measures for compensation.

Which tests can I perform in this folder type?

- Milestone Baseline & STS Screening (Standard Threshold Shift)
- PLH Baseline, Screening and Exit (Percentage Loss of Hearing)
- A combination of both Milestone & PLH Baselines or STS & PLH Monitoring

How do I start testing?

- 1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
- This next menu will appear for you to select the relevant test you want to perform. The test
 will begin automatically when you click on a button. You can return to the normal interface
 by clicking on the button "Select a new Test / Note / Interpretation / Notification" in the
 top left corner.
- 3. At any point during the test you can manually take over by clicking on pause.
- 4. Save the test once it is completed.

ollect baseline tests					
PLH (ZA) baselines:	Do 1st	Do 2nd	(Do 3rd)	Enter manual	
Milestone baselines / Audiometric zero:	Do 1st	Do 2nd		Enter Manual	Interpret
Combine PLH (ZA) and Milestone baselines:	Do 1st	Do 2nd	(Do 3rd)	Enter Manual	
llect entry/screening/follow-up/perio) screening:	H (ZA) and S	TS monitoring	g tests	Interpret
lect entry/screening/follow-up/peric PLH (ZA STS) screening: monitoring:	Do Do	TS monitoring	g tests	Interpret

If you want to collect a baseline result, select the type of test from the top section:

PLH (ZA) baselines:	Do 1st	Do 2nd	(Do 3rd)	Enter manual	
Milestone baselines / Audiometric zero:	Do 1st	Do 2nd		Enter Manual	Interpret
combine PLH (ZA) and Milestone baselines:	Do 1st	Do 2nd	(Do 3rd)	Enter Manual	

- Complete two baseline tests, or even a third if you suspect the patient is malingering.
- Click "Interpret" to use the assistive interpretation tool.
- Manually enter the baseline results of the patient if they were tested before, but are new in the KUDUwave database.

If you want to collect a follow up result, select the type of test from the bottom section: Collect entry/screening/follow-up/periodic/exit PLH (ZA) and STS monitoring tests

PLH (ZA) screening:	Do	Interpret
STS monitoring:	Do	Interpret
Combined PLH (ZA) screening and STS monitoring test:	Do	Interpret

- If the patient already has a baseline result in the database, continue to complete the follow up test (screening /monitoring).
- Click "Interpret" to use the assistive interpretation tool.

How to use the School Screening Smart Folder

This folder is a solution for mass screening of children, to quickly identify those who need help early on. The automatic test is designed to be efficient, sweeping four frequencies between 25 dB HL and 90 dB HL.

Which tests can I perform in this folder type?

• Pure tone test which finds thresholds from 25 - 90 dB HL at 500Hz, 1kHz, 2kHz and 4kHz.

How do I start testing?

- 1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
- This next menu will appear for you to start the automatic test. You can return to the normal interface by clicking on the button "Select a new Test / Note / Interpretation / Notification" in the top left corner.
- 3. At any point during the test you can manually take over by clicking on pause.
- 4. Save the test once it is completed.

Select a new Test / Note / Interpretation	n / Notification	x
Find thresholds between 25dBH	IL and 90dBHL at 500Hz, 1kHz, 2kHz and 4kHz	
Do screening test		

How to use the Humanitarian Screening Smart Folder

This folder is designed to screen masses efficiently and effectively. The quick automatic test sweeps through 5 frequencies between 25dB HL and 90dB HL.

Which tests can I perform in this folder type?

• Pure tone test which finds thresholds from 25 - 90 dB HL at 500Hz, 1kHz, 2kHz, 4kHz and 8kHz.

How do I start testing?

- 1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
- 2. A similar menu as the school screening smart folder above will appear for you to start the automatic test. You can return to the normal interface by clicking on the button "Select a new Test / Note / Interpretation / Notification" in the top left corner.
- 3. At any point during the test you can manually take over by clicking on pause.
- 4. Save the test once it is completed.

Working with Patients

Add and manage your patient data within the Patient Interface. The patient interface will appear when a new patient is created or by double clicking on the patient file in the data view pane of home page.

Adding a New Patient

To create a new patient, first select or create the folder under which the patient should be stored,

then click **+ add patient**. This will open the Patient Interface where you can add the patient's details in the Patient Data Pane (4). Any test data can be previewed in the Test Data Pane (5). To edit patient details, select the field by clicking in the field and enter the new information. All new tests will have the corrected information.

	Patient Example (38yr Male)	export all data of this patient delete this patient
Home Records	Patient details DEST/CHAC/FARMACRYSTASSACCO Name Vacios and messaging Email Meterification Notes In mice 2012 Email Meterification Notes In mice 212456/789 Passent Example Date of Early In mice 2000/01/01 See Made Company Default In mice In mice In mice In mice See time Desentimetric Desentimetric Weid / Of Or Other Namber 1 See time Desentimetric Desentimetric Namber 1 Namber 1 History Note / Test Date and time Significance Type	3 No directi notes. Cick on *+ Note / Test*
1 ×-check	4	5

Tips:

- Click the tab key to quickly navigate between fields.
- After entering a South African ID number, the date of birth, age and gender will automatically be populated.
- Folder names are assumed to be company names, and subfolders as job titles. These fields will be automatically populated with these details. Correct them if need be and the option will become available in the drop down menu for each patient which is added later. To delete an item from a drop down menu, select it, and then click the "X" icon.
- To refresh click 📿

Company	Default	~ 😣	Department/Ward	Testing	~ 🕄
	Hospital	/ Clinic / School		W	ard / OPD / Grade
Job title	Job	~ 😣	Number*	1	
	Job title / Bed / Ol	PD room / Class		Employee no / Fi	le no / Scholar no

Additional Details

There are four additional tabs within the Patient Data Pane.

Voice and Messaging

KUDUwave[™] software allows for SMS and/or voice communication, here is where you will add the details.

Add the phone numbers in the fields provided*. Select "Add another" to add additional numbers, to remove press "Delete".

Name	Voice and messaging	Email	Identification	Notes	
Mobile	numbers for voice	calls, t	text message	es and	notifications
Add ano	ther				Delete
082 123 4	1567	Mobil	e		^
021 321 7	654	Work			
		1.1			

*Note: Include country and area codes with telephone numbers. Do not add + before the country code.

Email

Email addresses linked to your patient can be stored here. Select the Email tab to add email addresses. Select "Add another" to add additional email addresses, and "Delete" to delete email addresses.

Patient details	2AB81FED008A4F878338CAC9A604102F
Name Voice and messaging Email I	dentification Notes
Email addresses for messages and	notifications
Add another	Delete
email@domain.com Work	

Identification

Occasionally, you will need to add additional identity numbers for verification such as employee ID, Social Security or medical insurance details. Here is where this can be done. Select Identification to add additional types of identity details for the patient.

Patient details	2AB81FED	008A4F878338CAC9A6041
Name Voice and messaging	g Email Identification Notes	
Identification numbers		
Add another		Delete
	ID / SS Issued by country:	^
	ID / SS number	
	Medical Scheme Number	
	Medical Scheme Name	
	My Patient file number	

Add the identity details to the relevant field provided, or click "Add another" to add additional forms of identification, and "Delete" to remove them.

Notes

Notes relating to the patient's demographics can be added under the Notes tab. Notes regarding tests are discussed later.

Name	Voice and messaging	Email	Identification	Notes	
More I	ext notes on demo	graphic	s of patient		
			8		

Notes and Tests

KUDUwave™ software bundles notes and tests within a single function. To add a new note or test

click on **+** Note / Test to get access to the following options:

Select a new Test / Note / Interpretation / Notification	Х
Audiometry: Assistive interpretation Audiometry: Pure tone - KUDUwave test Audiometry: Pure tone - Manual interpretation Audiometry: Pure tone - Manually enter results Audiometry: Speech - KUDUwave test Audiometry: Word Recognition (SD) - KUDUwave test File upload Photo	
Questions Send text message Text notes Tympanometry	

File upload

It may be necessary to upload additional digital documents to your patients records such as; clinical notes or old audiograms. To do this, select "File upload" from the **+Note / Test menu**.



Browse to the file you would like to upload to the patient profile, select it, name it and provide some details about the file you are uploading.

Click the save icon to upload the file.

Date and time	Significance	Туре	Signed	^
2018/10/09 13:08	None	File upload - KUDUwave software Backup 20		

Photo

To take a photograph of the patient, select "Photo" from the **+Note / Test menu**. Your computer's camera will automatically start.



If the image is in black and white, select "Try different settings". If you are happy with the image click anywhere on the image to take the photograph. You can make a note about the file upload in the "Note" field.

Click 😑 to save. The photo will now be available in the patient profile.

Click 🔀 to cancel and go back to the patient profile

Send a Text Message

In order to send a text message from the system, you need to be connected to the internet. Contact eMoyo to set this feature up for you. First, select "Send text message" from the **+Note** / **Test menu**.

	Patient Example (38yr)	export all data of this patient delete this patient
Home		i 🗵
Records	Mobile number that includes the country code i.e. "27824400826" (No + or	00):
	(160) Text message / SMS (Maximum 160 characters):	
X-check		
0		
Settings	🖹 Patient 📜 Send text message 🛛 add Note / Test	

From the drop down menu, select the

number to which you want to send a text message. This number would have been entered in the patient's details under "Voice and messaging".





to **cancel** the message. A record of

the sent sms will be saved in the patient history.

Text Notes

Select "Text notes" from the **+Note / Test menu.** Enter the name of the note and enter the note text.

Select to save or to cancel the note. The note is saved in the patient history.

	🗎 🗌
Note name	
Text Notes	
Notes	
Type your note here	

Patient History

The Patient Data Pane also contains a panel called History. Here, all Notes/tests will be listed by date.

Patient E	xamp	le (38yr))		
Patient de	tails			21E77C	706CF54F98A2DF357B355682C0
Name					
Name*	Patient			Surname*	Example
ID no.	123456	789		Passport no.	
Date	of Birth	1980/01/01	•	Sex	Male
Company		*	Θ	Department/Ward	~ Ø
	Ho	ospital / Clinic / So	:hool		Ward / OPD / Grade
Job title	he have been a first of the second se	v	Θ	Number*	1
History	Job title / E	led / OPD room / C	1833		Note / Test
Date and tim	ne	Significan	ce 1	Гуре	^
2018-03-01 1	7:02:42	None		Text notes - Text I	Note 2
2018-03-01 1	7:02:24	None	1	ext notes - Text P	NOTE 1

Exporting Patient Data

Exporting a Single Patient's Data

From within a patient profile, click on "export all data of this patient" at the top right corner of the patient management screen. This will bring up a dialogue box. Select where you would like to save the patient data, and click "Save".

Note: This exported data can only be viewed if imported back into the KUDUwave software.



Exporting Multiple Patients' Data

From within a folder, you can export multiple pure tone test results for all patients within a specific date range. In the folder view click "Export", select the date range and then click "Export all <u>KUDUwave Pure Tone results in this folder</u>".

Patients		🕂 Add patient	Import Export Move	Find
Default		~		X
	From date 9/ 8/2018 🔲 🗸	To date 10/10/2018		
Export	t all KUDUwave Pure Tone results in	this folder for this date range		

Select where you would like the file to be saved and click "Save" to finish. The software will inform you of the progress of the export.



Note: This exported data is saved in csv format and must be opened as a spreadsheet.

Importing Patient Data

To import patient data, select a folder from the Folder Management Pane and click "Import". You have a choice to import a single patient or multiple from a spreadsheet. Select the option you would like, locate the file in the browser and click "Open".

Patients	🕂 Add patient	Import	Export	Move
Import a patient and clinical data from an KUDUwave so Import multiple patients listed in a spreadsheet using th	oftware file that was exported on a he following format	<u>patient</u>		

Import a Single Patient from KUDUwave Software File

You can import a patient file which was exported from the KUDUwave software in a ".moyo" format.

Click on "Import a patient and clinical data from an KUDUwave software file that was exported on a patient".

Find and select the "**.moyo**" file, then click "Open" to import it.



Import Multiple Patients from a Spreadsheet

You can import multiple patients into a folder from a spreadsheet that is saved in a ".csv" format.

Select the folder you wish to assign all your patients into. Click on "<u>Import multiple patients listed in a</u> <u>spreadsheet using the following format</u>". Select the ".**csv**" file and click "OK".

Note: This file upload cannot be undone! Make sure you have selected the correct folder!



Browse your PC folders, select the csv file and upload. An example file can be downloaded by clicking on "<u>Save an example csv template for import...</u>". Your spreadsheet must include all headings in this order.

		Op	en		>
Look in:	E Desktop		~	G 🕸 📂 🛄•	
Recent places	🝓 Hor	megroup	13	Martinique_Koster	
Desktop	This	s PC		Libraries	
	Net Net	work		Default	
Libraries Libraries This PC	Exar	mple	A	KUDUwave softwar data example CSV File	e patient
Network					
TYCLWOIK	File name:	KUDUwave soft	vare patient data exa	ample 🗸	Open
	Files of type:	Comma Delimited	Files (*.csv)	~	Cancel

Your patient list will now appear in the data review pane.

Name	Surname	Date of Birth	Sex
Test	Example	2010/01/01	Unknown
Petra	Haselmaier	1984/08/29	Female
John	Mhlangu	1967/08/19	Male

Searching and Finding Patients

Search Recent patients Search

The search function can only be accessed from the Home screen. Search for patients using either: Name, Surname or Date of Birth. Begin typing in the search field and the software will automatically start bringing up possible matches.

Import

Export

Move

+ Add patient

Find

The find function can only be accessed from within a folder. Search for patients using either: Name or Surname. Begin typing in the search field and the software will automatically start bringing up possible matches.

QR Codes

Your KUDUwave software has the ability to automatically generate a QR code for each patient that you create. This code will appear on all reports associated with this patient. To view the QR code assigned to them click on the box in the right hand corner of the patient profile, or view any record saved in their history.

Petra Ha	selmaier (34yr)					export all data of this patient delete this patient
Patient de Name ID no. Date o Company*	petra 7003115143084 gf Birth* 1984/08/29 Intel Hospital/Clinic/School	Surname* Haselmaier Passport no. 45645665 Sex* Female Department* Circuitboard War	layou v 🔇		Print	
Job title*	Engineer V 🗞	Number 54321 Employee no / File	: no / Scholar no Test	14.34	R .	
Date and time	e Significance Type		Signed	0072303484A3400087r2C5ACE0095CC1 Assign a new QR code to this person (Me	Copy rge)	*

From this view you can print a page of these codes, copy the unique code associated to this QR code and assign a different QR code to your patient.

On the home screen you can scan this code on any of the printed reports and the software will take you directly to this patient's profile again.

Click on Click on to open the webcam view and hold the QR code in front of the camera lense of the computer. Once the code has been registered, click search and it will take you to the patient profile.

Find

Working with Clinical Tests

Create a New Test

Ensure that your KUDUwave[™] is plugged in before attempting to initiate a test.

To add a new test click on to get access to the following options: х Select a new Test / Note / Interpretation / Notification Audiometry: Pure tone - KUDUwave test Audiometry: Pure tone - Manual Interpretation Audiometry: Pure tone - Manually enter results Audiometry: Speech - KUDUwave test Audiometry: Word Recognition (SD) - KUDUwave test File upload Audiometry: Pure tone - KUDUwave test Text notes Tympanometry

Choose the test you want to do:

Select "Audiometry: Pure tone - KUDUwave test".

Taik KUDUwave ✓ Soft ~40dB ✓	
Connected to the KUDUwave	
Traditional Audiometer Custom settings Auto Air and Bone [Octaves 250Hz to 8kHz - SANS 10182] JT Custom Ototoxicity Auto Baseline [250Hz to 16kHz - SANS 10182] Ototoxicity Auto Exit [250Hz to 16kHz - SANS 10182] Ototoxicity Auto Screening [1kHz to 16kHz - SANS 10182] SANS 10083 Baseline - Auto Occ. Health [Min 0dBHL] SANS 10083 Baseline - Auto Occ. Health [Min 10dBHL] SANS 10083 Screening - Auto Occ. Health [Min 10dBHL] SANS 10083 Screening - Auto Occ. Health [Min 15dBHL] WHO School Screening [Min 25dBHL - 500Hz to 4kHz]	

Select the type of protocol to perform from the list and then press "Next".

This will start the "macro", automatic testing an protocol with preloaded settings that meet the standards mentioned in the label.

Alternatively. select "Custom Settings" to create a macro with your own settings.

If at any stage during a test you would like to communicate with the patient, use the "Talk Kuduwave" button.



Click to turn on. Click again to turn off.

Create a New Test Macro

Should you wish to customise your audiometry test, make sure the folder has default settings. You can check this by selecting the folder and noting the folder type in the top right hand corner. To change this refer to the Working with Folders section.

Select a patient in this default folder and click on



Select one of the test listed in the + Note/Test menu. You will now see this menu:

Traditional Audiometer Custom settings Auto Air and Bone [Octaves 250Hz to 8kHz - SANS 10182] Ototoxicity Auto Baseline [250Hz to 16kHz - SANS 10182] Ototoxicity Auto Exit [250Hz to 16kHz - SANS 10182] Ototoxicity Auto Screening [1kHz to 16kHz - SANS 10182] SANS 10083 Baseline - Auto Occ. Health [Min 0dBHL] SANS 10083 Baseline - Auto Occ. Health [Min 10dBHL] SANS 10083 Exit - Auto Occ. Health [Min 10dBHL] SANS 10083 Screening - Auto Occ. Health [Min 15dBHL] WHO School Screening [Min 25dBHL - 500Hz to 4kHz]

Each macro listed here is programmed to conduct testing protocols which adhere to the mentioned standard. Select the type of macro you wish to conduct.

Note: The macro you select **must** meet the standards which are required in your field. That is, Occupational Therapists must choose an already existing Occ. Health protocol, so that **all standards will be copied over** to the new macro which will be created.

Add a new Test setup Show settings when clicking the next botton Delete Test setup 1 New macro name Enter the new name for this Macro. Macro name: My New Macro OK Cancel Select "OK" Kuduwave All the settings from here onwards will be saved as a Macro with the name "My New Macro" Page 28 OK

Select "Add a new Test setup" at the bottom of the screen.

The Start Page will show you the automatic settings which have been copied from the previous Macro you selected.

Start page

Maximum permissable ambient sound pressure le	evels for AC	and C	Declud	ed Bo	C to te	st accu	urately	to 0 d	BHI
		125	250	500	1000	2000	4000	8000	H
○ ANSI/ASA S3.1 for KUDUwave headset ● SANS-10182 screening for KUDUwave headset				55	49	46	54	52	
				61	56	55	65	64	
SANS-10182 diagnostic for KUDUwave headset		56	56	59	56	55	65	64	
BS 6655 / EN 26189 / ISO 6189 for KUDUwave headset	GB SPL	69	68	57	52	49	58	58	
OSHA for KUDUwave headset				76	65	59	77	83	
ACC Guidelines NZ Nov 2012 for KUDUwave headset		83	78	67	58	52	67	67	

		125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	Minimum
O Type 1* Research Audiometer except for thresholds in maroon B	Air** one***	-50	70 25	90 45	90 45	90 55	90 60	90 60	90 60	90 50	80	70	-10 -10
O Type 2* Clinical Audiometer	Air**	60	80	100	-	100	100	100	100	100	90	80	-10
Type 3* Diagnostic Audiometer	Air**	-	70	90	-	90	-	90	90	90	80	70	-10
O Type 4* Screening Audiometer	Air**	-	70	60	-	60	-	60	60	60	60	-	0
Type 4* Screening Audiometer that can test to 70dBHL including 8kHz	Air**	-	70	70	-	70	-	70	70	70	70	70	0

Extended high frequencies

Extended High Frequencies are not enabled on this Audiometer. Please contact your supplier if you would like to upgrade to this functionality. (Extended High Frequencies go up to 16kHz)

Shorter	ed Ascending method (ISO 8253-1) v	
Type of tone Pure tone Warble tone	Tone duration 500 🚖 milli seconds (ms) Tones are always presented at this fixed duration	
Stenger offset:	10	

Click , to move on to the "Setup for automatic testing page", it will give you access to specific features you can choose to be tested in this new macro.

Setup for automatic testing page

Frequencies to test (Hz):

✓ Test these AC frequencies Left	✓ Test these AC frequencies Right	You can select
□ 125 🔽 2k 🗌 9k	□ 125 🔽 2k □ 9k	frequencies for
250 🗹 3k 🗌 10k	250 3k 10k	each ear for Air
✓ 500 ✓ 4k 11.2k	✓ 500 ✓ 4k 11.2k	Conduction (AC)
750 ⊻ 6k12.5k	750 6k12.5k	Conduction (AC)
▼1k ▼8k14k	✓ 1k ✓ 8k	and Bone
		Conduction (BC)
At the end of AC, redo the first frequency	that was tested again	testing.
		0
I hen redo all AC frequencies up to 8kHz w	with thresholds worse than 25 V db HL	
Then also test the following AC frequencies in	f any one AC threshold is worse than 25 🚖 dB HL	
125 250 500	$ \begin{tabular}{lllllllllllllllllllllllllllllllllll$	
Then redo all AC frequencies with thresho	lds worse than 25 🚖 dB HL where noise levels were too loud	
Then redo all AC frequencies with thresho	lds worse than 25 🔿 dB HL	
and where Orange and	Green overlaped more than 5 🚖 dB	
Then add these BC frequencies for each A	C frequency thresholds that is greater or equal to 15 🖨 dB HL	
✓ 250 ✓ 500 ✓	750 ♥ 1k ♥ 1.5k ♥ 2k ♥ 3k ♥ 4k Automatic masking	
Then also test the following BC frequencies it	fany one AC threshold is worse than 25 🚖 dB HL	
	750 1k 1.5k 2k 3k 4k Automatic masking	
Always test these BC frequencies Left —	Always test these BC frequencies Right	
Automatic masking	Automatic masking	
250 1.5K	250 1.5K	You can also alter
750 3 k	750 V 3k	the randomized
✓ 1k ✓ 4k	✓ 1k	delay between
		delay between
Then redo all BC frequencies up to 4kHz w	vith thresholds worse than 25 🚖 dB HL	tones.
Then redo all BC frequencies with thresho	lds worse than 25 🔿 dB HL where noise levels were too loud	
No. 1		
Prompt to apply the bone conductor when	bone conduction testing starts (
Block tones from being presented if the no	oise levels are too loud for 3 🚖 seconds	
Default test order: 1k, 1.5k, 2k, 3k, 4k, 6k,	8k, 9k, 10k, 11.2k, 12.5k, 14k, 16k, 750, 500, 250, 🗸	
Minimum testable threshold for each freque	ncy	
Hz 125 250 500 75		
Air conduction 0 0 0 0 0		
Bone conduction 0 🗢 0 🜩 0		
Hz 9000 10000 11200	12500 14000 16000	
Air conduction 0 10 0 10		
Maximum testable threshold		
• Use the maximum thresholds that this a	udiometer can test to	Click , to
O Use this maximum level 50 ♣ dB H		move on to the
	-	"Conditioning
Next frequency start threshold level		page".
30 🔶 dB HL		
Delay before randomization delay	ndomization delay before next tone	
	Enable randomised delay	
1000 🔷 ms	Returnen 0 A s 1000 A me	Page 30
		r age 30

Conditioning

C	onditioning	page	
Left	_	Right	
Present tone		Present tone	□ <mark>Mas</mark> k
Left loudness setting 40 dBHL (Soft) 60 dBHL (Normal) 80 dBHL (Loud) 100 dBHL (Very loud) 110 dBHL (Extremely loud)	1000 Hz	Right loudness setting 40 dBHL (Soft) 60 dBHL (Normal) 80 dBHL (Loud) 100 dBHL (Very loud) 110 dBHL (Extremely loud)	ud)
			de to start

This is the conditioning page. It allows you to play a sound to the patient and see how long they take to respond. This tests their response time and conditions them to the test environment.

Tones will be presented to them and they must press the response button to indicate they have heard the tone. If the patient does not respond in time, a pop up message will say: "Button not pressed in time". Explain the testing process again, e.g. "When you hear the sound, quickly press the response button and release."

If the patient was too slow in pressing the button, a pop up message will say: "Pressed bit too slow for automatic wait time". The wait time is how long it takes for patients to press the button. This is automatically set to 2,5 seconds (2500ms). You can extend or shorten this time by clicking on: "Increase wait time" or "Decrease wait time".

There are two options for patient conditioning: Manual and Automatic.

Auto conditioning

To switch between the two modes click:



This is the Automatic Conditioning page. Here you can select the prefered language of the patient. The conditioning process will now be explained to them in that language.

In Manual mode, begin conditioning at 40 dBHL and increase the intensity until the patient responds. This gives you an indication of where to begin testing.

Condition the patient for masking by selecting "Mask". This will play white noise to the ear selected on the conditioning page and present the toneto the opposite ear.

Once both ears have been conditioned, you will know the patient understands how the test is

conducted. Select "Next".

Conducting a Clinical Test

Automatic Test

The automated test will start running immediately after conditioning is completed. Wait for the test

L -		I		"C "		
to	complete	and	select	"Save"	 	l

Manual Test

II

After conditioning the patient, click Pause . Now manual testing can be performed.

Patient Example (38yr)			export all data of this patient delete this patient
< ?	Auto Pause Hide audiogram		
		· · · 0 · · · · 10	
		20	
	40		Stenger EHF Max masking levels No hearing loss bands v
		60 70	Notes:
		80	
		100	
125 250 5	00 750 1k 1.5k :	2k 3k 4k 6k 8k 10k 12k 14k 16k	

Use the keypad to move the cursor across the plane.



To present a tone at the set frequency (1000) and intensity (40), click To **increase** intensity (to make it **louder**) click ,

to decrease intensity (to make it softer) click

To **increase** frequency click _____, to **decrease** frequency click



The blue screen is for the left ear test and the red screen for the right ear. Use these buttons to switch between left and right or to show both.

After a tone is presented, this bar will become coloured as you wait for the patient to respond. It will be green and show a thumbs up if the patient responds in time.

If the patient was too slow it will turn orange and show a thumbs down. If the patient presses the response button without a tone being presented, a grey spot will mark the screen.



AC BC

To switch between air conduction and bone conduction testing, use these buttons.

Click "BC" to continue with bone conduction testing. The KUDUwave will automatically mask the ears when performing this test.



When counselling a patient or person interested in the testing results, use this button to view the speech area of the patient. On the screen it will show the various consonants and vowels available to the patient and also shows the intensity of sounds i.e. a baby crying or a dog barking.

Another feature you can use is applying hearing loss bands to the screen. To view the hearing loss

bands, click on No hearing loss bands

This is what the screen will look like if you selected Clark Degrees.



The ? will bring up the Help page and it will show you shortcut keys to perform tests quicker.

Speech Reception Threshold (SRT) Testing

To conduct a SRT test, select the "Speech - KUDUwave test" option from the New Test Menu.

Select a new Test / Note / Interpretation / Notification	Х
Audiometry: Assistive interpretation	^
Audiometry: Pure tone - KuDuwave test Audiometry: Pure tone - Manual interpretation	
Audiometry: Pure tone - Manually enter results	h
Audiometry: Speech - KUDUwave test	
Audiometry: Word Recognition (SD) - KUDUwave test	
File upload	
Photo	
Send text message	
Text notes	
Tympanometry	

Then select the list of words read in the specified language you wish to use.

Talk Kuduwave 💙 Soft ~40dB 🗸	(n∕ [*] ^{Talk}	
SRT - Afrikaans (Gauteng) w SRT - English (Maryland) wo SRT - English (South African)	ords read by a female [SRT afr ZA F1 Unilat] rds read by a female [SRT eng US F1 Unilat]) words read by a female [SRT eng ZA F1 Unilat]	

Select which ear you want to begin testing at the specified intensity level.

Initial test settings								
 Start with the LEFT ear at Start with the RIGHT ear at 	45 🛟	dBH	L					
ound booth to simulate								
ound booth to simulate Maximum permissable ambient sound pressure leve	els for Air	Cond	uction	and	Occlud	ed Bor	ne Cor tely to	duction 0 dBHL
ound booth to simulate Maximum permissable ambient sound pressure leve	els for Air	Cond	uction 250	and to 500	Occlud b test : 1000	ed Bor accura 2000	ne Cor tely to 4000	duction 0 dBHL 8000 H
ound booth to simulate Maximum permissable ambient sound pressure leve ANSI/ASA S3.1** for KUDUwave	els for Air dB SPL	Cond 125 58	uction 250 58	and 500 55	Occlud b test a 1000 49	ed Bor accura 2000 46	ne Cor tely to 4000 54	nduction 0 dBHL 8000 H: 52
ound booth to simulate Maximum permissable ambient sound pressure leve ANSI/ASA S3.1** for KUDUwave SANS-10182* screening for KUDUwave	els for Air dB SPL dB SPL	Cond 125 58 74	uction 250 58 74	and to 500 55 61	Occlud o test i 1000 49 56	ed Bor accura 2000 46 55	ne Cor tely to 4000 54 65	duction 0 dBHL 8000 H 52 64
iound booth to simulate Maximum permissable ambient sound pressure leve ANSI/ASA S3.1** for KUDUwave SANS-10182** diagnostic for KUDUwave SANS-10182** diagnostic for KUDUwave	els for Air dB SPL dB SPL dB SPL	Cond 125 58 74 56	uction 250 58 74 56	and 500 55 61 59	Occlud o test a 1000 49 56 56	ed Bor accura 2000 46 55 55	ne Cor tely to 4000 54 65 65	duction 0 dBHL 8000 H 52 64 64

The SRT page will open and automatically read the words to the patient once you select the play button on the control panel.

Example Patie	nt (24yr Ma	le)				export all data of this patients of the patient of	nt nt
	alk Kuduwave oft ~40dB	~ ~	بلاً: ح`ا)	Talk			
Left	L dB	1	×	[^] Controls		Notes	
Hotdog	45	1				^	1
Whitewash	40	1		Noise complia	int (-67dBHL)		
Woodwork	35	1		-			
Inkwell	30	1		sc.			
Oatmeal	25	1		Correct			
Mousetrap	20		×				
Doormat	25		×	Ø			
Playground	30	1		Incorrect			
Daybreak	25	1					
Toothbrush	20		×		1		
Railroad	25		×				
Sunset	30	1		Auto	couder		
Mushroom	25	1		Pancake			
Farewell	25						
Pancake						v	
Eardrum						Left Right	
Stairway							
Headlight						50 V SKI -20 V	
Northwest						-20 🗘 UCL -20 🛟	
Hardware						-20 MCL -20 M	
Horseshoe							
Cowboy				~		0 文 Dichotic % 0 文	

🖹 Patient 📜 Audiometry: Speech - KUDUwave test 🛛 add Note / Test



Click the "Correct" button with the thumbs up if the patient recites the word correctly. In automatic mode, the next word will be read to the patient at 5 dBs softer. Use the "Incorrect" button with the thumbs down if the patient did not recite the word correctly or did not hear the word. If incorrect, the next word will be read at 5 dBs louder.

Use the up and down keys to navigate through the word list. The "Play" button will read the word to the patient and the loudness of the word can be changed by clicking the "Softer" or "Louder" buttons.

Click the "Next" button to continue once testing of the left ear is complete. Select the Right ear option and specify the Intensity level testing should begin at.

nuc nound you nice to do next.	
Next, the LEFT ear at	
Next, the RIGHT ear at	

The same procedure must be done for the Right ear. Once complete click "Save".

Speech Discrimination (SD) Testing

To conduct a SD test, select the "Speech Discrimination - KUDUwave test" option from the New Test Menu.

Select a new Test / Note / Interpretation / Notification	Х
Audiometry: Assistive interpretation	^
Audiometry: Pure tone - KUDUwave test	
Audiometry: Pure tone - Manual interpretation	
Audiometry: Pure tone - Manually enter results	
Audiometry: Speech - KUDUwave test	
Audiometry: Word Recognition (SD) - KUDUwave test	
File upload	
Photo	
Questions	
Send text message	
Text notes	
Tympanometry	

Select the preferred word list you wish to use.

Afrikaans word list read by a man [SD afr ZA M1] Maryland CNC English word list read by a man [SD eng US M1] Pedi word list read by a man [SD mso ZA M1] South African English word list read by a man [SD eng ZA M1] Zulu word list read by a man [SD zul ZA M3]

Select which ear and intensity to begin testing with and click the next arrow.

• Present the first word list in the LEF	T ear a	t		_	-			
				30	Ţ	dBH	L	
O Present the first word list in the RIG	HI ear	at			_			
ound booth to simulate								
ound booth to simulate	ola for Air	Cond	untion	and	Ocelus	lad Ro		aduction
ound booth to simulate Maximum permissable ambient sound pressure lev	els for Air	Cond	uction	and	Occlud	led Boi accura	ne Cor	nduction
iound booth to simulate Maximum permissable ambient sound pressure lev	els for Air	Cond	uction	and t	Occlud b test	led Boi accura	ne Cor tely to	nduction 0 dBHL
Sound booth to simulate Maximum permissable ambient sound pressure lev	els for Air	Cond	uction 250	and t	Occlud o test 1000	led Bor accura 2000	ne Cor tely to 4000	nduction 0 dBHL 8000 H
ound booth to simulate Maximum permissable ambient sound pressure lev ANSI/ASA S3.1** for Kuduwave headset	els for Air dB SPL	Cond 125 58	uction 250 58	and 500 55	Occlud o test 1000 49	led Bor accura 2000 46	ne Cor tely to 4000 54	nduction 0 dBHL 8000 H 52
iound booth to simulate Maximum permissable ambient sound pressure lev ANSI/ASA S3.1** for Kuduwave headset SANS-10182* screening for Kuduwave headset	els for Air dB SPL dB SPL	Cond 125 58 74	uction 250 58 74	and 500 55 61	Occluc o test 1000 49 56	led Boi accura 2000 46 55	ne Cor tely to 4000 54 65	nduction 0 dBHL 8000 H 52 64
iound booth to simulate Maximum permissable ambient sound pressure lev ANSI/ASA 53.1** for Kuduwave headset SANS-10182* screening for Kuduwave headset SANS-10182** diagnostic for Kuduwave headset	els for Air dB SPL dB SPL dB SPL dB SPL	Cond 125 58 74 56	uction 250 58 74 56	and 500 55 61 59	Occluc o test 1000 49 56 56	led Boi accura 2000 46 55 55	ne Con tely to 4000 54 65 65	nduction 0 dBHL 8000 H 52 64 64
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The SD testing page will open and each word will be presented at the selected dB level.

Example Patient (24)	/r)								910 200	export all data of this paties delete this paties
Talk Kuduw Soft ~40dB	ave v	((² Talk								
Test progress			1	×	Replied	î	Controls			
Loft	burn	30						1		^
dBHI Progress	lot	30					Noise compliant (-oddHL)			
1 30 0/0 0%	sub	30								
2 -10 0/0 0%	home	30								
3 -10 0/0 0%	dime	30					Correct			
4 -10 0/0 0%	witch	30								
Right	keen	30					a l			
dBHL Progress	yes	30					Incorrect			
1 -10 0/0 0%	boat	30								
2 -10 0/0 0%	sure	30					- m			
3 -10 0/0 0%	hole	30					Auto Canture words			
4 -10 0/0 0%	door	30					Acco copiare nores			
	kite	30								
	sell	30								
	nag	30								
	take	30								
	fall	30								
	weak	30								
	death	30								
	love	30								
	tough	30								
	gap	30								0

Mark each word correct or incorrect with the thumbs up and down buttons. To change the dB level for the following words click on the next arrow.

Talk Kuduwave Soft ~40dB	v (n∕È Talk	
Test progress W dBH, Progress 1 30 4/4 100% 2 20 2/4 50% ↓ 4 -10 0/0 0% ↓ 4 -10 0/0 0% ↓ 1 -10 0/0 0% ↓ 1 -10 0/0 0% ↓ 2 -10 0/0 0% ↓ 4 -10 0/0 0% ↓	# Present the next word list in the LEFT ear at > Present the next word list in the RIGHT ear at Q resent the current test at	

Change the dB level and click the "Next" arrow again. Continue testing at the new dB level.

Talk Kudu Soft ~40	wave 🗸	Talk کے ا						$\left \right>$	H	\times
	Word	L dB	1	×	Replied ^	Controls				
Left	juice	20	1			Males complete / C	CONCERNING ST			^
dBHL Progress	mill	20	1			Worse compliant (-	soubline)			
1 30 4/4 100%	chief	20		×						
2 20 2/4 50%	keg	20	_	×		Sh .	\sim			
3 -10 0/0 0%	dead	20				Correct				
4 -10 0/0 0%	loaf	20								
Right	fail	20				<i>a</i> ;	1 a c			
dBHL Progress	bought	20				Incorrect	\sim /			
1 -10 0/0 0%	pick	20					× .			
2 -10 0/0 0%	thought	20								
3 -10 0/0 0%	hate	20				Se le	20 monde			
4 -10 0/0 0%	deep	20				AUCO Captore	. NO:US			
	soap	20								
	tool	20								
	four	20								
	rain	20								
	shack	20								
	white	20								
	shawl	20								
	dab	20								
	gaze	20								
	pike	20								

Click the "Next" arrow again and select the right ear to continue testing the right ear. Click "Save" at the end of the test.

Viewing Notes and Tests

Selecting a record in the history panel will open the file in the Test Data Pane (5).



Test Significances

You can change the Significance of a test or note by clicking on the highlighter, or right clicking on the test in the History Pane, and selecting the appropriate label from the drop down menu.

By selecting To Interpret, you can use the Assistive Interpretation feature found in the New Test menu.

Digital Signatures

To sign off a test record or report click on the pen icon. The patient must sign in the block with the red cross and the clinician / tester in the other block.

Sign this test result	
This is my test result	
	Patient Name _Suma
X	
This is the hearing test of Patient Name _Surna	me (118yr)
	eMoyo
	Leave Blank



None Worst Best Last significant General Baseline (Old) General Baseline General Baseline (Deleted) Comparison Screening Diagnostic Evit Deleted Baseline test PLH Baseline Milestone Baseline PLH/Milestone Baseline Entry Follow up Periodic Ototoxicity Baseline Ototoxicity Monitoring Ototoxicity Exit PLH Screening STS Screening PLH/STS Screening To interpret PLH Entry STS Entry PLH/STS Entry PLH Evit STS Exit PLH/STS Exit

Assistive Interpretation

To use the assistive interpretation feature, change the significance of the saved test to: "To interpret" or mark it as a Baseline test for PLH, Milestone or Ototoxicity.



Click on

Note / Tes

, and select the option from the menu for Assistive Interpretation.

Select a new Test / Note / Interpretation / Notification	Х
Audiometry: Assistive interpretation Audiometry: Pure tone - KUDUwave test Audiometry: Pure tone - Manual interpretation Audiometry: Pure tone - Manually enter results Audiometry: Speech - KUDUwave test Audiometry: Word Recognition (SD) - KUDUwave test File upload Photo	^
Questions Send text message Text notes Tympanometry	

Select the type of interpretation wanted:

Interpret the latest pure tone test marked as "To interpret" Ototoxicity interpretation PLH interpretation Milestone baseline / STS interpretation

The interpretations can now be viewed and saved from this window.

Interpretations Baseline calculations Follow-up calculations Comparisons
PLEASE NOTE: This information is an assitute tool for clinicians
PCASENEE FINIONES ON THE MOST RECENT To Interpret* SIGNIFICANT TEST DATED 2018-04-04 01:37:29 PM
PTA for aring the 2 adBHL
VPTA for aring the 2 adBHL
VPTA for aring the 2 adBHL
VPTA for aring the 1 adBHL
VPTA for aring to Unlateral hearing loss detected
No Asymmetrical or Unlateral hearing loss detected
No hearing loss in the better ear (VPTA is a input)
Level of hearing instrument (VHO):
No hearing loss in the better ear (VPTA is any interpret* SIGNIFICANT TEST DATED 2018-04-04 01:37:29 PM
VPTA for aring the 2 adBHL
VPTA for aring the 1 adBHL
VPTA for aring the 2 adBHL
VPTA for aring the 1 adBHL
VPTA for

Ototoxicity Monitoring with Assistive Interpretation

For ototoxicity monitoring, select the first baseline test as a "Ototoxicity Baseline" and the following test as "Ototoxicity Monitoring".



and select the option for assistive interpretation.

Select "Ototoxicity interpretation".

You can now view the interpretation notes and calculations for both the Baseline test, the Follow up test and comparisons of the two.

Interpretations	Baseline calculations	Follow-up	p cal	culati	ions	Com	pari	sons					
			125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
Baseline 04-04-2018	Difference Left and Difference Left and F Difference Air and Difference Air and E	d Right Air Right Bone Bone Left Bone Right	0		0	0	0		0	0	0		0
		5.505 S. 1.5 F. 6 (3)											
Interpretations	Baseline calculations	Follow-u	p cal	culat	tions	Con	npari	sons					
Interpretations	Baseline calculations	Follow-u	p cal	culat 250	tions	Con 750	npari 1k	sons	2k	3k	4k	6k	8k



Settings



From the home, folders or patient screens you can access the settings menu by clicking the settings icon.

JUWAVE Sattings	English
but the booth Settings	Installation ID: B5449/
	Checked! You do have the latest software version
Joload a letterhead	
)esign a letterhead	eMaya
dan se dan di bi	
Database	
Backup (Please do regular backups, Store th	e backup on an external drive like a memory stick)
Import a backup and merge it with this databa	se
Cloud dashboard service (You need to conne	ect to the Internet every so often to sync)
Change database (You need administrative right	to to perform this action)
Move all nations in the root folder to a senara	te folder
Import eMovo 4.0 data (Any version before eM	lovo 4.0 will automatically be imported)
Open SYNCTHING synchronisation administratic	on panel (We recommend you contact support family support
	B
Default smart folder	
When creating a new folder it must always be	the the following default smart folder:
Default folder type	~
Default folder type	~
QR codes	×
QR codes Print QR cards Quantity	v
Default folder type -QR codes Print QR cards Quantity 1 (*) Do not automatically start QR code scanning	when opening the home page
Default folder type -QR codes Print QR cards Quantity 1 (*) Do not automatically start QR code scanning	$\scriptstyle \lor$ when opening the home page $\scriptstyle \lor$
Default folder type QR codes Print QR cards Quantity 1 (*) Do not automatically start QR code scanning	\sim when opening the home page \sim
Default folder type QR codes Print QR cards Quantity 1 🔹 Do not automatically start QR code scanning Password protect "Settings"	vwhen opening the home page v
Default folder type QR codes Print QR cards Quantity Do not automatically start QR code scanning Password protect "Settings" Decomposed	when opening the home page

Backup

This function allows you to copy all patient data into one file, which will be saved to a chosen drive. Click on "Backup...", select the destination to send the backup data to and click "Save".

Import and Merge Data from a Backup

To import a previously backed up version of all patient data, select "<u>Import a backup and merge it</u> with this database...".

Note: A warning will pop up. Older versions of software my not support patient data which was backed up from a newer software version. Always run the latest version of software available.

Kuduwave	×
An older version of KUDUwave might show error messages if the import is from a newer version then update you software to the latest version of KUDUwave.	of KUDUwave. If this happens

Click "OK", and browse to the location of the backup file that you would like to import. Select the file and click "Open". The data will be merged with the current database and be available on the home screen.

Import eMoyo 4.0 Data

If you had eMoyo 4.0 you will need to import patient data into KUDUwave 5. By clicking "<u>Import</u> <u>eMoyo 4.0 data</u>", a new interface will open. Click "Start Migration". Once completed close this window and KUDUwave 5. Reopen the software and all patient data should be available. Contact support if data is found missing.

Upload a Letterhead

To include your personalised logo to patient reports, first create a 700x110 pixel image (click "<u>Design</u> <u>a letterhead</u>" to open Paint with a window automatically sized to these specifications) and save the image as a .bmp file. Click "<u>Upload a letterhead</u>", "OK", find your bmp file and "Save".

Set a default Smart Folder

All new folders created will have the settings associated to the smart folder type selected from the drop down menu.

Manage QR codes

Print multiple QR codes to later associate to patients, and set the webcam to automatically open with

the software.

Password Security

Add a password to the settings page to restrict access here.

X-check (Cross Check)

The X-check verifies the calibration of the KUDUwave. **Note:** This does not replace the need for calibrations as per local standards.



To cross check your KUDUwave click the X-check button in the system menu on the left hand side. If your KUDUwave is equipped with X-check the following start page will appear:



Follow the instructions and then click the Start button to run the X-check.

Note: that the X-check can only run if your KUDUwave is equipped with the cross check hardware. If this is not the case you will see the following screen:



After clicking the "Start" button the X-check will run automatically and the following test page will be shown:



The X-check should take about 23 seconds to complete if the tests pass. A message will then be shown to tell you if your device calibration verification has passed:

	compliance made easy	
Left	Text Result Pace	Retest
Right	KOR MODULE KOD	Retest
	Test Result: Pass	
	Congratulations, X-check has verified your calibration	
	Detail view Finish	

Clicking the "Finish" button will exit the X-check application. Clicking the "Detail view" button will show the following Detail page:



Deput	Amplitude Error (dD)	Test Frequency [117]	Amplitudo Essos (dD)	Desult
Result	Amplitude Error (dB)	lest Frequency [H2]	Amplitude Error (dB)	Result
Pass	0,19	125	0,16	Pass
Pass	0,38	250	0,46	Pass
Pass	-0,39	500	0,40	Pass
Pass	0,58	750	0,32	Pass
Pass	0,52	1000	-0,05	Pass
Pass	-0,06	1500	-0,31	Pass
Pass	0,58	2000	0,49	Pass
Pass	-0,04	3000	-0,24	Pass
Pass	0,25	4000	0,54	Pass
Pass	0,30	6000	0,23	Pass
Pass	-0,39	8000	-0,20	Pass
Pass	0,35	9000	0,13	Pass
Pass	-0,02	10000	0,44	Pass
Pass	-0,70	11200	-0,82	Pass
Pass	-0,10	12500	-0,45	Pass
Pass	-0,21	14000	0,12	Pass
Pass	0,14	16000	-0,58	Pass

This Detail page shows the test frequencies as well as the Amplitude Error.

The Amplitude Error is the discrepancy or difference between the calibrated level of the KUDUwaves air conduction output and the actual air conduction output, which has just been measured by the X-check. Ideally all of these values should be zero.

Print Report

button.This will

If you would like a PDF report, scroll down and click the generate and open a PDF, like the one shown here. The PDF report is automatically saved in the eMoyoDotNet/Pdf folder on your computer.





Test Details:

Cross Check Test Date: KUDUwave Calibration Date: KUDUwave Serial Number:

SG 67	15 Strates 423		All the second second	84
Result	Amplitude Error [dB]	Test Frequency	Amplitude Error [dB]	Result
Patz	0,19	315	0.24	Page
Patt	0,58	250	0,4a	Page
Patt	-0,04	500	0,40	Page
Pall	0.56	750	0.51	Paus
Patt	0.92	1000	-0.05	Page
Patt	-0,04	1.500	-0,81	Page
Patz	0,56	2000	0,48	Page
Patt	-0,04	0000	+0,24	Fact
Patt	0,25	9000	0,04	Page
Patt	0,50	8000	0,25	Page
Patt	-0,84	0000	-0,20	Page
Patt	0,85	9000	0,15	Page
Patt	-0.01	10000	0.44	Page
Patt	-6,76	13300	-0,83	Page
Patt	-0,30	12800	-0,48	Pass
Pass	-0,23	14000	0,23	Peak
Paul	0,14	14000	-0.20	France



X-check: Abnormal Test

If the test fails, a message will list common reasons which cause X-check to fail alternatively to your KUDUwave being out of calibration.

At least one test has failed. Please go through the checklist and click 'Retest':

- 1. Ensure that the sound tubes are plugged in tightly and deep enough
- 2. Ensure that the brass couplers are clean and you can see through them
- 3. Ensure that the sound tubes dont have damage nor are there any holes
- 4. Ensure that the KUDUwave is not moved or bumped while running the cross check

As an example, bumping or moving the KUDUwave while the X-check is running will prevent it from accurately measuring the air conduction output and cause the test to fail. Follow the instructions and click the "Retest" button for the failed side.



You can also click the "Detail view" button to go to the Detail page and get more information about why the test failed. Failed frequencies are shown in red along with a reason of why the test failed.

Result	Amplitude Error [dB]	Test Frequency [Hz
Pass	0,63	125
Pass	0,82	250
Pass	0,05	500
Pass	0,94	750
Pass	0,93	1000
Pass	0,32	1500
Pass	0,94	2000
Pass	0,25	3000
Pass	0,50	4000
Pass	0,34	6000
Fail (Amplitude Deviation Too High +Frequency Deviation Too High +SNR Too Low+Recording Not Stable)	10,79	8000

If the test still fails after you have followed the instructions then your KUDUwave could be out of calibration. Contact eMoyo to book a calibration.

Troubleshooting

Computer is not able to connect to the KUDUwave

If the computer is not able to connect to the KUDUwave, the following message will pop up.



This means that the KUDUwave audiometer was not plugged in correctly.

Please follow these steps to correct the problem:

- 1. Cancel the current test by selecting in the top right corner.
- 2. Unplug the KUDUwave from your computer, wait a few seconds, and plug it back in ensuring that both the KUDUwave and response button are firmly plugged in.
- 3. Restart the test.

The KUDUwave is incorrectly your current default audio record device

If a pop up error message says "AudioTympCtrl. The KUDUwave is incorrectly your current default audio record device. We will now try fix the problem", click "OK" and the software will correct your PC settings.

Remote Assistance

We offer to help you remotely by taking control of your laptop with the TeamViewer plugin.

To download the TeamViewer remote assistance plugin, please visit:

https://www.teamviewer.com/en/download/windows/

For live remote assistance, make sure you have:

- 1. Downloaded and installed TeamViewer on your PC
- 2. A active internet connection.
- 3. Your TeamViewer ID and Password handy.

	Team	Viewer	_ □	×
Activate the new user interface previ	Activate the new user interface preview here or in the options.			
Connection Extras Help	Feedback Ol 🏟 N	leeting	0	
Allow Remote Con vourid 724	trol 116 638 8520	Control Remote Partner ID	Compute	r
Unattended Access Unattended Access Unattended Access Assign device to account Grant easy access	5 ndows	Remote control File transfer CONNECT		
Ready to connect (secure connect)	ction)	4. Mart	inique Koster Corporate	»

Get in contact with our Support Team at: support@emoyo.net

Cleaning and Maintenance

General Care

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

Cleaning Procedure

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

When Cleaning the KUDUwave:

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

Warning: Never use acetone based cleaning products when cleaning the KUDUwave.

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

Warning: Make sure that there is no debris on the ear probe or inside the disposable 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. Remove the KUDUwave, turn it around so that the left side is on the right ear and the right side is on the left ear and redo the automatic KUDUwave tone threshold test. Compare the left and right thresholds of the two tests with each other. None of the thresholds of the compared sides may differ with more than 10 dB.

Note: Disposable 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 ear probe permanently. Cleaning solutions also damages the foam of the eartips and can lead to incorrect readings. It is an irresponsible risk to clean eartips for re-use, as cleaning solution or wax can end up inside the ear probe and give incorrect results.

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

Calibration

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

Daily Calibration Verification

It is advisable to perform a biological test at the start of each day that the KUDUwave will be used.

Annual Calibration

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

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

Ad Hoc Calibrations

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

Calibrations by Other Organisations

Due to the digital, robust and integrated design of the KUDUwave, chances of it going out of calibration are very slim. If another organisation wants to calibrate a KUDUwave, they may perform a typical calibration process to verify that the thresholds and frequencies of the unit are correct. After completing the calibration routine the calibration organisation will not need to adjust any thresholds

or frequencies. A calibration certificate must be issued to show that the KUDUwave is within calibration limits. In the unlikely event where the calibration shows limits outside acceptable limits, please contact eMoyo immediately.

Storage and Shipping

Warning: When shipping the KUDUwave please use the robust shock absorbing carry case to reduce the risk of damage to the device during transit.

Remember to seal the shipping container securely and to mark the container FRAGILE. Always store the KUDUwave out of direct sunlight in a clean and dry environment within the temperature and humidity limits detailed in the Technical Specifications.

Expected Service Life

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

Disposal and Recycling

It is advisable that the unit is returned to eMoyo for disposal and recycling. Please call +27 87 231 0132, or email support@emoyo.net, for instructions. Alternatively contact your international distributor or EU representative for disposal and recycling instructions.

Traveling with Your KUDUwave™

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

Please make sure to perform the following tasks:

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

Upgrades, Maintenance and Support

Upgrades and New Features

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

Frequently Asked Questions (FAQs)

Please refer to websites for more information.

Support Service

At eMoyo we are confident that we can deliver a unique support service specifically designed for clients in remote areas. Contact us directly on our website by going to <u>www.kuduwave.com</u> and going to our support page for useful information. Or you can fill us in on your KUDUwave related problems by leaving a message on our contact us page.

Loan Devices

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

Online Virtual Support and Training

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

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

Service, Support and Maintenance Contract

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

Troubleshooting

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

Troubleshooting Checklist

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

In Need of Assistance?

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

Technical Specifications

Standards

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

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

Instrument Specifications

Dimensions	210 x 260 x 110 mm		
Shipping dimensions	410 x 320 x 190 mm		
Net weight	250 g		
Shipping weight	1627 g		
Power supply	2x standard laptop USB ports (5 V, 500 mA max per port) Unplug laptop from mains while testing		
Data transfer	Twisted KUDUwave™ dual USB cable 2x standard 3 meter A Male to Mini B Male USB cables		
Environmental	Operational temperature	15 - 35 °C	
conditions Indoor use only	Operational humidity (non-condensing)	30 - 90 %	
	Operational ambient pressure	98 - 104 kPa	
	Shipping and storage temperature	10 - 40 °C	

	Shipping and storage humidity (non-condensing)	30 - 75 %
	Shipping and storage ambient pressure	70 - 106 kPa
Warm-up time	10 - 20 sec	
Patient response system	Handheld tactile push button (USB)	
Sound tube	Medical grade PVC 80 shore, Clear with white x-ray line, L 180 mm, ID 1.7 mm, OD 2.9 mm	

Audiometry Specifications

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

Pure Tone Testing Specifications

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

	Default = 5 Hz
Warble tone frequency deviation	5 - 25 % Default = 10 %
Masking	Narrow band noise automatically centered at the test frequency

*The default extended high frequency (9 kHz - 16 kHz) reference equivalent threshold sound pressure levels (RETSPL) are different to those of ISO 389-5 for insert earphones.

Speech Testing Specifications

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

Additional Audiometry Specifications

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

Air Conduction Frequency Specifications

Freq (Hz)	RETSPLs (dB)	Max Output (dBHL)
125	28.0	70
250	17.5	90
500	9.5	105
750	6.0	110
1000	5.5	110
1500	9.5	110
2000	11.5	110
3000	13.0	105
4000	15.0	100
6000	16.0	85
8000	15.5	85
9000	13.5	85
10000	12.5	80
11200	21.5	75
12500	25.5	75
14000	32.5	60
16000	41	50

Bone Conduction Frequency Specifications

Freq (Hz)	RETFLs (dB)	Maximum Mastoid Hearing Levels (dBHL)	Maximum Forehead Hearing Levels (dBHL)	Maximum Mastoid Hearing Levels (Occluded ear) (dBHL)
250	67.0	35	35	45
500	58.0	60	50	60
750	48.5	65	55	60
1000	42.5	70	60	65
1500	36.5	80	70	70
2000	31.0	80	70	70
3000	30.0	80	65	70
4000	35.5	65	60	60

Occluded ear (bilateral ear tips in sito)

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

Narrowband Masking Specifications

Replacement Item Specification

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

Electromagnetic Compatibility (EMC)

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

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

The use of accessories and cables other than those specified or sold by eMoyo may result in increased emission or decreased immunity of the KUDUwave. The list of cables and accessories below must be adhered to in order to ensure compliance.

The KUDUwave should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary then the KUDUwave[™] should be observed to verify normal operation in the configuration in which it will be used.

List of cables and accessories that affect compliance

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

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Power supply lines: not applicable, see note 2 ±1 kV for input/ output lines	See note 2
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable, see note 2	See note 2
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000- 4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not applicable, see note 2	See note 2
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
			Portable and mobile RF communications equipment should be no closer to any part of the KUDUwave [™] , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
Conducted RF	3 Vrms	3 Vrms	Recommended separation distance:	
IEC 61000-4-6	150 kHz to 80 MHz		$d = 1.2\sqrt{P}$	
			$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz	
			$d = 23\sqrt{P}$ 800 MHz to 2.5 MHz	
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	(((··)))	

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

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

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KUDUwave[™] is used exceeds the applicable RF compliance level above, the KUDUwave[™] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KUDUwave[™].
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

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

NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency applies. NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

End User License Agreement (EULA)

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

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

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

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

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

eMoyo reserves all rights not expressly granted.

Warranty and Disclaimer

Limited Warranty

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

This warranty

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

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

Disclaimer

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

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