KUDUwave™

thinking out the booth

User Manual

eMKW-TD0054-21| Date of Issue: 22 October 2020

Contents

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.

The KUDUwave is intended to:

- Test air and bone conduction thresholds (at conventional and extended high frequencies) to amplitude threshold levels of that of a Type 3 Basic Diagnostic Audiometer as described in BS EN 60645-1
- Test word recognition and speech reception thresholds as a Type B Basic Speech Audiometer in accordance with BS EN 60645-1
- Test aural acoustic impedance/admittance functions in accordance with the requirements for a Type 1 Diagnostic/ clinical Tympanometer as detailed in BS EN 60645-5.

Clinical Benefits

- Serving and accessing more patients as a result of the KUDUwave portability
- Boothless assessments allowing for diagnostic audiometry outside of the sound booth
- Comprehensive testing allowing for timely and cost-efficient auditory disorder management and direct referrals
- Ability to assess two ears simultaneously (bilateral tympanometry)
- Integrated with acoustic reflex measurements
- Has two tympanometers, which allows a hearing health clinic to continue functioning should one tympanometer stop functioning
- Effective first-time probe sealing as a result of KUDUwave TMP placement

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 distractions.

Indications

The KUDUwave can be used to perform behavioural pure tone (air and bone conduction) audiometry, speech audiometry, and objective acoustic immittance testing on test subjects. The KUDUwave is ideal

to use:

1. Inside a sound-treated booth, similar to traditional audiometer/ booth setup,
2. In healthcare facilities,
3. In the clinician's consultation room,
4. At schools, factories, shops and old age homes,
5. In conditions where open air testing is clinically required - for example, in cases of subjects with contagious diseases (i.e. MDR-TB),
6. Alongside a hospital bed, or inside a prison cell,
7. Where test room ambient noise certification services are limited,
8. Where trusted testing is needed in conditions where ambient noise levels fluctuate,
9. Where there is a need to conduct a remote test as a result of not having a clinician onsite to perform the test,
10. Where there is a need for automatic testing as a result of mass audiometric testing and/ or lack of qualified professionals onsite,
11. Where there are poor infrastructure and a shortage of technicians to calibrate audiometers and certify test rooms to be quiet enough for compliant testing, and
12. Where the audiometer needs to travel regularly from one test site to the next.

Contra-Indications

The KUDUwave cannot be used to do behavioural testing in subjects that cannot clearly indicate when they heard the sounds presented, for example younger children (less than 12 months of age) and mentally compromised test subjects.

The KUDUwave acoustic immittance and pure tone testing should not be conducted if;subjects have otorrhea, otitis externa, or the presence of a foreign body in the ear canal.

Residual Risk

- Cross-infection between patients when eartips are re-used. Please do not re-use eartips on various patients.
- Cross-contamination between patients when applied parts are not sufficiently cleaned according to the instructions provided. Please ensure that these parts are cleaned sufficiently between patients.
- Temporary threshold shift (TSS) can occur when loud tones are played for extended periods of time. Please do not present loud tones over extended periods of time.
- Possible temporary patient discomfort caused by the silicone sleeve of the KUDUwave OH. Although discomfort may be experienced by some patients, please do not modify the sleeve as it provides robustness and physical protection from shock, based on the device's intended purpose.

Device Description and Application

The KUDUwave is a portable, PC controlled, USB-powered, audiometric device capable of performing diagnostic testing for pure-tone, speech and aural acoustic impedance/admittance audiometry outside a certified sound room.

The device is manufactured as a headset with two ear cups and a head-band joining the two earcups. It connects to a Windows PC using two 3 m USB cables and is supplied with a USB Patient Response Button which can be plugged into the PC or the headset itself.

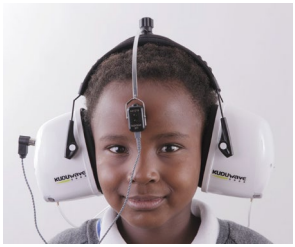
The device makes use of insert earphones and passive noise-attenuating ear cups to allow for compliant

testing outside a traditional soundproof booth. Custom sound-pressure-level meters are included to monitor the ambient noise.

The device 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 device 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.

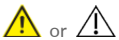
Training and Certification Requirements

Training is provided free of charge via an online session within the first 30 days of purchase for both facilitators and operators of the KUDUwave. Additional training resources are available via the KUDUwave academy (https://emoyo.net/kuduwave-academy/) as well as a comprehensive helpdesk available at emoyo.net/category/helpdesk/. The operator will receive a certificate of completion after successfully completing their training.

Additional technical support is also available via our ticket based system, online chat, email and telephone with the KUDUwave support team. Additional group or one-one training may be provided at a cost, to be determined at such time as it is necessary.

Description of Symbols

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

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

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 - eMoyo EMR
- 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™ OH	KUDUwave™ Prime	KUDUwave™ Pro	KUDUwave™ Pro TMP
Screening	Screening	Screening	Screening
-	-	Diagnostic (Bone VIbrator Included)	Diagnostic (Bone VIbrator Included)
-	-	Monitoring of Ototoxicity	Monitoring of Ototoxicity
-	-	Extended High Frequency (up to 16kHz)	Extended High Frequency (up to 16kHz)
-	-	-	Tympanometry

KUDUwave™ Serial Number

The unique serial number is clearly marked on 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.

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 (Pro and Pro TMP configurations only)
- Calibration certificate
- Two sound tubes with stainless steel ear tip couplers or silicone ear tip coupler/ TMP probes, attached to the KUDUwave (dependent on the KUDUwave configuration).
- Spares:
    - Prime and Pro configurations come with 6 sound tubes and 1 stainless steel coupler
    - TMP and OH configurations come with one spare tympanometer probe and one stainless steel ear tip coupler
- TMP configurations come with one calibration pod

Laptop Requirements

Laptop Minimum Requirements

- Core i3 Processor
- Windows operating system (no older than Windows 8)
- 4GB RAM
- No less than a 250GB hard drive
- WiFi enabled
- A Webcam

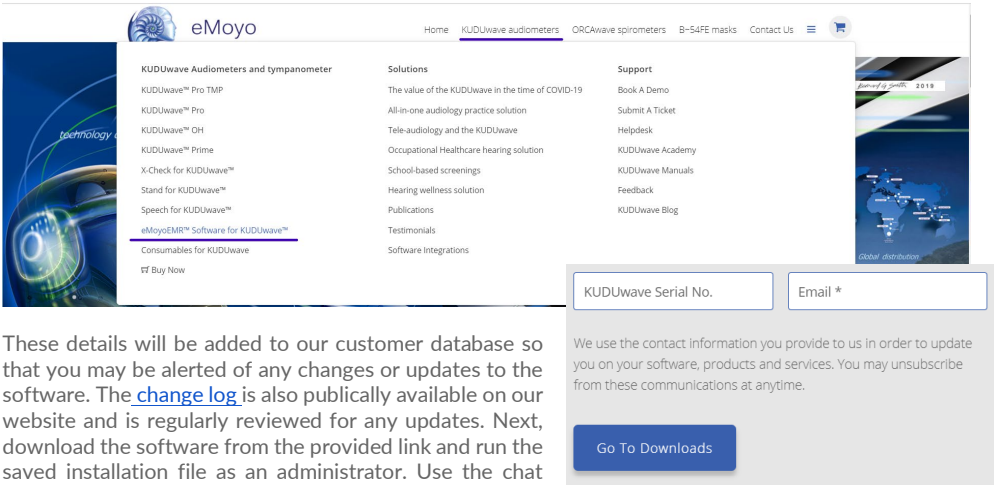
- 2 USB ports (response button can be plugged into one ear cup if necessary)

If a USB hub is required, please ensure it adheres to the following specifications:

- Self-powered (it must have its own power supply from an electrical wall plug)
- Supplies 5 Volts and 1 Amp per port
- USB 2.0
- at least 3 ports available for the KUDUwave connections (Left cup, Right cup and Response Button)
- A USB Hub cannot be used with the KUDUwave Pro TMP. Consult support if you require one.

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 eMoyo website (www.emoyo.net). Click on KUDUwave Audiometers in the main menu and select eMoyoEMR Software for KUDUwave. Submit your contact information to gain access to the downloads page.



These details will be added to our customer database so that you may be alerted of any changes or updates to the software. The change log is also publically available on our website and is regularly reviewed for any updates. Next, download the software from the provided link and run the saved installation file as an administrator. 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 eMoyoEMR shortcut on your PC's desktop. Alternatively you can find eMoyoEMR under programs in your start menu. Launch immediately after installation or, click the icon to launch.

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 computer screen. If the computer is being used so that the space bar is the patient response button, then the computer can face the patient, however the testing screen must be put into hidden mode. Read more under Working with Clinical Tests. 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 possible. Patients who are notably anxious should be calmed and reassured before testing. Furthermore, condition your patient as to how the test will be conducted and use the software conditioning page to show them what the pure tones and masking will sound like.

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. Ensure these are secure and pushed all the way in until the LED light comes on.

The KUDUwave will indicate the right side with a red light (**Note this is not a warning 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 a hazard.

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 the drivers did not install correctly, you will need to remove the old drivers and reintroduce the KUDUwave to the computer. Read more under Troubleshooting.

Warning: If you launch the KUDUwave software before the drivers are installed, the KUDUwave software will prompt you that it could not find the device, even though the device is plugged in. Close and reopen the software once the KUDUwave device is set up. Contact Support should the software still not find the device.

Performance Verification of the KUDUwave™

To test the KUDUwave hardware, plug in the device and perform X-Check (built in calibration verification tool). This will also indicate any performance issues. Report any faults found to your distributor.

Disconnecting the KUDUwave™

If it is required that the KUDUwave be disconnected, ensure all test data is saved and close the software. The USB cables can then be unplugged. For safe storage and to extend the lifespan, please wind the USB cables in large loops when returning to the case for storage.

Ear Inserts

Ear tips must be firmly attached to the plastic tubes using the stainless steel couplers or the plastic probe designed for silicone eartips. 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 either one of the ear cup USB ports, or into a third USB port in the PC. A light will pulse (come on and switch off again) if connected correctly.
Note: Not all KUDUwaves are powered the same by different laptops and the response button may not work when plugged into the ear cup USB port. Use the response button in the laptop port in these cases.

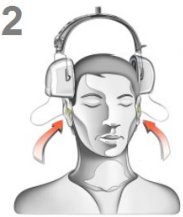
Positioning the KUDUwave™ Headset

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 (indicated by a Blue LED light) must be on the patient's left hand side and the right ear cup (indicated by a Red LED light) must be on the patient's right hand side.



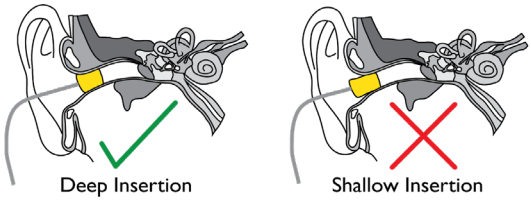
Step 2.1: Insert KUDUFoam Eartips

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 for adults, (pull the pinna down for 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.

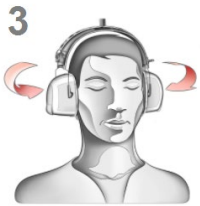
Yellow eartip inserts are intended for most ear canal sizes while beige eartip inserts are intended for very small ear canals (i.e. children).

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



Step 2.2: Insert Silicone Eartips

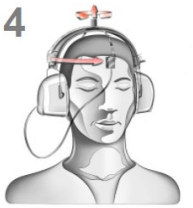
Select the correct size silicone eartip, pull the ear pinna up and back and insert the silicone ear tip in position. Ensure the eartip is firmly in place and flush with the ear canal. A loosely fitted ear tip or shallow insertion will result in testing inaccuracy. Silicone eartips are used only by KUDUwave OH and ProTMP models.



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 intended for forehead placement. 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 internet connections.

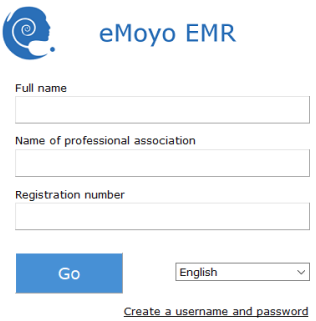
To test remotely:

- The trained operator positions the KUDUwave on the patient or the patient is instructed to position the KUDUwave on themselves.
- The trained facilitator can login to the patient's PC to control the test through a remote connection (like TeamViewer), or the test can be conducted on the patient's PC and the result emailed to the clinician at a later time.

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

Getting Started with the KUDUwave™ Software

Practitioner Details



Run the eMoyoEMR application by double clicking on the icon on your desktop, and enter your details (not mandatory). These details will appear on all reports and audiograms.

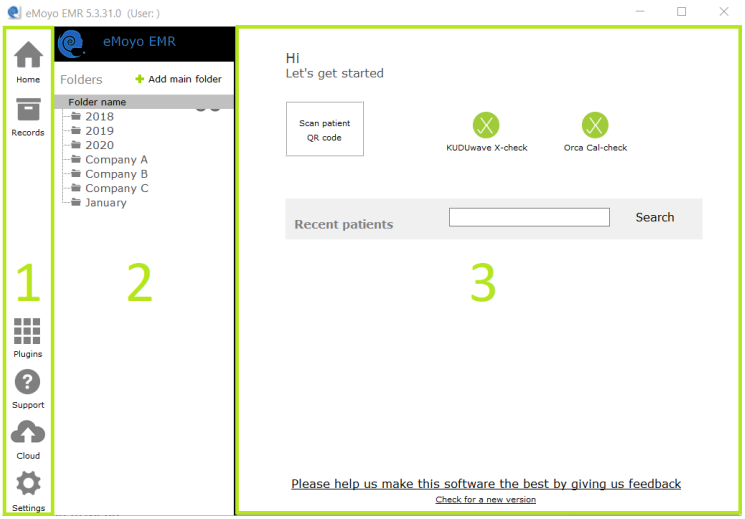
You can also select your language of choice.

Click the "Go" button to proceed.

Home Page

Your Portal to Patient Management

The home page appears as below with 3 main sections.



1. **System Menu**

   Here you have access to:

   - Home *(return to the home page)*
   - Records *(return back to the folder you were busy with)*
   - Plugins *(additional features which can be added to your software)*
   - Support *(Contact support here, or use these tools to troubleshoot)*
   - Cloud *(synchronization of data to eMoyo cloud storage)*
   - Settings *(backup data, personalise your reports and more)*

2. **Folder Management Pane**

   Folders can be created and managed here. It is recommended to organise patients either under alphabetical folders, organisation / company names or according to the date (month/year) they were tested.
   See more examples on the KUDUwave help desk at: emoyo.net/category/helpdesk/

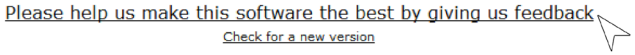
3. **Data View Pane**

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

   - Scan QR codes *(for quick retrieval of patient data)*
   - KUDUwave X-Check *(built in automated calibration verification tool)*
   - Orca X-Check *(spirometry calibration for the Orca)*
   - Search *(filter through your patients using 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.

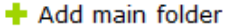


Or **contact us** through our website : www.emoyo.net.

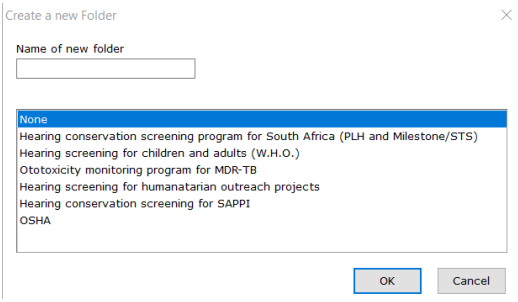
Working with Folders

Management of folders is done within the Folder Management Pane

Creating Folders and Subfolders

To create a folder click: 

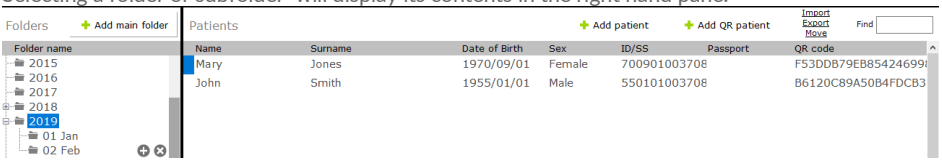
Enter the name of your folder in the space provided. Select a smart folder setting if you wish to use this feature. Learn more in the Smart folder section. Select "OK" to save.



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.

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.

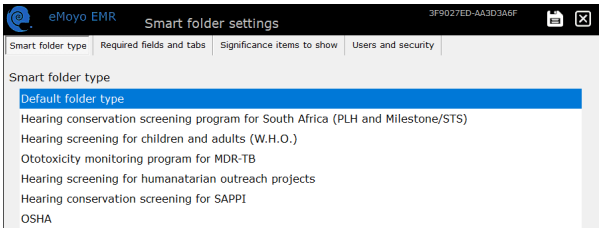


Smart Folders

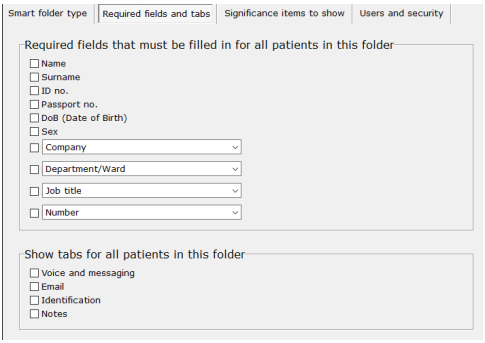
The KUDUwave uses multiple criteria (OSHA, SANS, WHO etc.) to develop testing protocols and assistive interpretations of results. The KUDUwave also uses these criteria to separate which test protocols are most needed and used by a particular industry.

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.

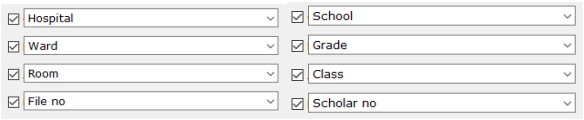
Under the “Smart folder type” there are seven available smart folder configurations, each with their own user interfaces and pre-selected tests for all patients in this folder. Select an option and save.



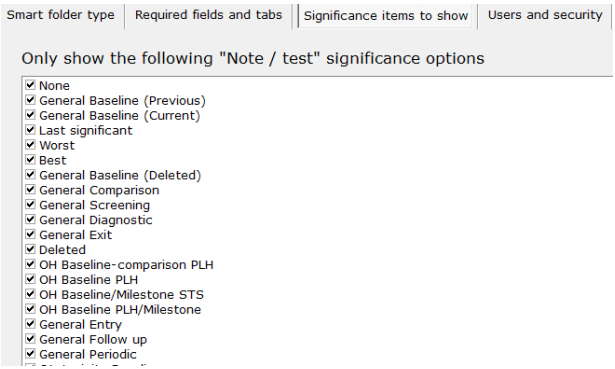
Under “Required fields and tabs”, you can customise the selected smart folder type by selecting which details you want to make required fields before any tests can be conducted.



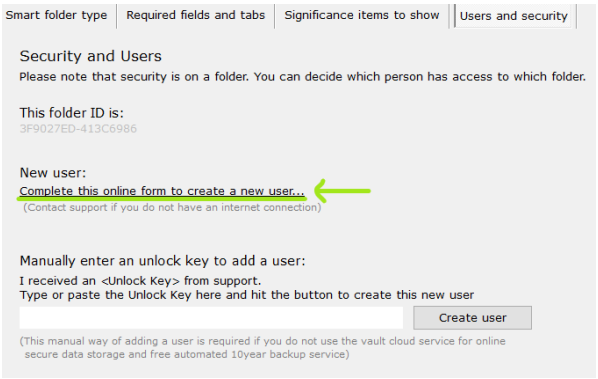
You can change the last four field names to relate to a hospital or school setting.



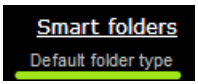
Under “Significance items to show”, you can select the labels which are available to use for the tests generated in this folder. Note: Some of these test significances are relevant for particular audiogram layouts which pertain to your industry. (i.e. PLH test significances are required for the software to do test comparisons and identify between baseline, screening and exit tests)



Under “Users and security”, you can set up folder security restricting access to particular folders. Contact eMoyo by completing the online form.



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



Listed below are the different types of smart folders and how you can use them.

Hearing Conservation Screening Program for South Africa (PLH and Milestone/STS)

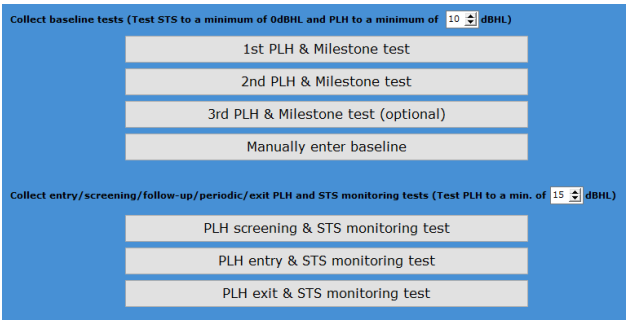
Using this smart folder type simplifies the method of testing to identify early hearing loss and to calculate measures for compensation.

Which tests can I perform in this folder type?

- Milestone Baseline & STS Screening (Standard Threshold Shift)
- PLH Baseline, Screening, Entry, Follow-up, Periodic and Exit (Percentage Loss of Hearing)

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 below 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.



Baseline Tests

- If you want to collect a baseline result, select from the top section.
- Complete two baseline tests, or even a third if you suspect the patient is malingering.
- Manually enter the baseline results of the patient if they were tested before, but are new in the KUDUwave database.
- Adjust the dB level to limit the test. By default this is set to 10dB

Follow Up Tests

- If the patient already has a baseline result in the database, and you want to collect a follow-up result, select the type of test from the bottom section.
- Adjust the dB level to limit the test. By default this is set to 15dB

Hearing Screening for Children and Adults (WHO)

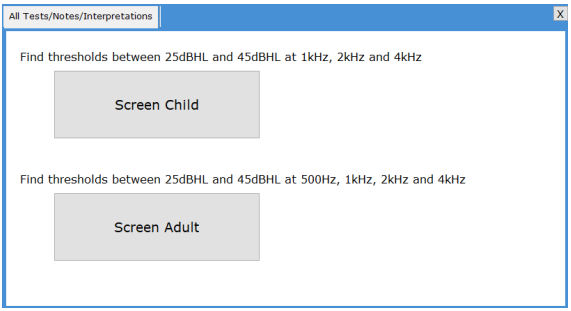
This folder is designed to screen masses efficiently and effectively using World Health Organization guidelines.

Which tests can I perform in this folder type?

- Pure tone test which finds thresholds between 25 - 45 dB HL at 1kHz, 2kHz and 4kHz for Children
- Pure tone test which finds thresholds between 25 - 45 dB HL at 500Hz, 1kHz, 2kHz and 4kHz for Adults.

How do I start testing?

1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
2. The menu below 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.



Ototoxicity Monitoring Program for MDR-TB

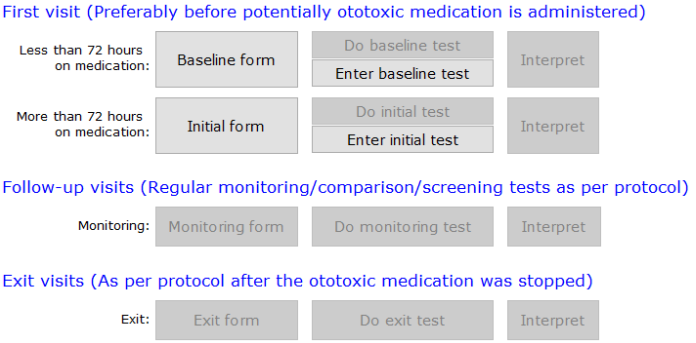
This folder specifically caters for the MDR-TB program set-up in South Africa, but can be applied to other projects across the world.

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
    - 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.

Hearing Screening for Humanitarian Outreach Projects

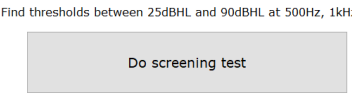
This folder is designed to screen masses efficiently and effectively.

Which test can I perform in this folder type?

- Pure tone test which finds thresholds between 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. The menu below 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.



Hearing Conservation Screening for Sappi

This folder type is relevant to the corporation Sappi in South Africa only.

OSHA

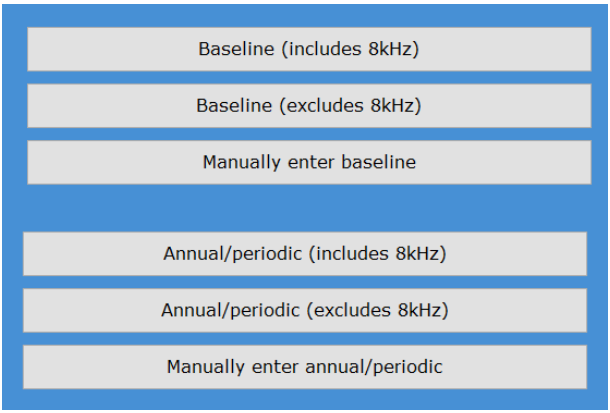
Using this smart folder type simplifies the method of testing to identify early hearing loss and to calculate measures for compensation.

Which test can I perform in this folder type?

- Pure tone test which finds thresholds between 25 - 90 dB HL at 500Hz, 1kHz, 2kHz, 4kHz and 8kHz.
- Milestone Baseline & STS Screening (Standard Threshold Shift)

How do I start testing?

1. After adding a patient to the smart folder, click on +Note/Test to open a new test.
2. The menu below 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.



Baseline Tests

- If you want to collect a baseline result, select from the top section, either including or excluding 8kHz.
- Manually enter the baseline results of the patient if they were tested before, but are new in the KUDUwave database.

Follow Up Tests

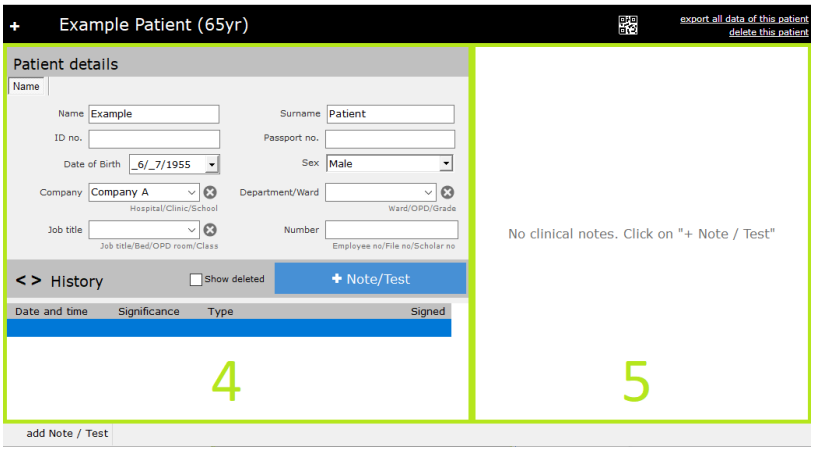
- If the patient already has a baseline result in the database, and you want to collect a follow up result, select the type of test from the bottom section, either including or excluding 8kHz.

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 the home page.

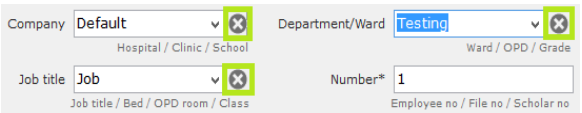
Adding a New Patient

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 tests thereafter will have the updated information. Patient information on saved tests cannot be edited.



Tips:

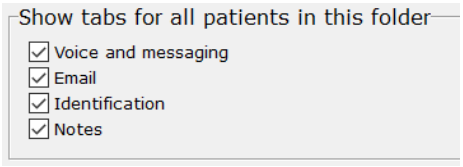
- *Click the tab key to quickly navigate between fields.*
- *After entering a South African ID number, click the Tab key to automatically populate the date of birth, age and gender..*
- *Folder names are assumed to be company names, and subfolders as job titles. These fields will be automatically populated with these details. Correct them if necessary 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*



Additional Details

There are four additional tabs which can be added within the Patient Data Pane.

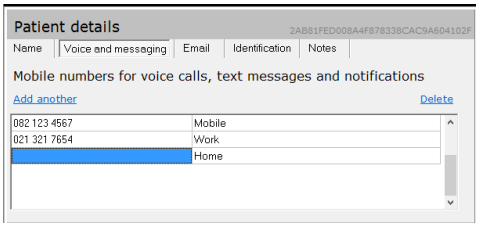
To add or remove these tabs from all patient files within the folder selected, click on Records then click on Smart folders in the top right hand corner of the screen. Go to Required Fields and Tabs. Check the box for each required tab in the patient file. Save the folder settings and return to your patient file to complete the information.



Voice and Messaging

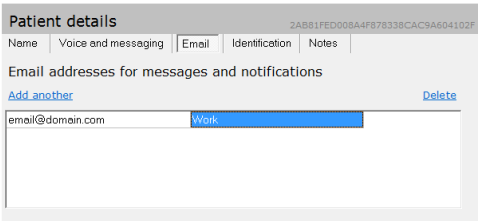
Add the patients phone numbers in the fields provided*. Select “Add another” to add additional numbers, and “Delete” to remove.

***Note**: Do not add **+** before the country code.*



Email

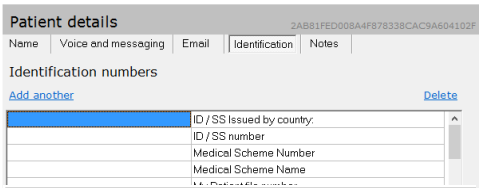
Email addresses linked to your patient can be stored here. Select the Email tab to add email addresses. Select “Add another” to add additional email addresses, and “Delete” to delete email addresses.



Identification

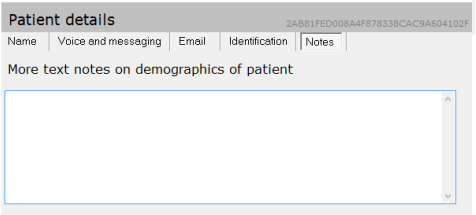
Select Identification to add additional types of identity details for the patient.

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



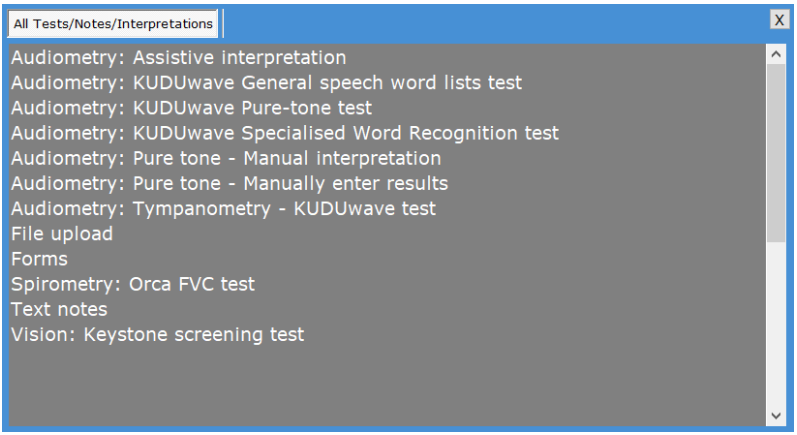
Notes

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



Notes and Tests

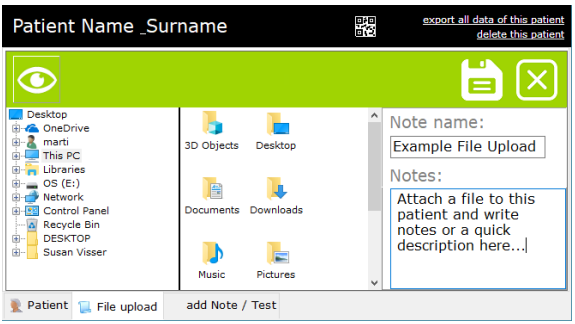
KUDUwave™ software bundles notes and tests within a single function. To add a new note or test click on + Note/Test to get access to the following options:



All audiometry listed items are discussed in the "Working with clinical tests" section. Request the Orca or Keystone User Manual to find out more about this added feature of the eMoyoEMR software.

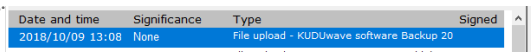
File upload

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



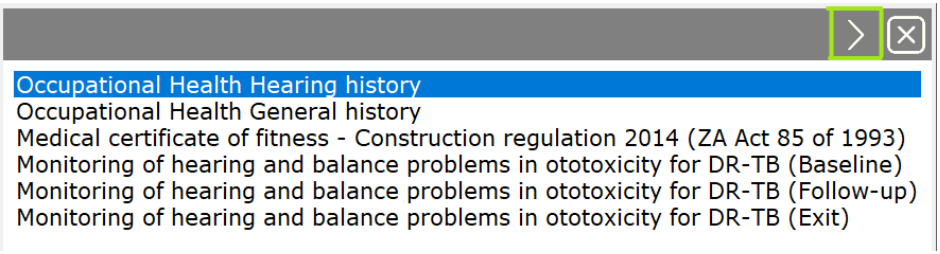
Browse to the file you would like to upload to the patient profile, select it, name it and provide some details about the file you are uploading.

Click the save icon to upload the file.



Forms

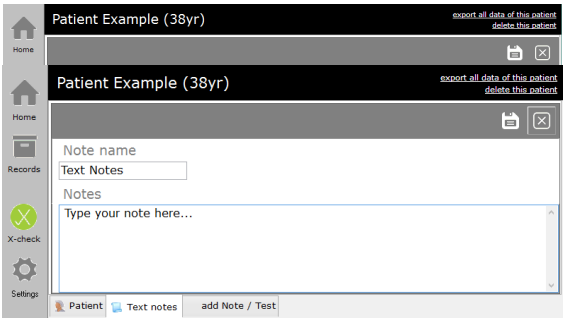
The software comes with built-in patient questionnaires to help supplement your test results. Click on any of the listed questionnaires, then click on the "Next" arrow to fill it in.



Text Notes

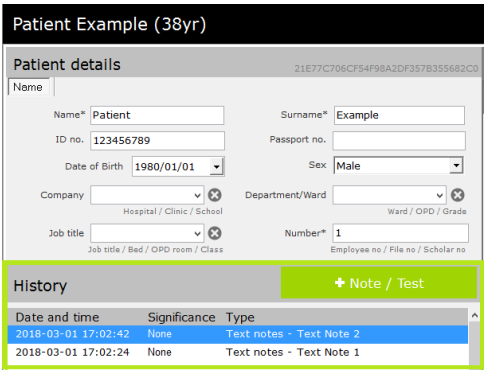
Select "Text notes" from the **+Note / Test menu.** Enter the name of the note and enter the note text.

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



Patient History

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



Patient Data Storage

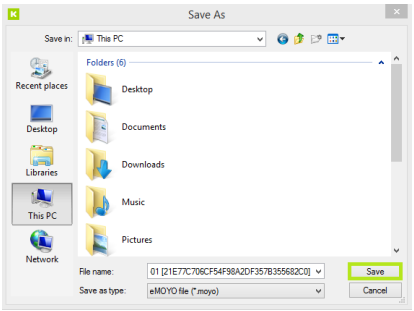
Data is obfuscated locally and only accessible/readable via the eMoyo software. No data can be deleted, it is only hidden from the end user in the software. The patient database is encrypted and stored in hidden folders under GUIDs that are linked to the respective tests or patients.

eMoyo does not take responsibility for the transmission of data off the PC, if the end user requires any backup solutions (cloud or hardware) it is done at their own risk. If third party integrations are utilised then it is the responsibility of the third party application to handle the data. Unless an agreement is made with eMoyo and the risks of data transfer are appropriately mitigated.

Exporting Patient Data

Exporting a Single Patient's Data

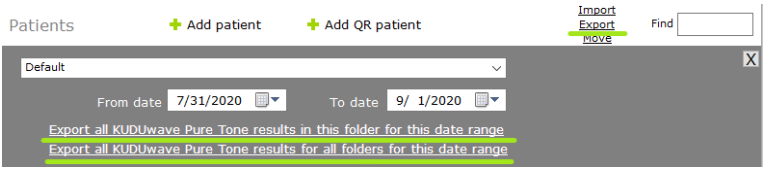
From within a patient profile, click on "export all data of this patient" at the top right corner of the patient management screen. This will bring up a dialogue box. Select where you would like to save the patient data, and click "Save".



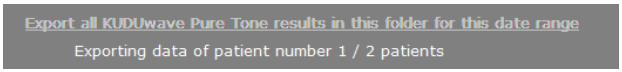
Note: This exported data can only be viewed if imported back into the eMoyo software.

Exporting Multiple Patients' Data

From within a folder, you can export multiple pure tone test results for all patients within a specific date range. This can include patients from that folder alone, or all patients in all folders. In the folder view, click "Export", select a date range and then click "Export all KUDUwave Pure Tone results in this folder for this date range" to only include patients in this folder. Click "Export all KUDUwave Pure Tone results for all folders for this date range".



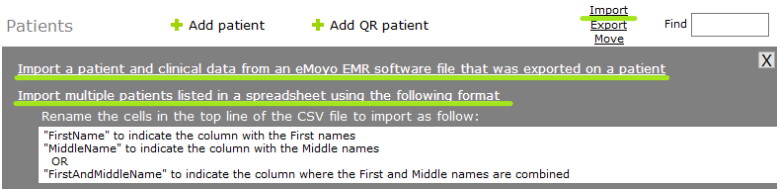
Select where you would like the file to be saved and click "Save" to finish. The software will inform you of the progress of the export.



Note: This exported data is saved in csv format and must be opened as a spreadsheet. If all data is stored in one column, convert the Text to Columns by choosing the delimiter as a comma.

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".



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 eMoyo EMR software file that was exported on a patient". Find and select the "**.moyo"** file, then click "Open" to import it.

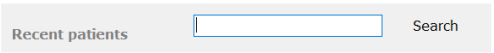
Import Multiple Patients from a Spreadsheet

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 "Import multiple patients listed in a spreadsheet using the following format". Select the "**.csv**" file and click "OK".

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

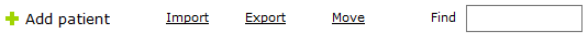
Finding Patients

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.

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 eMoyo EMR 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.

In the Settings menu you can print multiple of these codes, copy the unique code associated to the QR code printed and assign it to the patient. This will override the automatically generated QR code and replace it with the one you printed.

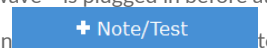
On the home screen click on 

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

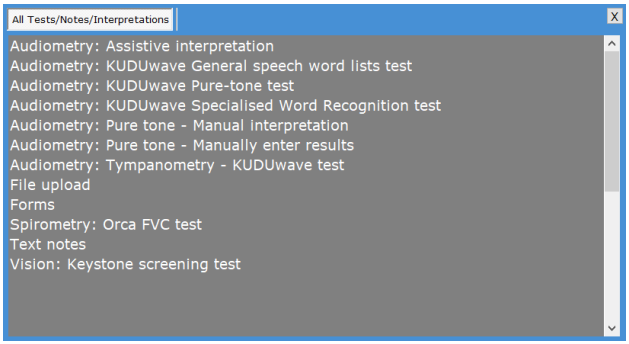
Working with Clinical Tests

Create a New Test

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

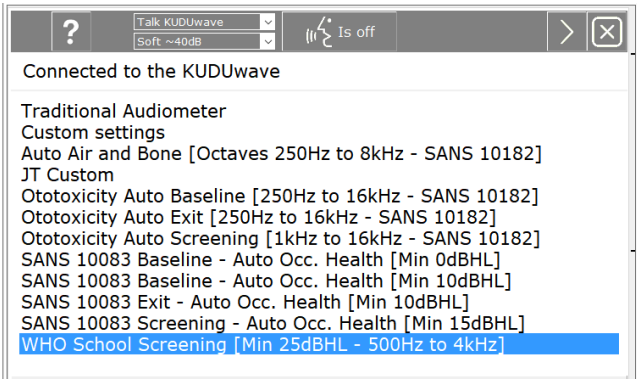
To add a new test click on 

to get access to the following options:



To do pure tone audiometry select :

"Audiometry: KUDUwave Pure-tone test"



From this next test protocol menu select the type of protocol to perform from the list and then press "**Next**".

This will start the "**macro**", an automatic testing 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 forward button, seen below.

Click here to turn on .
Click here again to turn off.

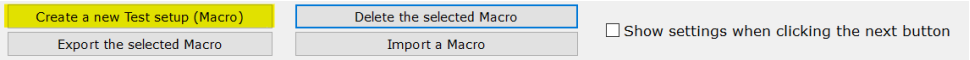
Create a New Test Macro

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 ✚ Note/Test.

Select “Audiometry: KUDUwave Pure-tone test” and you will then see the test protocol menu as on the previous page.

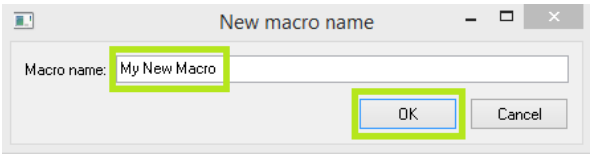
Note: You can copy the preset settings of the default macros in this menu to your new test macro. This is an easier way to make minor adjustments to the already existing test protocols. Just click on one of the pre existing test macros, and then click on the button at the bottom of the screen “Create a new Test setup (Macro)”. To start from scratch, just click on this button without a test protocol preselected.



You can view the settings of any test macro before proceeding to the test, by checking the box next to: “Show settings when clicking the next button”.

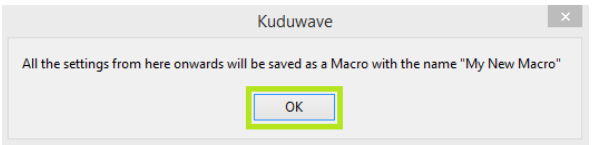
Delete any unwanted test macros by selecting the test macro and clicking “Delete the selected Marco”.

Export and Import custom or default test macros using the two options respectively mentioned at the bottom of the screen.



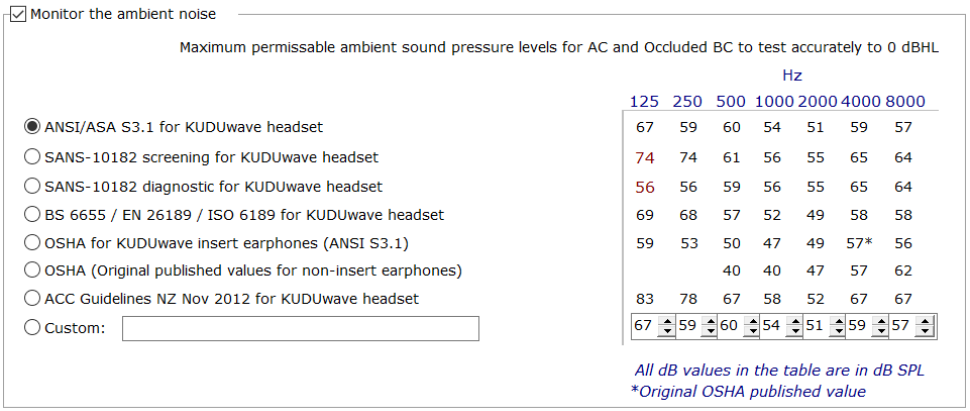
Once you have clicked on “Create a new Test setup (Macro)” enter the new name for this Macro.

Select “OK” twice.

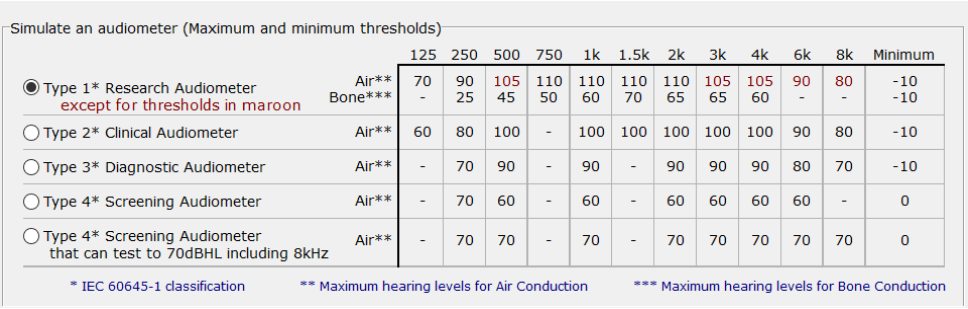


Your first option to select is the standard by which you would like to monitor the ambient noise in the room.

Start page



The second option relates to the type of audiometer required for the testing. This only limits the area which will be tested. For example the Diagnostic audiometer settings has a higher dB range than the screening audiometer. This must be noted carefully, as not all audiometer simulations allow you to test all frequencies.

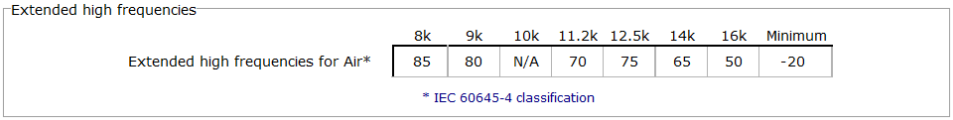


Simulate an audiometer (Maximum and minimum thresholds)

		125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	Minimum
◉ Type 1* Research Audiometer except for thresholds in maroon	Air**	70	90	105	110	110	110	110	105	105	90	80	-10
	Bone***	-	25	45	50	60	70	65	65	60	-	-	-10
○ 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
○ 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

* IEC 60645-1 classification ** Maximum hearing levels for Air Conduction *** Maximum hearing levels for Bone Conduction

The table below is applicable only to devices with extended high frequencies.

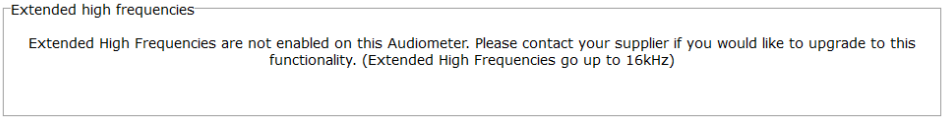


Extended high frequencies

	8k	9k	10k	11.2k	12.5k	14k	16k	Minimum
Extended high frequencies for Air*	85	80	N/A	70	75	65	50	-20

* IEC 60645-4 classification

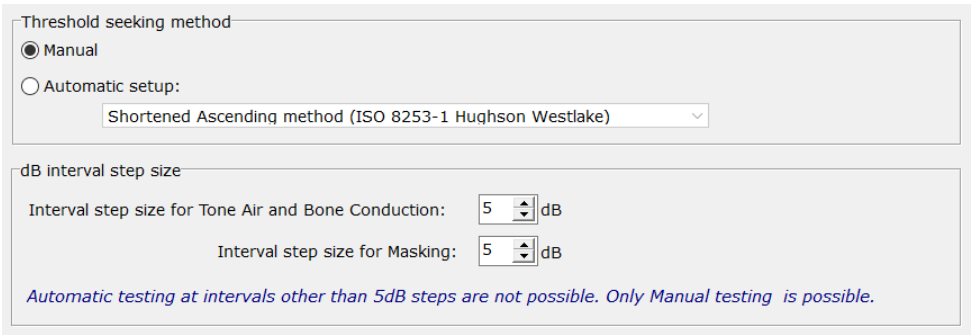
If your device does not have this capability then you will see this:



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)

Following the extended high frequency selections is the Threshold seeking method options. Here you can choose between automated and manual threshold seeking methods, as well as the choosing the desired intensity seeking step-size (e.g. 5 dB or 2 dB step-size).



Threshold seeking method

◉ Manual

○ Automatic setup:

Shortened Ascending method (ISO 8253-1 Hughson Westlake)

dB interval step size

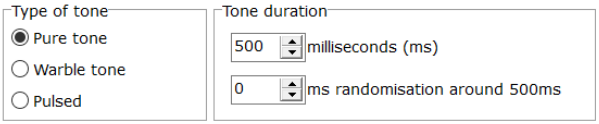
Interval step size for Tone Air and Bone Conduction: 5 dB

Interval step size for Masking: 5 dB

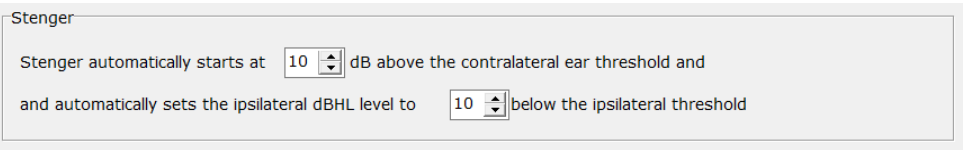
Automatic testing at intervals other than 5dB steps are not possible. Only Manual testing is possible.

Below this section is the option of tones which can be presented, the duration of the tone and the

randomisation interval between presentations.

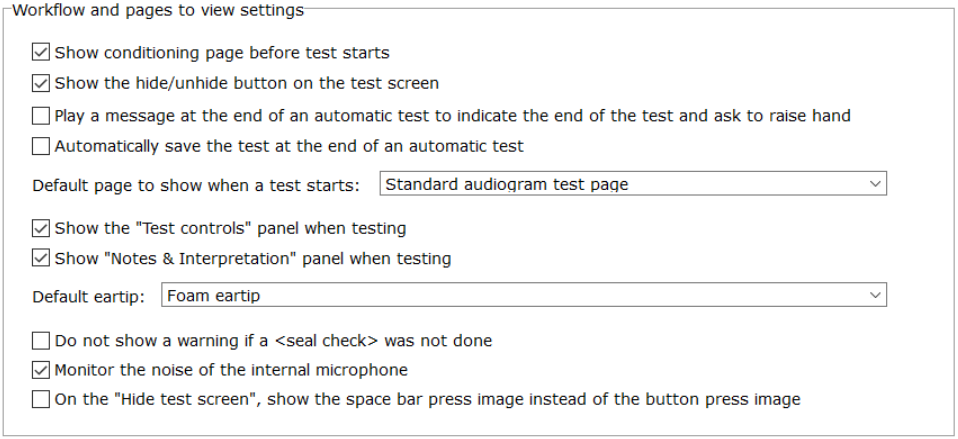


The parameters of the stenger test can be set here:

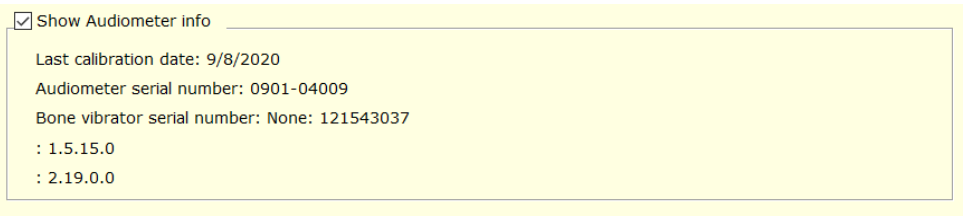


To use the stenger test, you will need to click on the button later on in the test.

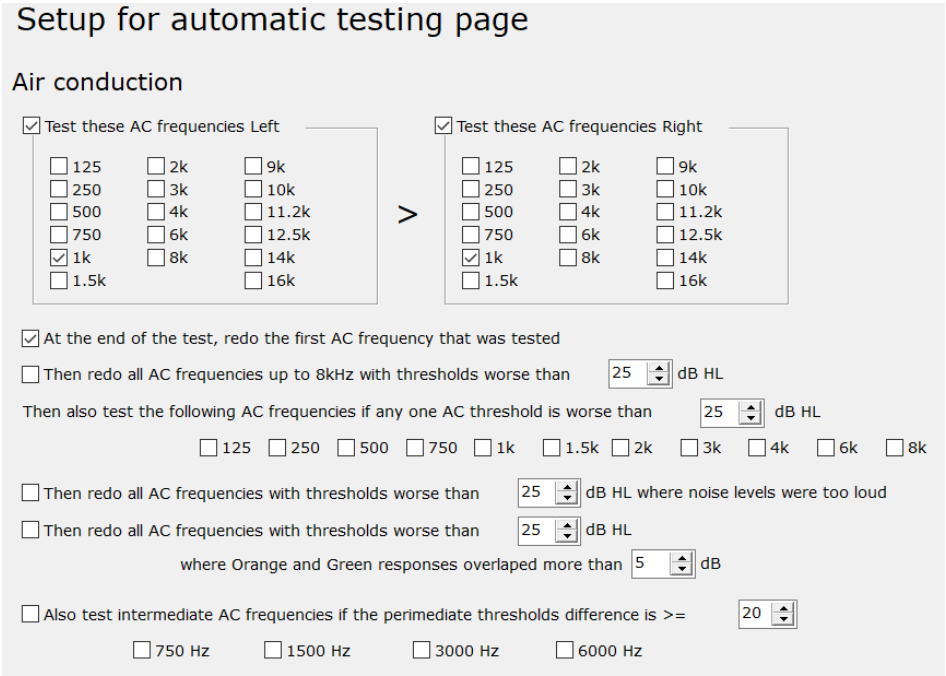
Workflow and pages to view settings, seen below, includes a variety of options which can be viewed by the operator or patient before the test begins. Check the box for any option which is required.



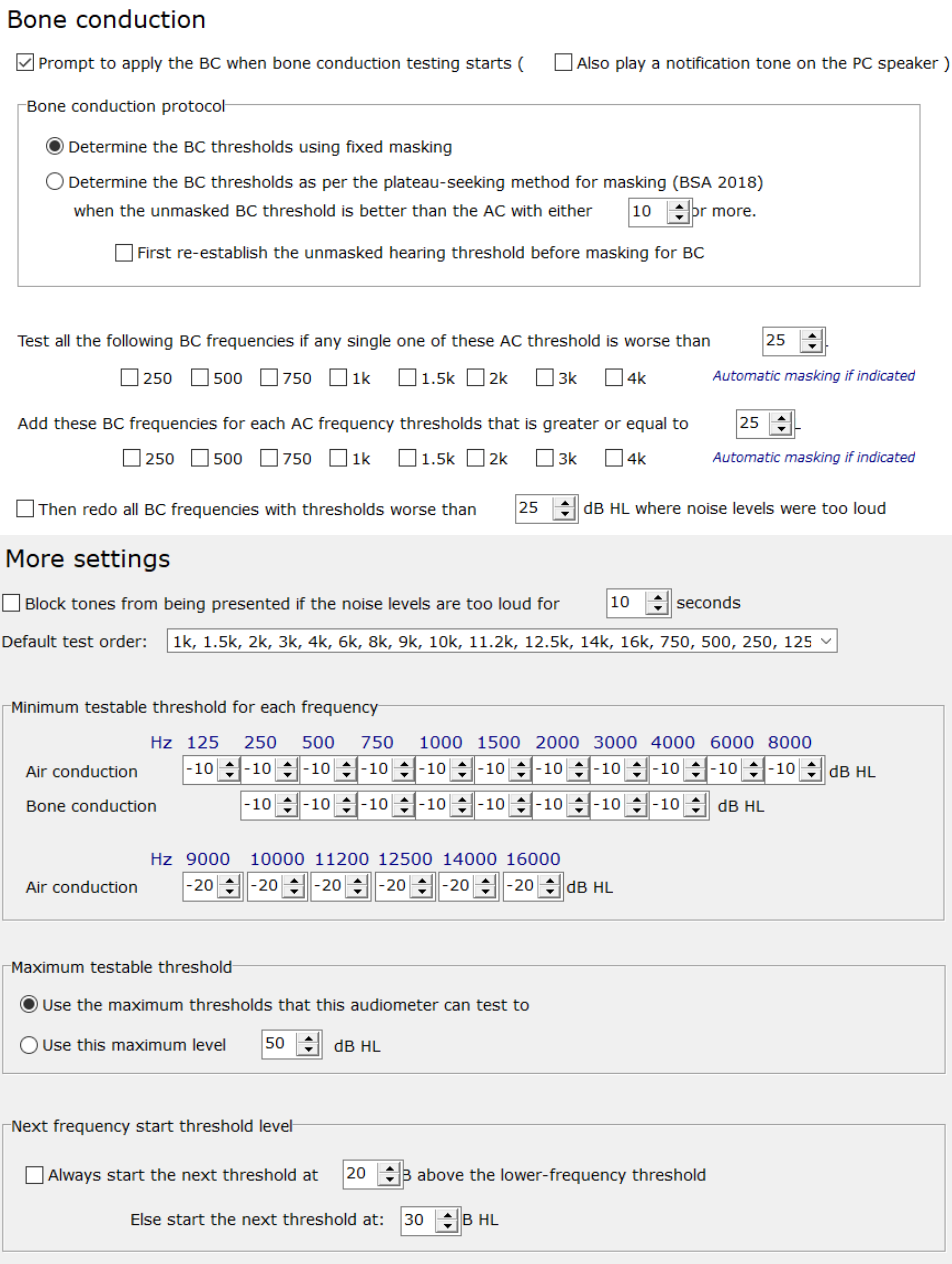
To view details regarding your KUDUwave audiometer, check the box below:



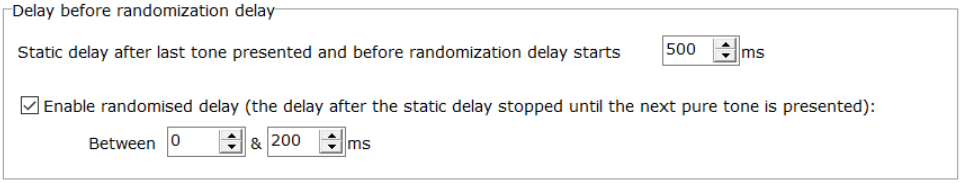
Click Next >, to move on to the “Setup for automatic testing page”, or if you have chosen the manual method of threshold seeking, you will move onto the “Masking and Occlusion Effect Rules” page.



Select frequencies to be tested for each ear for air conduction and edit further settings to design your custom macro. Scroll down to then select all the bone conduction frequencies which should be tested.



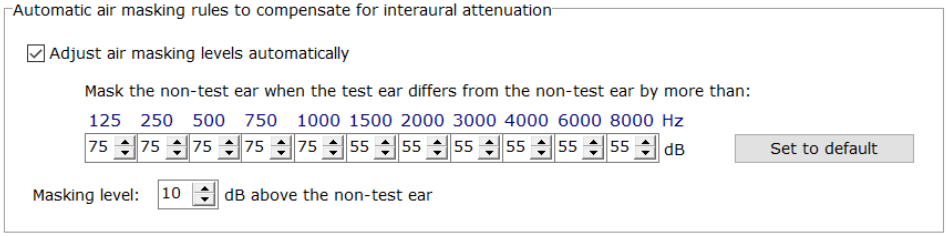
Under “more settings” you can edit whether tones must be blocked if noise levels are detected to be too loud, minimum and maximum test thresholds and what dB level you want each frequency to begin testing from.

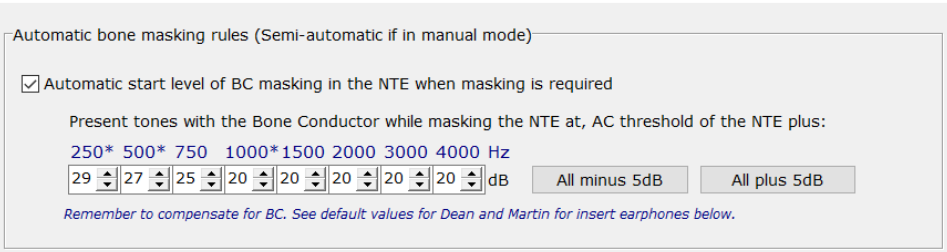


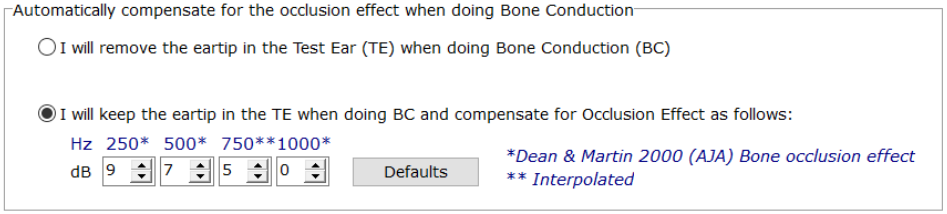
Lastly, you can edit the time frame before tones are presented, either increasing or decreasing delays and the randomized delays.

Click  , to move on to the "Masking and Occlusion effect rules" page.

Masking and occlusion effect rules







Deselect these check boxes if you want to mask manually during the test.

Click  , to move on to the "Conditioning page".

Conditioning Your Patient

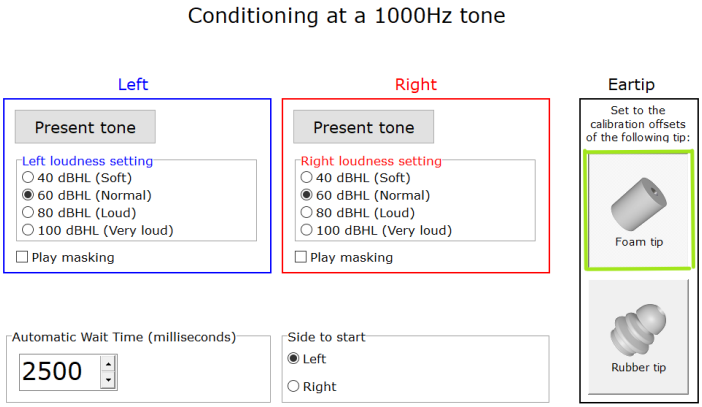
Below is the conditioning page. First select the correct eartip which is currently being used (foam or rubber). If silicone (rubber) eartips are being used, you will need to do a Seal Check before presenting a tone.

Present a tone to the patient on this page at either, 40, 60, 80 or 100 dBHL at 1kHz, and assess if they respond by pressing the response button well within the waiting time. Automatically the wait time is set to 2,5 seconds (2500 milliseconds). You can lengthen or shorten this time period. This is very important for automatic testing, however during manual testing you can use your own discretion.

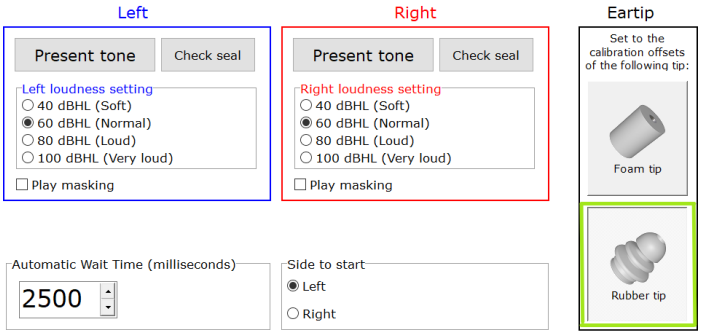
You can also show the patient how masking will work by checking the box and playing the masking sound at this stage as well.

If the patient responds in good time, a green message will appear and you can proceed to the test. If the patient does not respond in time, a pop up message will say: “Button not pressed in time”. Explain the testing procedure 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 a bit too slow for automatic wait time”.

Manual Mode: (Foam Eartips)



Manual Mode: (Silicone Eartips)



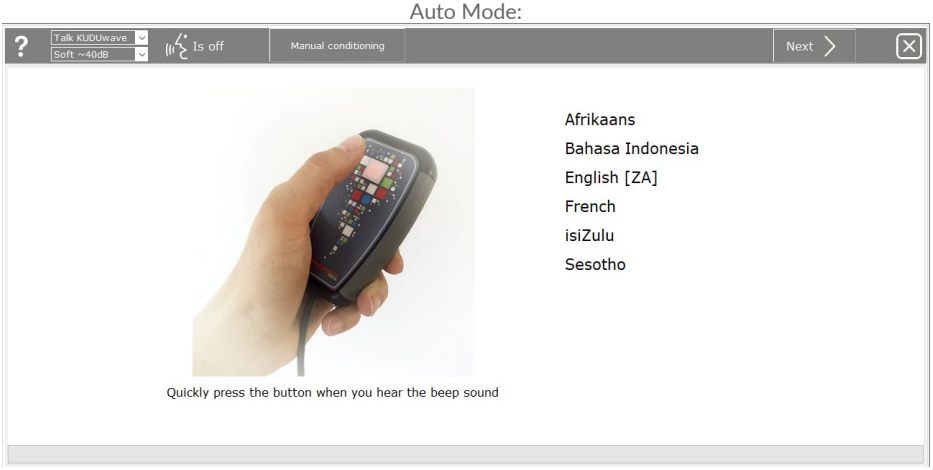
Conditioning can be done manually, using the talk forward feature to explain the test procedure to the patient. Alternatively revert to an automatic conditioning method, where a pre-recorded message will be read to the patient explaining the test procedure. To switch between these modes click on the button at the top of the screen that says: Auto Conditioning or Manual Conditioning.

To begin the automatic conditioning, click on the preferred language listed on the right hand side. The pre-recorded message will play immediately once the language is selected. Once conditioning is completed the automatic test will commence.

If manual conditioning was done, select 

to proceed to the test.

Auto Mode:



Conducting a Clinical Test

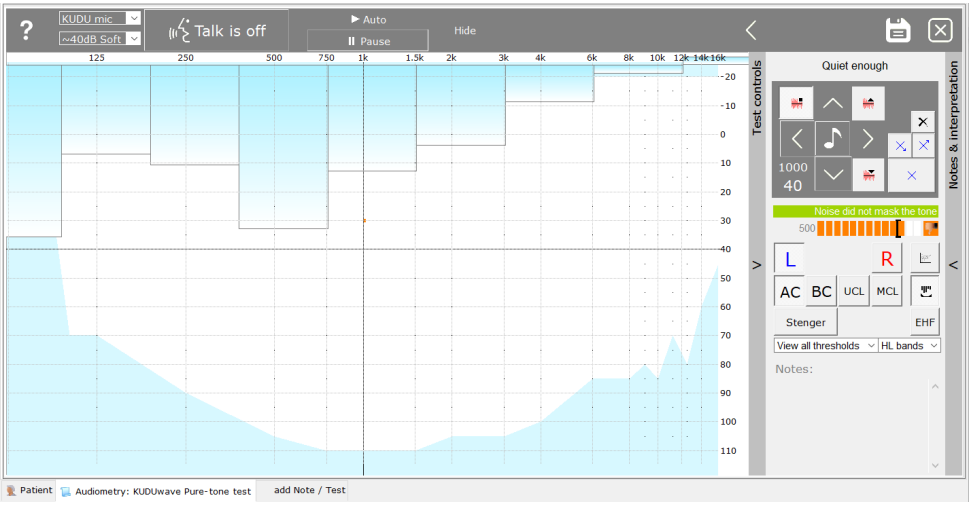
Automatic Test

The automated test will start running immediately after conditioning is completed. Wait for the test to complete and select “Save”. 

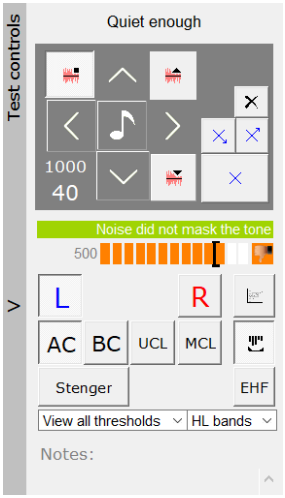
Manual Test

After conditioning the patient, click 

. Now manual testing can be performed. Alternatively, create a custom test macro, and choose the manual option for tone threshold seeking.



On the right hand side of the test screen, you will see the Test Controls Panel. Use this keypad on the screen or keyboard shortcuts to move the cursor across the plane. Click on the question mark in the top



left corner to see the shortcuts table under the help guide, or press F12 on your keyboard.

Presenting Tones

To switch between air conduction and bone conduction testing, click AC or BC. AC BC.
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 .
To switch between left (blue screen) and right (red screen) click on the blue L or red R.
After a tone is presented, the white bar will become coloured as you wait for the patient to respond. It will fill up green and show a thumbs up if the patient responds in time.

Action	Key
Patient response button (If not using the standard USB response button)	Space bar
Present a tone	Right Shift key
Mark the Threshold	Enter key
Mark a Minimum Plateau Threshold (If the patient did not respond at soft thresholds due to loud ambient noise levels or because you decided not to test softer)	"/"
Mark a No Response	"\"
Delete a threshold mark	Del key
Air Conduction mode (AC)	"A"
Bone Conduction mode (BC)	"B"
UCL mode (UCL)	"U"
MCL mode (MCL)	"M"
Left Ear (L)	"L"
Right Ear (R)	"R"
Forward talking on/off	"T" (Escape will also cancel Talk Forward)
Masking level louder	Page Down
Masking level softer	Page Up
Mute masking	Home
Lower frequency (Move the presentation mark on the grid left)	Left arrow
Higher frequency (Move the presentation mark on the grid to the right)	Right arrow
Softer (Move the presentation mark on the grid up)	Up arrow
Louder (Move the presentation mark on the grid down)	Down arrow
Save and close	Ctrl + S

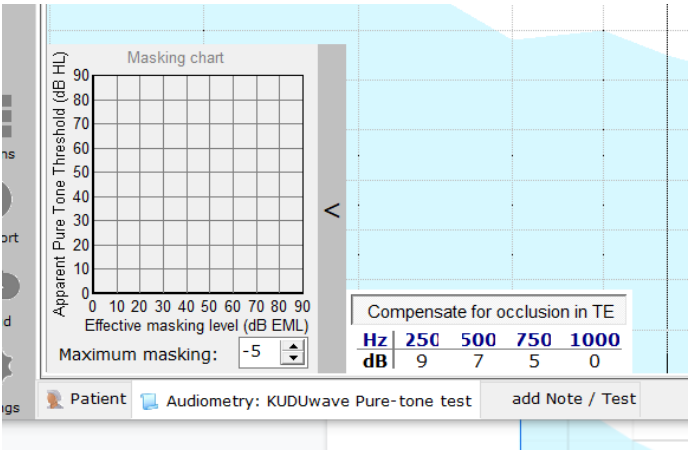
If the patient was too slow it will turn orange and show a thumbs down (indicated in the image alongside). If the patient presses the response button without a tone being presented, a grey spot will mark the screen, indicating a false response.

Masking

Use masking keys to move the masking level down, and onto the test screen to begin masking.

Stop masking by clicking:
Red icons mask the right ear, while the pure tone is presented to the left ear.
Blue icons mask the left ear, while the pure tone is presented to the right ear.
The KUDUwave will automatically mask the ears when performing bone conduction tests, unless this is removed for manual tests macros.

During Bone conduction testing, select No mask if you would like to determine unmasked threshold levels (non-ear specific), and to determine if there's a need for masked bone conduction thresholds.

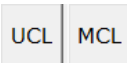


When using the plateau masking method during bone conduction testing, the masking chart automatically populates the effective masking levels (EM) and the apparent threshold. This indicates the effective masking level that was required in order for the tester to establish a threshold in the test ear by masking the non-test ear.

Marking the Threshold

The KUDUwave uses markers stipulated in ISO standards and which are relevant for air conduction using insert earphones and forehead placement for bone conduction. The blue crosses/red circles on the side bar are to mark the minimum plateau threshold, threshold and the points the patient did not respond as a result of maximum output level reached. Use to delete.

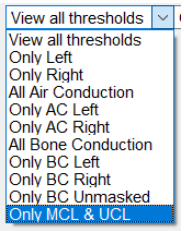
To determine and plot the Most Comfortable Loudness (MCL) and Uncomfortable Loudness (UCL) levels on the audiogram, click MCL/ or UCL. The MCL and UCL are mostly used to provide an indication of the gain level of the hearing aid which will be most comfortable for the patient. On the KUDUwave audiogram, the MCL is marked as M M for each ear, and the UCL is marked as U U for each ear.



Counselling Tools

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. This is available on the test viewing page after the test has been saved as well.

Another feature you can use is applying hearing loss bands to the screen. To view the hearing loss bands, click on HL bands and select one of the options from the menu (Clark, WHO, BSA).



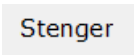
Other Features

The test view is automatically set to view all thresholds. Edit this by selecting which thresholds you would like to view on the screen from the drop down menu

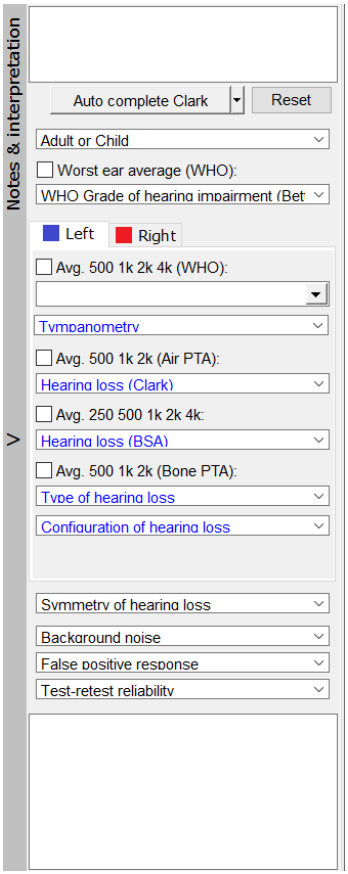
provided.

To extend the testing screen to view the extended high frequencies more clearly, click on the EHF button.

To hide or view the ambient noise sound bars, click on this icon.



To utilize the Stenger test, click on the Stenger button. For more information on how to use this test please read our blog found here: https://emoyo.net/post-kudu/stenger-test-and-patient-response-monitoring-with-kuduwave/

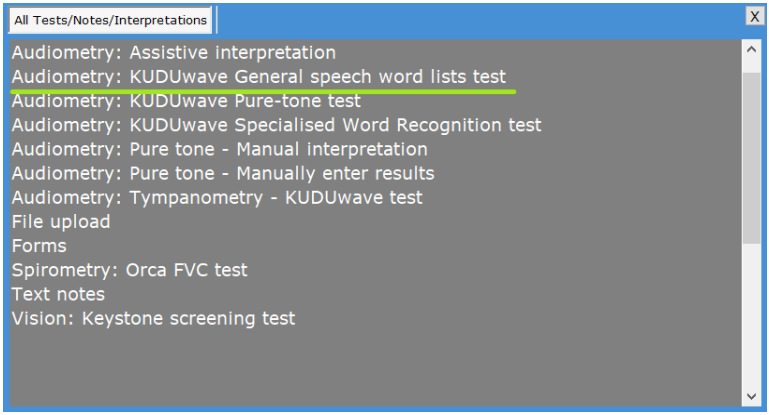


Notes and Interpretations

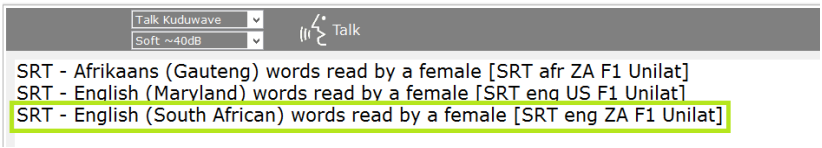
Under this side panel, any notes regarding the audiometry test or patient notes can be made and saved to the audiogram report.

Speech Reception Threshold (SRT) Testing

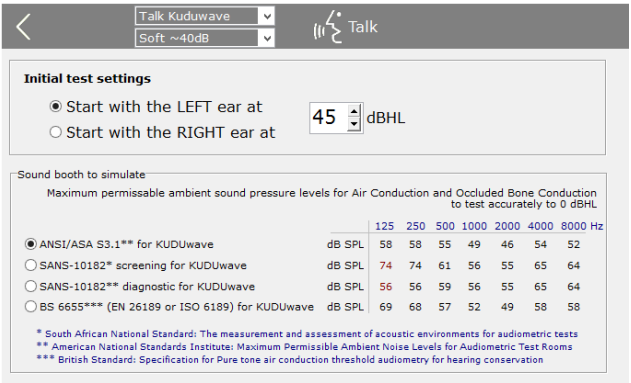
To conduct a SRT test, select the "Audiometry: KUDUwave General Speech Word Lists Test" option from the New Test Menu.



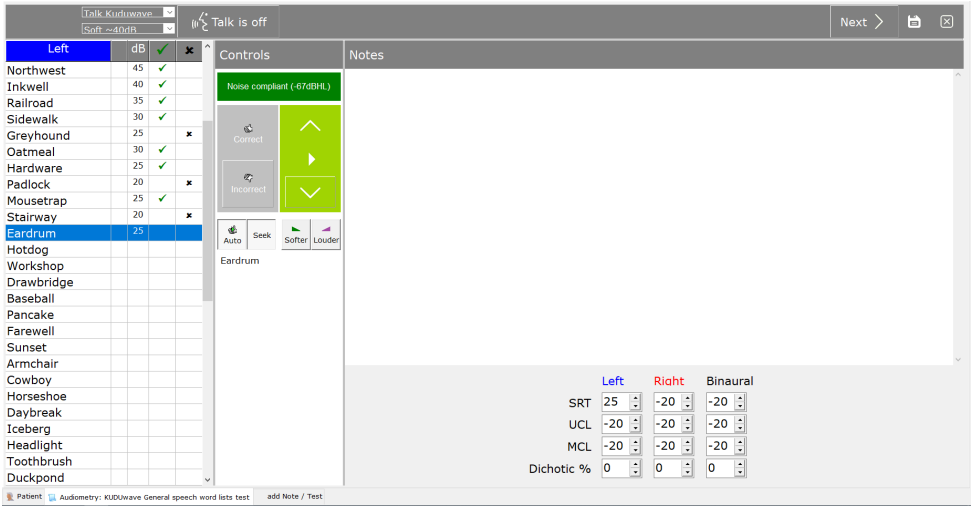
Then select the list of words read in the specified language you wish to use. More languages are available from the emoyo website.

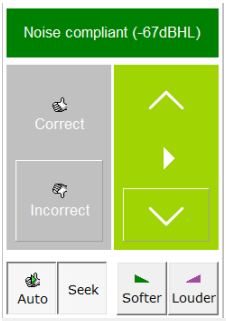


Select which ear you want to begin testing at the specified intensity level.



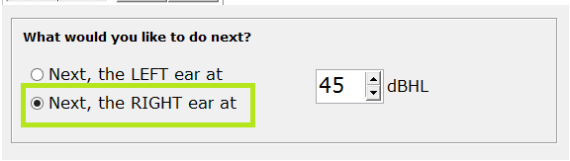
The SRT page will open and automatically read the words to the patient once you select the play button on the control panel.





Click the "Correct" button with the thumbs up if the patient recites the word correctly. If Auto and Seek is selected, 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. Deselect Auto if you do not want the next word to be played immediately. Deselect Seek, if you do not want the dB level to change automatically.

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.

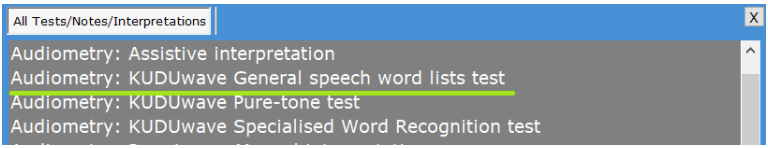


Click the "Next" button to continue once testing of the left ear is complete. Select the Right ear option and specify the Intensity level testing should begin at.

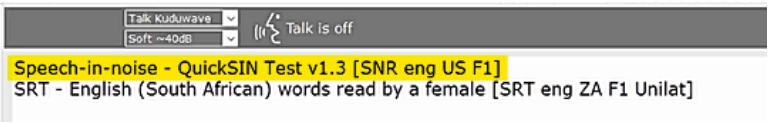
The same procedure must be done for the Right ear. Once complete click "Save".

Speech in Noise Testing with QuickSIN

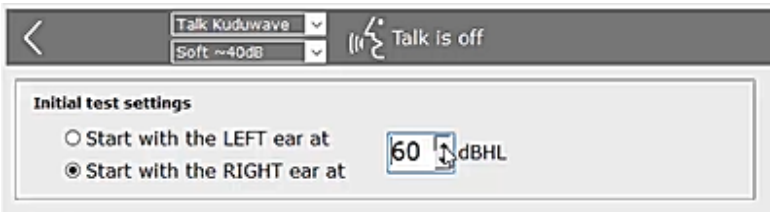
The assessment of speech in noise provides important diagnostic information which the pure tone audiogram cannot reliably predict. The KUDUwave provides speech in noise testing through its integration with QuickSIN. Once purchased online, access QuickSIN by adding a patient or select an already existing patient. Click on the button: "+Note/Test" and from the menu, select the Audiometry: KUDUwave General Speech word lists test.



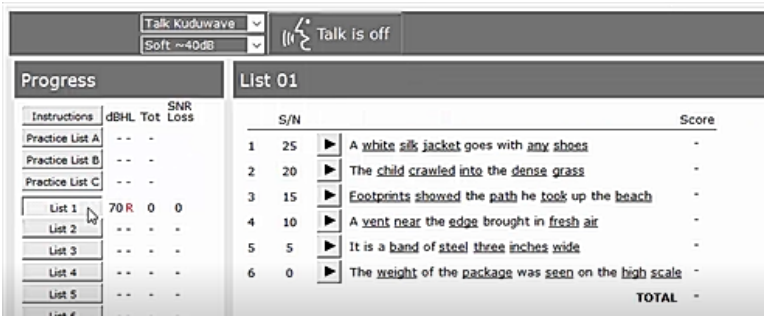
Select QuickSIN from the next test menu.



To begin, select the ear you wish to start with and set the appropriate intensity level. Then click Next.

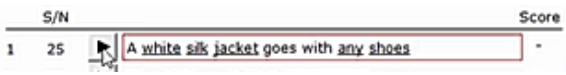


Click on List 1 to view the first list of sentences which will be tested.



How Speech in Noise works

A list of 6 sentences with 5 keywords per sentence, is presented within a babble noise. The sentences are presented at a signal to noise ratio which decreases in increments of 5dB's, from 25 (which is very easy), to 0 (which is very difficult). To begin the test, press the play button. ▶



Once the patient has responded with what they have heard, score the results by counting the number of keywords

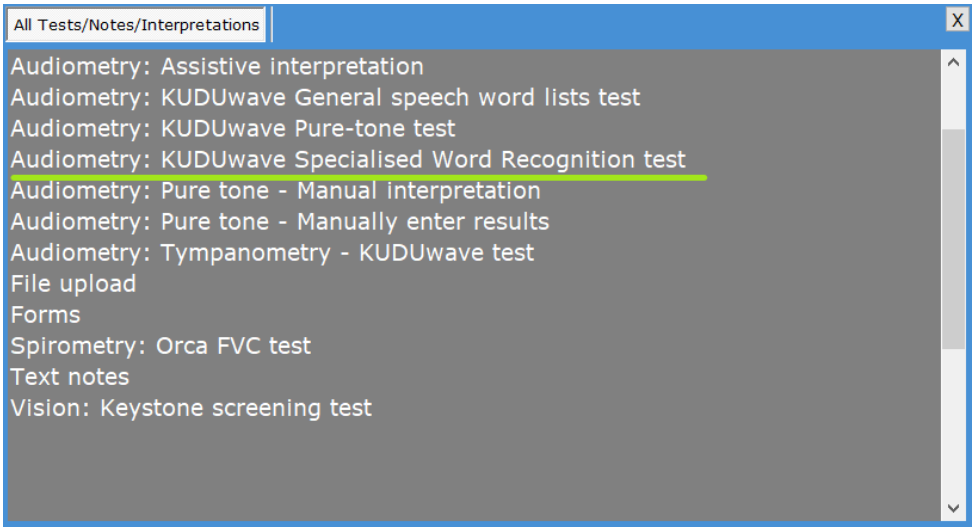
underlined that the patient got correct.

The KUDUwave has two different scoring pads which you can choose from. The scoring section above allows you to click on the number (score from 0 to 5) and the KUDUwave will immediately begin playing the next sentence.

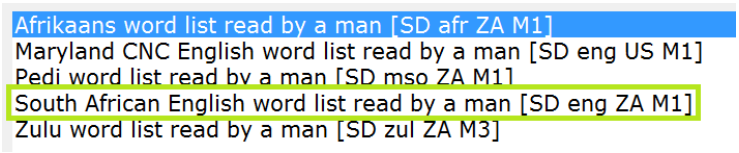
The below scoring section allows you to click on the number (score from 0 to 5) and the KUDUwave will wait until you press play for the next sentence or to save the test result. There are a total of 12 lists each with 6 sentences.

Word Recognition (WR) Testing

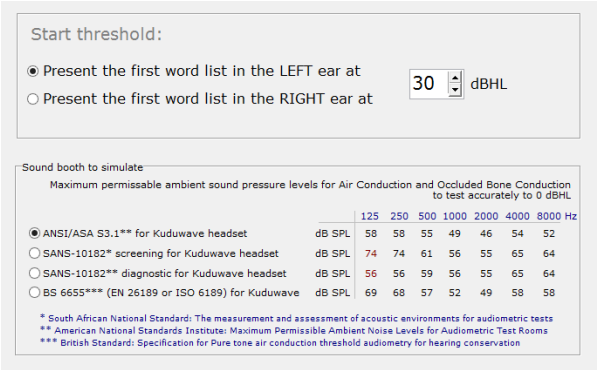
To conduct a word recognition test, select the "Audiometry: KUDUwave Specialised Word Recognition test" option from the New Test Menu.



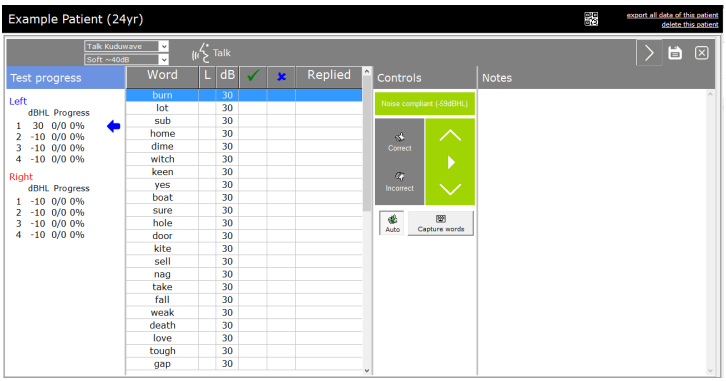
Select the preferred word list you wish to use. More are available to download from the eMoyo website.



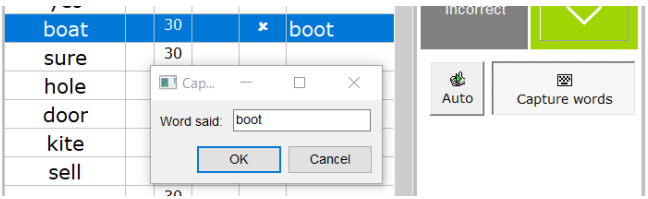
Select which ear and intensity to begin testing with and click the next arrow.



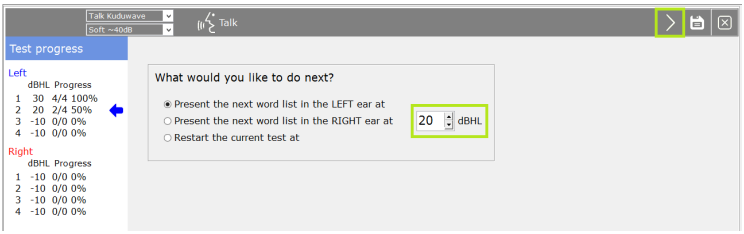
The testing page will open and each word will be presented at the selected dB level.



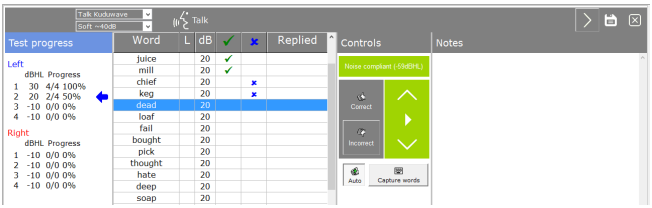
Mark each word correct or incorrect with the thumbs up and down buttons. To capture the words incorrectly iterated, select “Capture”. Once a word is marked as incorrect, you can capture the word and save it to the report.



To change the dB level for the following words click on the next arrow.



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

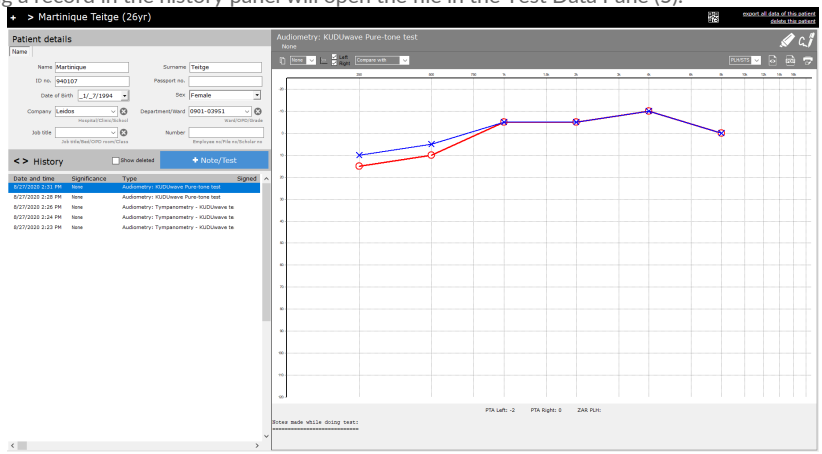


Click the “Next” arrow again and select the right ear to continue testing the right ear.

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).



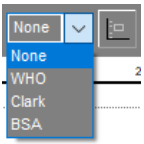
Above the test preview, you will have the option to view, print or save a pdf of the current test

selected.

Alongside these options, is the layout choice for the audiogram. From the drop down menu select one of the below options:

1. Standard — *Standard audiogram with test notes included*
2. PLH/ STS — *Occupational /Industrial Health Audiogram layout with test comparisons (must be used with OH Baseline, Screening and Exit test significances)*
3. HSE — *Patient Categorization from 1 to 4*
4. OSHA — *STS test comparisons (must be used with OH Baseline, Screening and Exit test significances)*

Copy the audiogram from the eMoyo software to your PC clipboard with this button. You can paste it into another document by pressing Ctrl + V.



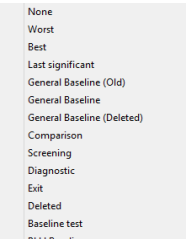
Show Hearing loss Bands on the audiogram by choosing one of the options from the drop down menu.

Click on the icon beside the drop down menu, to illustrate consonants and sounds mapped across the audiogram for counseling purposes.

Check the boxes for Left or Right to view the corresponding threshold on the audiogram. You can also compare the currently selected audiogram with a previous test, listed in the drop down menu "Compare with".

Test Significances

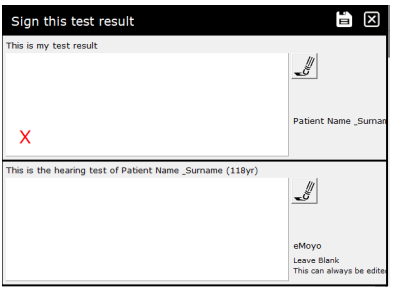
You can change the Significance of a test or note by clicking on the highlighter, or right clicking on the test in the History Pane, and selecting the appropriate label from the drop down menu.



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

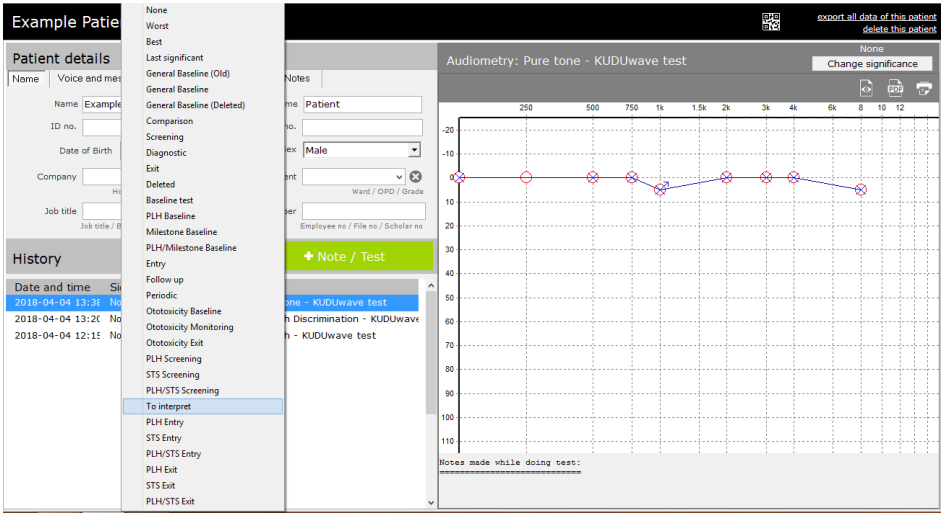
Digital Signatures

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.

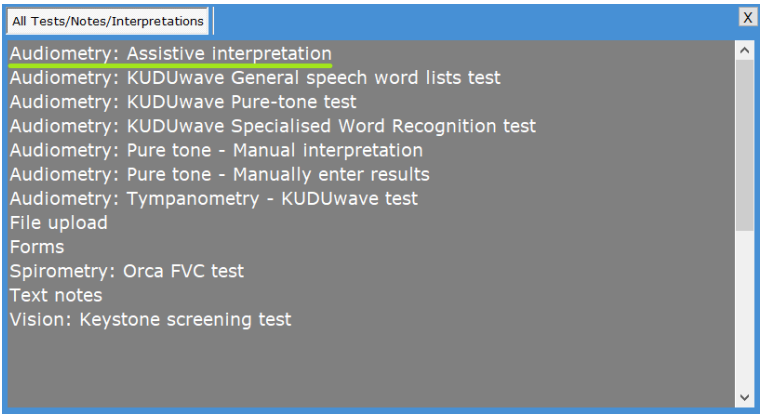


Assistive Interpretation

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/Test, and select an option from the menu for Assistive Interpretation.



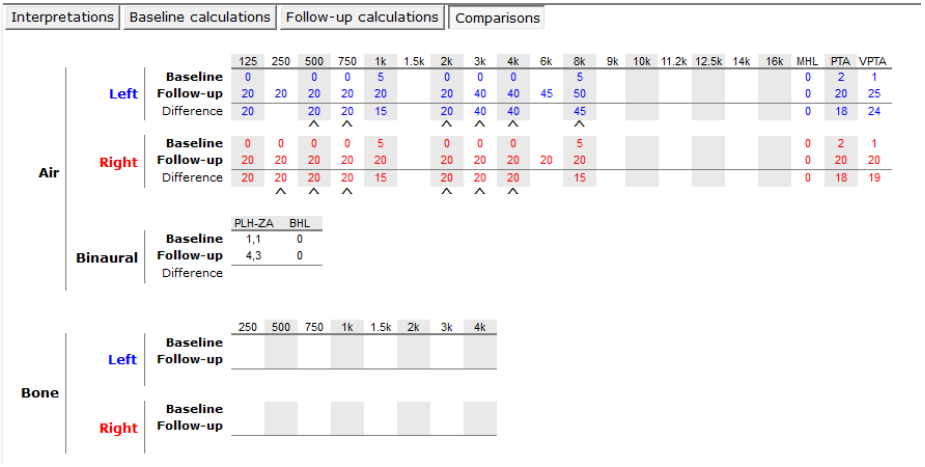
Select the type of interpretation wanted:

Interpret the latest pure tone test marked as To interpret
Ototoxicity interpretation
PLH interpretation for South Africa
Milestone baseline (Audiometric Zero) / STS interpretation

The interpretations can then be viewed and saved.

Ototoxicity Monitoring with Assistive Interpretation

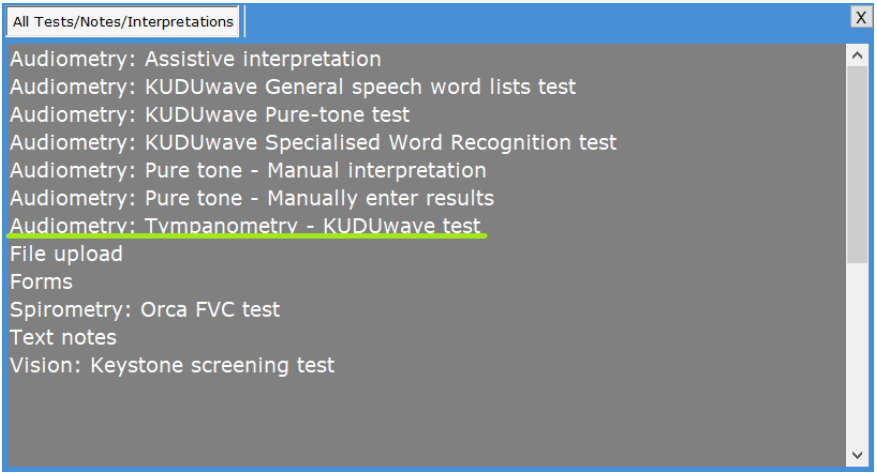
For ototoxicity monitoring, select the first baseline test as a “Ototoxicity Baseline” and the following test as “Ototoxicity Monitoring”. Click on ✚ Note/Test and select the option for assistive interpretation. Select “Ototoxicity interpretation”. You can now view the interpretation notes and calculations for both the Baseline test, the Follow up tests and comparisons of the two.



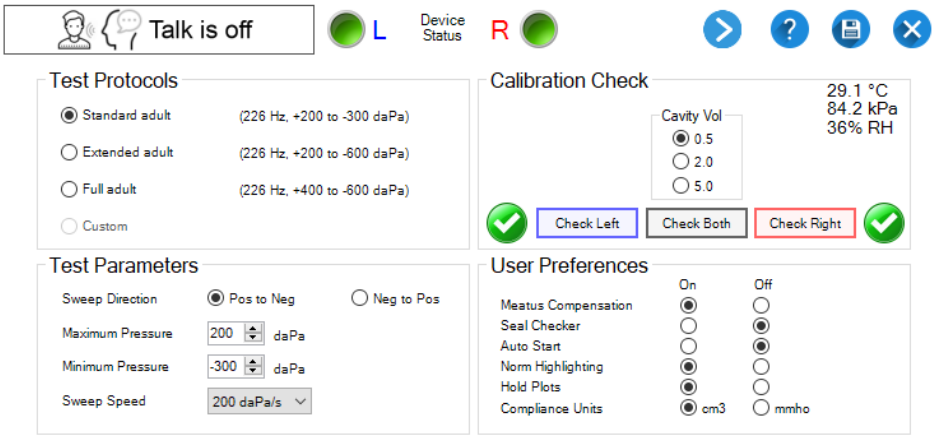
KUDUwave™ Tympanometer

Begin a Tympanometry Test

Click on the + Note / Test button and select Tympanometry from the list.



This opens up the homepage of the tympanometry software



Check the Device Status

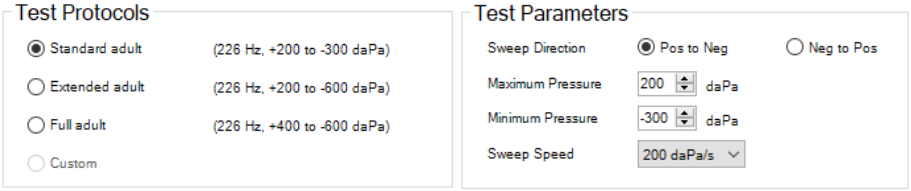
The Device Status indicates whether each side of the device is connected and ready to perform tests. The left light will indicate if the left tympanometer is ready for testing and the right light will indicate if the right tympanometer is ready.

A green light indicates that the specific side of the device is connected and ready

A red light indicates that the specific side of the device is not connected. Unplug and reconnect this side. A test cannot be conducted until the green light is on.

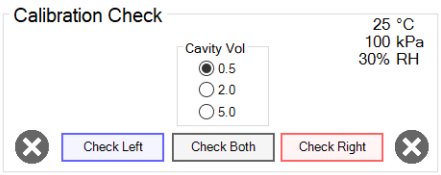
Select Test Protocols and Parameters

Under Test Protocols, select one of the pre-set protocols. Alternatively adjust the test parameters manually in the Test Parameters box.



Perform a Calibration Check with the Calpod

The calibration check allows for the calibration of the device to be tested at the current ambient temperature and barometric pressure. This is important for the accuracy of the device. The device has an environmental sensor which measures the temperature, barometric pressure and relative humidity.



Select the first cavity volume to be checked (make sure the probe is inserted into the same cavity volume in the calpod). All three cavity volumes must be processed for the check to pass and to conduct a test. Insert the probe (**without an ear-tip**) into the respective cavity volume indicated on the calpod. Press it hard to make sure it's securely inserted.

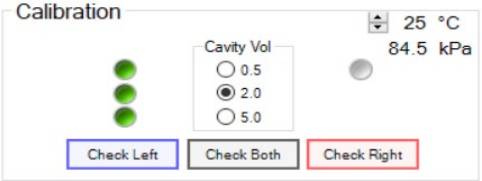
Click on the **Check Left** / **Check Right** button for the respective side you are testing. Repeat this process for each cavity volume and on the other side. If **two calpods** are being used, both sides may be checked at the same time, just click on **Check Both**.

As the check is being done, lights appear next to the respective cavity volumes on the respective side:

A white light indicates that the specific cavity has been processed

A green light indicates that all cavities have been processed and the specific cavity passed the calibration check

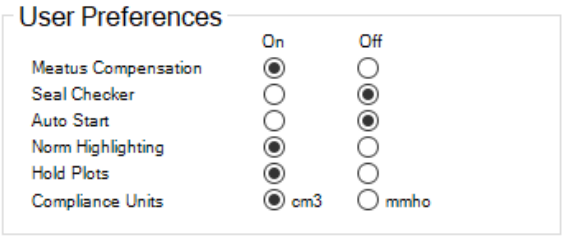
A red light indicates that all cavities have been processed but the specific cavity failed the calibration check



If no lights appear, a stable reading cannot be obtained. Check that the correct side is inserted into the calpods or if there is excessive ambient noise, try shielding the device from it.

Select User Preferences

Various user preferences can be selected. These will be saved for next time you open the software.



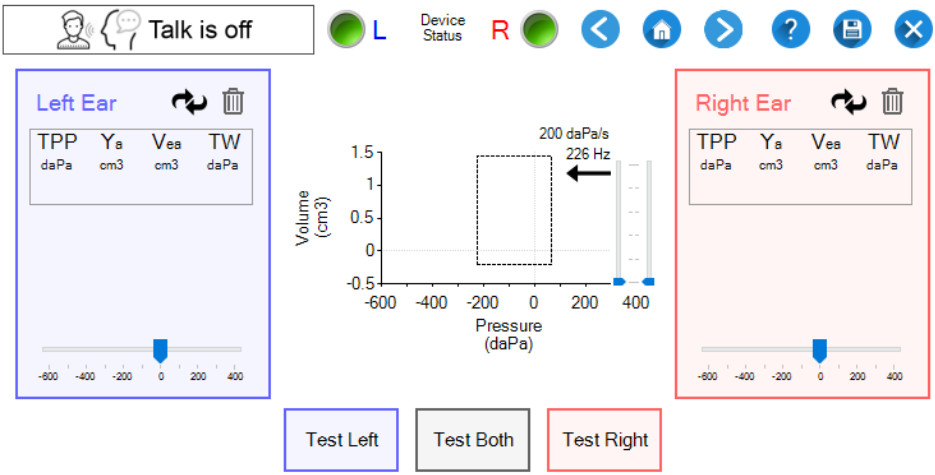
- Meatus Compensation *Compensates for the admittance of the air in the ear canal*
- Seal Checker *Automatically checks for a seal*
- Auto Start *Automatically starts a sweep once a seal is obtained*
- Norm Highlighting *Highlights the metrics that fall outside general norms*
- Hold Plots *Superimposes the current and previous tympanograms*
- Compliance units *Selects units of mmho (Acoustic cgs) or cm^3*

Communicate with talk forward

At any point during the tympanometry test you can communicate with the patient using the talk forward button. Click it once to turn the talk forward on and again to turn off. Talk forward must be disabled before running any tests.

Move to the Testing Page

To move on to testing, click on the Next button  . This opens up the testing page and conducts the tympanometry test automatically according to your previously chosen settings.



Select an Appropriate Ear-tip

Choose an ear-tip that is big enough to seal the ear canal but not too big that it hurts the patient when inserted.

Note: Do not use the foam ear-tips for tympanometry tests! The foam ear-tips do not provide an adequate seal. Only the silicone eartips are to be used.

Insert the Eartip Into the Ear Canal and Perform a Sweep

Place the device around the neck of the patient or on their head so that their ears are still accessible.

Insert the ear-tips into the ear canal and ensure it makes a good seal.

If the Seal Checker user preference is on, the status of the seal will be indicated.

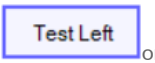
A black light indicates that the probe is out of the ear or Seal Checker is off. This will show after a successful sweep.

A yellow light indicates that there is a leak and a good seal cannot be obtained. Try re-inserting the ear-tip.

A green light indicates that there is a good seal and a sweep can be started.

The Seal Checker can be temporarily stopped by clicking on the light indicator.

If the **Auto Start** user preference is on, the sweep will begin as soon as a good seal has been obtained.

Run a sweep by clicking on the Test button for the respective side: 

or 

If ear-tips are inserted into both ear canals, bilateral testing can be done by clicking: 

. A test can also be started by pressing the hot keys “L”, “R” and “B” or spacebar for left, right or both

respectively.

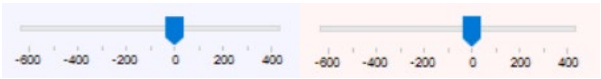
To the left and right of the test buttons are indicator lights.

A purple light indicates that a sweep is underway.

An orange light indicates that audio is being played but the sweep is not underway yet.

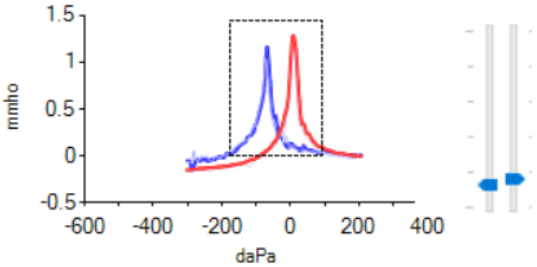
A white light indicates that the pump is initialising or resetting itself.

The pressure in the ear canal is updated in real time and is displayed on the pressure bars on each side.



The tympanogram is updated in real-time and is displayed on the graph in the centre.

The blue line is for the left ear tympanogram. The red line is for the right ear tympanogram.

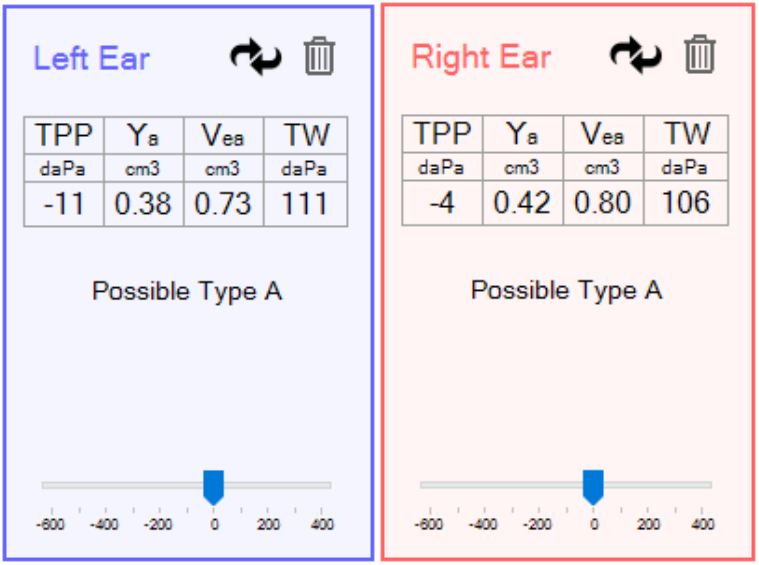


The ear canal volume is indicated as a metric and is visually displayed on the bars to the right of the graph (left bar for left ear, right bar for right ear). The scale runs from 0 cm^3 to 5 cm^3.

If the seal is lost during a test, the sweep is aborted and the pump is reset. To delete a tympanogram click on the Discard button

View the Tympanograms Metrics

Various metrics are displayed for the tympanogram for each side:



- **Vea** (cm^3) *the equivalent volume of the ear canal*
- **TW** (daPa) *the tympanogram width*
- **Peak** (daPa) *the pressure at which the peak occurred (also called tympanometric peak pressure)*
- **Peak** (mmho) *the peak compliance*
- **Type suggestion** *the suggested classification of the tympanogram as a whole*

(note that this is just a suggestion, not a diagnosis)

Several tympanograms may be overlaid by turning on **Hold Plots** in the user preferences at the start page or by pressing the hot key "H". This can be used for Eustachian Tube Function or for checking test-retest reliability. Increasingly fainter shades of blue or red are used to differentiate between the tympanograms. The metrics shown at the side are for the top-most tympanogram in the brightest colour. Tympanograms can be cycled to the top using the cycle button to view their metrics. The delete button deletes the top-most tympanogram.

Page Navigation and Help

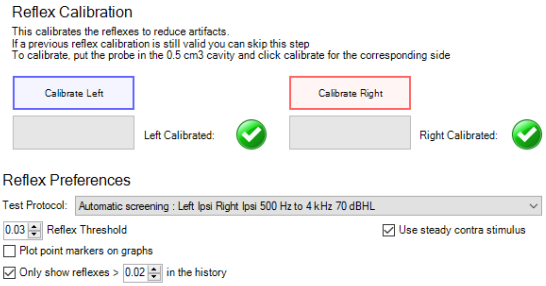
Back Next Home Help Save Exit

- To create a report from the current data, click on the Save button.
- To exit the tympanometry software, click on the Exit button.

Acoustic Reflex Test

Move to the Reflex Start Page

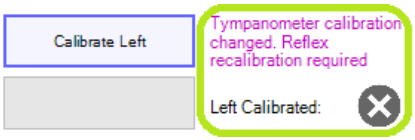
To move on to the reflex start page, click on the Next button  from the tympanogram page. This opens the reflex calibration page where the reflexes can be calibrated to remove artefacts and reflex test preferences can be selected:



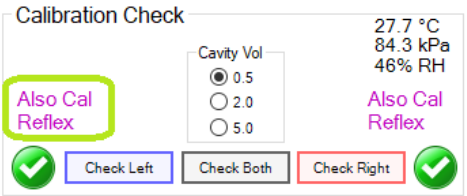
Reflex Calibration

To calibrate, put the left probe in the 0.5 cm^3 cavity and click “Calibrate Left”. When it has completed, repeat for the right side. The reflex calibration only needs to be repeated if the tympanometer calibration has changed significantly.

If reflex calibration is needed it will be indicated by a grey cross and purple message next to the calibrate button. These calibration messages could also indicate that the probe was not inserted properly or inserted differently when calibrating the tymp or reflexes.

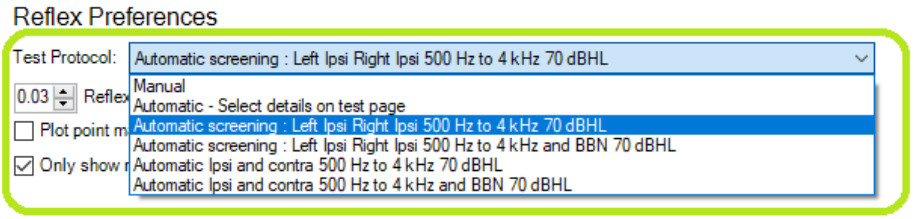


When reflex recalibration is needed it will also be indicated on the start page. This is so that you can see in advance that reflexes will need calibration so that you do not arrive at the reflex test with the KUDUwave on the patient's head before realising that reflexes need calibration.



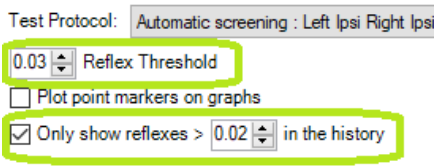
Reflex Test Selection

A test protocol can be selected from the “Test Protocol” drop down menu.



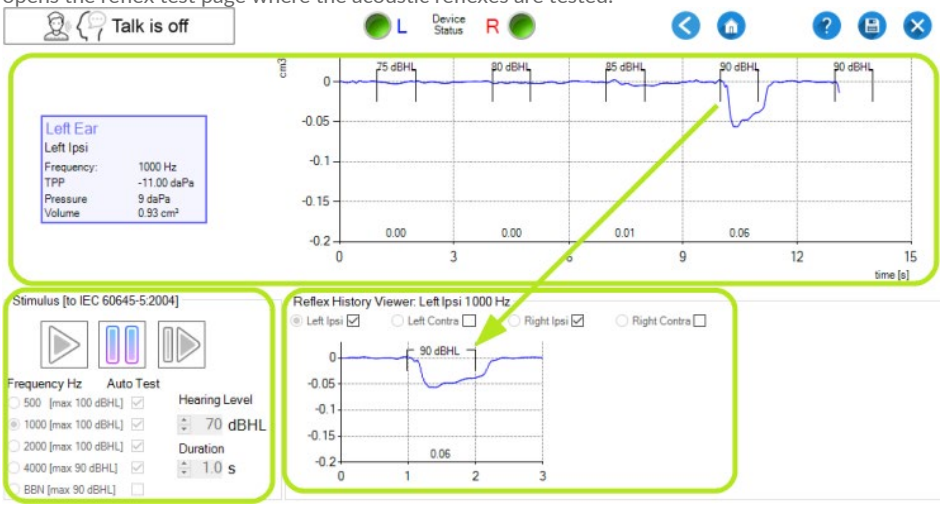
The reflex threshold used by the automatic test protocols is selectable at the "Reflex Threshold" control.

The reflex history records all reflex segments which will go into the report data saved for the test. You can select a history threshold for reflex segments to save to avoid saving a large amount of segments that do not contain reflex responses.



Move to the Reflex Test Page

To move on to the reflex test page, click on the Next button from the tympanogram page. This opens the reflex test page where the acoustic reflexes are tested:



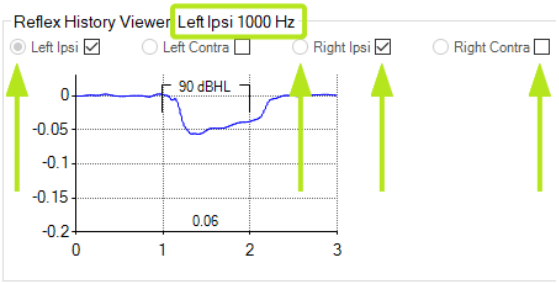
Reflex Test Page Layout

The top part of the reflex test page shows a graph of the most recent measurements in the probe ear at a single stimulus type (e.g. 1000 Hz). Information about the current test is shown at the top left. This includes the probe ear, current stimulus, TPP, Pressure and indicated volume. The indicated volume is not the same as the Ear Canal Volume (ECV) since ECV is measured when the tympanic membrane is stiffened by probe pressure.

Reflex History

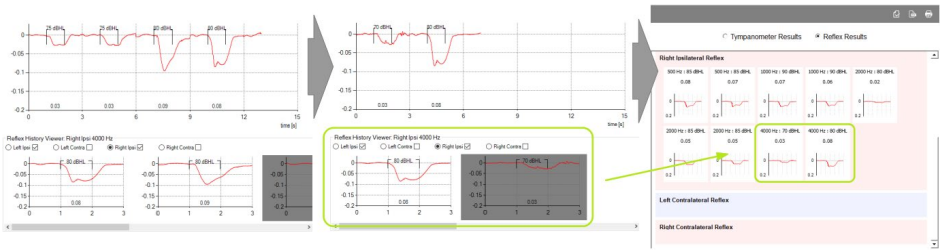
The lower right part of the reflex test page shows the reflex history. It contains all reflex tests which had a measured reflex deflection greater than the history threshold selected at the Reflex Start page. In this case note that only the 90 dBHL reflex measurement has gone into the reflex history since the others are below the reflex history threshold. The reflex history shows tests chronologically with the most recent test at the left.

The reflex type that is being **tested and displayed** in the Reflex History Viewer is selected in the Reflex History Viewer by the radio buttons. ◉ In this example it is Left Ipsi. To view another reflex type in the history click the corresponding radio button. ○ To view history for another stimulus, select the radio button for that stimulus at the stimulus parameters.



When an automatic test mode has been selected the reflex types that will be tested are shown by the check boxes ☑. In this example Left Ipsi and Right Ipsi will be tested. To change the reflex types that will be tested check or uncheck the relevant check boxes.

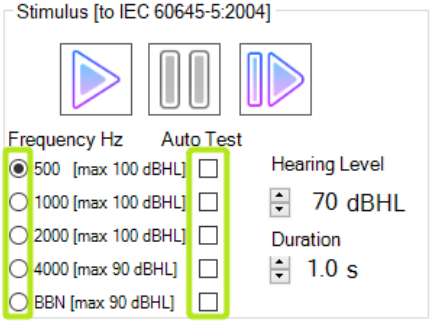
You can delete unnecessary reflex tests to prevent them from cluttering the saved report by clicking the graph in the Reflex History Viewer and then pressing the "Delete" key.



Stimulus parameters and test controls

The lower left part of the reflex test page shows the stimulus parameters and test controls.

Automatic Reflex Test

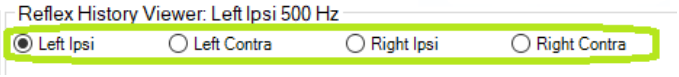


In automatic modes the stimuli that will be tested are selected by checking the checkboxes under "Auto Test". The start button ▶ starts or re-starts the automatic test. The pause button ⏸ pauses an automatic test and the resume button ⏯ will continue the test from where it was last paused. The lower Hearing Level that the automatic tests start out at is selectable by the "Hearing Level" control.

Manual Reflex Test

In manual mode you need to manually present each stimulus by clicking the stimulate left/right buttons or by pressing the "L" keyboard key for left and the "R" keyboard key for right.

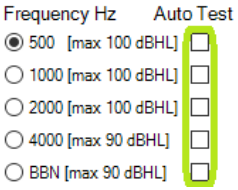
1. Select the reflex type (probe ear and stimulus ear) by clicking the corresponding radio button at the "Refex History Viewer"



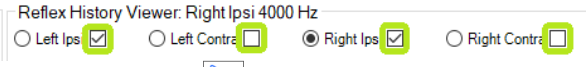
2. Select the stimulus parambers (stimulus and HL) at the lower left stimulus parameters controls
3. Click the stimulate button or press "L" for left or "R" for right
4. You can use the keyboard hot-keys "F" to change the stimulus, + or - to increase or decrease the HL (use the num pad keys)

Automatic Reflex Test

1. Select one of the automatic test protocols at the reflex start page
2. Select the stimuli to be tested by checking the checkboxes next to the stimuli



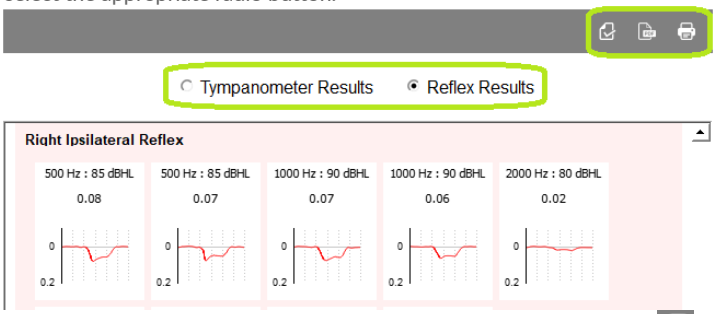
3. Select the reflex types (probe and stimulus ear) to be tested by checking the checkboxes in the reflex history viewer



4. Click the start button 
5. The top graph shows the measurement that is in progress. You can pause and resume the test if desired. To repeat only a subsection of the tests, uncheck the relevant checkboxes and click the start button

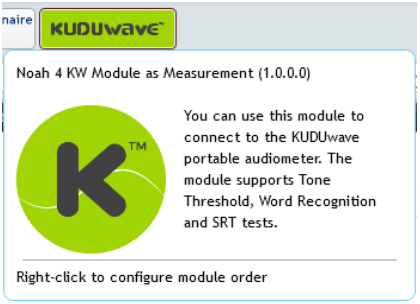
Viewing and generating reports from previous tympanometry tests

The software can view previously saved tympanometry tests. To switch between Tympanogram and Reflex results select the appropriate radio button.



You can preview the report before printing or saving by clicking the preview button  . Reports can be saved as PDF using the PDF button  . To print the report use the print button  .

KUDUwave™ Integrations

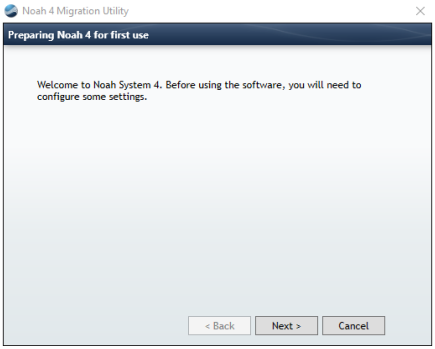


Noah Integration

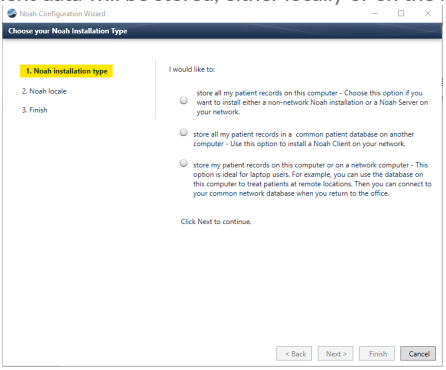
If the end user intends to use the KUDUwave device with Noah, the user needs to have a valid Noah license. Ensure that you have the latest version of KUDUwave 5 (version 5.2 or above) and Noah (version 4.8 or above) to avoid incompatible versions. You can download the latest KUDUwave software from www.emoyo.net and Noah from www.himsa.com.

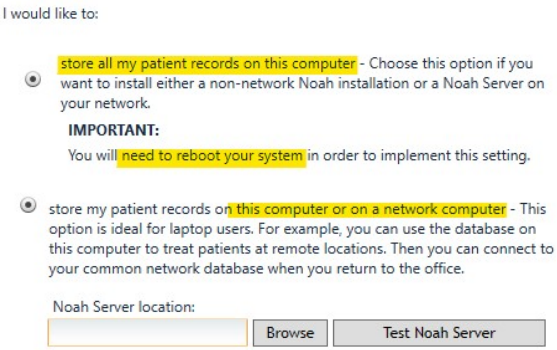
First Time Noah Users

Once you have downloaded and installed Noah, you will need to do an initial configuration of your settings. Click Next to move forward.

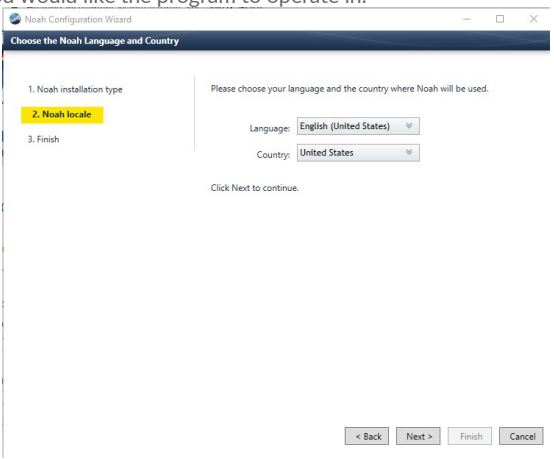


First choose where your patient data will be stored, either locally or on the Noah server.

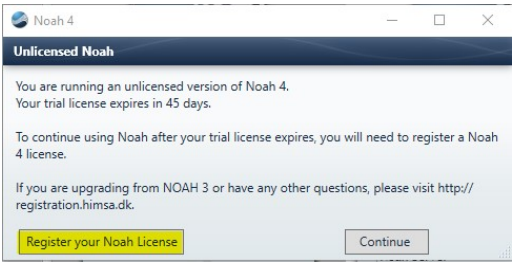




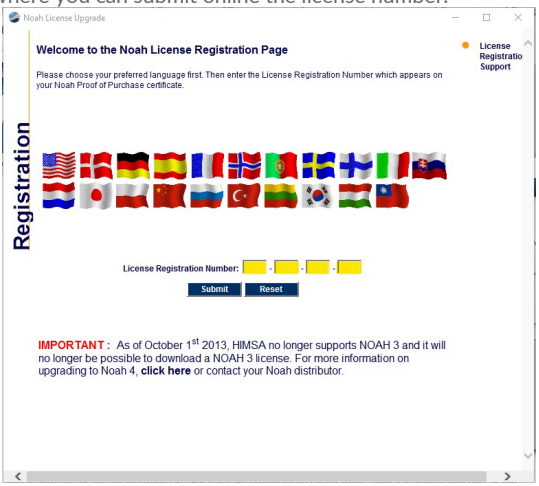
Select the language you would like the program to operate in.



Finally, click Finish to save the setup. Noah will automatically open. Click OK to begin registering your license.



A web page will open where you can submit online the license number.



Make sure all your details are correct and click register to close and continue.

Installing the KUDUwave Plugin

To integrate your Noah and KUDUwave applications, ensure you have installed the following in consecutive order:

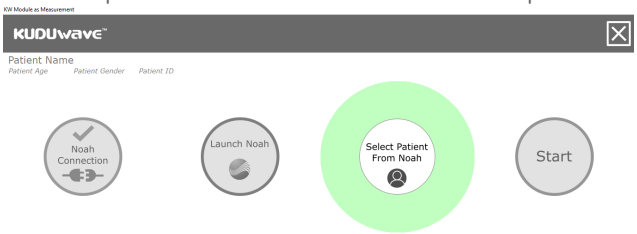
1. KUDUwave 5 software/ eMoyo EMR
2. KUDUwave Noah Module

Please refer to our website to download each file, or contact support to assist you.

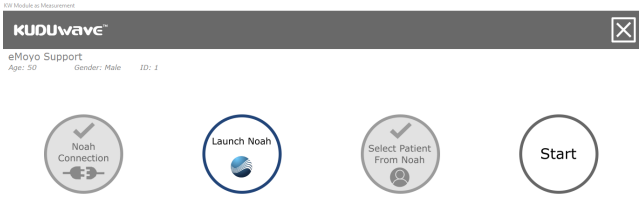
Getting Started with the KUDUwave Noah Module

Once both files have been installed, you will have two desktop shortcuts (one for the normal eMoyo software to control the KUDUwave and another which is the Noah plugin). If chosen to test with Noah, do not use the eMoyo shortcut, only this one is linked to Noah. Alternatively, launch Noah and select KUDUwave from the integrations menu.

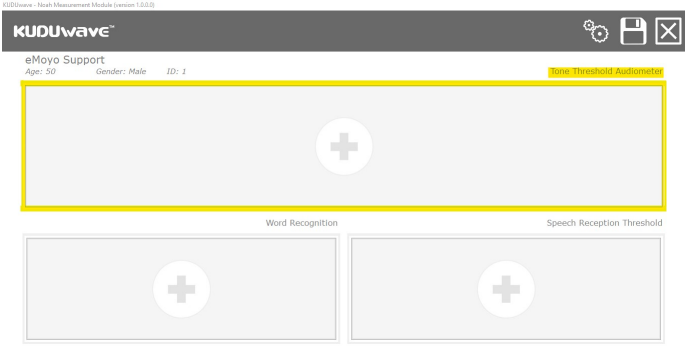
You will be able to access all patients which are created in Noah from this portal.



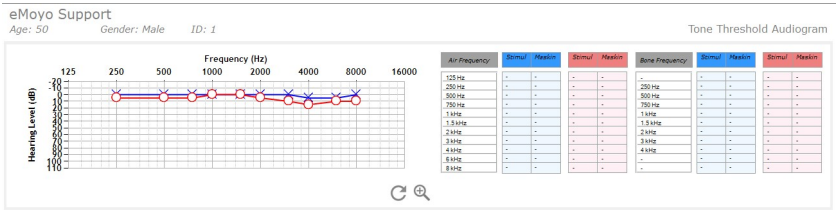
Once a patient is selected, begin the audiometry test with the KUDUwave by clicking “Start”.



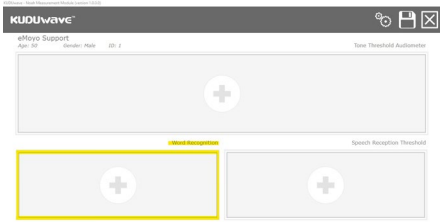
Click on the top half of the screen to begin the Pure Tone Threshold Audiometry test.



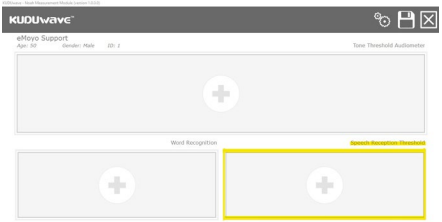
Once the test result has been saved, the audiogram will fill this space.



The bottom left hand corner, begins the Word Recognition KUDUwave test.



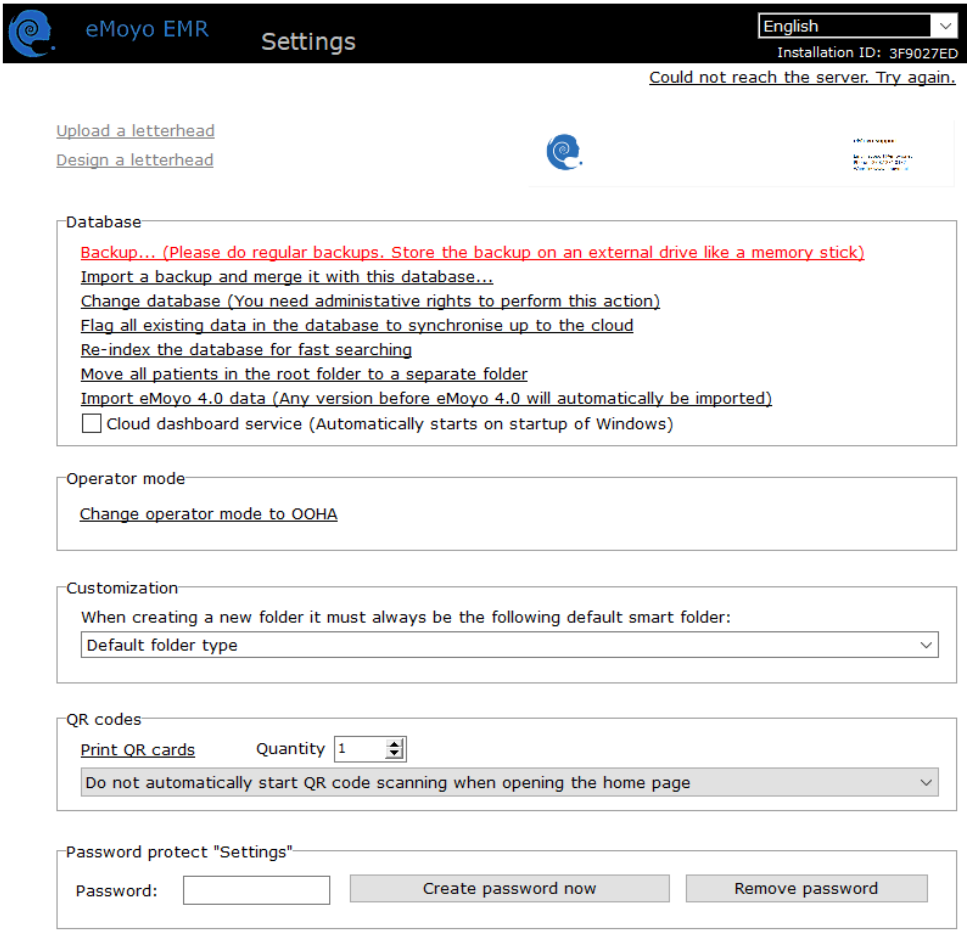
The bottom right hand corner, begins the Speech Reception Threshold test.



Settings

Find the settings button in the bottom left side of the home screen.

Settings



Installation ID

Your Unique Installation ID can be found in the top right hand corner.

Language

You can change the software language from the drop down menu in the top right hand corner.

Upload a Letterhead

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

Design a Letterhead

This option will open the Microsoft Paint program, automatically sized in the correct ratio for the KUDUwave letterhead. Design your letterhead in this space and save it in the bitmap (bmp) format. Later on upload the letterhead as explained above.

Backup

This function allows you to copy all patient data into one file, which will be saved to a chosen drive. Click on "Backup…(Please do regular backups. Store the backup on an external drive like a memory stick)", select the destination to send the backup data to, and click "Save".

Import and Merge Data from a Backup

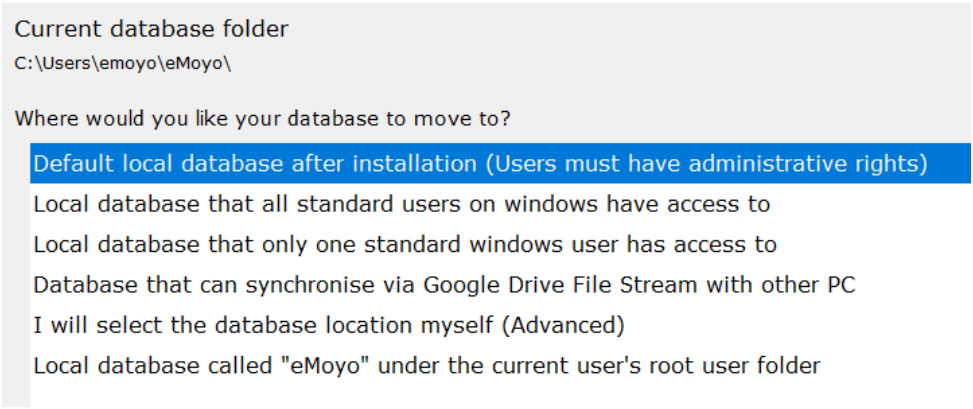
To import a previously backed up version of all patient data, select "Import a backup and merge it with this database…".

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

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.

Change database

This allows you to change the location of where all patient data is saved on your local hard drive. Administration rights are needed to make these changes. The following options are available once "Change database (You need administrative rights to perform this action)" is clicked on:



At the top you can see the current location of your database. Select an option from the list, then click the arrow key in the top left hand corner to move the database location. Click the save icon to save the setting change.

Warning: Data is not automatically moved with the database location change. You will need to create a backup file and then import it into the new location. Alternatively call support for assistance.

Flag all existing data in the database to synchronise up to the cloud

All data previously captured in earlier versions (before 5.2) of KUDUwave 5 software, will not be flagged for syncing to the eMoyo server. Click this option to process all existing data for syncing. This is only necessary once, all tests done thereafter will be automatically flagged. To upload data to the eMoyo server, click on the cloud button on the left hand side of the screen. Please contact support for assistance. For private customers it is recommended to sync to your personal cloud storage account, support can help you set this up. The eMoyo server is reserved for contracted cloud storage solutions.

Re-index the database for fast searching

To enhance the speed of the search tool on your home screen, click this option and the database will be re-indexed.

Import eMoyo 4.0 Data

If you previously had eMoyo 4.0 you will need to import patient data into KUDUwave 5. By clicking "Import eMoyo 4.0 data", 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.

Move all patients in the root folder to a separate folder

Set a default Smart Folder

All new folders created will have the settings associated with 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. Automatically start the camera for QR code scanning on the home page

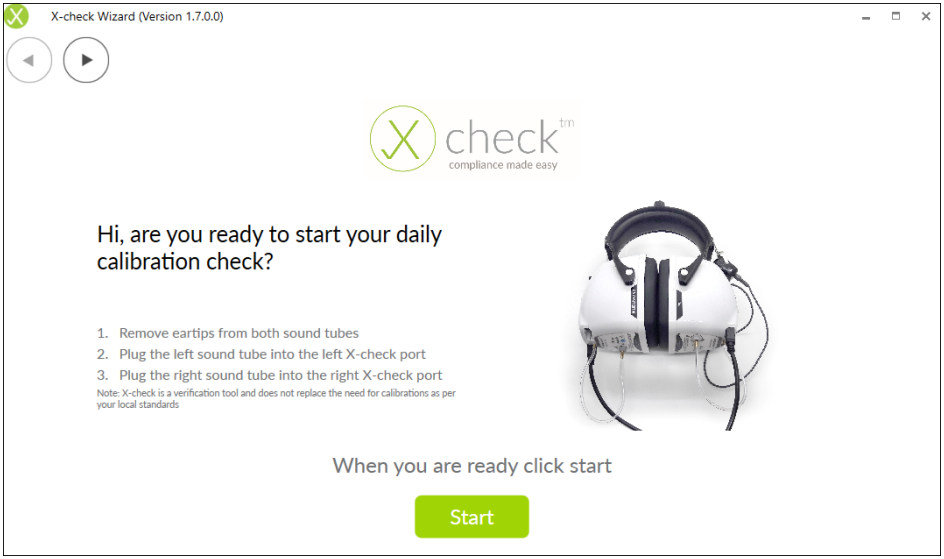
Password Security

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

X-check (Cross Check)

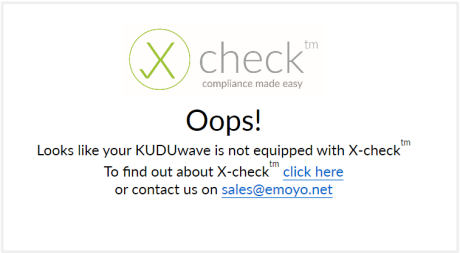
The X-check verifies the calibration of the KUDUwave.
Note: This does not replace the need for calibrations as per local standards.

To cross check your KUDUwave click the X-check button either on the homepage or under Plugins on the left hand side. If your KUDUwave is equipped with X-check the following start page will appear:

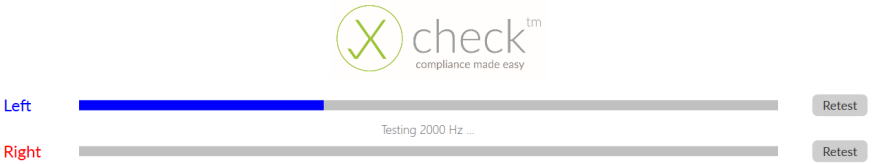


Follow the instructions and then click the Start button to run the X-check.

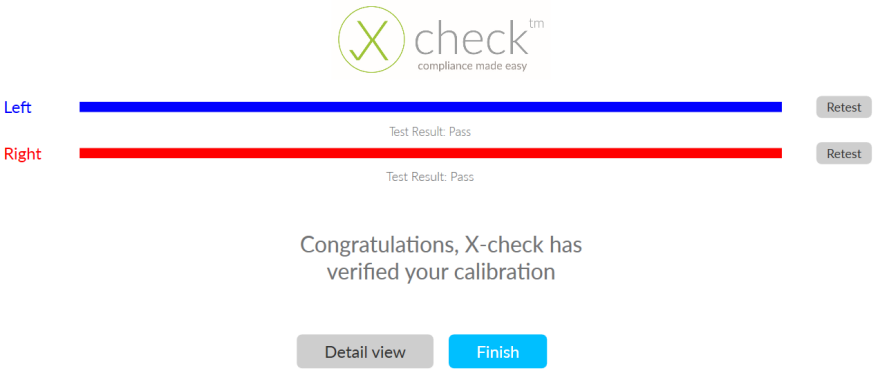
Note: that the X-check can only run if your KUDUwave is equipped with the cross check hardware. If this is not the case you will see the following screen:



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 30 seconds to complete. A message will then be shown to tell you if your device calibration verification has passed:



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

Left Right

Result	Amplitude Error [dB]	Test Frequency [Hz]	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 report 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 KUDUwave's 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.

If you would like a PDF report, scroll down and click the 

button. This will generate and open a PDF, like the one shown here. Depending on the version of X-Check you are running. The PDF report is automatically saved in the C:\Program Files (x86)\eMoyoDotNet\Pdf folder on your computer, or C:\Program Files (x86)\eMoyoDotNet\eMOYO\Data\Apps\KUDUwave\X-check_tests.

KUDUwave Cross Check Report

Test Details:

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

Left | Right

Result	Amplitude Error [dB]	Test Frequency [Hz]	Amplitude Error [dB]	Result
Pass	0,19	113	0,16	Pass
Pass	0,58	150	0,46	Pass
Pass	-0,04	200	0,40	Pass
Pass	0,56	750	0,01	Pass
Pass	0,51	1000	-0,05	Pass
Pass	-0,04	1400	-0,01	Pass
Pass	0,56	2000	0,47	Pass
Pass	+0,04	3000	+0,14	Pass
Pass	0,15	4000	0,24	Pass
Pass	0,60	6000	0,26	Pass
Pass	-0,07	8000	-0,10	Pass
Pass	0,55	9000	0,15	Pass
Pass	-0,01	10000	0,44	Pass
Pass	-0,76	11500	-0,83	Pass
Pass	-0,16	12500	-0,48	Pass
Pass	-0,11	14000	0,11	Pass
Pass	0,14	16000	+0,26	Pass

KUDUwave™
thinking out the booth

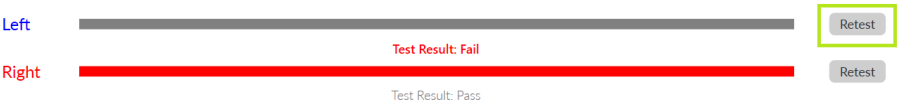
X-check: Abnormal Test

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 regarding why the test failed.

Left

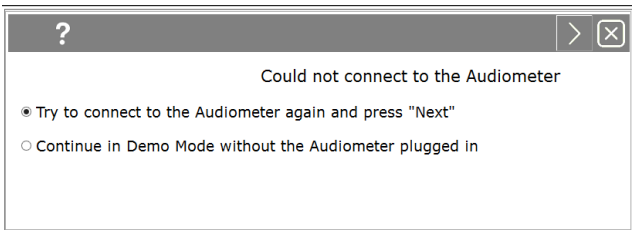
Result	Amplitude Error [dB]	Test Frequency [Hz]
Pass	0,63	125
Pass	0,82	250
Pass	0,05	500
Pass	0,94	750
Pass	0,93	1000
Pass	0,32	1500
Pass	0,94	2000
Pass	0,25	3000
Pass	0,50	4000
Pass	0,34	6000
Fail (Amplitude Deviation Too High +Frequency Deviation Too High +SNR Too Low+Recording Not Stable)	10,79	8000

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. Go to Support and click on “Remove old drivers”
3. Follow the instructions given by the software. 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.
4. Restart the test.

Assistance from the Manufacturer

Contacting eMoyo

Any serious incident that has occurred in relation to the KUDUwave should be reported to eMoyo Head Office and the competent authority of the Member State in which the user and/or patient is established.

- Email: info@emoyo.net / support@emoyo.net
- Phone: +27 087 231 0132 / +27 082 440 0826
- Website: www.emoyo.net

Remote Assistance

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

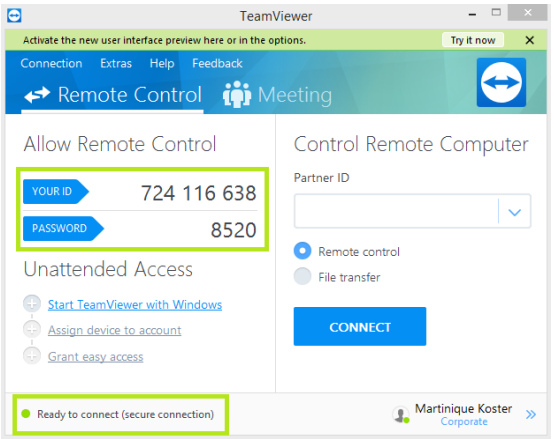
To download the TeamViewer remote assistance plugin, please visit:

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

Alternatively in the eMoyoEMR software, go to Plugins and install the TeamViewer app readily available there.

For live remote assistance, make sure you have:

1. Downloaded and installed **TeamViewer** on your PC
2. An active **internet** connection.
3. Your **TeamViewer ID** and **Password**.



Get in contact with our Support Team at: support@emoyo.net and provide them with these details.

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 stainless steel 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 pure 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 pure 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 a 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 damage 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 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 https://www.emoyo.net

Frequently Asked Questions (FAQs)

Please refer to https://emoyo.net/category/helpdesk/ 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 https://emoyo.net/category/helpdesk/ 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 https://emoyo.net/category/helpdesk/.

Troubleshooting Checklist

Problem	Possible Solution
Software does not recognise that the KUDUwave is connected.	Check that the USB cables have been firmly connected in both ear cups to the USB ports on the computer. The left and right LED's will indicate if power is being received from the USB port. If you are using a USB hub ensure that it meets the specifications mentioned under Laptop Specifications and that it is powered externally.
	Try a second set of USB cables in case the original set has been damaged.
	Ensure the Patient Response Handset has been connected to a USB port. It might not be powered enough by the earcup port, plug it into the laptop directly instead.
	Click on the Support button in the software. Click on Remove old drivers and follow the instructions given by the software.
	Restart the computer and try to launch the software again.
Responses from the Patient Response button are not being recorded by the software.	Ensure the Patient Response Handset has been firmly connected to the left ear cup.
	If another Patient Response Handset is available try it instead to ascertain if the response button is broken.

	Ensure that the patient environment is not too noisy so non-compliant results are not being recorded.
	Confirm that the operator can hear sounds being presented using the same headset.
The patient cannot hear sounds being presented even at high intensities.	Inspect the ear probes and eartips for debris that may be blocking the sounds.
I have run out of ear foam eartips.	Contact your sales representative to obtain new eartips. Do not continue using the existing ones or attempt to clean and reuse them.
The KUDUwave 5 software keeps telling me I have X days until the device needs calibration.	Ensure that you send your KUDUwave to eMoyo to be calibrated whenever prompted. Contact your local sales representative for more details.

In Need of Assistance?

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

Technical Specifications

WARNING: No modification of this equipment is allowed.

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) Tympanometry BS EN 60645-5 (Type 1)
Other Standards	BS EN 60601-1, BS EN 60601-1-2, BS EN 60601-1-6, BS EN ISO 13485, BS EN ISO 14971, BS EN 62304, BS EN ISO 14155, BS EN ISO 15223-1, EN 1041
Medical CE mark	European Council Directive 93/42/EEC
Medical device class	IIa
Calibration	Laboratory calibrated in accordance with: BS EN 60645-1, EN 60645-2, SANS 10154-1 and SANS 10154-2

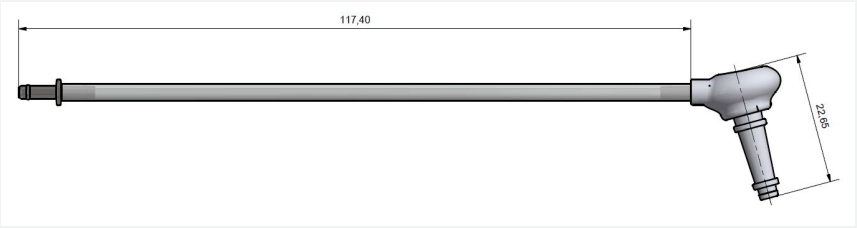
Instrument Specifications

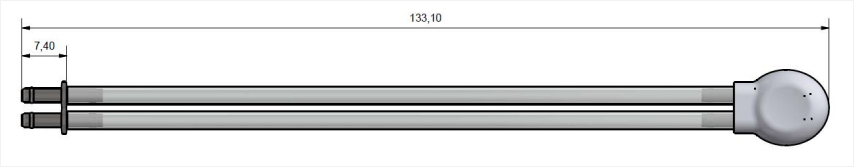
Dimensions	210 x 260 x 110 mm
Shipping	410 x 320 x 190 mm

dimensions		
Net weight	697 g	
	813 g (including Tympanometer functionality)	
Shipping weight	1759 g	
	1930 g (including Tympanometer functionality)	
Power supply	2x standard laptop USB ports (5 V, 900 mA max per port) Unplug laptop from mains while testing	
Data transfer	Twisted KUDUwave™ dual USB cable 2x standard 3 meter A Male to Mini B Male USB cables	
Environmental conditions Indoor use only	Operational temperature	15 - 35 °C
	Operational humidity (non-condensing)	30 - 90 %
	Operational ambient pressure	98 - 104 kPa
	Shipping and storage temperature	10 - 40 °C
	Shipping and storage humidity (non-condensing)	30 - 75 %
	Shipping and storage ambient pressure	70 - 106 kPa
Warm-up time	10 - 20 sec	
Patient response system	Handheld tactile push button (USB)	
Sound tube	Medical grade PVC 80 shore, Clear, L 180 mm, ID 1.7 mm, OD 2.9 mm	

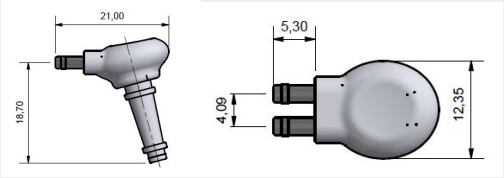
Additional Tympanometer Information

Probe Dimensions: Complete Probe and Associated Tubing with Stainless Steel Couplers

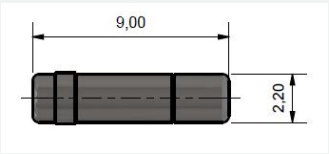




Probe Dimensions: Probe



Probe Dimensions: Stainless Steel Coupler



Maintenance: Probes, Eartips and Associated Tubing

The probe can be cleared of any debris using only the cleaning kit provided by eMoyo. Special care should be taken not to push any debris further into the tubes. Eartips are SINGLE-USE ONLY.

Audiometry Specifications

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

Pure Tone Testing Specifications

Air conduction transducer	KUDUwave™ 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 ™ 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 (tolerance-3 dB to +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 0dBHL (ANSI S3.1, ISO 8253-1, SANS 10182)	< 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 system sound attenuation characteristics using Ambi-dome™ technology Combined ear-cup and immittance silicone insert eartip	9.0 dB at 125 Hz 10.0 dB at 250 Hz 30.0 dB at 500 Hz 33.3 dB at 750 Hz 29.7 dB at 1000 Hz 33.0 dB at 1500 Hz 38.0 dB at 2000 Hz 46.0 dB at 3000 Hz 44.3 dB at 4000 Hz 35.7 dB at 6000 Hz 27.0 dB at 8000 Hz

Air Conduction Frequency Specifications

Freq (Hz)	RETSPLs (dB) Foam Ear-Tip	ETSPLs(dB) Silicone Ear-Tip	Max Output (dBHL)
125	28.0	40.0	60
250	17.5	25.5	70
500	9.5	13.5	100
750	6.0	10.5	100
1000	5.5	12.5	100
1500	9.5	11.5	100
2000	11.5	16.5	100
3000	13.0	17.0	100
4000	15.0	14.0	100
6000	16.0	15.0	90
8000	15.5	19.5	80
9000	13.5	-	80
10000	12.5	-	85
11200	21.5	-	75
12500	25.5	-	80
14000	32.5	-	65
16000	41	-	45

Tested Bone Conduction Frequency Specifications

Freq (Hz)	RETFLs (dB)	Maximum Forehead Hearing Levels (dBHL)
250	79	35
500	72	50
750	61.5	60
1000	51	60
1500	47.5	70
2000	42.5	60
3000	42	60
4000	43.5	50

Maximum Permissible Ambient Noise Levels for the KUDUwave™

According to BS EN ISO 8253-1:2010

Hz	Average attenuation provided by industry standards headsets	Average attenuation provided by KUDUwave	Difference between the average attenuation provided by the two earphones	MPANL in one-third-octave bands, for air conduction audiometry for hearing threshold level measurements down to 0 dB when typical current supra-aural earphones are used.			Difference in attenuation + MPANL for typical supra-aural earphones for hearing threshold level measurements down to 0 dB. (MPANL when a KUDUwave is used)		
125	3	31.0	28.0	28[1]	39[2]	51[3]	56.0[1]	67.0[2]	79.0[3]
250	5	37.7	32.7	19[2]		37[3]	51.7[2]		69.7[3]
500	7	43.8	36.8	18			54.8		
1000	15	40.8	25.8	23			48.8		
2000	26	38.1	12.1	30			42.1		
4000	32	52.3	20.3	36			56.3		
8000	24	45.8	21.8	33			54.8		

According to ANSI S3.1-1999

Hz	Average attenuation provided by industry standards headsets	Average attenuation provided by KUDUwave	Difference between the average attenuation provided by the two earphones	Maximum permissible ambient noise levels dB SPL for a typical Supra-aural headset Testing to a minimum threshold of 0dB HL, Test Frequency Range 125 - 8000Hz.	Maximum permissible ambient noise levels dB SPL for the KUDUwave insert earphones with forehead bone conductor Testing to a minimum threshold of 0dB HL, Test Frequency Range 125 - 8000Hz.	Maximum permissible ambient noise levels dB SPL, KUDUwave insert earphones. Testing to a minimum threshold of 25dB HL, Test Frequency Range 500 - 8000Hz.
125	3	31.0	28.0	35	63.0	-
250	5	37.7	32.7	25	57.7	-
500	7	43.8	36.8	21	57.8	82.8

[1] Test Tone Range: 125Hz - 8000Hz
[2] Test Tone Range: 250Hz - 8000Hz
[3] Test Tone Range: 500Hz - 8000Hz

1000	15	40.8	25.8	26	51.8	76.8
2000	26	38.1	12.1	34	46.1	71.1
4000	32	52.3	20.3	37	57.3	82.3
8000	24	45.8	21.8	37	58.8	83.8

Narrowband Masking Specifications

Freq (Hz)	Max Output (dBHL)	Tested Type 3 Max Output (dBHL)	Lower Cut-Off Frequency (Hz)	Upper Cut-Off Frequency (Hz)
125	60	60	110	148.75
250	60	60	215	292.5
500	75	75	430	577.5
750	90	80	650	885
1000	90	80	865	1160
1500	90	80	1287.5	1762.5
2000	90	80	1750	2287.5
3000	90	80	2612.5	3537.5
4000	90	80	3475	4730
6000	90	-	5291.7	7131.9
8000	80	-	6760	9360

Replacement Item Specification

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

Tympanometry Specifications

Tympanometry General

Tympanometer transducer	KUDUwave™ built-in transducer
Influence of ambient pressure and temperature on calibration	The KUDUwave™ Pro TMP contains an environmental sensor which measures atmospheric pressure, temperature and relative humidity. Conversion between volume and admittance is handled automatically. The unit will ask for recalibration with the calibration cavities if the environment changes significantly.
Probe dimensions	Use only the tympanometry probes (identified on the packaging)
Maintenance information	The probe should be visually inspected at each use. If it is dirty it should be cleaned using the cleaning kit provided. If it shows signs of damage it should be replaced with a new probe.

Probe Signal

Frequencies	226Hz
Level	85 dB SPL (≈ 69 dB HL) ±3 dB in an IEC 60318-5 coupler Typical variation with loading: 6 dB at 0.5 cm^3, 0 dB at 2 cm^3, -6 dB at 5 cm^3
Frequency accuracy	±1%
THD	<1%

Pneumatic system

Pressure range	+400 daPa to -600 daPa
Speed	50 daPa/s 200 daPa/s 400 daPa/s
Direction	Positive-to-negative and negative-to-positive
Maximum limits	-750 daPa and +550 daPa as measured in a 0.5 cm^3 cavity
Safety mechanism	Automatic valve release at safety maximum limits
Pressure accuracy	±10 daPa or ±10%, whichever is greater (in cavities from 0.5 cm^3 to 5 cm^3)
Speed accuracy	50 daPa/s: ±10 daPa/s 200 and 400 daPa/s: ±40 daPa/s (in cavities from 0.5 cm^3 to 5 cm^3)
Control	Automatic or manual
Indicator	Graphical display on PC

Admittance Measurement

Units	cm^3 or acoustic mmho (1 acoustic mmho = 10^{-8} $m^3/(Pa{\cdot}s)$
Range	0.2 cm^3 to 5 cm^3 (measurement plane)
Accuracy	±5% or ±0.1 cm^3 of the equivalent volume or ±0.1 acoustic mmho, whichever is greater. This is applicable for both static and dynamic modes of operation
Dependence on barometric pressure	The KUDUwave™ Pro TMP contains an environmental sensor which automatically compensates for the conversion between volume and admittance

Analysis performed	Compliance peak level; compliance peak pressure level; ear canal volume; peak width; tympanogram type

Reflex Measurements

Reflex test types	Ipsilateral, contralateral and bilateral (simultaneous ipsi- and contralateral)
Reflex stimuli	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz and broadband noise Frequency: ±1 % THD: < 5 % Broadband noise: ±5 dB from 500 Hz to 4000 Hz
Stimulus level control	Step: 5 dB Accuracy: ±5 dB

Stimulus	Minimum [dBHL]	Maximum [dBHL]
500 Hz	50	100
1000 Hz	50	100
2000 Hz	50	100
4000 Hz	50	90
Broadband noise	50	90

Stimulus presentation control	on-off ratio: >70 dB rise and fall times: 20 ms residual A-weighted SPL with stimulus off: <25 dBSPL
Stimulus level variation with ear canal volume	Since both ipsilateral and contralateral stimulus use probes the stimulus sound pressure level in the ear canal may vary depending on the ear canal volume. Possible variations are tabulated below relative to a 2 cm^3 cavity (in which the stimulus is calibrated):

Stimulus frequency [Hz]	Ear canal SPL for different ear canal volumes relative to 2 cm^3 [dB]	
	0.5 cm^3	1.0 cm^3
500	14	8
1000	11	6
2000	12	7
4000	12	7

Reflex sensitivity	0.01 cm^3 is the smallest displayed volume change

Reflex stimulus artefact level	At stimulus levels greater than these levels there is a possibility of artefactural change which exceeds 0.03 cm^3 occuring in the measurement display synchronously with the reflex stimulus in an ipsilateral measurement. Measured in cavities from 0.5 to 5 cm^3.

Test Signal	Ipsilateral reflex stimulus [dBHL]
500 Hz	>100
1000 Hz	>100
2000 Hz	>100
4000 Hz	>95
Broadband noise	>95

Temporal reflex characteristics	Initial latency: 20 ms ±15 ms Rise and fall time: 30 ms ±15 ms Terminal latency: 10 ms ±15 ms Undershoot and overshoot: <10 %
Pulsed stimulus characteristics	Rise and Fall time: 5 ms On time: 55 ms Off time: 60 ms Accuracy: 0 ms

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 60601-1-2:2015 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 components 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 components 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 components 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 all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 100 kHz repetition frequency (SIP/SOP port)	Power supply lines: not applicable, see note 2 ±1 kV for input/ output lines 100 kHz repetition frequency (SIP/SOP port)	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 50 Hz or 60 Hz	3 A/m 50 Hz or 60 Hz	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
Conducted RF IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be no closer to any part of the KUDUwave™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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 - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	

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

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

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

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.
NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

End User License Agreement (EULA)

The eMoyoDotNetza (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

eMoyoDotNetza (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 a 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 affected 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 damages 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.

KUDUwave™

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eMoyo

ISO 13485 Medical Devices Quality Management

CE 2797