eMoyo

WELL BEYOND INNOVATION

KUDUWAVE™

AUDIOMETER

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

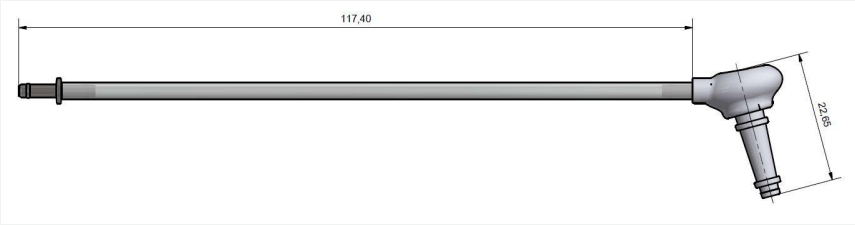
Instrument Specifications

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

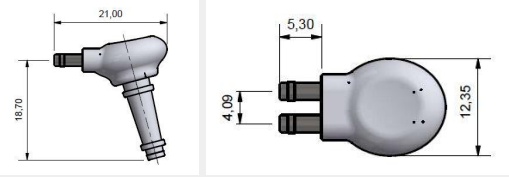
	Shipping and storage humidity (non-condensing)	30 - 75 %
	Shipping and storage ambient pressure	70 - 106 kPa
Warm-up time	10 - 20 sec	
Patient response system	Handheld tactile push button (USB)	
Sound tube	Medical grade PVC 80 shore, Clear, L 180 mm, ID 1.7 mm, OD 2.9 mm	

Additional Tympanometer Information

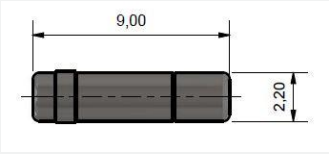
Probe Dimensions: Complete Probe and Associated Tubing with Stainless Steel Couplers



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	Maximum permissible ambient noise levels dB SPL for the Kuduwave insert earphones with forehead bone conductor Testing to a minimum	Maximum permissible ambient noise levels dB SPL, Kuduwave insert earphones. Testing to a minimum threshold of 25dB HL, Test

[1] Test Tone Range: 125Hz - 8000Hz

[2] Test Tone Range: 250Hz - 8000Hz

[3] Test Tone Range: 500Hz - 8000Hz

				Frequency Range 125 - 8000Hz.	threshold of 0dB HL, Test Frequency Range 125 - 8000Hz.	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
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
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	$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:

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.