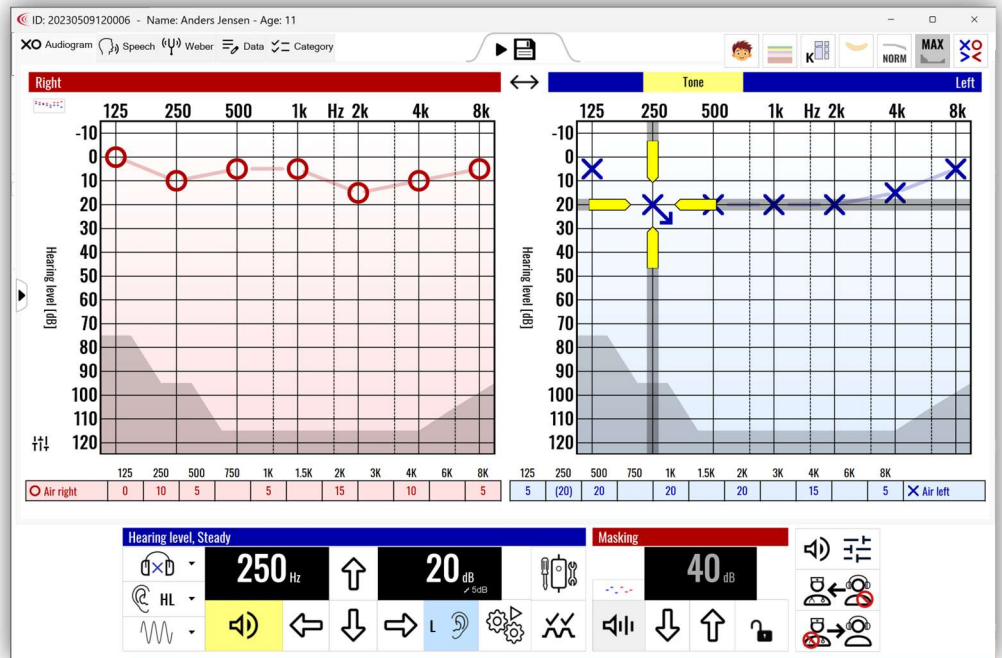


Instructions for Use

Oscilla® A30, A50, A60 Diagnostic Audiometers
& AudioConsole® software version 4.6.0

English



Contents

1. General Description	3
2. Installation	4
Connecting to AudioConsole.....	4
System Requirements	4
3. Device Overview	5
4. Operation	6
Pure-tone	6
Masking (A50 & A60 only).....	7
Connecting Bone Conductor (A50 & A60 only).....	7
5. Device Configuration and Settings.....	8
General.....	8
Manual Hearing Test.....	9
Automatic Hearing Tests.....	10
6. Automatic Test	11
7. Ear Protection Test.....	12
8. Weber Test (A50 & A60 only).....	13
10. SISI Test (A50 & A60 only).....	14
11. Speech Operation with Speech Material (A60 only).....	15
12. Speech Operation with Live Voice (A60 only).....	17
13. Speech Setup (A60 only)	19
14. Technical Specifications	20
15. Service and Maintenance.....	23
Cleaning.....	23
Calibration.....	23
Service and Repair.....	23
16. Warning and Safety Notices.....	25
17. Symbols.....	26
18. EMC.....	27
19. Manufacturer	28
Responsibility of the Manufacturer	28
Warranty	28
What is excluded from the warranty?	28



This manual contains safety instructions. Read these instructions carefully and completely before using the product.

1. General Description

Oscilla® A30, A50 and A60 are USB powered Diagnostic audiometers for manual and automatic testing. The audiometers are operated using a PC with Oscilla AudioConsole® software.

Features	Configurations		
	Oscilla A30	Oscilla A50	Oscilla A60
Air conduction	●	●	●
Automatic Test	●	●	●
Ear protection Test	●	●	●
SISI Test		●	●
Bone Conduction		●	●
Weber Test		●	●
Talk Over			●
Speech Test			●

Intended Use

Diagnostic audiometric testing. (Oscilla® A30, A50 and A60)
Software user interface for audiometric medical devices. (Oscilla AudioConsole software)

Intended Users

Audiologists, ENT specialists and other healthcare professionals conducting hearing tests on their patients.

Intended Patient Population

All patient groups from five (5) years through adulthood, provided that the patient can respond to the signals.

Intended Use Environments

Professional Healthcare Facility Environments in clinics, schools, institutions, etc.

Contraindications

Patient is uncooperative.

Clinical Benefit

The Oscilla audiometer is used to conduct diagnostic audiometric testing, thereby providing a means to determine the presence, type and degree of hearing loss and assist in the diagnosis of otologic disorders.

Essential Performance

The device is designed to offer a high degree of protection of the patient's hearing. If excessive or unwanted audio signals occur, refrain from using the device and seek assistance for service of the device.

Please note! Not all configurations support all measurement types and tests described in this manual. See table of features vs configurations at the top of chapter 1, General Description.

2. Installation

Connecting to AudioConsole

The device is powered by the USB port of the connected computer. The operator is qualified to perform the installation.

1. Install the AudioConsole software on the PC.
2. Connect the device to the computer's USB port. Windows automatically detects and installs the device. Wait for the automatic installation to finish.
3. Launch AudioConsole.

Refer to the AudioConsole User Manual for a general introduction to Oscilla® AudioConsole and information about how to use the patient database, generate reports and export data to other patient-management systems.

System Requirements

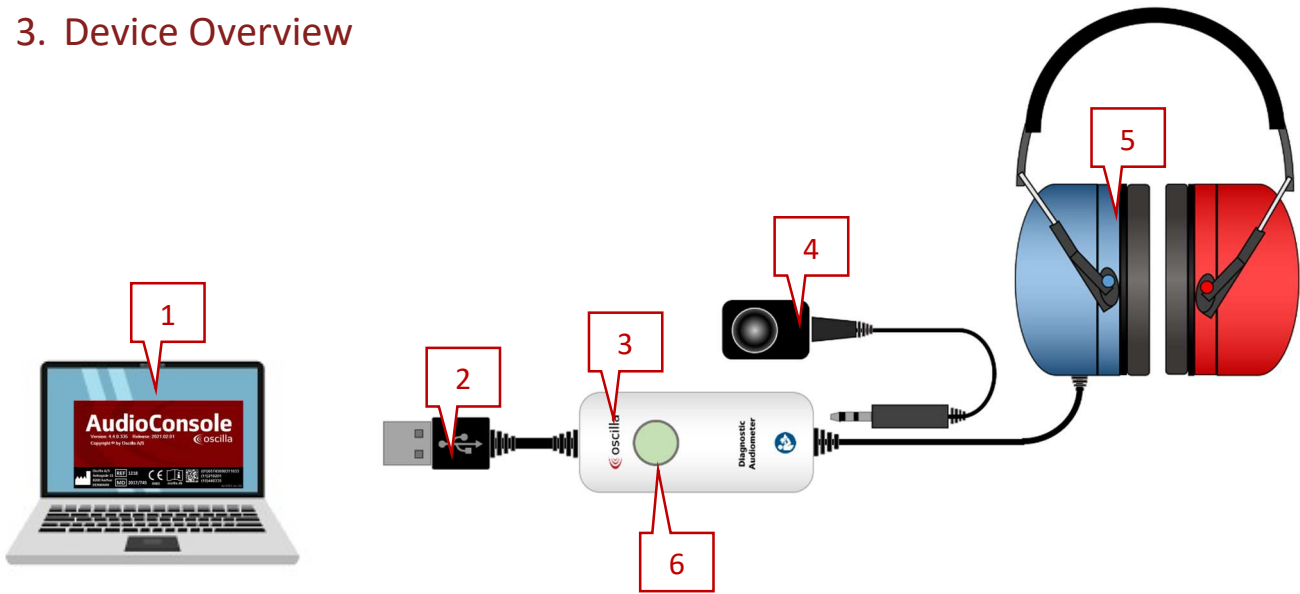
Minimum System Requirements

- **Processor:** 2 GHz
- **RAM:** 2 GB
- **Free space:** 150 MB
- **Display resolution:** 1024 x 600 (1440 x 900 recommended for best performance)
- Available USB port for the audiometer
- Available USB port for the operator headset (relevant for A60 only)

Supported Operating Systems

Microsoft Windows 10 and Windows 11

3. Device Overview



1. PC with the AudioConsole software.
2. USB connector (Type-A).
3. Main unit.
4. Bone conductor (A50 & A60 only).
5. Patient Headset.
6. Patient response button with status light indicator.
7. USB flash drive with the AudioConsole software and IFU.



Status light indicator

Dim white light



The device is in sleep-mode

Bright white light



The device is active and connected to the AudioConsole software

Orange light



The device is in test mode

Green light

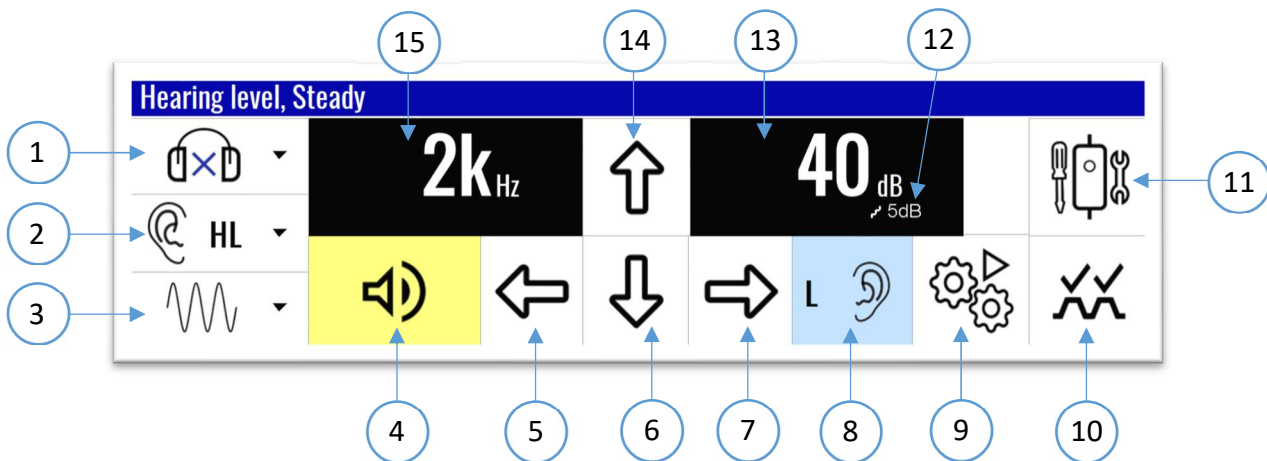


The Patient button is activated

4. Operation

Pure-tone

This is the control panel for pure-tone operation:



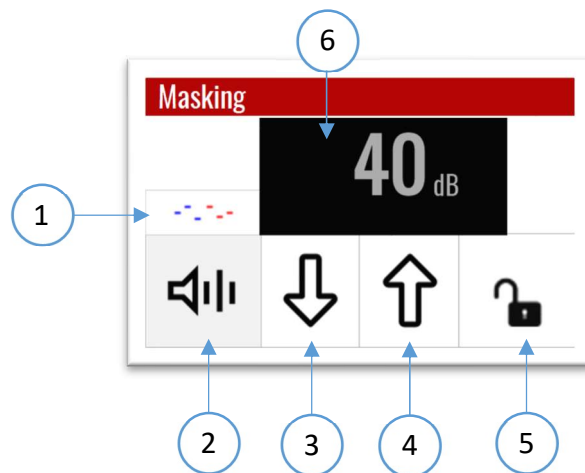
1. Select output transducer:
Left, right or binaural
2. Select curve type
3. Select stimulus type:
Steady, pulse or warble tone
4. Present tone to patient
5. Frequency down
6. Hearing level up
7. Frequency up
8. Switch between left and right ear
9. Start automatic test
10. SISI test
11. Setup
Refer to section *Device configuration and settings* for more information
12. Select dB increase for hearing level adjustment:
1 dB, 2 dB or 5 dB steps
13. Current hearing level
14. Hearing level down
15. Current frequency level



Sound stimuli above 100 dB HL can cause potential hearing loss if the exposure time is more than 1.5 minutes.

Masking (A50 & A60 only)

This is the masking control panel for pure-tone operation:



1. Toggle common/separated masking – Set masking levels for each frequency
2. Turn masking on/off
3. Masking dB level down
4. Masking dB level up
5. Turn masking lock on/off – Masking follows the tone attenuator control
6. Masking level dB

Connecting Bone Conductor (A50 & A60 only)

The bone conductor plug must be connected to the bone connector found on the back of the main unit's right side. See the illustration below.

Make sure the plug is pressed all the way in before using the bone conductor.



5. Device Configuration and Settings

Click the control panel's setup button to configure:

- General settings
- Manual hearing test settings
- Automatic hearing test settings

General

Audiometer setup

General Manual hearing test Automatic hearing test SISI test

Keyboard shortcuts

Tone	Spacebar	Delete symbol	Delete
dB level down	Up arrow	Toggle Heard/Not heard	Q
dB level up	Down arrow	Curve type	C
Frequency up	Right arrow	Output transducer	B
Frequency down	Left arrow	SISI test	S
Pulse or steady	P	Masking on/off	M
Autotest	A	Masking dB level up	K
Setup	Home	Masking dB level down	O
Left/Right	E	Masking lock on/off	N
Left	L	Masking lock level up	J
Right	R	Masking lock level down	I
Binaural	U	Talk-through	T
Insert symbol	Enter/Return	Talk-back	Y

Frequency selection

- 125 Hz
- 250 Hz
- 500 Hz
- 750 Hz
- 1 KHz
- 1.5 KHz
- 2 KHz
- 3 KHz
- 4 KHz
- 6 KHz
- 8 KHz

Set 'Not heard' when testing

Cancel Ok

Keyboard shortcuts

Set up keyboard shortcuts for pure-tone testing using the drop-down menus.

Frequency selection

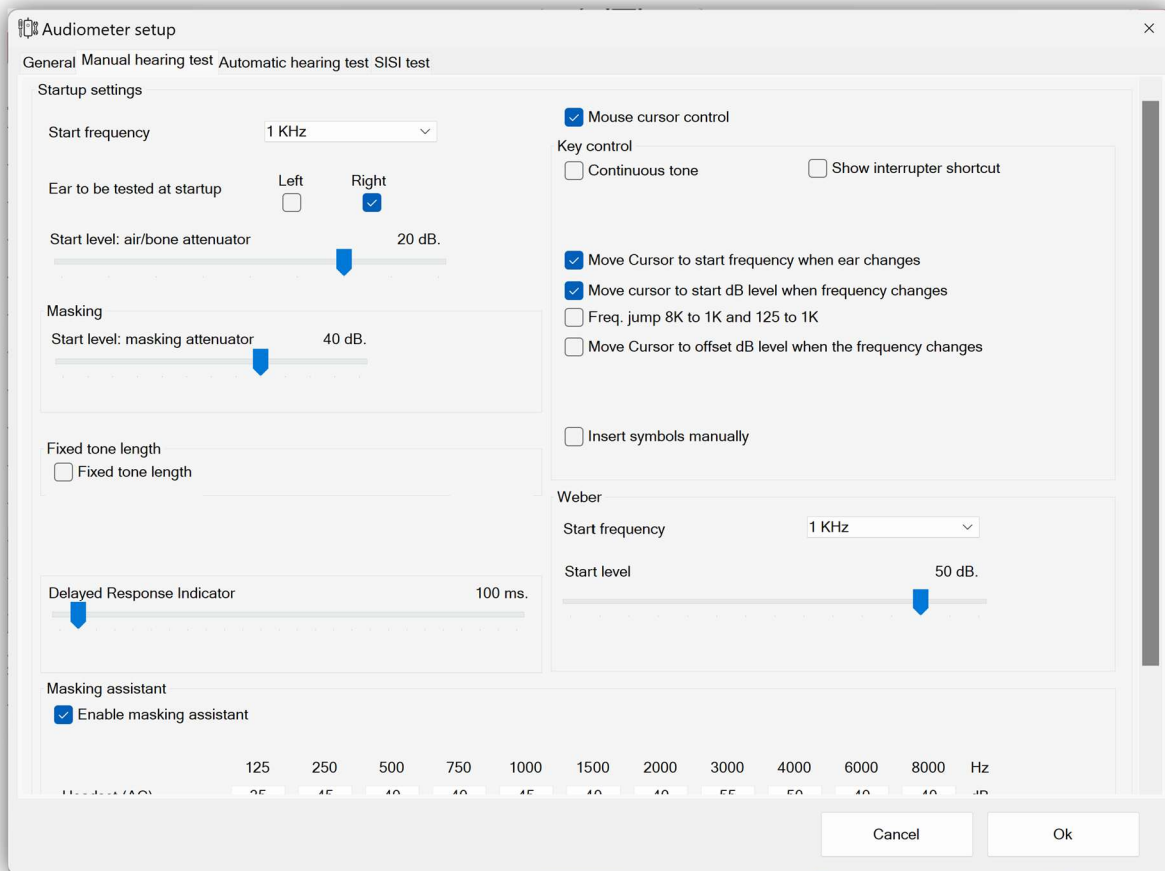
Enable or disable frequencies.

Set "Not heard" when testing

Enable or disable the *not heard* symbol.

When this setting is enabled, a symbol will appear in the audiogram if the patient does not respond.

Manual Hearing Test



Startup settings

Configure start-up settings for pure-tone tests:

- Select a start frequency between 125 Hz and 8000 Hz
- Select which ear to test first during manual testing
- Select a start hearing level between -10 dB and 30 dB

Mouse cursor control

Enable or disable attenuator and frequency control using the mouse.

Masking

Adjust the initial masking level.

Key control

Enable or disable continuous tone and cursor settings for frequency changes during manual testing.

Weber

Adjust the initial frequency and volume level.

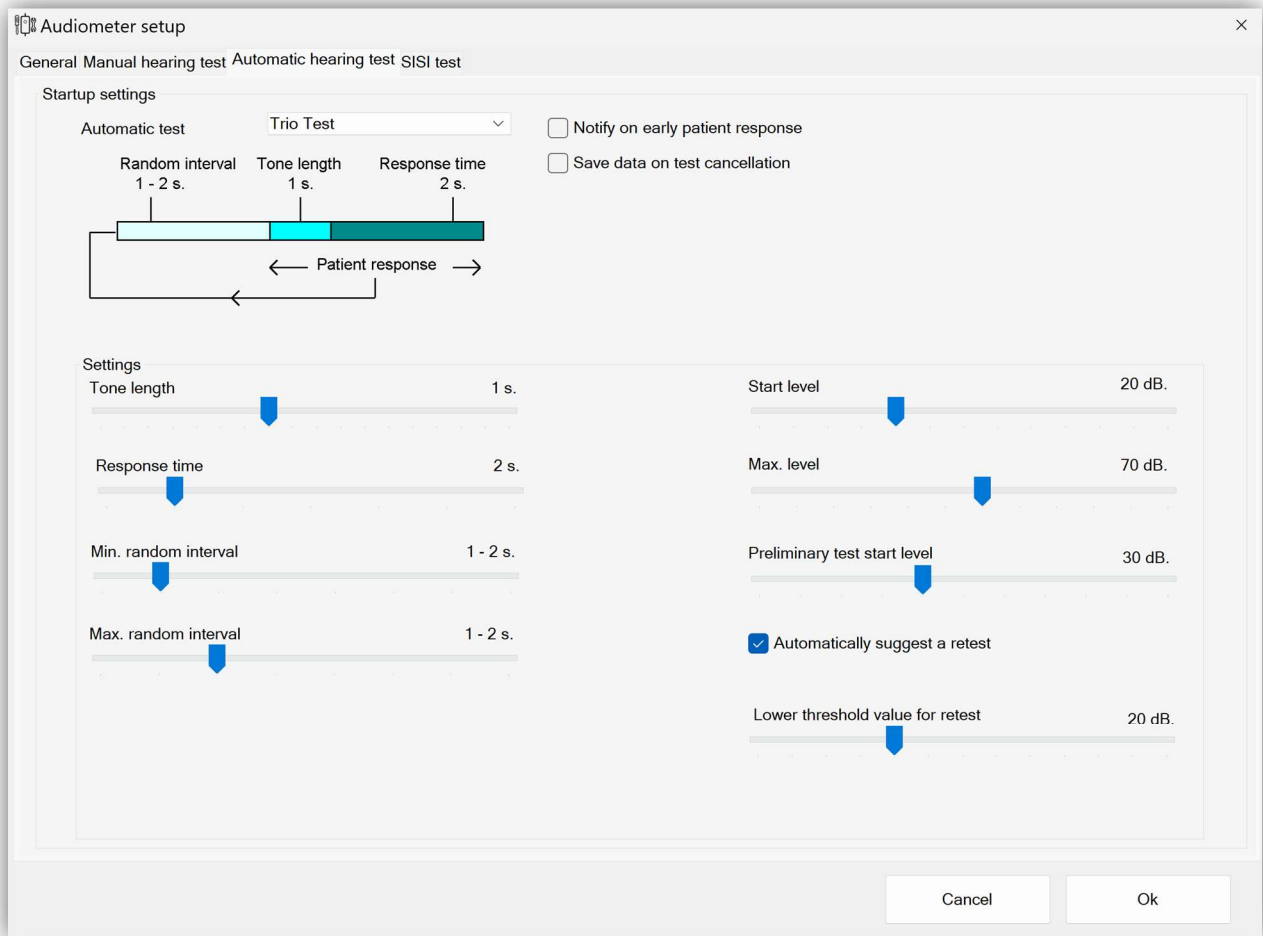
Fixed tone length

Click the check box to set a fixed tone length between 0.3 and 2.5 seconds.

Masking assistant

Enable or disable the masking assistant. Based on audiogram data for the opposite ear, the masking assistant gives advice on when to use masking.

Automatic Hearing Tests



Startup settings

Select which of the automatic hearing test to set as default:

- 20 dB test
- 20 dB random test
- Hughson Westlake test
- xx dB test
- xx dB random test
- Decrease 10 dB random test
- Decrease 5 dB random test
- Trio Autotest

Enable/disable notification when a patient presses the response button before a tone is presented.

Enable or disable automatic saving of test results when an automatic test is cancelled before it is completed.

Settings

Adjust tone length, response window and interval between tones for automatic testing:

- Tone length: 0.3 to 2 seconds
- Response window: 1 to 7 seconds
- Minimum random interval: 0 to 7 seconds
- Maximum random interval: 0 to 7 seconds

Adjust start, maximum and minimum hearing levels for automatic testing.

The Hughson Westlake test has the following options:

- 2 out of 3 required patient responses
- 3 out of 4 required patient responses

6. Automatic Test

20 dB Test

Automatic screening test with a default hearing level set to 20 dB. The hearing level will increase in steps of 5 dB until the patient responds. When the patient responds, the frequency changes to the next frequency and the hearing level resets to 20 dB. This procedure is repeated for every new frequency. The test continues until all frequencies have been tested on both ears.

20 dB Random Test

A randomised version of the 20 dB automatic screening test. The test starts at a 20 dB default hearing level at 1000 Hz in the right ear followed by 20 dB at 1000 Hz in the left ear. The test will then randomly switch between frequencies and ear until all frequencies have been tested on both ears.

Hughson Westlake Automatic Test

The Hughson Westlake test is an automatic threshold test. The test starts at 1000 Hz and a default hearing level of 20 dB in the right ear. The hearing level automatically increases in steps of 5 dB until the patient responds.

The test requires the patient to respond to 2 out of 3 presentations of the same hearing level at each frequency before moving on to the next frequency.

Once the test is completed for the left ear, the same procedure is automatically repeated for the right ear before the test is concluded.

xx dB Test

Automatic screening test based on the 20 dB test with an adjustable initial hearing level.

xx dB random Test

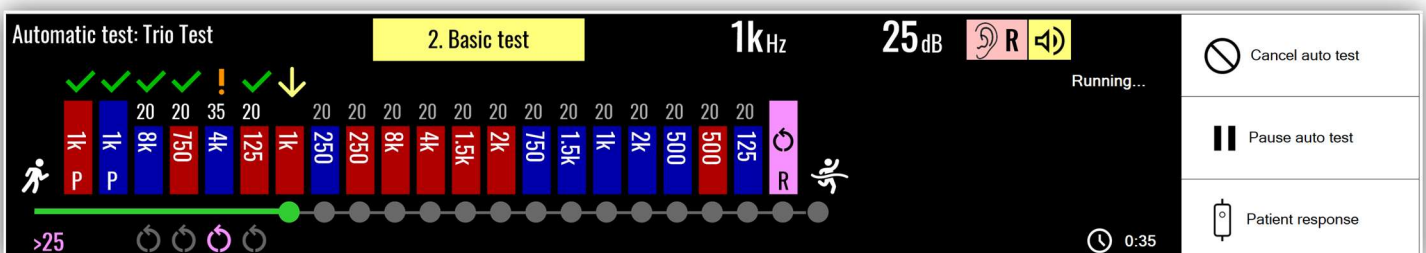
Automatic screening test based on the 20 dB random test with an adjustable initial hearing level.

Trio Autotest

The automatic screening test is optimized for use with children. It consists of three phases:

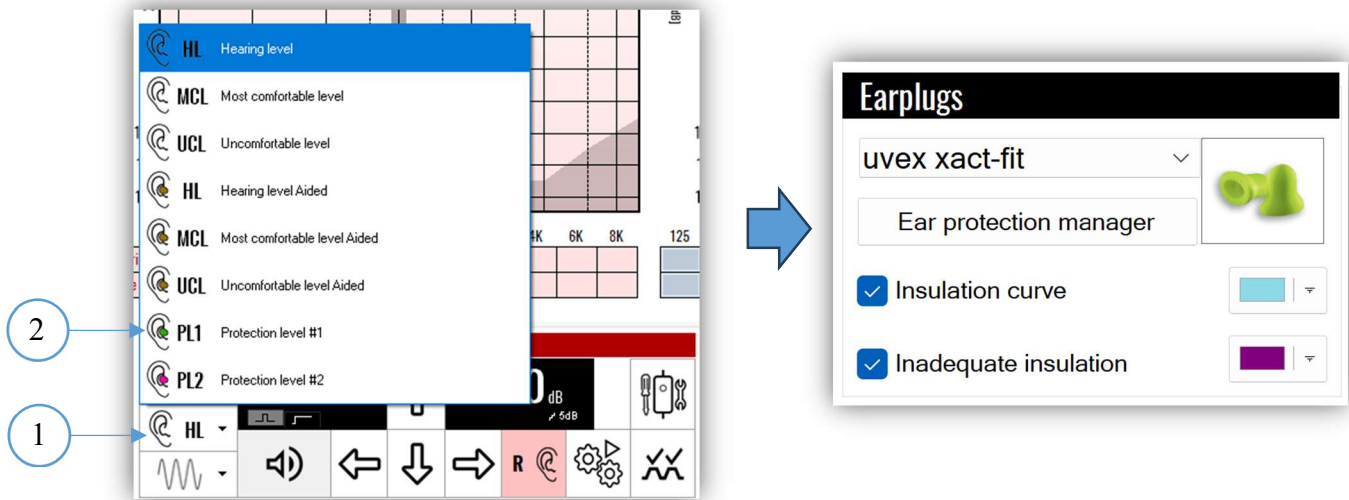
1. Initial Test: Used to determine if the child understands the test.
2. Basic Test: During the screening, it will automatically suggest which frequencies should be re-tested.
3. Re-test: After completing the basic test, the re-test is conducted on the suggested frequencies. Once this phase is complete, the test is finished.

In the settings for Trio Autotest, you can adjust everything from the start level and the threshold for when retesting should occur, to the duration between tone presentations and the time each tone is active.

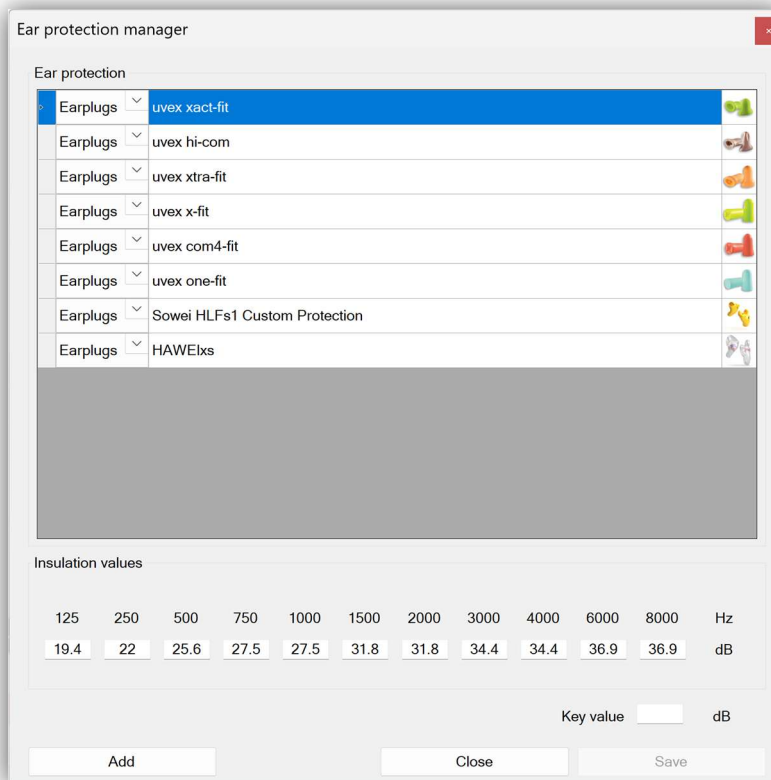


7. Ear Protection Test

To start the ear protection test, select Protection Level (PL1 or PL2) as curve type in the Pure-tone panel. In the Ear protection control panel, select the type of ear plug to test:




Click *Ear protection manager* to add a new type of ear plug or edit an existing type. You may also customize the data to visualize in the audiogram and the associated colors.

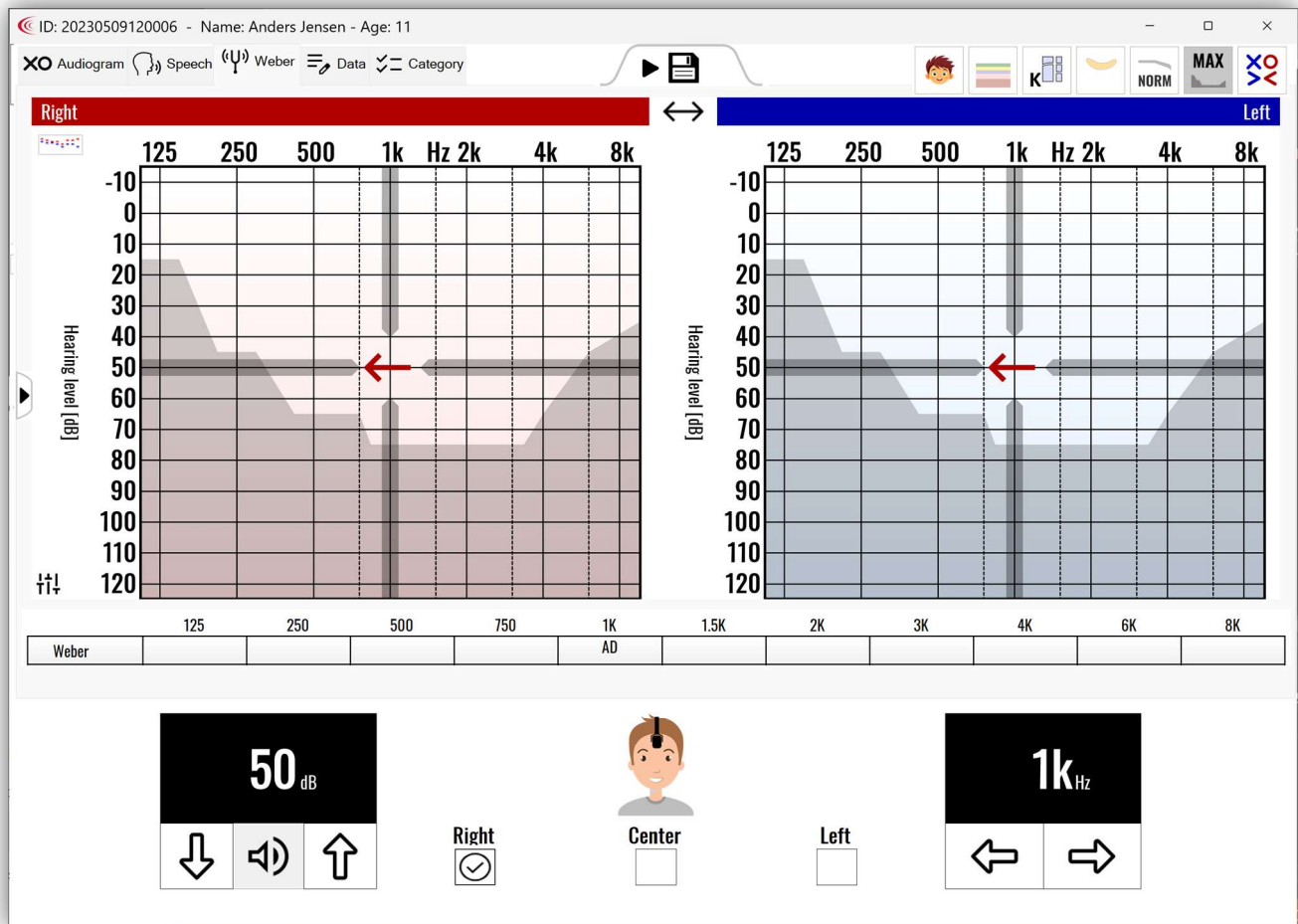


1. Conduct a hearing test without ear protection.
2. Instruct the patient to insert ear plugs.
3. Conduct a hearing test with ear protection.
4. Check whether the ear protection provides adequate insulation.

It is possible to conduct and store up to two ear protection tests in one workflow.

8. Weber Test (A50 & A60 only)

Click the  tab and the current control panel will be replaced with a Weber control panel. Use the bone conductor to conduct a multi-frequency Weber test:



1. Adjust the dB hearing level and the frequency if needed.
2. Present a tone to the patient.
3. Select the direction where the patient perceived the tone most clearly.

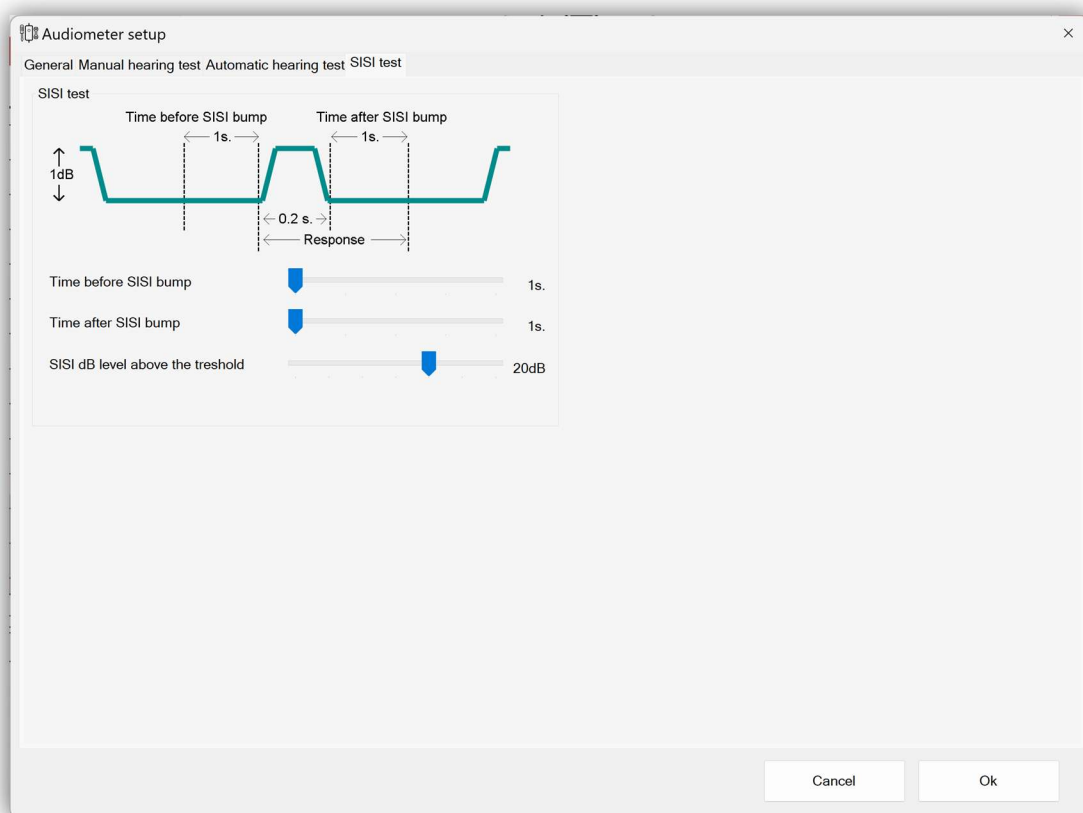
You can carry out this test for the full range of frequencies.

10. SISI Test (A50 & A60 only)

The Short Increment Sensitivity Index test (SISI test) is still widely used to determine whether the patient has cochlear pathology. This test is based on a phenomenon known as recruitment (abnormal loudness growth).

Difference Limen for Intensity (DLI):

Is the smallest detectable change in the intensity of a pure-tone. Patients with normal hearing often have difficulty detecting small changes in intensity close to threshold. Patients with cochlear pathology will be able to better detect the change in intensity because of the phenomenon of recruitment. DLI can safely be assumed to be an indirect indicator of recruitment.

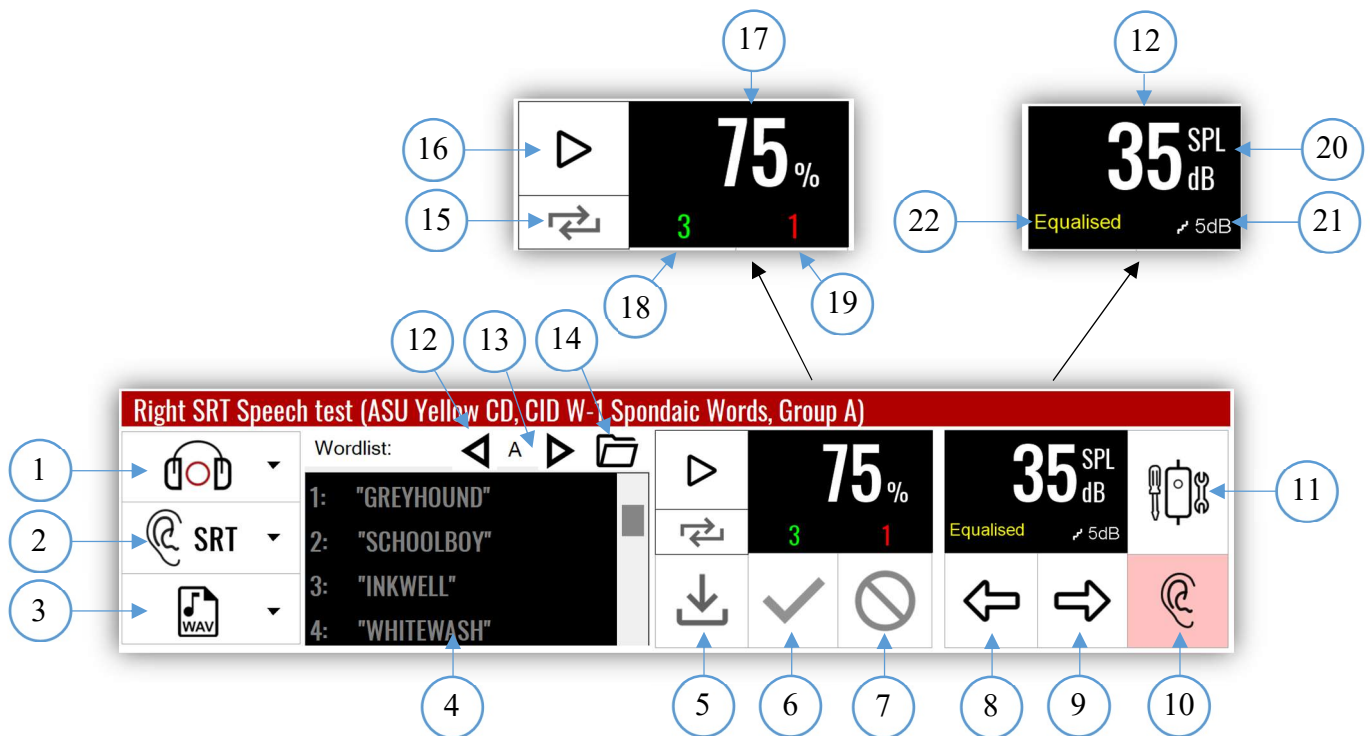


SISI test

Adjust time interval and hearing level.

11. Speech Operation with Speech Material (A60 only)

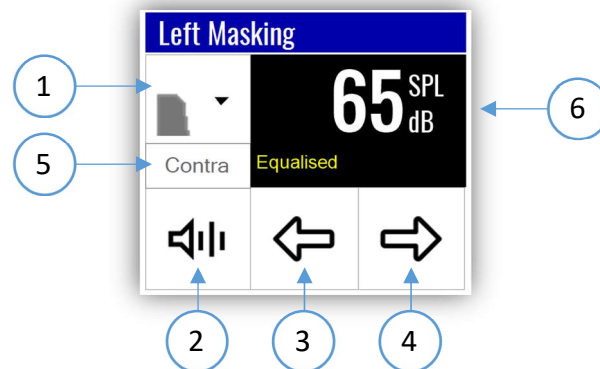
This is the control panel for speech operation with speech material:



1. Select output transducer:
Left, right or binaural
2. Select speech test type
3. Input selection
4. Wordlist
5. Store point
6. Correct
7. Incorrect
8. dB hearing level down
9. dB hearing level up
10. Toggle left/right ear
11. Setup
12. Previous wordlist
13. Next wordlist
14. Select wordlist
15. Play word again
16. Start and stop speech test
17. Score in percentage
18. Number of correct answers
19. Number of incorrect answers.
20. Current dB hearing level
21. Select dB level steps
22. The indicator shows that the Equalizer, as specified in IEC 60645-2017 Section 6.1.2, is active.

Masking and Speech Material

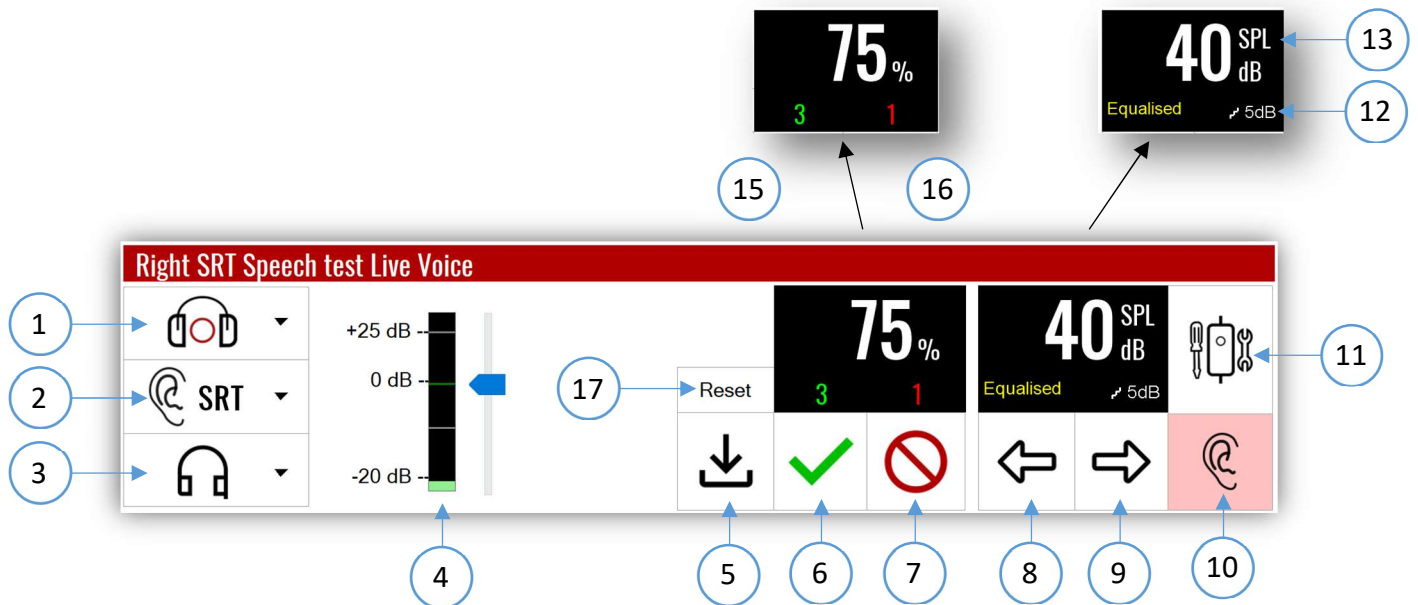
This is the masking control panel for speech operation with speech material:



1. Select masking type:
NB, SN and WN
2. Turn masking on/off
3. Masking dB level down
4. Masking dB level up
5. Switch between contralateral and ipsilateral masking.
6. Masking level dB

12. Speech Operation with Live Voice (A60 only)

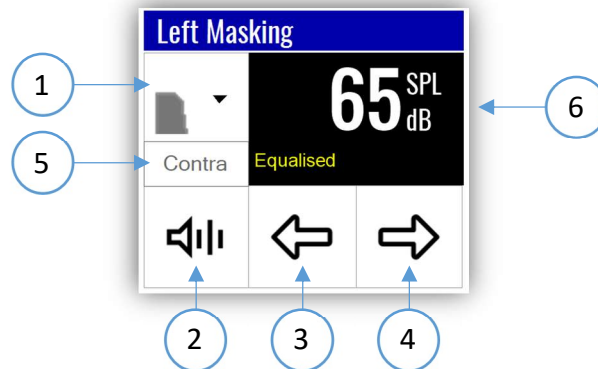
This is the control panel for speech operation with live voice:



- | | |
|----------------------------|--|
| 1. Output transducer | 10. Toggle left/right ear |
| 2. Select speech test type | 11. Settings |
| 3. Input selection | 12. Select dB level steps:
1 dB, 2 dB or 5 dB |
| 4. Volume meter | 13. Current dB level |
| 5. Store point | 14. Score in percentage |
| 6. Correct | 15. Number of correct answers |
| 7. Incorrect | 16. Number of incorrect answers |
| 8. dB hearing level down | 17. Reset score to 0 percent |
| 9. dB hearing level up | |

Masking and Live Voice Speech Testing

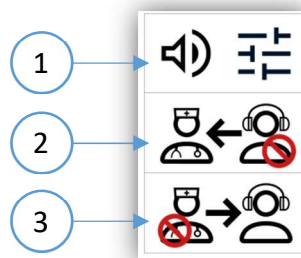
This is the masking control panel for live voice speech testing:



1. Select masking type:
NB, SN and WN
2. Turn masking on/off
3. Masking dB level down
4. Masking dB level up
5. Select dB level steps
1 dB, 2 dB or 5 dB
6. Masking level dB

Patient Communication during Speech Tests

This is the control panel for patient communication during live voice speech tests:



1. Adjust mixer settings
2. Patient to operator communication on/off
3. Operator to patient communication on/off

13. Speech Setup (A60 only)

Click the setup button in the speech control panel to configure:

- General settings
- Calibration settings

Audiometer setup

General Calibration

Keyboard shortcuts

Start speech test: F

Play word again: R

Store point: S

Correct: O

Wrong: W

dB level up: Down arrow

dB level down: Up arrow

Input: I

Output transducer: B

Left/Right: E

Audiometer setup: Home

Masking on/off: M

Masking Type: Q

Masking dB level up: Page down

Masking dB level down: Page up

Talk-through: T

Talk-back: Y

SpeechTest Type: A

PTA frequency selection

125 Hz

250 Hz

500 Hz

750 Hz

1 KHz

1.5 KHz

2 KHz

3 KHz

4 KHz

6 KHz

8 KHz

Default

Assign material

SRT DS MCL UCL

Active

Material: Collège National

Type: Listes dissyllabiq

Group: 1

Word interval/Delay

Word interval (MCL/UCL) 0,5 s.

Word interval (SRT) 0,5 s.

Start level

Start level 65 dB

Masking level dB 65 dB

Show warning when no operator headset is connected

Activate equalizer (IEC 60645-2017 sec 6.1.2)

Speech audiogram in SPL

Install new Speech material

Cancel Ok

Assign material

Select the default speech material.

Word interval

Adjust the time interval between words in MCL, UCL and SRT tests.

Start level

Adjust the start dB hearing level for speech and masking.

14. Technical Specifications

Device Compliance

Performance IEC 60645-1:2017, Type 3

Electrical safety IEC 60601-1:2005/A1:2012 (Edition 3.1)
Class II, Type B applied parts, IPX0

EMC IEC 60601-1-2:2014 (Edition 4.0)

Device Performance

Headset Oscilla H210A

Air conduction Frequency range	Frequency	Maximum hearing level	RETSPL PTB 4106973** Ref.: 20 µPa	Maximum NBN	NBN RETSPL Correction* Ref.: 20 µPa
	Hz	dB HL	dB	dB HL	dB
Maximum hearing level		70	34.7	60	4
Puretone RETSPLs in accordance with ISO 389-8:2004	125	90	16.5	80	4
	250	110	5.1	100	4
	500	110	0.9	100	5
	750	110	3.1	100	6
NBN RETSPLs in accordance with ISO 389-4:1994	1000	110	0	100	6
	1500	110	-2.9	100	6
	2000	110	-0.7	100	6
	3000	110	9.2	100	5
	4000	100	17.8	90	5
	6000	90	22.3	80	5
8000					

*: ISO 389-4 Table 1

** : The investigation of the equivalent threshold sound pressure levels for Oscilla H210A was conducted regarding ISO 389-8 and ISO 389-9 by The Physikalisch-Technische Bundesanstalt (PTB) in Braunschweig, August 2021.

Report Reference No.: 1.61 - 4106973

Headset RadioEar DD65v2

Frequency	Maximum hearing level	RETSPL PTB & AAU Ref.: 20 µPa	Maximum NBN	NBN RETSPL Correction*** Ref.: 20 µPa
		dB		dB
Hz	dB HL	dB	dB HL	dB
125	70	30.5	60	4
250	90	17.0	80	4
500	110	8.0	100	4
750	110	5.5	100	5
1000	110	4.5	100	6
1500	110	2.5	100	6
2000	110	2.5	100	6
3000	110	2.0	100	6
4000	110	9.5	100	5
6000	100	21.0	90	5
8000	90	21.0	80	5

Hearing level accuracy 125 Hz - 4000 Hz: ± 3 dB
6000 Hz - 8000 Hz: ± 5 dB

Frequency accuracy
Harmonic distortion

Tolerance: $\pm 2\%$
Total harmonic distortion for Air conduction: 2.5 %
Total harmonic distortion for Bone conduction: 5.5 %

Bone conduction

Frequency range

Maximum hearing level

RETFLS / RETVFL in accordance
with ISO 389-3:2016 and ANSI S3.6-
2010

Frequency	Maximum hearing level	RETFLS / RETVFL Ref.: 1 μ N	BC forehead ISO 389-3 table C.1
Hz	dB HL	dB	dB
125	10	82.5	12
250	40	67.0	12
500	60	58.0	14
750	60	48.5	13
1000	70	42.5	8,5
1500	70	36.5	11
2000	70	31.0	11,5
3000	70	30.0	12
4000	60	35.5	8
6000	40	40.0	11
8000	30	40.0	10

Bone vibrator accuracy

125 Hz - 4000 Hz: ± 3 dB
6000 Hz - 8000 Hz: ± 5 dB

Placement

Mastoid

Frequency-modulated signal
(Warble)

Frequency: 250 Hz – 8000 Hz
Waveform: Triangular
Tolerance: 3 %
Repetition rate: 5 Hz $\pm 10\%$
Frequency deviation: 5% $\pm 10\%$

Warm-up time

< 10 minutes

Earphones sound attenuation

Frequency	H210A (ISO 4869-1)	DD65 (ISO 4869-1)
Hz	dB	dB
125	13	12.7
250	18	17.7
500	31.2	30.2
750	-	-
1000	37	36.6
1500	-	-
2000	33.2	32.8
3000	-	-
4000	32.0	32.0
6000	-	-
8000	37.3	37.3

Device Specifications

Applied parts

Main unit with patient responder and patient headset.
Bone conductor.

Transducers

DD65, H210A Static force 4.5 N ± 0.5 N
B71, B81, BC-2 Static force 5.4 N ± 0.5 N

Power supply	5 VDC \pm 5% from PC/tablet USB port
PC connection	USB
Data storage	PC hard drive

Environmental Conditions for Operation

Mode of operation	Continuous operation
Ambient temperature	15 °C to 35 °C (59 °F to 95 °F)
Relative humidity	30 % RH – 90 % RH (non-condensing)
Ambient pressure	700 hPa to 1060 hPa (70kPa – 106kPa)
Amplitude	Maximum 2000m elevation below and above sea level

Environmental Conditions for Storage and Transport

Ambient temperature	-20 °C to 50 °C (-4 °F to 122 °F)
Relative humidity	90% or less (non-condensing)
Ambient pressure	700 hPa to 1060 hPa (70kPa – 106kPa)


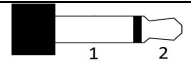
Physical characteristics

Dimensions	150 mm x 140 mm x 110 mm (5.9 in x 5.5 in x 4.3 in)
-------------------	--

Accessories and Detachable Parts

Included in package	Configurations		
	Oscilla A30	Oscilla A50	Oscilla A60
Main unit	•	•	•
Patient headset	•	•	•
AudioConsole Software	•	•	•
Carrying bag	•	•	•
Bone Conductor		•	•
Operator Headset			•

Pin Assignment

Socket	Connector	Pin 1	Pin 2	Pin 3	Pin 4	Input spec.	Output spec.
Power	 4 3 2 1 USB type-A	+5 V _{DC}	Data –	Data +	Ground	Z _{IN} = 90 Ω U _{IN} = 5 V _{DC}	Z _{OUT} = 90 Ω
Bone conductor	 1 2 3.5 mm mono jack	Ground	Signal	-	-	Z _{IN} = 10 Ω	Z _{OUT} = 1 Ω U _{OUT} < 4 V _{PP}

15. Service and Maintenance



The main unit and patient headset and other accessories that are in contact with the patient must be cleaned on a regular basis for hygienic reasons.

It is recommended that the patient completes hand washing before and after the examination.

Cleaning of the test environment should include: Tables, chairs, doorknobs and other elements that may come in contact with the patient.

Cleaning

- Disconnect the device from the PC.
- Use a soft lightly dampened cloth with cleaning solution or disinfectant (non-alcohol) towelettes to clean all exposed surfaces.
- Do not let liquid come into contact with any part inside the headphones or main unit.
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid.
- Do not use disinfection wipes containing alcohol or other abrasive cleaners, as they will dry out the materials.
- Do not use hard or pointed objects to clean any part of the instrument or accessory.
- The operator should wear disposable gloves when handling ear cushions, headsets and patient buttons.

Recommended Cleaning Solutions

- Warm water with mild, nonabrasive cleaning solution (soap).
- Disinfectant (non-alcoholic) towelettes.

When cleaning is completed between examinations, make sure all exposed surfaces are dry before testing the next patient.

Calibration

It is recommended that the device be calibrated annually by Oscilla A/S or a technician authorized by Oscilla A/S. Contact your Oscilla® distributor for further information regarding calibration.

Service and Repair

All service and repair except installation and cleaning must be performed by Oscilla A/S or a technician authorised by Oscilla A/S. Contact your Oscilla® distributor for further information regarding service and repair.



To maintain electrical safety during the lifetime of the instrument, a safety check must be conducted regularly according to IEC 60601-1, Class II, Type B applied parts; e.g. when annual calibration is done.

Disposal

The device can be disposed of as normal electronic waste according to local regulations.

Shipping Recommendations

The audiometer should be packaged in a manner that prevents it from being damaged during transport. For example, the device can be packaged in bubble wrap and shipped in an ordinary cardboard box or similar.

16. Warning and Safety Notices



WARNING

1. Incorrect handling and accidental damage can impact the safety and functionality of the device. Contact your Oscilla® distributor or Oscilla A/S for guidance.
2. The Intended Use, Intended Users, Intended Patient Population and Intended Use Environments stated in the “General Description” section must be followed to avoid compromising patient safety.
3. The Operator must instruct the patient to give signal or take of the headset if a very high stimulus is uncomfortable or painful.
4. It is recommended to use the device in an environment that minimizes amount of static electricity.
5. Do not operate, transport or store the device at temperatures and humidity exceeding the environmental conditions stated in the Technical Specifications.
6. Keep the device away from liquids. Liquids in contact with parts inside the device can damage the device and may result in a risk of electrical shock to the user or patient.
7. Do NOT use the device in the presence of flammable gaseous mixtures or in a highly oxygen-enriched environment such as a hyperbaric chamber, oxygen tent, etc.
8. All accessories connected to the device must be identical to the type supplied with the system.
9. It is recommended that an annual calibration be performed on accessories containing transducers. Furthermore, it is recommended that calibration be performed if the equipment has suffered any potential damage, see the “Maintenance” section.
10. Unwanted noise may occur if the device is exposed to a strong radio field. Such noise may interfere with the performance of the device. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity (less than 30 cm) of the audiometer be restricted. Likewise, we recommend that the instrument is not used in the vicinity of devices sensitive to electromagnetic fields.
11. No modifications of the device nor accessories are allowed.
12. Any PC, tablet or other control unit connected to the device must comply with the requirements of UL/IEC62368-1.
13. Do not touch non-medical parts such as the laptop/computer or printer and the patient at the same time.
14. If there are signs that could indicate the equipment is faulty or damaged, DO NOT USE IT and contact your supplier for guidance.
15. Electrical equipment such as PC, printer, cables, light sources, etc. that is considered non-medical equipment, must be placed out of reach of the patient, i.e. no closer than approx. 1.5 meters/5 ft.
16. The device must always be installed in accordance with the instructions for use.
17. For safety reasons and in order to not void the warranty, service, calibration and repair of the equipment must be carried out only by Oscilla A/S or by personnel authorized by Oscilla A/S. In case of defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.
18. Under no circumstances disassemble the audiometer. Contact your supplier. Parts inside the audiometer must only be inspected or serviced by authorized personnel.
19. Any serious incident that has occurred must be reported to the manufacturer and competent authority.
20. When the customer uses the built-in database in AudioConsole, data is stored exclusively on the customer's PC or server. Therefore, the customer is fully responsible for data security and data backup.

17. Symbols



Manufacturer



Serial number



Catalogue/product number



Caution



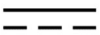
Follow Instructions for Use



Consult Instructions for Use



Type B applied part



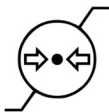
Direct current



Medical device according to Regulation (EU) 2017/745 (MDR)



Humidity limitation



Atmospheric pressure limitation



Temperature limit



The device must be recycled or disposed of in a proper manner in accordance with the WEEE Directive 2012/19/EU



Do Not Use if Package is Damaged symbol





Medical Device

18. EMC

- The Oscilla audiometer complies with IEC 60601-1-2:2014 and EN 60601-1-2:2015. Please observe the guidelines below.
- This Oscilla audiometer is an electro-medical device and is therefore subject to special safety precautions. For this reason, the installation and operating instructions provided in this document must be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of the Oscilla audiometer.

Guidance and manufacturers declaration for electromagnetic emissions		
Emission standard	Type	Compliance to standard
CISPR 11	RF emissions	Yes, Group 1, Class B
Guidance for application Environment		
The Oscilla audiometer is suitable for use in professional as well as domestic environments, including environments where connected to the public low-voltage network. The device must emit electromagnetic energy in order to perform as intended. Nearby electronic equipment may be affected.		

Guidance and manufactures declaration for electromagnetic immunity				
Emission standard	Type	Compliance level	Specific guidance for application environment	
EN/IEC61000-4-2	Electrostatic discharge (ESD)	± 8kV contact ±2kV, ±4kV, ±8kV, ± 15kV air	Suitable for use on wood, concrete or ceramic floor materials. Keep relative humidity below 30% when used on floors of synthetic materials e.g. carpets.	
EN/IEC6100-4-8	Power frequency magnetic field	30 A/m 50/60 Hz	The level of power frequency magnetic fields corresponds to the levels typical for a professional or domestic environment.	
EN/IEC 61000-4-6	Conducted disturbances, induced by RF fields	150kHz to 80MHz 3V RMS (6V ISM + Amateur Radio Bands)	Portable and mobile radio devices, including their wires, should not be used closer to the unit than the recommended safe distance or 30 cm.	
EN/IEC61000-4-3	RF electromagnetic fields. Proximity fields from RF wireless communication equipment.	80 MHz to 2.7 GHz, 80% AM at 1 kHz, 10 V/m		 WARNING Avoid stacking or placing the device close to other equipment.  WARNING Do not use cables or accessories other than those provided by Oscilla A/S as these may negatively affect EMC performance.
		Test freq.	V/m	
		MHz		
		385	27	
		450	28	
		710, 745, 780	9	
810, 870, 030	28			
1720, 1845, 1970	28			
2450	28			
5240, 5500, 5785	9			

19. Manufacturer



Oscilla A/S
Aabogade 15
DK-8200 Aarhus N
Denmark

Phone: +45 61 72 81 70
Website: www.oscilla.dk
Mail: info@oscilla.dk

Responsibility of the Manufacturer

The manufacturer is only responsible for the safety, reliability and performance of the device if:

- All assembly operations, extensions, readjustments, modifications, service, calibration and repairs are carried out by the device manufacturer or by personnel authorized by the manufacturer.
- The electrical installation to which the device is connected complies with EN/IEC requirements.
- The device is used in accordance with the Instructions for Use.

The manufacturer reserves the right to waive all responsibility for the operational safety, reliability, and performance of devices serviced, calibrated, or repaired by unauthorized parties.

Warranty

Oscilla offers a 3-year warranty on the most advanced and costly component, the main PCB. For all other parts, such as cables, headsets, power supplies, printers, headset cushions, enclosures, bone conductors, and other accessories, Oscilla provides a 2-year warranty.

Oscilla will correct, without any charge for parts or labor, all defects in the goods arising from faulty manufacture or failure of original materials or components. This is provided that the goods are returned to Oscilla A/S before the expiry of the standard warranty period, along with a full account of the defects, and the notification is determined to be correct.

What is excluded from the warranty?

- Repairs arising from theft, attempted theft, malicious damage, or damage caused by fire, explosion, or water/sprinkler.
- Costs or loss of revenue or income arising from not being able to use your equipment or from loss or damage caused when the equipment breaks down (consequential loss).
- Cosmetic damage such as damage to paintwork or dents or scratches to the equipment, unless such damage is noted at the time of delivery to the site.
- Repairs arising from failure to follow the manufacturer's instructions and guidelines for use of the equipment.
- Repairs arising from abnormal working conditions, accidents, misuse, neglect, or damage caused by fire or explosion.
- Repairs arising from floods, lightning, storms, frost, or other bad weather conditions.
- Repairs arising from any problem with the supply of electricity, gas, or water.
- Damage or failure of the equipment due to a software virus; the configuration of user settings; the process of backing up or recovery of data; loss, corruption, or damage to data or operating systems.
- Repairs for equipment not notified to Oscilla within 30 days of the issue first becoming apparent.
- Repairs for an accessory used with the equipment not purchased from Oscilla as part of the original order for the equipment.

An Oscilla Warranty will not protect against claims arising from third parties or personal injury, however sustained.