oscilla

Instructions for Use

Oscilla® A30, A50 and A60
Diagnostic Audiometers
English

CE 0483

EU MDR
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This manual contains instructions regarding safety. 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.

Intended Users

Audiologists, ENTs and other healthcare professionals in testing the hearing of their patients.

Intended Patient Population

All patient groups from 5 years through adulthood, provided that the patient is able to 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, assist in the diagnosis of otologic disorders.

Essential Performance

The device is designed to offer a high degree of protection of the patients hearing. In the presence of excessive or unwanted audio signals 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 the table of Features vs configurations on the top of this page.

2. Installation

Connect to AudioConsole

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

1. Install the AudioConsole software on the PC.

2. Connect the device to the computer via USB. 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 how to use the patient database, generate reports and export data to other patient management systems.

System requirements

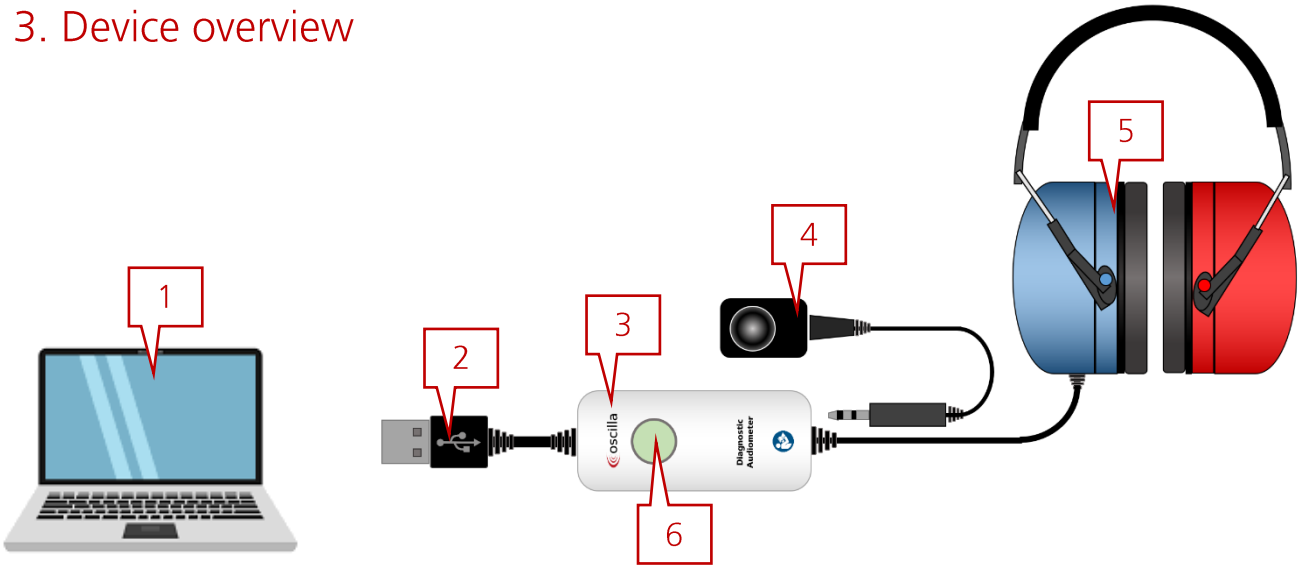
Minimum system requirements

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

Supported operating systems

Microsoft Windows 10

3. Device overview



1. PC with the AudioConsole software.
2. USB Plug.
3. Main unit.
4. Bone conductor (Only A50 & A60).
5. Patient Headset.
6. Patient response button with status light indicator
7. USB Flash Disk with the Software and IFU

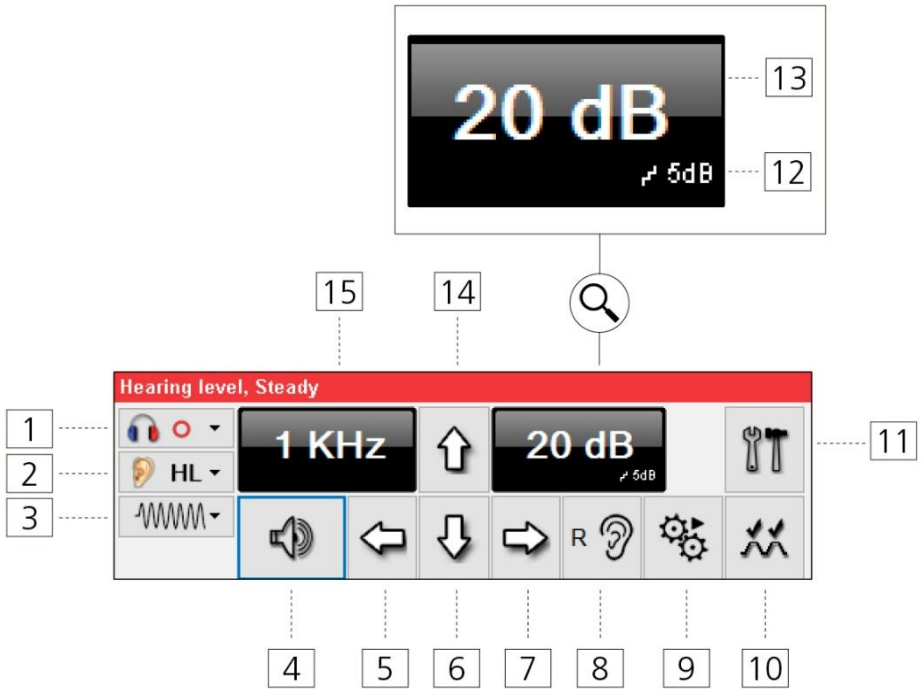
Status light indicator

Dim white light	Bright white light	Orange light	Green light
			
The device is in sleep-mode	The is active and connected to the AudioConsole software	The device is in test mode	The Patient button is activated

4. Operation

Pure tone

This is the control panel for pure tone operation:

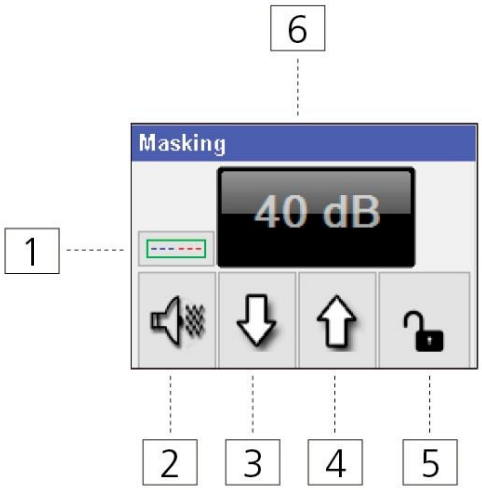


1. Select output transducer:
   Left, right or binaural
2. Select curve type
3. Select stimuli type:
   Steady, pulse or warble tone
4. Present tone to patient
5. Frequency down
6. Hearing level up
7. Frequency up
8. Switch between left and right ear
9. Start automatic test
10. SISI test
11. Setup
    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

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

Masking (Only A50 & A60)

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 – The masking follows the tone attenuator control
6. Masking level dB

Connection of Bone conductor (Only A50 & A60)

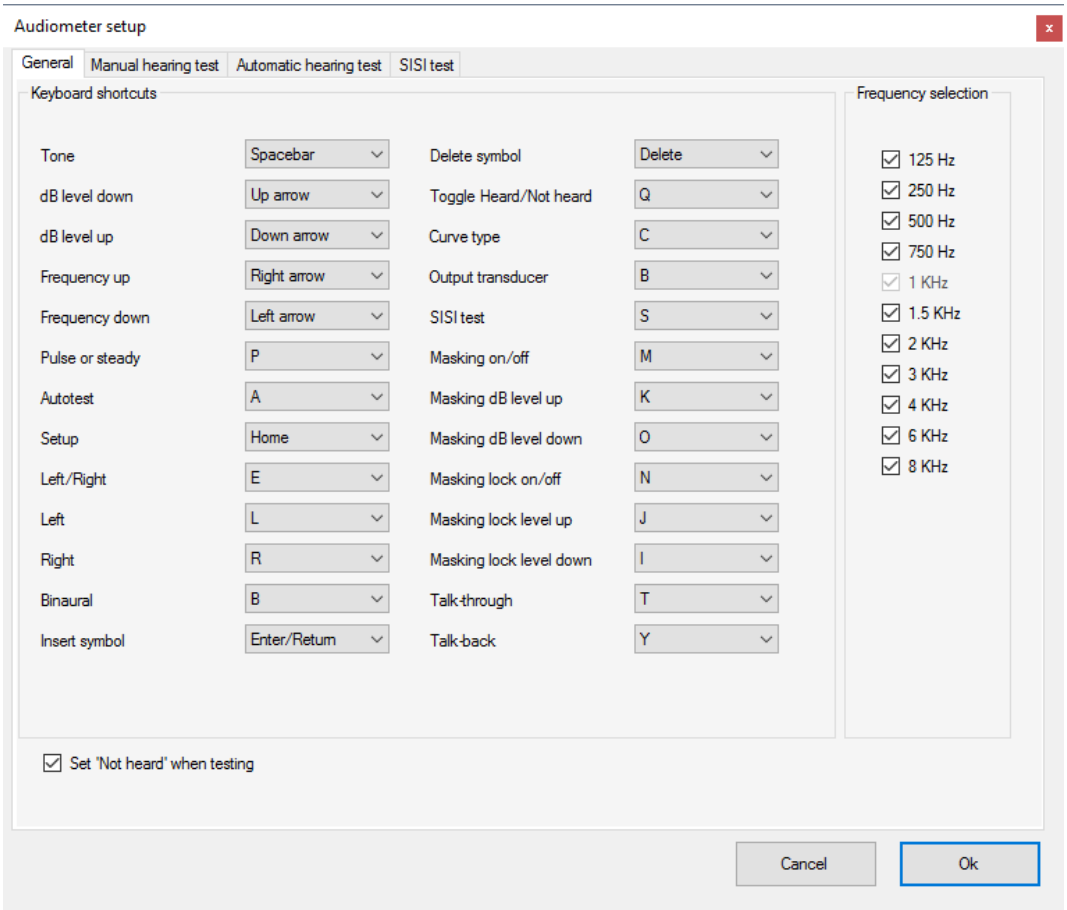
The plug for the bone conductor must be connected to the bone connector in the back of the main unit's right side. See the drawing below.
Make sure the plug is pressed all the way in, before using the bone conductor

5. Device configuration and settings

Click the setup button of the control panel to configure:

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

General



Keyboard shorcuts

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

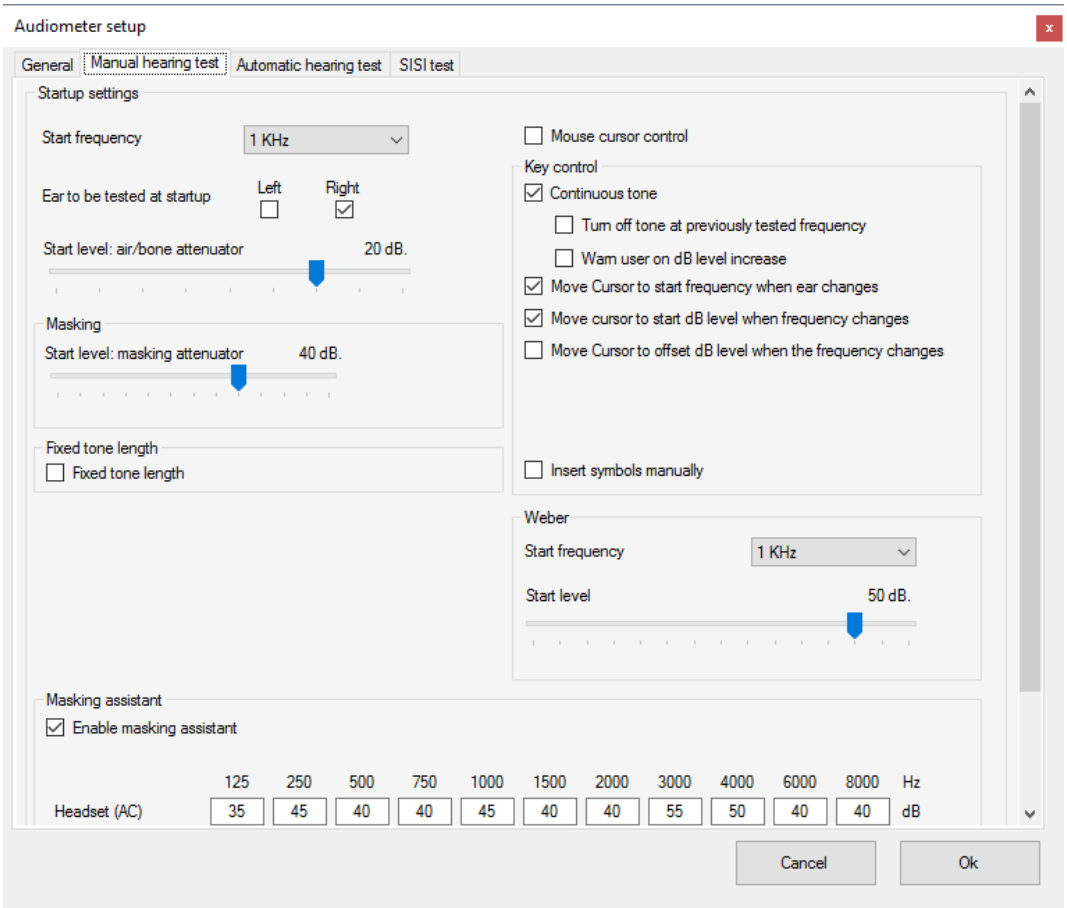
Frequency selection

Enable or disable frequencies

Set 'Not heard' when testing

Enable or disable the *not heard* symbol.
When the setting is enabled a symbol will appear in the audiogram when the patient does not respond.

Manual hearing test



Startup settings

Configure start-up settings for pure tone tests:

- Select a start frequency within the range of 125 Hz to 8000 Hz
- Select which ear to begin with during manual tests
- Select the start hearing level within the range of -10 dB to 30 dB

Mouse cursor control

Enable or disable attenuator and frequency control via the mouse.

Masking

Adjust the initial masking level.

Key control

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

Weber

Adjust the initial frequency and volume level.

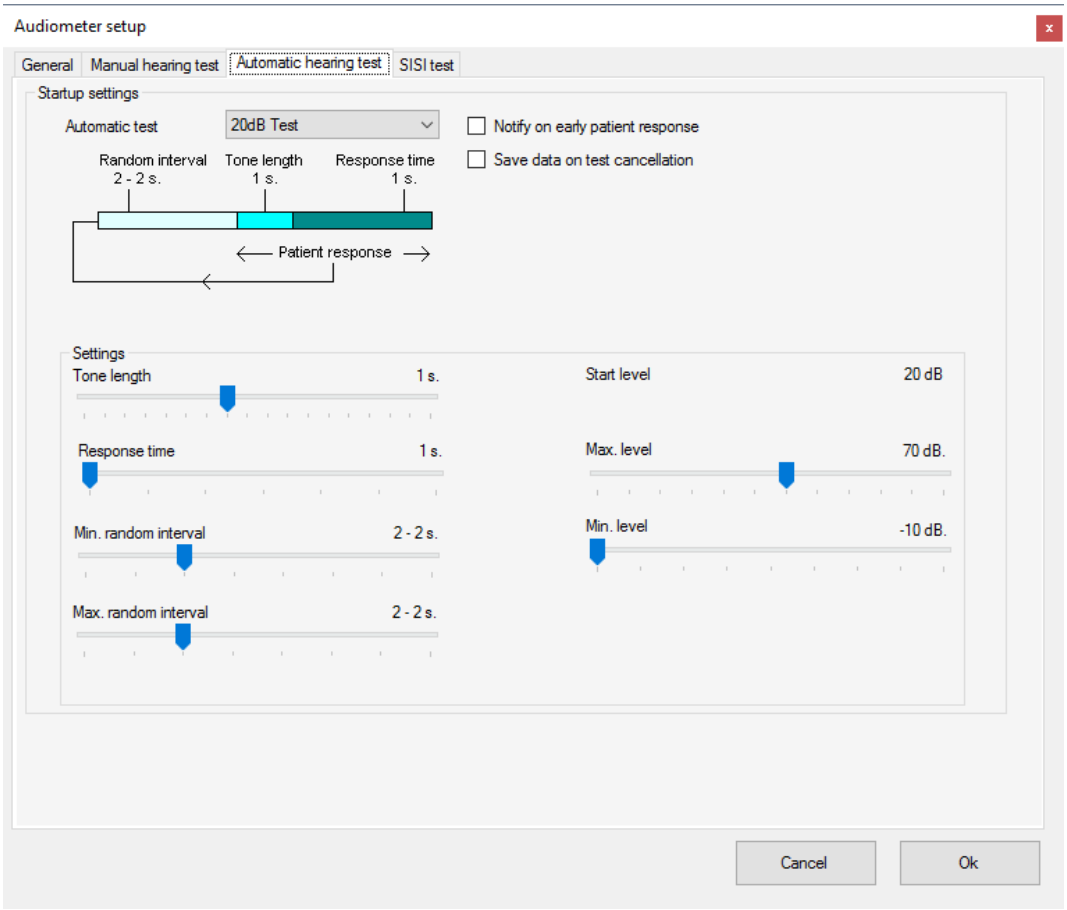
Fixed tone length

Click the check box to set a fixed tone length of 0.3 – 2.5 seconds.

Masking assistant

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

Automatic hearing tests



Startup settings

Select which of the automatic hearing test to use 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

Enable/disable notification if a patient presses the response button before a tone has been presented.

Enable or disable automatic saving of test results if an automatic test is cancelled before it is finished.

Settings

Adjust tone lengths, response windows and intervals between tones in automatic tests:

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

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

For the Hughson Westlake test it is possible to switch between:

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

6. Automatic tests

20 dB test

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

20 dB random test

A randomised version of the 20 dB test automatic screening test. The test starts at default hearing level of 20 dB at 1000 Hz to the right ear and then 20 dB at 1000 Hz to the left ear. Afterwards, the test will randomly switch between frequency 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 will automatically increase in 5 dB steps 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 has finished in the left ear, the same procedure is automatically repeated in the right ear before the test is completed.

xx dB Test

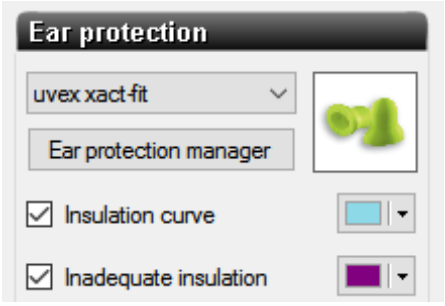
Automatic screening test based on the *20 dB test* with an adjustable start hearing level.

xx dB random test

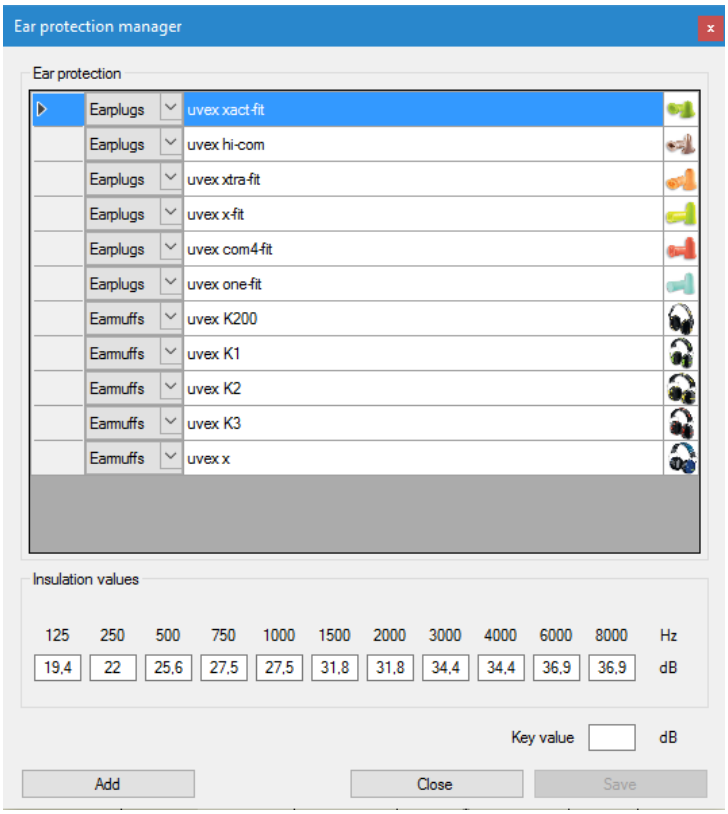
Automatic screening test based on the *20 dB* random *test* with an adjustable start hearing level.

7. Ear protection test

To start the ear protection test select **P**rotection **L**evel as curve type. 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 one. You can also customize which data will be visualized in the audiogram, and with which colors.

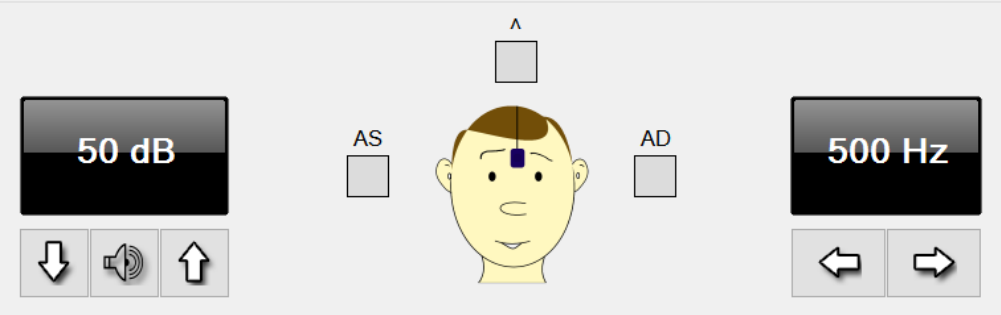


1. Conduct a hearing test without ear protection.
2. Instruct the patient to insert the ear plugs.
3. Conduct a hearing test with ear protection.
4. Check whether the ear protection provides adequate insulation.

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

8. Weber test (Only A50 & A60)

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:



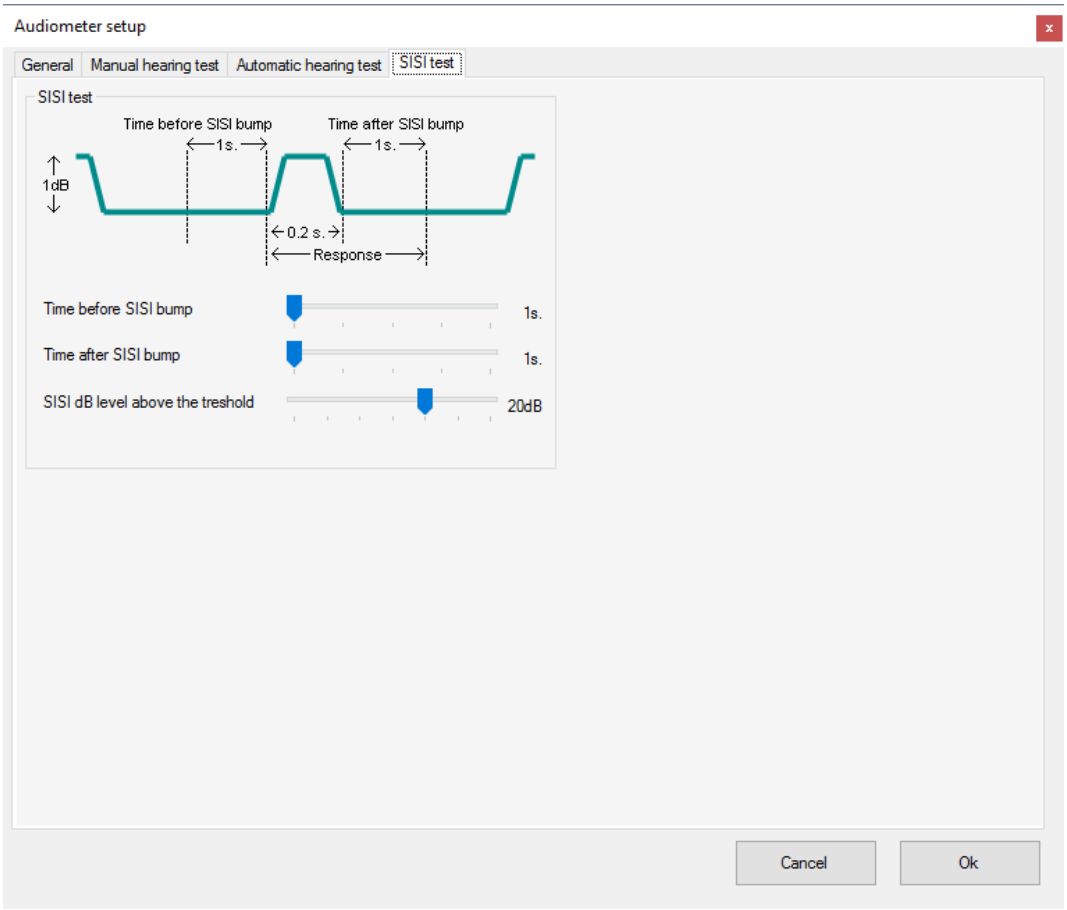
1. Adjust the dB hearing level and the frequency if needed
2. Present a tone to the patient
3. Afterwards, select the direction where the patient perceived the tone most clearly.

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

10. SISI test (Only A50 & A60)

The Short increment sensitivity index test (SISI test) is still widely used to determine whether the patient is having cochlear pathology. This test is based on a phenomenon known as recruitment (abnormal loudness growth).

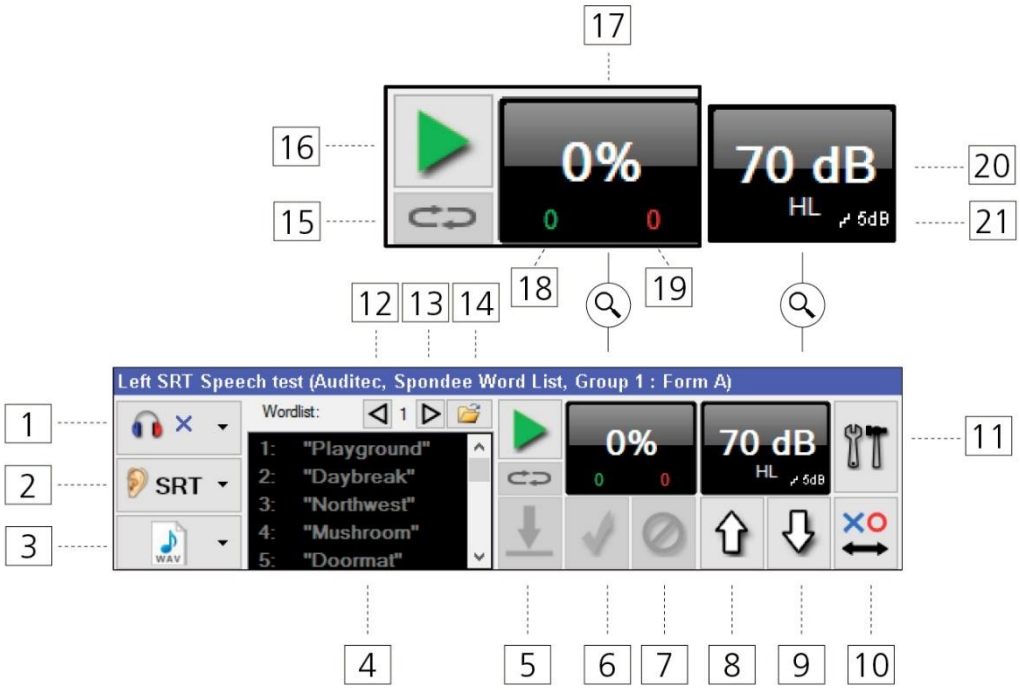
Difference limen for intensity (DLI):
is the smallest change in the intensity of a pure tone which can just be detected. It is usual for patients with normal hearing to have difficulty in detecting small changes in intensity close to threshold. Patients with cochlear pathology will be able to appreciate the change in intensity better because of the phenomenon of recuritment. DIL could safely be assumed to be an indirect indicator of the phenomenon of recruitment.



SISI test
Adjust time intervals and hearing level.

11. Speech operation with speech material (Only A60)

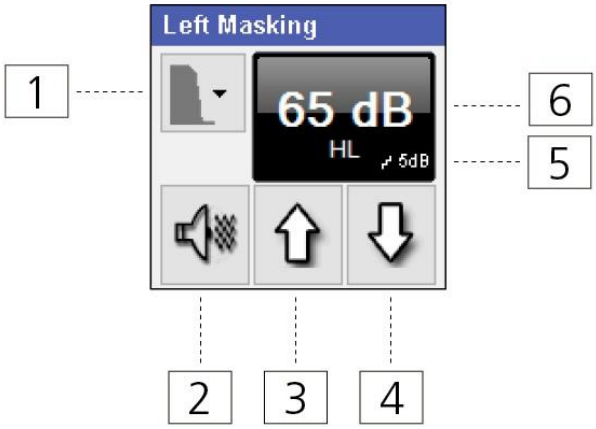
This is the control panel for speech operation with speech material:



1. Select output transducer: Left, right or binaural
2. Select speech test type
3. Input selection
4. Wordlist
5. Store point
6. Correct
7. Wrong
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 wrong answers
20. Current dB hearing level
21. Select dB level steps

Masking and speech material

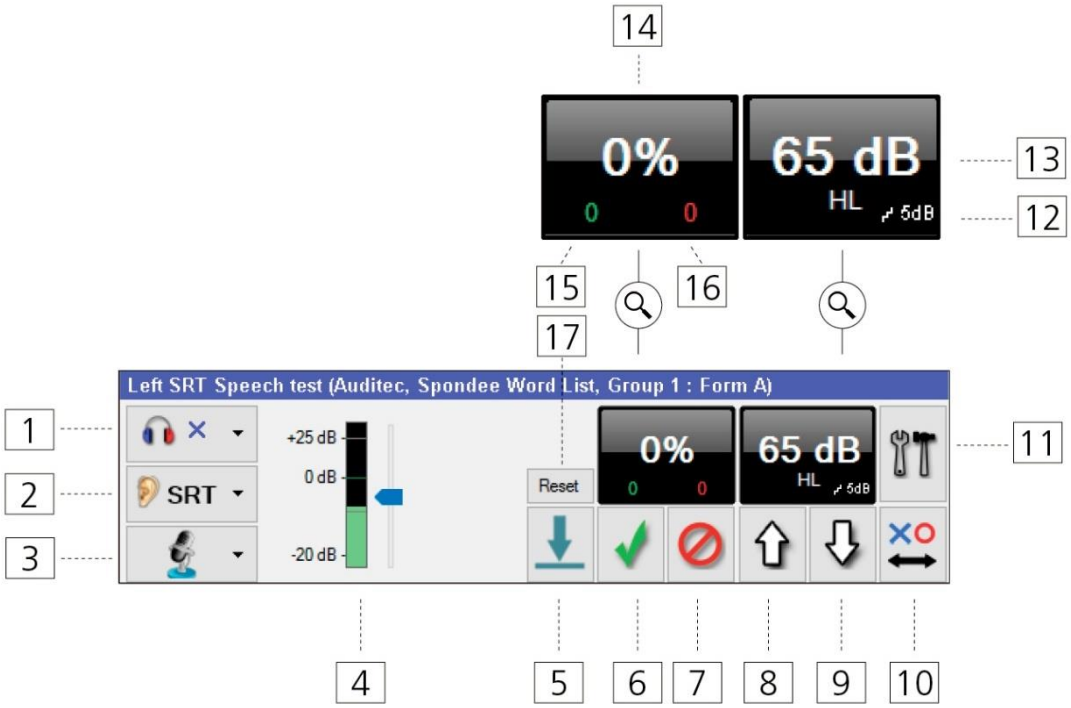
This is the masking control panel for speech operation with speech material:



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

12. Speech operation with live voice (Only A60)

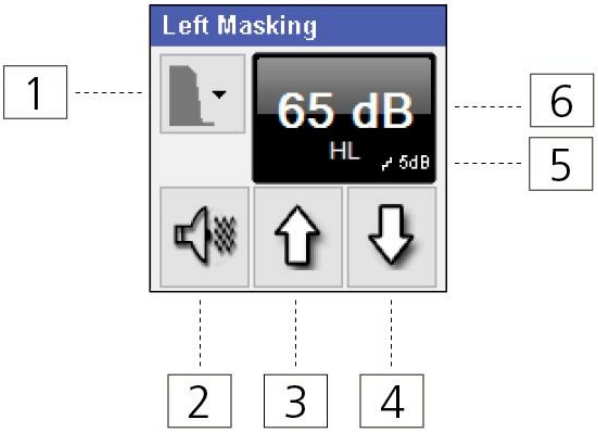
This is the control panel for speech operation with live voice:



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

Masking and live voice speech testing

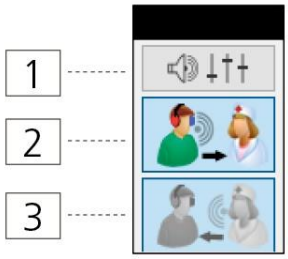
This is the masking control panel for live voice speech testing:



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:

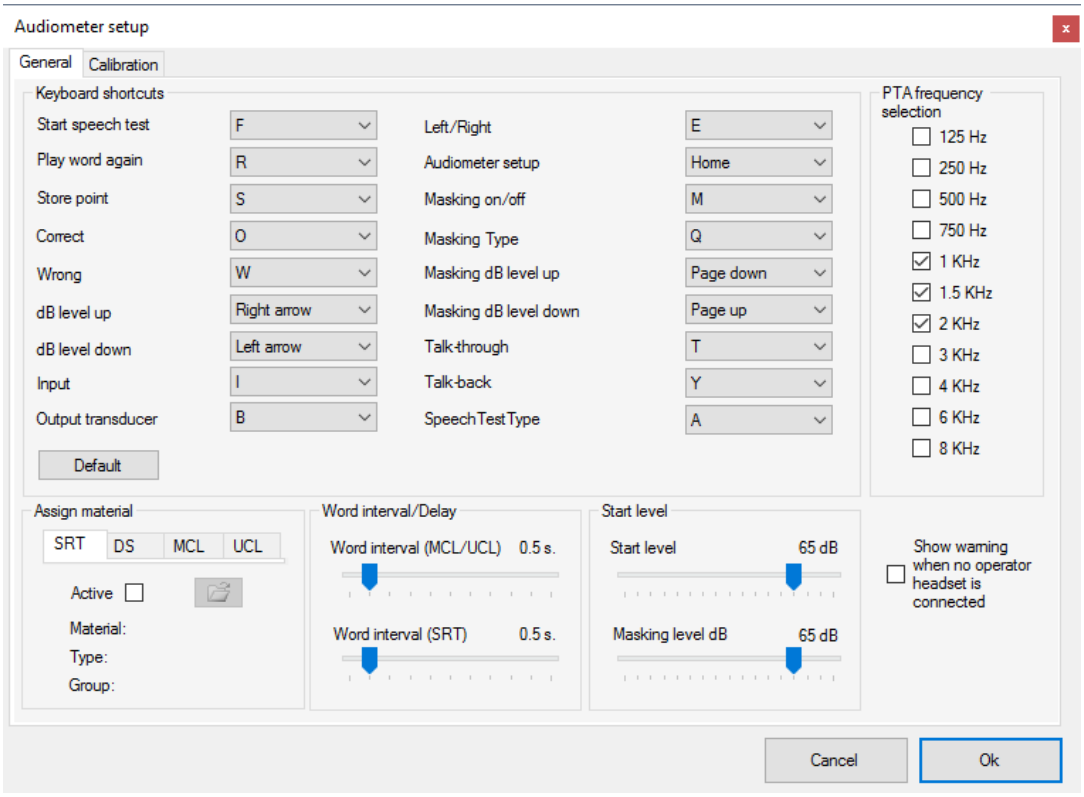


1. Adjust mixer settings
2. Patient to operator communication on/off
3. Operator to patient communication on/off

13. Speech setup (Only A60)

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

- General settings
- Calibration settings



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

Air conduction

Frequency range

Maximum hearing level

Puretone RETSPLs in accordance with ISO 389-8:2004

NBN RETSPLs in accordance with ISO 389-4:1994

*: 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 Oscilla H210A

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
125	70	34.7	60	4
250	90	16.5	80	4
500	110	5.1	100	4
750	110	0.9	100	5
1000	110	3.1	100	6
1500	110	0	100	6
2000	110	-2.9	100	6
3000	110	-0.7	100	6
4000	110	9.2	100	5
6000	100	17.8	90	5
8000	90	22.3	80	5

Headset RadioEar DD65v2

Frequency	Maximum hearing level	RETSPL PTB & AAU Ref.: 20 µPa	Maximum NBN	NBN RETSPL Correction*** Ref.: 20 µPa
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 Tolerance: ± 2 %

Harmonic distortion
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 µN	BC forehead ISO 389-3 table C.1
Hz	dB HL	dB	dB
125	5	82.5	12
250	35	67.0	12
500	60	58.0	14
750	60	48.5	13
1000	60	42.5	8,5
1500	60	36.5	11
2000	60	31.0	11,5
3000	60	30.0	12
4000	60	35.5	8
6000	35	40.0	11
8000	35	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 ± 10%
Frequency deviation:	5% ± 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, BC2 Static force 5.4 N ±0.5 N

Power supply

5 VDC ± 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 elevations below and above sea level.

Environmental conditions for storage & 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)

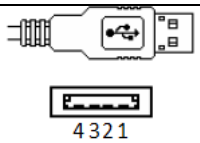
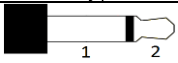
Physical characteristics

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

Accessories & 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	 USB type-A	+5 V_{DC}	Data –	Data +	Ground	Z_{IN} = 90 Ω U_{IN} = 5 V_{DC}	Z_{OUT} = 90 Ω
Bone conductor	 3.5 mm mono jack	Ground	Signal	-	-	Z_{IN} = 10 Ω	Z_{OUT} = 1 Ω U_{OUT} < 4 V_{PP}

15. Service & Maintenance

The main unit and patient headset need to be cleaned on a regular basis for hygienic reasons.

Cleaning

- Disconnect the device form the PC.
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with any parts inside the headphones or main unit.
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid.
- Do not use hard or pointed objects to clean any part of the instrument or accessory

Recommended cleaning solutions

- Warm water with mild, nonabrasive cleaning solution (soap)

Calibration

It is recommended to have the device calibrated every year by Oscilla A/S or a technician authorised by Oscilla A/S. Contact your Oscilla® distributor for further information regarding calibration.

Service & Repair

All service & repair expect installation & Cleaning must be performed by Oscilla A/S or a technician authorised by Oscilla A/S. Contact your Oscilla® distributor for further information regarding calibration.

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

Disposal

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

Shipping recommendations

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

16. Warning and safety notices

1. Incorrect handling and Accidental damage and can have impact on safety and functionality of the device. Contact your Oscilla® distributor or Oscilla A/S for advice".
2. The Intended Use, Intended Users, Intended Patient Population and Intended Use Environments stated in the "General description" section must be followed not to reduce the patient safety.
3. The Operator must instruct the patient to give signal or take of the headset if a very high stimuli is uncomfortable or painful.
4. It is recommended to use the device in an environment with a 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 it 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 and 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 this 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, Table 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 advice.
15. Electrical equipment like PC, Printer, cables, light sources, etc. that is Non-medical equipment, must placed out of reach of the patient, i.e. not closer than approx. 1.5 meters/5 ft.
16. Smust always be installed in accordance with the instructions for use
17. For the sake of safety and in order not to void the warranty, service, calibration and repair of the equipment should be carried out only by Oscilla A/S or by personnel authorized by the Oscilla A/S. In case of any 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 checked or serviced by authorized personnel
19. Any serious incident that has occurred need to be reported to manufacturer and competent authority of the Member State

17. Symbols


Manufacturer

Serial number

Catalogue/product number


Caution


Follow instruction for use

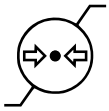

Consult instruction for use


Type B applied part

Direct current


Medical device according to Medical Device Directive 93/42/EEC.


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.

18. EMC

- The Oscilla audiometer comply to 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 manufactures 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 suitable for use in both 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 its intended function. Nearby electronic equipment may be affected.		

<table>
<tr><th colspan="5">Guidance and manufactures declaration for electromagnetic immunity</th></tr>
<tr><td>Emission standard</td><td>Type</td><td colspan="2">Compliance level</td><td>Specific guidance for application environment</td></tr>
<tr><td>EN/IEC61000-4-2</td><td>Electrostatic discharge (ESD)</td><td colspan="2">± 8kV contact
±2kV, ±4kV, ±8kV,
± 15kV air</td><td>Suitable for use on wood, concrete , or ceramic floor materials.
Keep relative humidity below 30% when used on floors of syntitic materials e.g. carpets.</td></tr>
<tr><td>EN/IEC6100-4-8</td><td>Power frequency magnetic field</td><td colspan="2">30 A/m
50/60 Hz</td><td>The level for Power frequency magnetic fields corrosponds to the levels typical for professional or domestic Environment.</td></tr>
<tr><td>EN/IEC 61000-4-6</td><td>Conducted disturbances, induced by RF fields</td><td colspan="2">150kHz to 80MHz
3V RMS
(6V ISM + Amateur Radio Bands)</td><td rowspan="3">Portable and mobile radio devices, including their wires, should not be used closer to the unit than the recommended safe distance or 30 cm.
 
WARNING
Avoid stacking or locating 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.</td></tr>
<tr><td>EN/IEC61000-4-3</td><td>RF electromagnetic fields.

Proximity fields from RF wireless communication equipment.</td><td colspan="2">80 MHz to 2.7 GHz,
80% AM at 1 kHz,
10 V/m</td></tr>
<tr><td></td><td></td><td>Test freq. MHz</td><td>V/m</td></tr>
<tr><td></td><td></td><td>385
450
710, 745, 780
810, 870, 030
1720, 1845, 1970
2450
5240, 5500, 5785</td><td>27
28
9
28
28
28
9</td></tr>
</table>

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, re-adjustments, modifications, service, calibration or 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 operating safety, reliability and performance of devices serviced, calibrated or repaired by unauthorised parties.