amplivox

For everyone

Anova™

Instructions for use

D-0134954-B Anova Operating Manual
October 2025

About this manual

Read this operating manual before attempting to use the device.

This manual is valid for the Anova audiometer.

This product is manufactured by:
Amplivox Ltd, 3800 Parkside, Solihull Parkway,
Birmingham Business Park, Birmingham,
West Midlands, B37 7YG
www.Amplivox.com

For all enquiries, please contact us under:

Amplivox Ltd, 3800 Parkside, Solihull Parkway,
Birmingham Business Park, Birmingham,
West Midlands, B37 7YG
United Kingdom
Tel: +44 (0)1865 880846

hello@Amplivox.com

Amplivox Ltd
10393 West 70th Street
Eden Prairie
MN 55344
United States

Tel: 888 941 4208
Fax: 952 903 4100
info@Amplivox.us

CE 0123

EC REP

DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart, Denmark

Table of contents

1. Introduction

1.1. Thank you

Thank you for purchasing an Amplivox audiometer. The Amplivox Anova is a screening and diagnostic audiometer (depending on the configuration you have purchased) that will give many years of reliable service if treated with care.

For supply in the US only:

Caution: Federal law restricts this device to sale by or on the order of a licensed medical professional.

1.2. Intended purpose

The Anova audiometer performs both air and bone conduction tests with or without masking (depending on configuration).

1.3. Intended user

The device is designed for use by trained and qualified personnel only, such as audiologists, ENT surgeons, doctors, general practitioners, hearing aid dispensers, child health professionals and hearing healthcare professionals with a similar level of education. It is not recommended to use the equipment without the necessary knowledge.

1.4. Intended patient target group

This product is suitable for testing patients aged 4 and over.

1.5. Contraindications

Always visually inspect the outer ear and the external auditory canal for abnormalities before testing. Testing should not be performed on patients if the following conditions are applicable:

1. The presence of other sensitivity to loud sounds, that may contraindicate testing when high intensity stimuli are used
2. Outer or middle ear abnormalities or infections
3. Recent ear surgery

1.6. Unpacking

Open the shipping carton and carefully remove all the equipment. Check against the delivery note that all the accessories ordered have been included with your audiometer. If anything is missing, please contact Amplivox customer support. If you have purchased from a distributor, you should contact them directly.

Please retain the shipping carton and packing materials as the audiometer will need calibrating on an annual basis and should be returned to Amplivox in its original shipping carton.

1.7. Firmware version

This operating manual is for firmware versions 1.1.19 onwards. To check the version of firmware on your audiometer, please return to the home screen of your Anova and press 'home'. This screen is also displayed on powering the device up. An example of this screen is provided below:

1.8. Configurations

The Anova comes in different configurations. The desired configuration is locked by a license key loaded on the product pre purchase.

There is two main configurations Screener and Diagnostic. Both can be configured with the additional featured Sound Room Monitor, Automatic test (Hughson Westlake) and Békésy.

The license on the device is shown on the startup splash screen.

S = Screener

D = Diagnostic

M = Sound Room Monitor

A = Automatic test (Hughson Westlake)

B = Békésy

1.9. Standard contents

- Anova audiometer
- Audiometric headset: RadioEar DD45
- Patient response switch
- USB-C cable
- USB mains power adapter
- Calibration certificate
- Carrying case

1.10. Optional accessories

- Insert earphones: RadioEar IP30*
- Audiometric headset: (RadioEar DD65v2)*

- Bluetooth printer: HM-E200
- Amplivox Audiocups (noise-reducing earphone enclosures)
- Bone conductor headset: B71*
- Sound Room Microphone (SRM): TB2*

*Require additional license purchase and calibration.

2. Important safety instructions

The Anova audiometer must be used only by practitioners qualified to perform audiometric tests. It is intended for use as a screening and diagnostic tool. The target patient population is suitable for patient over the age of 4.

2.1. Precautions

Read this operating manual before attempting to use the device

To comply with the IEC 60601-1 standards for safety and IEC 60601-1-2 standards for EMC, the audiometer is designed to be used only with the medically approved accessories detailed in this document.

Do not use any other type of accessory with this device.

External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 62368-1 or 60950-1 for IT equipment and the IEC 60601-1 for medical electrical equipment. In addition, all such combinations – medical electrical systems shall comply with the safety requirements stated in the general standard IEC 60601-1, clause 16.

Any person who connects external equipment to signal input, signal output or other connectors has formed a medical electrical system and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

Any equipment not complying with the current leakage requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation device* to reduce the leakage currents.

*A separation device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a separation device is required when a network connection is made. The requirement for the separation device is defined in in IEC 60601-1, clause 16.

The audiometer is for indoor use only and should only be used as described in this manual.

The transducers supplied with the audiometer are specifically calibrated with it; if these transducers are changed, calibration will be required.

Do not immerse the unit in any fluids. See section 8.1 of this manual for the proper cleaning procedure for the device and its accessories and the function of single-use parts.

Do not use the device in an oxygen-rich environment or in the presence of a flammable anaesthetic mixture or other flammable agents.

Do not drop or otherwise impact this device. If the device is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the device if any damage is suspected.

The device must be stored and used within the specified temperature, pressure and humidity ranges (see sections 7 and 9).

Do not attempt to open, modify or service the device. Return the device to the manufacturer or distributor for all repair and servicing requirements. Opening and modifying the device will void the warranty.

In the unlikely case of a serious incident, inform Amplivox as well as the competent Authority in the country where the user is established.

2.2. Electromagnetic compatibility (EMC) considerations

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in appendix 1. This provides guidance on the electromagnetic environment in which to operate the device.

Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment. The device should not be used adjacent to or stacked with other equipment; if this is necessary the device should be observed to verify normal operation.

2.3. IT networks

Please note that connecting the device to a PC implies connecting the device to an IT-network. The connection to an IT-network may result in previously un-identified risks which must be identified, analysed, evaluated, and mitigated by the responsible organisation.

The Anova is not intended to be incorporated into an IT-NETWORK.

Any change to the IT-network (network configuration, (dis)connection of items, update, or upgrade of equipment) may introduce new risks that require additional analysis.

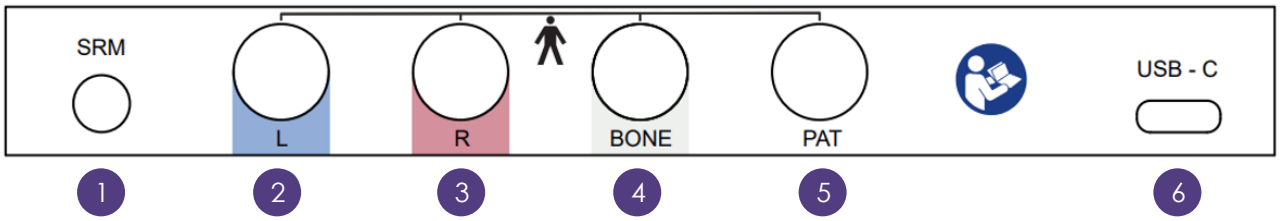
2.4. Power supply

The audiometer is designed for continuous operation and may be powered either by a mains adapter (which is supplied and specified as part of the equipment) or via direct connection to a computer/laptop. A connected computer/laptop must apply to IEC-62368-1.

The audiometer device has a dedicated isolation within its circuitry. This has been implemented to protect the device in the case of any surges in power to the unit.

2.5. Audiometer connections

Transducers and accessories can be attached on the back of the audiometer. The below section details how this can be done.



All the relevant accessory terminals and connections are labelled to ensure correct identification and connection; these are detailed in the table below which are displayed alongside the supporting image (above).

Socket number	Socket label	Socket type	Colour code	Connected part
1	SRM	3.5mm jack	Not applicable	Calibrated environment noise microphone/sound room microphone*
2 3	L R	6.3mm jack 6.3mm jack	Blue (Left) Red (Right)	Air conduction headset*
4	BONE	6.3mm jack	Grey	Bone conduction headset*
5	PAT	6.3mm jack	Black	Patient response switch
6	USB-C	USB Type C connector	Not applicable	Mains power supply / computer (via USB port)*

For connected parts marked with * only connect the accessories supplied with the device or supplied by Amplivox or an Amplivox distributor. These parts have been tested for use with the Anova audiometer for compliance with the standards IEC 60601-1 and IEC 60601-1-2. The use of accessories other than those specified may compromise compliance with these standards.

2.6. Data transfer to a printer

Refer to appendix 2 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment.

The audiometer can be purchased with an optional Bluetooth thermal printer which is used for printing audiometry results (see section 4.13).

Upon receipt of the printer, it must be initially charged prior to use.

2.7. Data transfer to a computer

Please refer to appendix 2 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment.

The audiometer is supplied with the Amplisuite software to allow connection to a PC for both the control of the device and transfer of test results (see section 4.11). You must use the designated USB-C cable which is available from Amplivox.

3. Principles of operation

3.1. Otoscopic examination

Trained and qualified personnel only (see section 1.3) should perform a thorough otoscopic examination to establish whether the condition of the ear is suitable for the test options selected and that no contraindications are present.

3.2. Principals of pure tone audiometry

The purpose of pure tone audiometry is to measure the patients' hearing threshold which is then compared to the hearing threshold of an average normal hearing person. The examination starts with air conduction on the ear with better hearing, or if not specified differently, on the right ear. The BSA (British Society of Audiology), 2018 recommends starting the test at 1000 Hz to then next measure the higher frequencies. When done with the high frequencies 1000 Hz shall be retested and to then continue with the lower frequencies. When done with the air conduction, the bone conduction can be assessed.

In cases of asymmetrical hearing, it might be required to mask the air and bone conduction to prevent hearing the test tone on the opposite ear.

Audiometric testing should be performed in an adequately quiet environment. Ideally, hearing tests are conducted in a soundproof room.

BSA (2018). Recommended procedure: pure-tone air-conduction and bone conduction threshold audiometry with and without masking.

Available from: https://www.thebsa.org.uk/wp-content/uploads/2023/10/od104-32-recommended-procedure-pure-tone-audiometry-august-2018-final-1.pdf

4. Using the audiometer

4.1. General precautions

When operating the device, please observe the following general precautions:

CAUTION

1. Use this device only as described in this manual
2. Be sure to use only stimulation intensities acceptable to the patient
3. Clean any accessories which may be in contact with the subject/patient regularly using a recognised disinfectant
4. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

Please note:

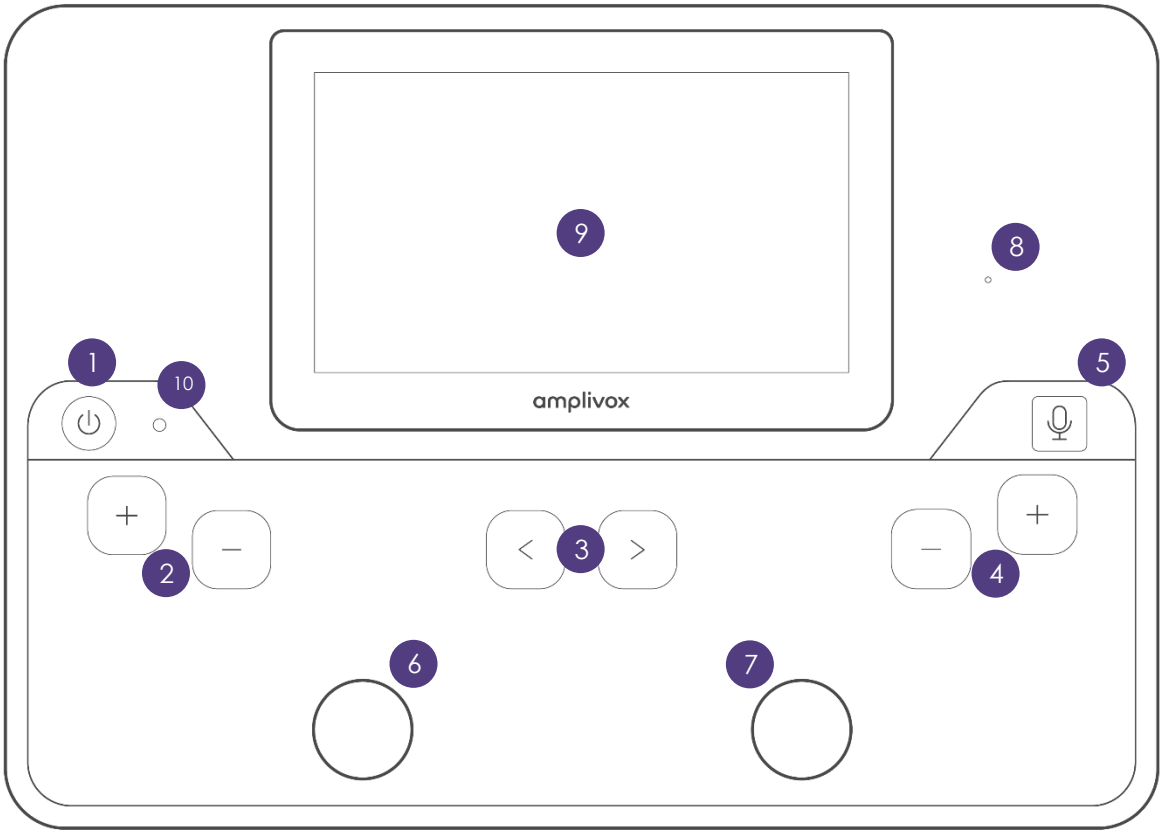
Careful handling of the device whenever in contact with a patient should be given high priority. Stable positioning on a flat surface (e.g. desk) while testing is preferred for optimal accuracy.

1. Never clean the transducer housing with water or insert non-specified devices into the transducer
2. Do not drop and avoid other undue impact to this device. If the device is dropped or in any other way damaged, return it to the manufacturer for repair and/or calibration. Do not use the device if any damage is suspected.

4.2. Controlling the audiometer

The Anova audiometer has several buttons and a touchscreen. Depending on the different sections of the interface the user is in, the buttons and the touchscreen will provide different options for selection and performance.

This section gives an overview of the different buttons available on the unit and the following sections will explain different functionality based on the area of interface that's been selected.



Button/function number (as labelled in above image)	Button/function name	Function description
1	Power button	Enables device to be powered on/standby
2	Left increase / decrease buttons	Used to increase/decrease intensity level when testing
3	Horizontal selection	Used to increase/decrease test frequency during testing
4	Right increase / decrease buttons	Used wither to increase/decrease intensity level when testing or to increase/decrease masking level during testing
5	Talk-over	Push and hold to enable talk-over function
6	Left attenuator	Used to present/interrupt tone during testing
7	Right attenuator	Used to store a threshold point during testing

8	Talk-over microphone inlet	Position of talk-over microphone on unit
9	Touchscreen	Displays user interface and has touch-enabled elements which can vary based on the section of interface selected by the user
10	LED power indicator	Green LED indicates when a power source is connected.

4.3. Powering the audiometer on/off

Press and briefly hold the button marked ⏻ (located on the front panel – as shown in section 4.2).

The device will power on automatically when connected to a power source, either mains outlet supply or pc/laptop.

To switch off, press the button marked ⏻ again, please note that you must be in the home screen of the device to be able to switch it off.

4.4. Talk-over

The talk-over button allows for the operator to communicate with the test subject through the active air-conduction audiometry headset. This functionality is only available when in the manual or automatic test screens.

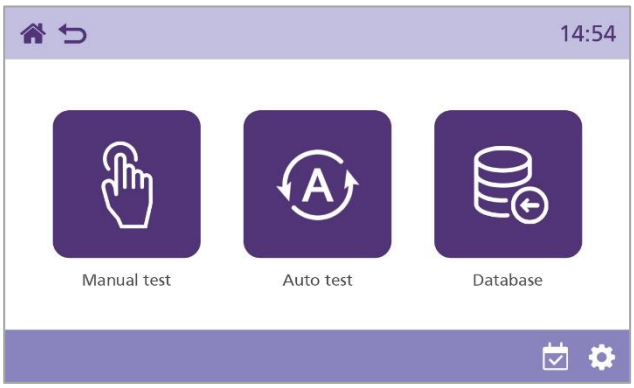
The operator must keep the button held down for this to happen and they also have the possibility to increase/decrease the intensity level of this communication for the patient by using the left side up/down intensity keys.

When the talk over function is active the interface will display as shown below. All other functions of the audiometer will deactivate when this is enabled (i.e. If masking is active then it will silence in order for the talk over signal to take priority).

4.5. The home screen

The home screen is the main menu and the first screen shown when the device has been powered on. From here the user can select the functions as described in the next few sections of this document.

A clock with the configured time (and time format) is always displayed in the top right of the interface and the back/home button is always displayed in the top left of the interface. This is the case for all test screens/displays on the device. The home screen appears as shown below.



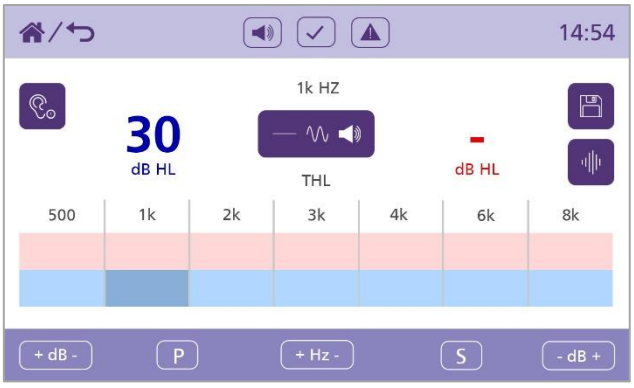
4.6. Manual test screen

The manual test screen is where manually controlled audiometry can be performed.

The user can use the physical buttons (as described in section 3.1) to manipulate the test signal intensity and frequency, stimulate a tone and store the relevant threshold. There is also the possibility to enable/disable contralateral channel masking stimuli (depending on the licensing of your device).

Within this interface the operator can see indicators which will present when a tone stimulus is driven through the transducer, a patient response light which will indicate when the response button is pressed and the environment noise indicator which will indicate when the environment noise is at an elevated level during testing, measured using the Sound Room Microphone.

This interface displays the tone stimulus and intensity. The stored thresholds are shown within a table in the bottom section of the interface. An example of the manual test screen has been provided below.



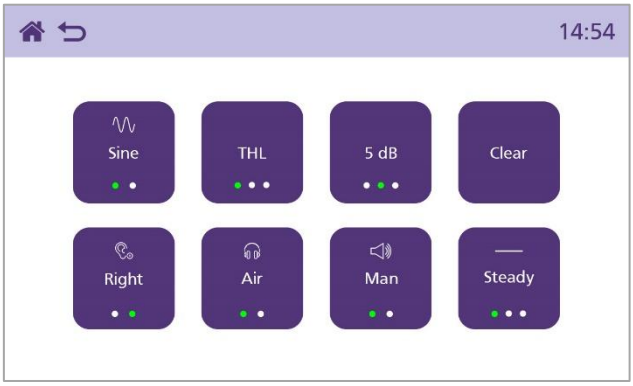
The following icons are present in the manual test screen. The table below has been provided to describe their purpose and function.

Icon name	Icon	Description
Environmental noise indicator (Sound Room Monitor)		This icon will light up when the environment noise microphone detects that the pre-configured environment noise limits have been breached. This icon will only light up when the Anova audiometer has been licensed and calibrated for the environment noise microphone.
Patient response indicator		This icon will light up when the patient response button has been pressed.
Stimulus presentation indicator		This icon will light up when a stimulus is driven through channel 1.
Bone conduction		Pressing this configures channel 1 to output the test signal via the Bone Conductor transducer (where licensed and calibrated for your Anova audiometer).
Air conduction		Pressing this configures channel 1 to output the test signal via the air-conduction transducer
Air conduction through Insert phones		Pressing this configures channel 1 to output the test signal via the insert earphone air-conduction transducer
Left ear side		This button enables the data collected to be labelled for the left ear side.
Right ear side		This button enables the data collected to be labelled for the right ear side.
Test sub-settings		Pressing in the middle of the test screen allows the user to access the sub-settings. This area allows the operator to make amendments to the test signal.
Save session		Pressing this icon will save the session.
Masking		Pressing this icon will enable masking through channel 2 (where licensed).

Masking off		Pressing this icon will disable masking through channel 2 (where licensed).
Sinewave		Pressing this icon configures the test stimulus to be driven as a sinusoidal tone.
Fm/warble	FM	Pressing this icon will configure the test stimulus to be driven as a FM (frequency-modulated) / warble tone.
Continuous		Pressing this icon will configure the test stimulus to be driven continuously, meaning the tone will present until the attenuator/present button is pressed to interrupt it.
Single pulse		Pressing this icon will configure the test stimulus to be driven as a single timed pulse.
Multi pulse		Pressing this icon will configure the test stimulus to be driven as multiple timed pulses.
Present		This icon is a label for the behaviour of attenuator button left or right.
Store		This icon is a label for the behaviour attenuator button left or right. Long press on this will store a No Response (NR) value.

4.6.1. Temporary options

During manual testing you can press on the icons in the middle of the screen to access the temporary testing options. On pressing this the below menu will be presented.

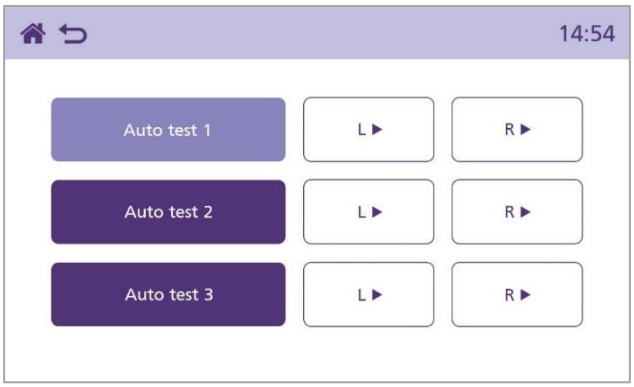


This menu allows manipulation of parameters and settings which can influence the stimuli when performing manual testing and each button will allow the user to press and cycle through the options.

4.7. Auto test screen

The auto test screen is where automatic audiometry can be performed.

The user is first presented with a list of 3 preset protocols when entering this screen, these settings are pre-configured in the auto test area of the settings menu (described in section 4.10 and appendix 3).



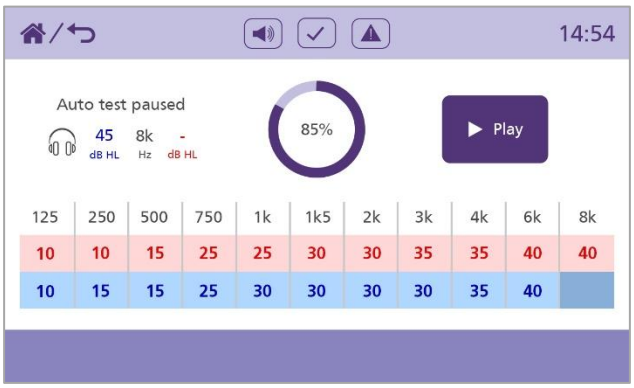
The user can press the play button on the starting ear side for the protocol they wish to run, and the auto test will start.

When the auto test is running the system will automatically adjust based on the pre-configured settings and the test subject's input/response via the patient response button.

Response time for the test subject is when signal is on (1 sec for HW).

This interface clearly displays the tone stimulus and intensity. The stored thresholds are shown within a table in the bottom section of the interface.

Within this interface the operator can see indicators which will present when a tone stimulus is driven through the transducer, a patient response light which will indicate when the response button is pressed and the environment noise indicator which will indicate when the environment noise is at an elevated level during testing. An example of the auto test screen has been provided below.



Some of the icons shown in the auto test screen have a similar application to those show in the manual test screen. Please see the table in section 4.6 for a description of these and their function.

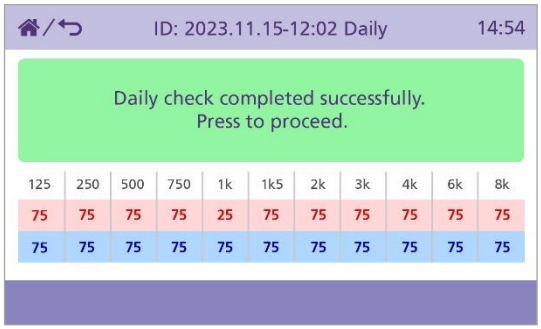
4.8. Daily check screen

The daily check screen is used for daily verification of the device's performance. This can be performed on an ER-75 electro-acoustic ear simulator or subjectively on an operator's head. The use of ER75 or without can be set in Settings /General.

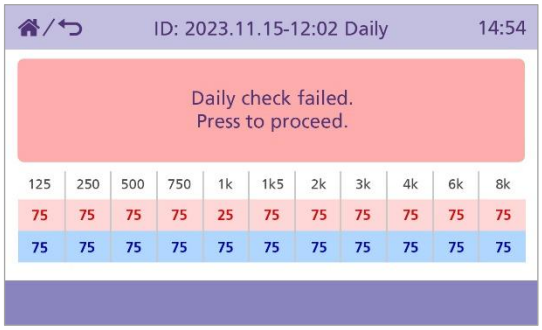
This screen is dedicated to allowing verification of the devices output and performance ahead of testing and use.

The screen layout is similar to the auto test screen when using ER-75, and it performs in a similar manner where the system will automatically present set stimulus levels and then store a threshold based on the indicated response via the patient response button input.

On completion of this daily verification the system will report whether this is successful or not, as shown in the below images.

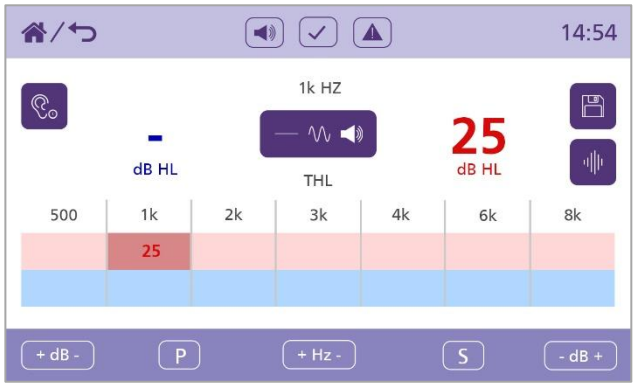


Successful

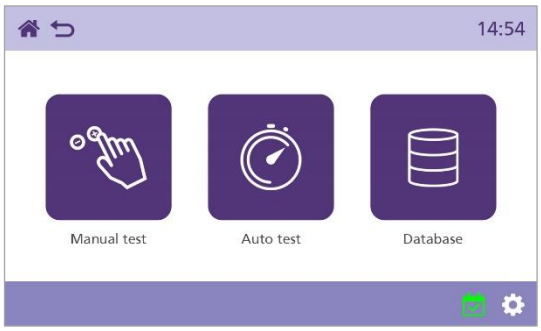


Unsuccessful

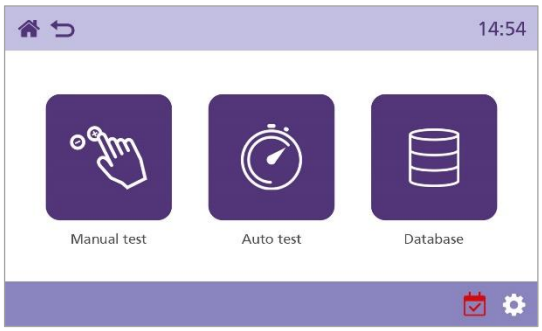
If the ER-75 is not used the manual testing screen is presented. For a manual daily check the user needs to where the headset and present a tone. It is recommended to start under the user's threshold on a chosen frequency and turn up until a threshold is present. Daily check is passed when a threshold is saved.



In addition to the performance of this process, the icon for the daily check screen in the bottom right corner of the home screen will change based on whether this process has been Successful (green) or Unsuccessful / not performed (red) – as shown below.



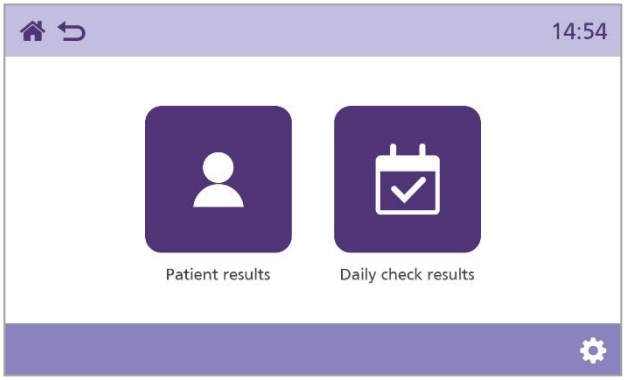
Successful



Unsuccessful

4.9. Database screen

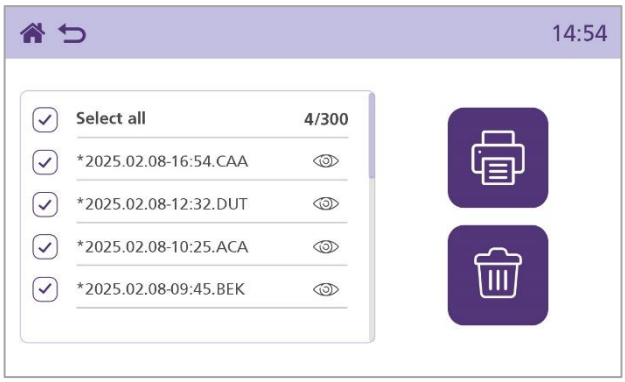
The database screen allows the operator to view and manage the data files stored within the devices memory. On entering the database screen the user will be presented with the following options:



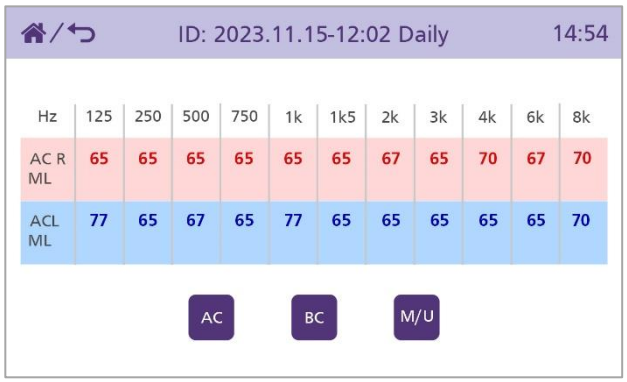
Pressing 'Patient results' will take the operator into a database where patient results and test sessions are collated. Pressing 'Daily check results' will show the data for daily check result.

Once in these different areas of the database, the operator can scroll through the different saved files to view, mark or process them as they see relevant.

From this section of the device the details can be deleted, printed and reviewed. An example of this screen is provided in the image below.

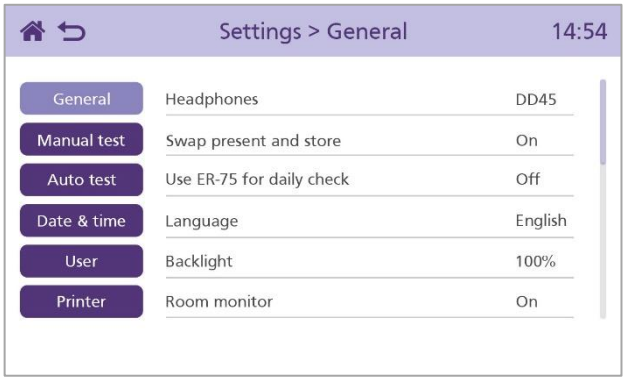


On selecting to view a record the thresholds are displayed as shown in the image below. The user can press on the different indicators (AC, BC and M/U) to view air conduction, bone conduction or most comfortable level/uncomfortable level thresholds.



4.10. Settings

In the settings screen the operator is able to configure and manage all aspects of the device's configuration and settings. There is a string displayed in the top of this display to simplify navigation for the user.



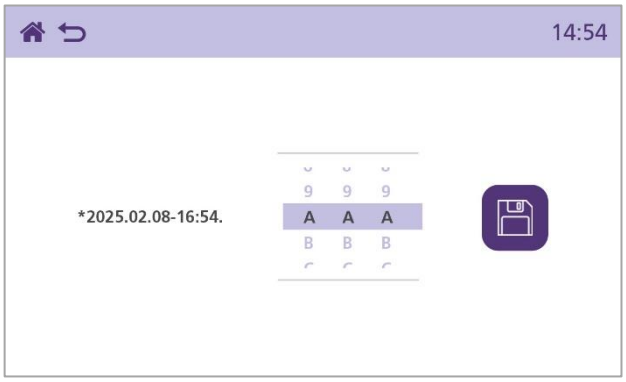
The operator can simply select the category of setting they wish to amend on the left of the screen and then in the right/central body of the display they can scroll and amend the relevant setting. An example of the settings screen is provided in the image below.

A full overview of all the possible settings for the Anova have been provided in appendix 3 of this document.

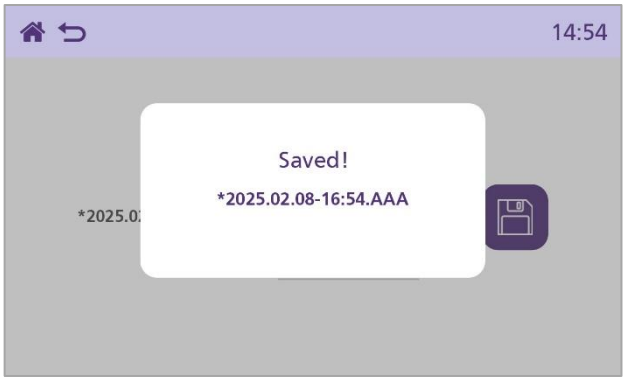
4.11. Saving audiograms in internal memory

The user may store up to 300 audiograms (AC & BC data), referenced by number, in the internal memory of the audiometer. Data will be retained in the device memory at the end of a test when the 'save' icon is pressed.

On pressing save the store file ID name is pre-populated based on the time and date. The only configurable elements of this are the last 3 digits of the file ID name which the user can input by scrolling through the alpha-numeric characters and pressing on the save icon. This has been fixed in this way to ensure patient/subject confidentiality on the device. An example of the save file ID string name is shown in the image below.



Once complete and the operator presses save there is a short confirmation message with the final file ID name to confirm the data has saved. An example of this is shown in the image below.



4.12. Printing audiometric data

An optional thermal Bluetooth printer is available for use with the Anova audiometer.

When using this printer for the first time you will need to enter the settings to pair the printer with your Anova audiometer.

1. Ensure the printer is fully charged, switched on, loaded with paper and ready to print
2. In the settings menu, navigate to the bottom option (printer)
3. Search for a printer and you should see the available printers in your environment
4. Choose the printer you wish to connect to
5. Once paired, power cycle your device
6. You can now print directly to the thermal printer following testing or navigate through your internally saved tests to select which sessions you want to print.

5. Specification

Air conduction audiometry	
Frequency range (kHz)	0.125, 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, 8
Frequency accuracy	<1%
Distortion	<2%
Output level range	-10dB HL to 120dB HL
Test method	Manual and automatic audiometry, Békésy, Hughson Westlake
Level steps	1, 2 and 5 dB
Bone conductor	ANSI S3.6-2018 and IEC 60645-1:2017 Type 3
Data management	
Internal database	300 patient records
Optional printer	Thermal printer (Bluetooth)
Data transfer	USB to Amplisuite, Noah, OtoAccess® and other EMR systems.
Languages	English, Mandarin and Spanish
Power	USB-C powered (5v ±5% minimum 4.5 w) Or USB3.x
Safety and standards	IEC 60601-1:2005+AMD:2012+AMD2:2020; - Medical electrical equipment - part 1: general requirements for basic safety and essential performance IEC 60601-1-2:2014+AMD1:2020 - medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.
Performance	ANSI S3.6:2018 Specifications for audiometers type 3 IEC 60645-1:2017 Pure tone audiometers type 3 If bone conductor license is not present device complied to type 4
Warm-up time	< 1minute
CE mark	Complies to EU medical device regulation (MDR 2017/745)
Sound room microphone	Octave band measurements at 125, 250, 500, 1000, 2000, 4000 and 8000 Hz
License	Automatic test (Hughson Westlake), Békésy, sound room monitor, bone conductor

5.1. Maximum hearing levels provided at each frequency

Frequency, Hz	DD45/Audiocups, dB HL	DD65v2, dB HL	IP30, dB HL	Bone conduction, dB HL
125	80	80	90	-
250	105	100	105	45
500	120	110	110	65
750	120	115	115	70
1000	120	115	120	70
1500	120	115	120	70
2000	120	115	120	75
3000	120	115	120	80
4000	120	110	115	80
6000	110	100	100	50
8000	100	95	90	40

5.2. Physical data

Dimensions: 170x 132 x 40mm

Weight: 574g

6. Symbols

The following symbols appear on the audiometer or mains adapter:

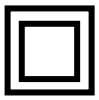
Definition: identifies the control by means of which the device is switched on from (or returned to) a standby condition.

Definition: refer to the instruction manual (mandatory).

Definition: type b applied part – an applied part providing protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.

The applied parts are the left & right earphones, bone conductor, insert earphones, patient response switch and the associated cables.

Definition: the output from the mains ac adapter is direct current.



Definition: class ii equipment – equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Definition: medical device

Definition: talk over microphone function

7. Technical information

Audiometer

Audiometer type:	Type 3 (IEC 60645-1:2017) Type 3 (ANSI S3.6:2018)
Frequencies:	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz with an accuracy of 1 %
Stimulus:	Pure tone, continuous or pulsed 1 second duration pulsing 200 Ms on 200ms off
Rising and falling time:	35 +/- 15 ms
Accuracy SPL:	Acoustic sound pressure levels: ± 2dB
On / off ratio:	Greater than 70 dB
Distortion (THD):	Acoustic sound pressure levels: below 2%
Sound Room Microphone:	octave band measurements at 125, 250, 500, 1000, 2000, 4000 and 8000 Hz

Masking sounds

Masking sounds available:	Narrow band at test frequencies
Narrow-band noise bandwidth:	Meets IEC 60645-1:2017; ANSI S3.6-2018 5/12 Octave filter with the same centre frequency resolution as pure tone
Reference levels:	Refer to ISO 389-4 1994
Calibration method:	With 2cc coupler compliant with IEC 126

Power supply

Model:	UES60LCP-200300SPC
Input:	100-240Vac 50/60Hz 1.3A
Output:	5.0Vdc (Used for Anova automatic selected) 9.0Vdc 12Vdc 15Vdc 20Vdc

Frequency modulation (warble)

4-20 Hz sine +/- 5% modulation

Transducers

DD45 6ccm uses IEC 60318-3 or NBS 9A coupler and RETSPL comes from ISO 389-1:2017, ANSI S3.6-2018 and ISO389-1:2017. Force 4.5N ±0.5N

DD65V2 Artificial ear uses IEC 60318-1 coupler with type 1 adaptor and RETSPL comes from PTB 1.61-4091606 2018 & AAU 2018, Force 11.5N ±0.5N

IP30 2ccm use ANSI S3.7-1995 or IEC 60318-5 coupler (HA-2 with 5mm rigid Tube) and RETSPL comes from ANSI S3.6-2018 and ISO 389-2:1994.

B71 use ANSI S3.13 or IEC 60318-6:2007 mechanical coupler and RETFL come from ANSI S3.6:2018 and ISO 389-3:2016 Force 5.4N ±0.5N

Environmental

Operating temperature:	+15°C to +35°C
Transport temperature:	-20°C to +50°C
Storage temperature:	0°C to +50°C
Humidity operating:	30% to 90% (non-condensing)
Ambient pressure:	98kPa to 104kPa

Input / output			
Input / output type	**Connector Type**	**Sensitivity**	**Impedance**
Power Input/Communication:	USB-C connector	-	-
Input Patient response	6,3 mm Mono Jack	3VDC	3 kOhm
Output Right	6,3 mm Mono Jack	3Vrms	10 Ohm Nominal load impedance
Output Left	6,3 mm Mono Jack	3Vrms	10 Ohm Nominal load impedance
Output Bone	6,3 mm Mono Jack	5Vrms	10 Ohm Nominal load impedance
SRM Microphone input	6,3 mm Mono Jack	100mVrms FS	3 kOhm

Pure tone RETSPL				
Transducer	**DD45**	**DD65 v2**	**IP30**	**B71**
Impedance	10 Ω	10 Ω	10 Ω	10 Ω
Coupler	**6ccm**	**Artificial ear**	**2ccm**	**Mastoid**
	RETSPL	RETSPL	RETSPL	RETFL
Tone 125 Hz	47.5	30.5	26	
Tone 250 Hz	27	17	14	67
Tone 500 Hz	13	8	5.5	58
Tone 750 Hz	6.5	5.5	2	48.5
Tone 1000 Hz	6	4.5	0	42.5
Tone 1500 Hz	8	2.5	2	36.5
Tone 2000 Hz	8	2.5	3	31
Tone 3000 Hz	8	2	3.5	30
Tone 4000 Hz	9	9.5	5.5	35.5
Tone 6000 Hz	20.5	21	2	40
Tone 8000 Hz	12	21	0	40

DD45 6ccm uses IEC 60318-3 or NBS 9A coupler and RETSPL comes from ISO 389-1:2017, ANSI S3.6-2018 and ISO389-1:2017. Force 4.5N ±0.5N

DD65V2 Artificial ear uses IEC 60318-1 coupler with type 1 adaptor and RETSPL comes from PTB 1.61-4091606 2018 & AAU 2018, Force 11.5N ±0.5N

DD450 Artificial ear uses IEC 60318-1 coupler with type 1 adaptor and RETSPL comes from ANSI S3.6-2018 and ISO 389-8:2004. Force 9N ±0.5N

IP30 2ccm use ANSI S3.7-1995 or IEC 60318-5 coupler (HA-2 with 5mm rigid Tube) and RETSPL comes from ANSI S3.6-2018 and ISO 389-2:1994.

B71 / B-81 use ANSI S3.13 or IEC 60318-6:2007 mechanical coupler and RETFL come from ANSI S3.6:2018 and ISO 389-3:2016 Force 5.4N ±0.5N

Sound attenuation values For earphones			
Frequency	Attenuation		
	DD45 with MX41/AR or PN 51 Cushion	IP30	DD65V2
[Hz]	**[dB]***	**[dB]***	**[dB]***
125	3	33	8.3
250	5	36	15.5
500	7	38	26.1
750	-		
1000	15	37	32.4
1500	-		
2000	26	33	43.6
3000	-		
4000	32	40	43.8
6000	-		
8000	24	43	45.6

*ISO 8253-1:2010

Nb noise effective masking level				
Transducer	**DD45**	**DD65 v2**	**IP30**	**B71**
Impedance	10 Ω	10 Ω	10 Ω	10 Ω
Coupler	**6ccm**	**Artificial ear**	**2ccm**	**Mastoid**
	EM	EM	EM	EM
NB 125 Hz	51.5	34.5	30	
NB 250 Hz	31	21	18	71
NB 500 Hz	17	12	9.5	62
NB 750 Hz	11.5	10.5	7	53.5
NB 1000 Hz	12	10.5	6	48.5
NB 1500 Hz	14	8.5	8	42.5
NB 2000 Hz	14	8.5	9	37
NB 3000 Hz	14	8	9.5	36
NB 4000 Hz	14	14.5	10.5	40.5
NB 6000 Hz	25.5	26	7	45
NB 8000 Hz	17	26	5	45

Effective masking value is RETSPL / RETFL add 1/3 octave correction for Narrow-band noise from ANSI S3.6-2018 or ISO 389-4:1994.

Nb noise max. Hl				
Transducer	**DD45**	**DD65 v2**	**IP30**	**B71**
Impedance	10 Ω	10 Ω	10 Ω	10 Ω
Coupler	**6ccm**	**Artificial ear**	**2ccm**	**Mastoid**
	Max. HL	Max. HL	Max. HL	Max. HL
NB 125 Hz	60	65	80	
NB 250 Hz	80	85	90	35
NB 500 Hz	95	95	100	55
NB 750 Hz	100	100	105	45
NB 1000 Hz	100	100	105	60
NB 1500 Hz	95	100	100	60
NB 2000 Hz	95	95	100	65
NB 3000 Hz	95	100	100	65
NB 4000 Hz	95	95	100	65
NB 6000 Hz	85	85	95	45
NB 8000 Hz	90	80	90	40

8. Routine maintenance

8.1. How to clean Amplivox products

The Anova audiometer is a precision device. Handle it carefully to ensure its continued accuracy and service. If the surface of the instrument or accessories can be cleaned using a soft cloth moistened with a mild solution of water and dish washing detergent or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the USB cable during the cleaning process and be careful that no liquid enters the instrument or the accessories.

- Before cleaning always switch off and disconnect from power
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to meet the metal parts inside the earphones / headphones
- 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
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components.

Recommended cleaning and disinfection solutions:

- Warm water with mild, non-abrasive cleaning solution (soap)
- 70% isopropyl alcohol.

Procedure:

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution
- Clean cushions and patient hand switch and other parts with a lint free cloth lightly dampened in cleaning solution
- Make sure not to get moisture in the speaker portion of the earphones and similar parts.

8.2. Insert earphones

The disposable foam ear tips supplied with the optional IP30 insert transducers are for single use only - that is, each ear tip is intended to be used only once for a single ear on a patient. Do not re-use ear tips as this will pose the risk of ear-to-ear or patient-to-patient cross infection. Further guidance is provided below:

- Ensure that the black tubing protruding the foam ear tip **is not** applied to the patient; this must be attached to the sound tube of the insert transducer
- Roll the foam ear tip into the smallest possible diameter
- Insert the ear tip into the ear canal of the patient
- Hold the ear tip until it has expanded, and a seal is achieved
- After testing the patient, the foam ear tip including the black tubing must be detached from the sound tube
- The insert transducer should be examined prior to attaching a new foam ear tip.

8.3. Mains adapter maintenance

Before use check the mains AC adapter for signs of wear and/or damage. If you find any signs replace the adapter immediately by contacting Amplivox or your Amplivox distributor.

9. Device storage and transportation

This device can be stored or transported within the following environmental parameters:

Transportation temperature:	-20°C to +50°C
Storage temperature:	0°C to +50°C
Humidity storage/transport:	10% to 95% (non-condensing)

10. Calibration and repair of the device

Amplivox recommends that this audiometer should be calibrated on an annual basis (yearly). Please contact Amplivox or the designated distributor for details of calibration services. Refer to ISO 8253-1 for additional guidance.

The device should be returned to the manufacturer for service & repair. There are no user-serviceable parts within it.

When packing the device for shipping, please use the original shipping carton and packing materials. Please also ensure that the headset leads are not wrapped around the headband of the headset.

11. Guarantee

All Amplivox devices are guaranteed against faulty materials and manufacture. The device will be repaired free of charge for a period of two years from the date of dispatch if returned and carriage paid to the Amplivox service department. Return carriage is free of charge for customers in the UK and chargeable for overseas customers.

Important note:

The following exceptions apply:

Earphones, bone conductor, Sound Room Microphone (SRM) and other transducers may go out of calibration due to rough handling or impact (dropping). The life of the leads is also dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

12. Disposal information

Amplivox limited is fully compliant with the WEEE (Waste Electrical and Electronic Equipment) regulations. Our PRN (Producer Registration Number) is WEEE/GA0116XU and we are registered with the approved WEEE compliance scheme, B2B compliance, approval number WEEE/MP3338PT/SCH.

The main purpose of the WEEE regulations is to encourage the segregation of waste electrical items from the general waste stream and into reuse, recovery and recycling routes. For any waste electrical units purchased from Amplivox that either:

- Bear the crossed out wheeled bin symbol with black bar underneath
- Or have been replaced with new Amplivox products on a like-for-like basis.

Please contact our WEEE compliance scheme using the details below. B2B compliance will be able to provide further information on how to recycle your waste electrical units and answer any queries you may have.

B2B compliance

Tel: +44 (0) 1691 676 124 (option 2)

Email: operations@b2bcompliance.org.uk

Appendix 1 - EMC guidance & manufacturer's declaration

Electromagnetic Compatibility (EMC)

This equipment is suitable in hospital and clinical environments except for near-active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Notice: ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:

This equipment does not have an ESSENTIAL PERFORMANCE absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.

Final diagnosis shall always be based on clinical knowledge.

Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories and cables can be found in this section.

Portable rf communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This equipment complies with IEC60601-1-2:2014+AMD1:2020, emission class B group 1.

Notice: there are no deviations from the collateral standard and allowances uses.

Notice: all necessary instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.

Notice: if non-medical electronic equipment (typical information technology equipment) is attached, it is the responsibility of the operator to ensure that this equipment complies to applicable standards and the system as whole complies to the EMC requirements. Commonly used standards for EMC testing information technology equipment and similar equipment[1] are:

Emissions testing

EN 55032 (CISPR32)	Electromagnetic compatibility of multimedia equipment – emission requirements
EN 61000.3.2	Electromagnetic compatibility (EMC) – limits for harmonic current emissions (AC mains only, equipment input current less than or equal to 16 a per phase)
EN 61000.3.3	Electromagnetic compatibility (EMC) – limits – limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems (AC mains only, equipment input current less than or equal to 16 a per phase)

Immunity testing

EN 55024 (CISPR24)	Information technology equipment – immunity characteristics – limits and methods of measurement

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Anova audiometer is intended for use in the electromagnetic environment specified below. The customer or user of Anova audiometer should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>The Anova audiometer uses RF energy only for its internal function. Therefore, its rf emissions are very low and are not likely to cause interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">The Anova audiometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

[1] Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, Wi-Fi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Anova audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Anova audiometer should assure 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 ±15 kV air	±8 kV contact ±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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines (100v/60Hz & 240V/50Hz) IEC 61000-4-11	0% UT (100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% UT (30% dip in UT) for 500ms	0% UT 100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% UT (30% dip in UT) for 500ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Anova audiometer requires continued operation during power mains interruptions, it is recommended that the Anova audiometer be powered from an uninterruptible power supply or a battery.

	0% UT (100% dip in UT) for 5 sec	0% UT (100% dip in UT) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note u_t is the a.c. Mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
The Anova audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Anova audiometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile rf communications equipment should be used no closer to any part of the Anova audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance D = 1.2√p D = 1.2√p 80mHz to 800mHz D = 2.3√p 800mHz to 2.5GHz Where p is the maximum output power rating of the transmitter in
Conducted RF IEC 61000-4-6	10 Vrms 150kHz to 80MHz	10 Vrms 150kHz to 80MHz	

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
Radiated RF IEC 61000-4-3	10 V/m 80mHz to 2.7GHz	10 V/m 80mHz to 2.7GHz	Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (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 80mHz and 800mHz, 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 radio 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 Anova audiometer is used exceeds the applicable rf compliance level above, the Anova audiometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Anova audiometer.

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

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

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	m		
W	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$D = 1.2\sqrt{p}$	$D = 1.2\sqrt{p}$	$D = 2.3\sqrt{p}$
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 80MHz and 800MHz, the separation distance for 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.

Note 3 warning: portable rf communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Anova audiometer including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Appendix 2 – Anova settings

This appendix provides a full overview of the settings possible on the Anova audiometer and a brief description of its use/application.

General

Setting name	Option 1	Option 2	Option 3	Setting description
Headphones	DD45	IP30	DD65v2	Selection of which AC headphone they system will use. Device can contain calibration data for two headsets.
Swap present and store	Off	On		Allows swap of present and store buttons for left-handed use
Use er-75 for daily check	Off	On		Selection of whether the daily check function is performed on an er-75 or not
Language	Eng	Esp	Cn	Language selection
Backlight	50 % to 100 % in steps of 5			Backlight brightness intensity
Room monitor	Off	On		Activation of room monitor microphone
Custom noise limits Sound Room monitor				
Custom noise limits	Shows list with octave band frequencies.			Allows customisation of noise limit level per octave band
125 Hz	40 to 90 dB in 1 dB steps			
250 Hz	40 to 90 dB in 1 dB steps			
500 Hz	40 to 90 dB in 1 dB steps			
1000 Hz	40 to 90 dB in 1 dB steps			
2000 Hz	40 to 90 dB in 1 dB steps			
4000 Hz	40 to 90 dB in 1 dB steps			
8000 Hz	40 to 90 dB in 1 dB steps			

Manual test

Name	Option 1/min	Option 2/max	Default setting	Setting description
Start level	0	70	30	Specify the starting level
Start ear	Left	Right	Left	Specify the starting ear
Activate next frequency	Off	On	On	Enable/disable auto shift to next frequency on store
Frequency procedure	Re-test 1kHz	Rolling	Re-test 1kHz	Specify the frequency shift behaviour
Masking	Untracked	Tracked	Untracked	Specify the style of masking
Frequencies	Edit			Opens a new screen where you can enable/disable all required test frequencies

Auto test

Name	Option 1/min	Option 2/max	Default setting	Setting description	HW*	Békésy*
Auto test name	Edit			Customise name of auto test	X	X
Test procedure	HW	Békésy	HW	Specify test procedure method	X	X
Save on	2 of 3	3 of 5	2 of 3	Specify how many responses required for threshold	X	
Pulsed	Off	On	On	Enable pulsed tone stimulus	X	
Max deviation	5	30				X
Signal	Tone	FM (warble)	FM (warble)	Specify signal type	X	X
Familiarisation	Off	On	On	Activate familiarisation process	X	X
Re-confirm 1kHz	Off	On	Off	Activate re-confirmation of 1khz threshold	X	?
Ear	Single	Both	Both	Selection of one or both ears for test	X	X

Start level	30	70	30	Test start intensity selection	X	X
Min level	-10	30	-10	Test min intensity selection	X	X
Max level	80	110	100	Test max intensity selection	X	X
Retry count	0	3	0	Selection of no. Retries on error	X	X
Stop on error	No	Yes	No	Selection of stop test on error	X	X
Pause on excessive noise	Off	On		Activate pause when test has excessive noise	X	X
Frequencies	Edit			Opens a new screen where users can enable/disable all required test frequencies	X	X
Auto masking	Off	On		Activate automatic masking		

*Columns marked with an asterisk specify whether setting is fixed and available for selected protocol

Date & time

Name	Option 1	Option 2	Option 3	Setting description
Date format	DD:MM:YY	YY:MM:DD	MM:DD:YY	Specify date format according to region
Clock format	AM/PM	24h		Specify time format according to region
Adjust	Set			Opens up a roller where you can adjust unit date and time

User

Name	Option 1	Option 2	Option 3	Setting description
Start in	Home	Manual	Auto	Specify test screen the unit will power up and open into
Save id	Auto	Enter xyz		Specify file save ID behaviour
Manual end of test	Print	Clear		Specify what happens at the end of manual test
When saved, then	Print	Clear		Specify what happens at the end of manual test after save
Auto end of test	Save			Specify what happens at the end of an auto test
When saved, then	Print	Clear		Specify what happens at the end of auto test after save

Appendix 3 - battery replacement

The battery is used to power the real time clock within the Anova audiometer. If the battery is not working RTC Error will appear on the screen. Battery type is CR2032.

1. Place the device with the top downwards.
2. Unscrew the 6 screws on the backside of the device.
3. Swap the device around so the top face upwards and device front the user.
4. Lift the top in a 90˚ angle. You don't have to dismount ribbon cables this way.
5. Remove the old battery placed in the right-hand side of the printed circuit board buy using a small flat screwdriver to release the lock gently
6. Place the new battery in with the "+" side up under the metal part on the left side of the battery holder and press the left side gently until the battery in locked under the plastic hugs on the right side.
7. Put the top back again.
8. Fasten the 6 screws.