Model 270+

INSTRUCTION FOR USE



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ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the Model 270+ (from firmware version 1.3.1.0 onwards).

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1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing an Amplivox Model 270+, a diagnostic audiometer that will give many years of reliable service if treated with care.

For supply in US only: Caution: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

1.2. INTENDED APPLICATIONS

This instrument is designed for use by trained 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 and training.

The audiometer is capable of undertaking both air and bone conduction tests with or without masking, and has many additional features such as the facility to support speech audiometry from live or recorded sources, the option to select free field equivalent output from the headphones in speech mode and a range of clinical audiometry tests.

1.3. 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 when high intensity stimuli are used.
2. Recent outer ear surgery.

1.4. STANDARD AND OPTIONAL ACCESSORIES

Shipping documentation will reference the stock number quoted below, and images of the parts alongside the relevant stock number are available on the Amplivox website (www.amplivox.com). The required fitting instructions are supplied with each part.

STANDARD ACCESSORIES			
Model 270+ Audiometer	8514279	Audiogram cards (pack of 50)	8013007
Audiometric headset, Earphones DD45 [1]	8517340	Operating Manual & ampliSuite on USB stick	8517684
Bone vibrator headset B71 [2]	8517050	Carrying case	8004673
Mains adaptor	8512734	Cable USB – A & B connector	8011241
Patient response switch [1]	8011155	Calibration certificate	8011512

[1] Applied part according to IEC60601-1
[2] This part is not certified according to IEC 60601-1

OPTIONAL ACCESSORIES			
Masking monitor earpiece [2]	8507921	Audiocups add-on (noise reducing earphone enclosures) [1]	8010855
Microphone and monitor headset	8010870	Foam Eartips for Insert Phones, standard, 50 each	8500090
MPT-II Printer	8535338	Foam Eartips for Insert Phones, small, 50 each	8001772
Printer cable	8505753	Interconnect Stero Cable Set (Booth kit)	8510195
Insert phones IP30 [1]	8101884	SP90A speaker kit	8104161
Talk back microphone	8518110	Stereo line in cable for CD	8031036

1.5. GUARANTEE

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

1.6. WARNINGS

Throughout this manual, the following meanings of warnings and cautions apply:



WARNING

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The CAUTION label identifies conditions or practices that could result in damage to the equipment.

2. UNPACKING AND INSTALLATION

2.1. GENERAL

Please check the contents of the shipping carton against the delivery note to make sure that all items ordered have been included. If anything is missing, please contact the distributor who supplied the audiometer or Amplivox if purchased directly.

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



CAUTION

For supply in US only: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

2.2. MARKINGS

The following markings can be found:

Symbol	Explanation
	Refer to instruction manual.
	**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 vibrator, insert masker, patient response switch and the associated cables.
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to appropriate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
 0123	The CE-mark indicates that Amplivox Ltd meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Serial number.
	Date of manufacture.
	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.
	Keep dry.
	Transport and storage humidity range.
	Transport and storage temperature range.
amplivox	Logo.
	Turns the instrument on or off. Long press to turn off. Short press to wake the device from sleep mode (display off).
MD	Medical device
	Operators live speech/external talkover microphone (3.5 mm jack)
	Operators monitor earphone (3.5 mm jack)
	Patient talkback microphone (6.35 mm jack)
	Line Out for external amplifier (3.5 mm jack)

2.3. SAFETY INSTRUCTIONS

2.3.1. GENERAL

The following safety precautions must be observed at all times. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

Amplivox Ltd is aware that safety rules within individual organisations vary. If a conflict exists between the instructions in this manual and the rules of the organisation using this instrument, the more stringent rules should take precedence.

The Model 270+ is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), nurses or technicians who have been trained in the proper use of the device.

2.3.2. CAUTIONS – GENERAL



CAUTION

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Amplivox's specifications.

Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

This product and its accessories will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Amplivox Ltd.

Equipment is not user repairable. Repairs must be performed by an authorised service representative only. No modifications of the equipment are allowed by anyone other than a qualified Amplivox Ltd representative. Modification of the equipment could be hazardous.

Amplivox Ltd will make available, on request, component part lists, descriptions, calibration instructions, or other information that will assist authorised service personnel to repair those parts of this instrument that are designated by Amplivox Ltd as repairable by service personnel.

No parts of the equipment can be serviced or maintained while in use with the patient.

Connect only accessories purchased from Amplivox Ltd to the Model 270+. Only accessories which have been stated by Amplivox Ltd to be compatible are allowed to be connected to the device.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for electromagnetic compatibility (EMC) the audiometer is designed to be used only with the medically-approved mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument.**

The output from the mains adapter is fitted with electronic circuit protection. In case of overload the adapter will shut down. When the fault is cleared the adapter will operate as normal. However, the input to the mains adapter is protected with a non-replaceable fuse. If this fails the adapter will not operate.

The mains adapter is the mains disconnect device and therefore the audiometer should be positioned such that easy access to the mains adapter is possible.

2.3.3. ENVIRONMENTAL FACTORS

CAUTION



Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30% and 90% (non-condensing).

Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorised service technician.

2.3.4. ELECTRICAL AND ELECTROSTATIC SAFETY

CAUTION

Before performing any service to the headphones or insert earphones you must remove the Model 270+ transducers from the patient.

WARNING

Do not touch the contacts on the back of the instrument and the patient at the same time. The consequence could be a leakage current to the patient.

Do not open, modify or service the case of the instrument. Refer servicing to qualified personnel.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. 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 these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar item, beware of not touching the PC and patient simultaneously.

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, a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.

Do not use any additional multiple socket-outlet or extension cord. **Use only the Amplivox Mains Power Adaptor.**

2.3.5. ELECTROMAGNETIC COMPATIBILITY (EMC)



CAUTION

Although the instrument fulfills the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to Section 7 regarding EMC.

2.3.6. EXPLOSION HAZARDS



WARNING

Risk of explosion.

Do NOT use in the presence of flammable anesthetics or other gases.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

Do NOT use the Model 270+ in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

2.3.7. MEASURING ACCURACY

To guarantee that the Model 270+ works properly, the instrument should be checked and calibrated at least once a year. The transducers supplied with the audiometer are specifically calibrated with it; if these transducers are changed recalibration will be required.

The service and calibration must be performed by an authorised service technician. If these checks are not performed, EU Medical Device Regulation (MDR) and other regulations may be violated and warranties may be void.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

2.3.8. MISCELLANEOUS

Please note: DO NOT connect the Model 270+ hardware to the computer before the software has been installed.

Storage in temperatures below 0°C /32°F and above 50°C /122°F may cause permanent damage to the instrument and its accessories.

Do not place the instrument next to a heat source of any kind.

Great care should be exercised when handling transducers, as rough handling, for example dropping onto a hard surface may break or damage the parts.



Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore have to be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.
Outside the European Union, local regulations should be followed when disposing of the product after its end of life.

2.3.9. USE OF EQUIPMENT AFTER TRANSPORT AND STORAGE

Please make sure that the instrument is functioning correctly before use. If the instrument has been stored in a cold environment (even for short period of time), please allow the instrument to become acclimatised. This can take a long time depending on the conditions (such as environmental humidity). You can reduce the condensation by storing the instrument in its original packaging. If the instrument is stored under warmer conditions than the actual use conditions no special precaution is required before use. Always ensure proper operation of the instrument by following routine check procedures for audiometric equipment.

2.3.10. MAINS SUPPLY OPERATION

The audiometer is designed for continuous operation and is powered by a mains adapter which is supplied and specified as part of the equipment. If a replacement is required, please contact your Amplivox distributor.

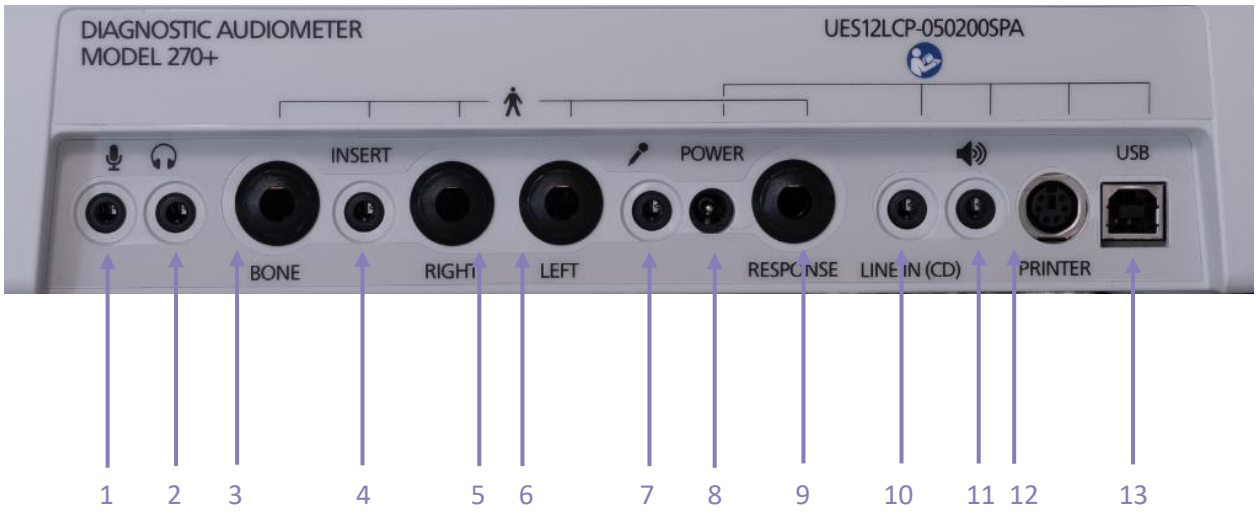
All other connections must be made **before** connecting the output lead from the adapter into the POWER input socket on the back of the audiometer. Switch on the mains supply - the POWER indicator on the audiometer will illuminate green, showing that the instrument is ready for use.

The output from mains adapter is fitted with electronic circuit protection. In case of overload the adapter will shut down. When the fault is cleared the adapter will operate as normal. However, the input to the mains adapter is protected with a non-replaceable fuse. If this fails, the adapter will not operate.

The mains adapter is the mains disconnect device and therefore the audiometer should be positioned such that easy access to the mains adapter is possible.

2.4. CONNECTIONS

All connections are made to the rear panel of the audiometer as shown below.

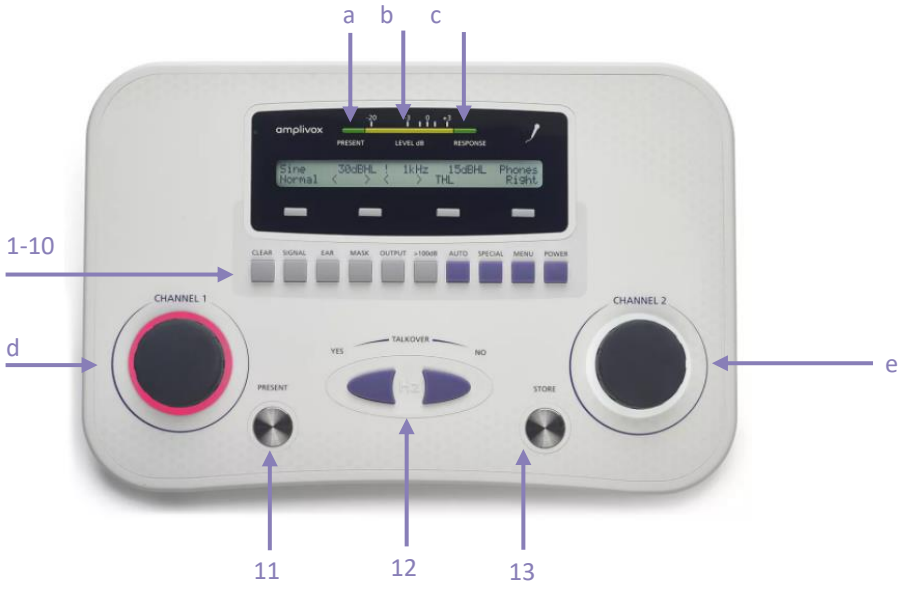


1	**MIC 1**	3.5 mm jack	Operators Live Speech/External Talkover Microphone
2	**Monitor**	3.5 mm jack	Operators Monitor Earphone
3	**Bone (Grey)**	6.3 mm jack	Bone Vibrator Headset
4	**Insert**	3.5 mm jack	Masking Earphone
5	**Right (Red)**	6.3 mm jack	Air Conduction Headset (Right Ear)
6	**Left (Blue)**	6.3 mm jack	Air Conduction Headset (Left Ear)
7	**MIC 2**	3.5 mm jack	Patient Talkback Microphone
8	**Power**	2.5 mm DC jack	Mains AC/DC Adapter
9	**Response (Black)**	6.3 mm jack	Patient Response Switch
10	**Line IN**	3.5 mm jack	CD / Tape Player /MP3
11	**Line OUT**	3.5 mm jack	External Amplifier
12	**Data**	6 pin mini DIN	Printer
13	**USB**	USB connector	Computer (via USB port)

Please note: Only connect the accessories supplied with the instrument or supplied by Amplivox or an Amplivox distributor. These parts have been tested for use with the Amplivox Model 270+ 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.

2.5. CONTROLS AND INDICATORS (BASE UNIT)

The Model 270+ consists of an LCD screen, three button groups in total to operate the instrument and three status LEDs.

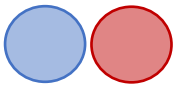


a	**Tone presentation**	When a signal is presented to the patient, the light will illuminate green.
b	**VU meter**	Indicates speech level
c	**Response light**	When the patient response switch is pressed, the light will illuminate green.
d	**Attenuator**	Controls channel 1
	Light ring left	Indicates selected test ear
e	**Attenuator**	Controls channel 2
	Light ring right	Indicates presentation on contralateral test ear
1	**Clear**	Clears all displayed test results
2	**Signal**	Switch between tone and speech testing
3	**Ear**	Change ear
4	**Mask**	Activate masking
5	**Output**	Select transducer to present signal
6	**> 100 dB**	Test above 100 dB
7	**Auto**	Start auto test
8	**Special**	Select special test
9	**Menu**	Change instrument settings, save and reload tests
10	**Power**	Switch device on or off
11	**Present**	Present test stimulus
12	**Frequency**	Decrease and increase test frequency
		In Speech Assessment used for ‘Yes and No’

12	**Talkover/Talkback**	Pressing both frequency buttons to activate talkover and talkback
13	**Store**	Save measured point

2.6. LIGHT INDICATORS

The indicators on the Model 270+ show the status of the selected ear and test mode.

LIGHT	LIGHT RING LEFT	LIGHT RING RIGHT
Red light: Right ear selected as test ear.		
Blue light: Left ear selected as test ear.		
White light: Masking		
Blue and white lights: Both channels active.		

2.7. HARDWARE INSTALLATION

Connect the relevant transducers, the patient response switch and, if used, the speech and free field with the device, before connecting the power adapter.

The instrument is designed for continuous operation and is powered by a mains adapter. Connect the output lead from the adapter into the **POWER** input socket on the back of the Model 270+.

2.8. THE SANIBEL MPT-II PRINTER

2.8.1. INSTALLING THE SANIBEL MPT-II PRINTER

The Sanibel MPT-II thermal printer is available as an option for use with the Model 270+ and is connected using the cable supplied. The printer may be specified when ordering and only this printer should be used. It will be correctly configured for use.



1. Open the lid by pushing on the sides, insert paper roll as shown,
2. and close the lid.
3. Insert the battery.

2.8.2. SWITCHING THE PRINTER ON AND OFF



Push POWER BUTTON for two seconds in order to power ON or OFF. One short beep will be heard at power ON, two short beeps at power OFF.

The green power indicator will be lit if the printer is powered by battery.

2.8.3. USING THE PRINTER

Printer self-test: While printer is powered **OFF**, press and hold **PAPER FEED** button, then press and hold **POWER BUTTON** simultaneously. When beep is heard after approx. 3 seconds, release both buttons, and a test page will print with information on current status and character samples.

Paper feed: When powered, press **PAPER FEED** button. Paper will feed as long as the button is pressed.

Connecting process:

- Connect the printer via the cable with the device
- Power on printer
- Select print option in Model 270+

Please note: Do not have several printers powered on and within range while searching.

3. PRINCIPLES OF OPERATION

3.1. OTOSCOPIC EXAMINATION

A suitably-qualified health care professional should perform a thorough otoscopic examination to establish that the condition of the ear is suitable for the test options selected and that no contraindications are present. The latter would include obstruction of the external ear canal due to excessive wax and/or hairs, both of which would need to be removed. This is required to ensure that the pure tone delivered by the earphone is able to reach the ear drum and is not reflected by cerumen or debris and thereby alter the test result.

3.2. PRINCIPALS OF PURE TONE AUDIOMETRY

Ideally, hearing tests are conducted in a soundproof room. The purpose of pure tone audiometry is to measure the patient's 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 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 air conduction is completed, bone conduction is performed.

In cases of unsymmetrical hearing, it might be required to mask the air and bone conduction in order to prevent hearing the test tone on the opposite ear. This phenomenon is called 'crossover' and occurs more often while testing bone conduction then air conduction.

3.3. PRINCIPALS OF SPEECH AUDIOMETRY

Speech audiometry has become a strong tool to assess hearing loss. In addition to pure-tone audiometry, the degree and type of hearing loss can be determined and further information about word recognition and tolerance to speech stimuli can be identified. Also, speech audiometry is used to fit hearing aids or other amplifying devices.

3.4. PRINCIPALS OF FREEFIELD AUDIOMETRY

Speech audiometry is often conducted in a free field audiometry setup, to evaluate the use and benefit of hearing aids for the patient.

4. USING THE MODEL 270+

4.1. GENERAL PRECAUTIONS

When operating the instrument, 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 the headphones, insert phones and patient response switch 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 instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.

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

4.2. SWITCHING THE INSTRUMENT ON AND OFF



Select the POWER button for 1 second to switch the instrument on. The display will briefly show the model and the type of headphone currently selected for use. No warm-up time is required, although a short diagnostic routine will run for a few seconds.

To switch the instrument off again, hold the button for approx. 2 seconds and the instrument will turn off.

4.3. SWITCHING HEADPHONES

If a secondary headphone has been enabled (e.g. IP30 together with DD45) it will be necessary to select the required headphone as follows: Select **MENU** and move to the item **SELECT OUTPUT**.



Select the headphones to be used with the audiometer with the softkeys **F1** and **F2**. Confirm your selection by pressing softkey **F4** (**SAVE**).

4.4. OPERATING LANGUAGE

The instrument will be set in English by default.



To select the operating language for the audiometer (English, Polish or German) continue to hold the power button when switching on.



An additional display will allow the selection of English (F1) or Deutsch/Polish (F2). After selecting a language, the start-up screen will show.

4.5. SYSTEM INFORMATION

The system information is briefly displayed when switching on the Model 270+ unit.



Information about the firmware version (as in image above 1.3.2.1), the Model 270+ and the type of headphone currently selected for use.

4.6. FUNCTION BUTTONS

4.6.1. PRESENTING A TONE



The presentation button is located to the right of the Channel 1 rotary control (attenuator). The button is conductive, by touching it the test signal will be presented to the patient (presentation mode) or interrupted (continuous mode).

4.6.2. STORING A TEST POINT



The store button is located to the left of the Channel 2 rotary control (attenuator). The button is conductive, by touching it the current test level and frequency will be stored to the temporary memory of the device.

No response can be plotted by holding the **STORE** button for 2 seconds. The threshold will then be marked as **NR** for “no response”.

4.6.3. TALKOVER AND TALKBACK



Pressing both frequency buttons at the same time, will bring you to the talkover and talkback screen.

For talkover (you use this to talk to the patient), the internal microphone or an external headset can be used.

Please note: It is not possible to use both an external and an internal microphone at the same time. The used microphone needs to be defined via the settings. Select **MENU** and **CONFIG.** to choose if the external microphone shall be used instead of the built-in microphone.

When pressing both frequency buttons, the screen will show the talkover and talkback screen. Talkover is active as soon as the buttons are both pressed. The level of talkover can be controlled with the Channel 1rotary control.



When starting up the unit, talkback is switched off and needs to be activated manually every time the device is started up. Use **F4** to activate talkback. The function will now be enabled during the entire operation of the device. Use the Channel 2 rotary control to control the talkback level in your monitor headset. When activated, the talkback function will be active constantly and has to be manually deactivated, if required.

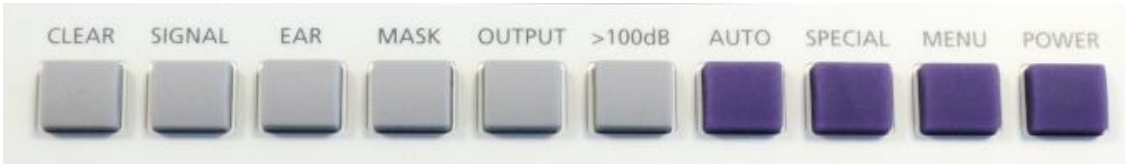


4.6.4. MENU OPERATION

When the start-up sequence is complete, the **TONE AUDIOMETRY** screen is displayed.

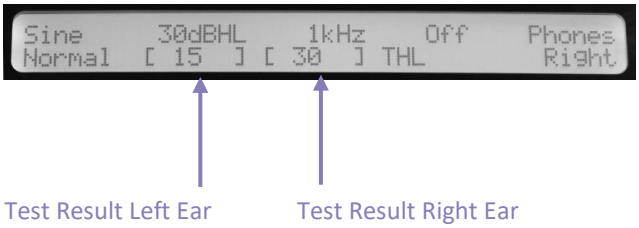


The instrument can be operated using the four softkeys below the display as well as the 10 functional button keys below.



4.6.5. CLEAR (ON-SCREEN RESULTS)

Test results from the current or a previous session can be displayed on-screen and are shown below the current test level and frequency.



In order to clear the screen display, select **CLEAR**.



Use the **F1** to **F4** to either clear the current shown test result (**F1**) or to store the data by choosing a reference number using **F3** and confirm by selecting **F2**. After successful storage, the test results will be deleted from the screen. Use **CANCEL** (**F4**) or select the **CLEAR** button again to leave the menu without any changes.

Please note: In order to load stored measurements, the load function in the **MENU** can be used. Please refer to chapter 4.7.4 for further information about how to review stored measurements.

4.6.6. SIGNAL

4.6.6.1. SELECTION OF TONE AND SPEECH MODULE

Select **SIGNAL** to change between **TONE** and **SPEECH** audiometry.



For **TONE** audiometry the option is given to use sinusoid or warble stimuli. Select **F1** for **SINE** to present a sinusoid signal. Pressing **F2** will present a **WARBLE** signal in the tone audiometry test.

For **SPEECH** select **LINE** for using external speech files, such as from a CD player. Select **MIC.** to use the microphone to present speech to the patient. After selecting **LINE** or **MIC.**, the speech module will open.

Select **SIGNAL** button again to leave the menu without changes.

4.6.6.2. CONTINUOUS, PRESENT AND PULSE

In the tone audiometry module, select **F1** to choose between present, pulse, continuous and continuous pulse.



Select **NORMAL** to start the present mode. **PULSE** will activate a pulsed signal in present mode. Select **CONT.** to change the presentation mode to continuous presentation. **C.PULSE** will activate a pulsed continuous test signal.



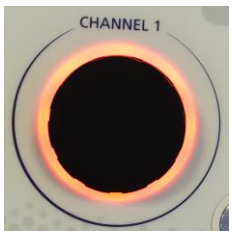
4.6.7. EAR (SELECTION)

Select the **EAR** button to change the current selected ear. You can also use softkey **F4** to change the ear selection.





In addition to the on-screen display of the selected ear, the LED-light around the Channel 1 rotary control will light in the colour of the selected ear (right = red, left = blue).



Right ear selected (red light)



Left ear selected (blue light)

4.6.8. MASK (ACTIVATE MASKING)

Select the **MASK** button to activate or deactivate masking.



Select **NONE** (**F1**) to switch masking off.



As soon as the masking channel is switched on, the light ring around the Channel 2 rotary control illuminates white.

Use **MASK** (**F2**) to switch masking noise on and control the level manually. Select **TRACKED** (**F3**) to increase and decrease the masking level in relationship to the test signal.

Select **CANCEL** (**F4**) or the **MASK** button again to leave the masking menu without changes.

4.6.9. OUTPUT (AC, BC AND FREEFIELD)

Select the **OUTPUT** button, to select the transducer the test signal will be presented to.



Select **F1** to present the signal to the AC (air conduction) **PHONES**, using **F2** will present the tones to the **BONE** vibrator (BC, bone conduction). Selecting **F3** will utilise the connected loudspeakers to present the signal via **FREEFIELD**. Select **CANCEL** (**F4**) or the **OUTPUT** button again to leave the menu without changes.

4.6.10. AUTO (AUTOMATIC TESTING)

The **AUTO** function defines whether the tone audiometry test is conducted manually or automatically.

Select **AUTO** and Continue (**F3**)



Select **MANUAL** (**F1**) to perform manual audiometry (default setting).

Automatic testing can be conducted on both ears or on the current selected ear. To test only one frequency (currently selected frequency) on the currently selected ear automatically, select **1 FREQ** (**F2**). To run a full audiogram on the current selected ear, select **1 EAR** (**F3).** To run a full audiogram on both ears (the start ear is the currently selected ear), select **BOTH** (**F4**). Select the **AUTO** button again to leave the menu without changes.

4.6.11. >100dB (EXTENDED RANGE)

When an extended range, above 100 dB is required, select the **>100dB** button to present tone levels up to 20dB higher.



On the display '+' will indicate that levels greater than 100dBHL can be used.

4.6.12. SPECIAL (SPECIAL TEST SELECTION)

Selecting the **SPECIAL** key enables the selection of the following special tests:

- Stenger Test
- Alternate Binaural Loudness Balance (ABLB)
- Short Increment Sensitivity Index (SISI)
- Master Hearing Aid (MHA)
- Hearing Loss Simulation (HLS)
- Decay Test (Carhart Test)

Select the **NEXT** (**F2**) or the Channel 1 rotary control to move through the different test options. To choose a special test, select **F3**. After confirmation, the selected test screen will show. Select **CANCEL** (**F4**) or the **SPECIAL** button again to leave the menu without changes.

Please note: Please refer to chapter 4.10 for how to use the special tests.

4.7. MENU

4.7.1. GENERAL

The **MENU** contains the system settings as well as the data processing options.



- The **CONFIGURATION** (**F1**) submenu contains general instrument and test settings regarding the audiometric tests.
- **AUTO** contains all settings related to auto-test (**F2**)
- Data can be saved and re-loaded for review, to be printed or sent to the PC software (**F3**)
- The current reviewed measurement can be printed (**F4**)

Within each setting, using the softkey **F3** (**NEXT**) or the Channel 1 rotary control allows the operator to step through the options and modify the settings as required. Pressing the softkey **F4** (**SAVE**) exits the option menu and saves the settings.

4.7.2. CONFIGURATION

In **CONFIGURATION** the instrument settings can be modified. Use **F1** and **F2** to change the current selected setting and use **F3** (**NEXT**) to move on to the next setting. Select **SAVE** (**F4**) or the **MENU** button again to leave the menu with the latest changes stored.

ITEM	DESCRIPTION	DEFAULT
Present Time:	Select the time that a stimulus can sound when the PRESENT key is pressed; either continuously while the present button is pressed or for 1.0-2.0 sec.	1.0-2.0 sec
FF Speech Units:	The units displayed for freefield speech can be shown in dBHL and dBSPL.	dBHL
High Gain Line:	When yes is selected, the line-in signal will be amplified. It is important to note that distortion can happen, when amplifying the test signal more than necessary.	No
Bone Masking:	Selects the headset (Phones) or the optional insert masking earpiece (Insert) as the means of masking.	Phones
Select Output:	In the case that several transducers are available (e.g. DD45 and IP30), select the headset required.	DD45
Headphone eq. FF:	This option is only available if DD45 is the selected headset; if activated, free-field equivalent levels will output to the headset in speech mode.	Yes
Set Freefield Level:	This option provides access to the freefield calibration function; refer to Appendix A for details.	No
Step Size:	Enables the operator to set either 1, 2 dB or 5dB as the default step size.	5dB

External Talkover:	Select **NO** to use the internal microphone and **YES** to use an external headset with microphone.	No

4.7.3. AUTO-TEST SETTINGS

ITEM	DESCRIPTION	DEFAULT
Retry count:	Select the number of times a frequency is repeated (0, 1, 2 or 3 times) if an error in testing occurs (for example, if there is an erratic response from the patient).	0
Computer test:	Select which auto-test procedure should be chosen: Computer or Békésky.	Békésky
Stop on error:	When an error during the auto-test sequence is found, the test can be stopped (select **yes**) or continued (select **no**).	No
Familiarisation:	Runs a test sequence (select **yes**) for the patient to get used to the procedure or directly starts with the test (select **no**).	No
Repeat 1 kHz:	Repeat the 1 kHz measurement for **both ears, 1 ear**, **No** during the auto-test.	No
Pulse:	Use a pulsed signal in the auto-test sequence (select **yes**) or a regular tone (select **no**).	No
Store on:	Automatically stores a threshold if the responses made for two out of three test signals are at the same hearing level.	3 out of 5
Frequencies:	Choose the test frequencies which shall be tested during a full auto-test session. All frequencies can be deselected except for 1 kHz.	0.5, 1.5, 2, 3, 4 and 6 kHz
Auto mask:	Activate (select **yes**) if masking should be automatically applied during an auto-test. The masking will be applied in air conduction and bone conduction tone audiometry test. Select **No** if auto-masking is required.	Yes

4.7.4. LOAD/SAVE

The user may store up to 10 audiograms, referenced by number, in the internal memory of the audiometer. These test results can also be reviewed in the Model 270+ device by using the **LOAD** function.



To **SAVE** the current set of audiogram thresholds, select (**F1**) the location slot (1-10) and press **F3** (**SAVE**). Any results for thresholds including THL, MCL and UCL (also known as ULL) as well as speech testing results can be saved.

Measurements can also be saved directly by selecting the **STORE** button.

Please note: The save process will overwrite any records that exist in the memory location.

To load the stored set of audiogram thresholds, select the location slot (1-10) under which the data is stored (**F1**) and press **F2** (**LOAD**). Select **CANCEL** (**F4**) or the **MENU** button again to leave the menu without changes.

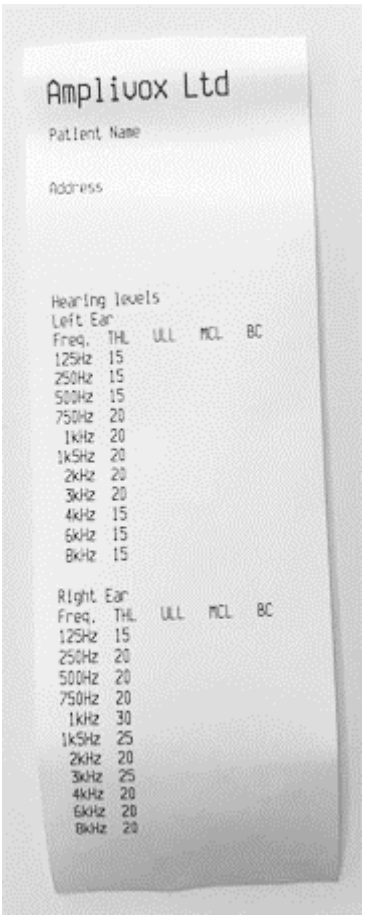
4.7.5. PRINT

The Sanibel MPT-II is the designated thermal printer to be used with the Model 270+. Learn more about the MPT-II printer in chapter 2.8. When using the printer, ensure it is switched on and ready to print.

The printed audiogram will be the current shown threshold, which had either just been recorded or loaded from the internal memory. Select **PRINT** in the **MENU**.



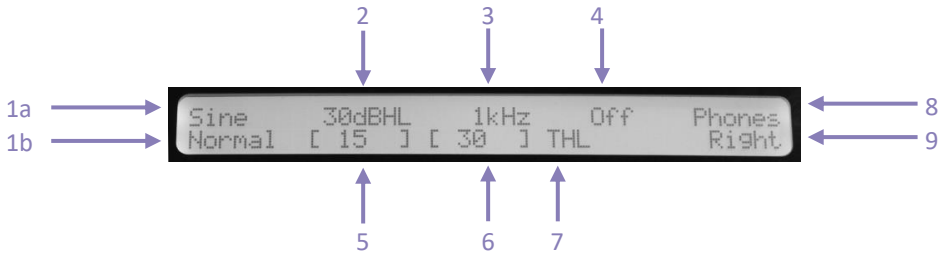
As soon as the printer is ready, select the **F1** key to confirm. The audiogram will then print.



4.8. PERFORMING PURE TONE AUDIOMETRY

4.8.1. PURE TONE SCREEN

The instrument will always start from the tone audiometry screen. The following information is provided on the screen:



1a	**Test Stimuli and Tone present**	Sine or Warble
1b		Pulsed, Continuous
2	**Test Level**	Current present level of selected ear (in this example right ear)
3	**Test Frequency**	Current test frequency
4	**Masking**	Masking Level at current test frequency (in this example masking is off)
5	**Stored Test Level Left Ear**	Test Level stored for Left Ear or Loaded Test Level from previous Test
6	**Stored Test Level Right Ear**	Test Level stored for Right Ear or Loaded Test Level from previous Test
7	**Threshold**	Testing THL, MCL or ULL (also known as UCL[3])
8	**Transducer**	Phones, Insert, Bone, FField (FreeField)
9	**Test ear**	Left, Right, or Both (Speech and Special Tests)

4.8.2. CLEARING PREVIOUS RESULTS

In some cases a previous conducted test might still be present in the Model 270+.



Hit the **CLEAR** button to ensure no remaining results are stored in the short-term memory.

4.8.3. PERFORMING PURE TONE AUDIOMETRY



Use the **SIGNAL** button to choose either AC or BC testing.

Use the Channel 1 rotary control to control the level of the test stimulus. Use the ◄ left and right key ► to change the frequency.

[3] Uncomfortable Loudness Level



Use the **> 100 dB** button, in order to present tones louder than 100 dB.

To change the ear, select either the **EAR** or the **F4** button.

To present (or interrupt) the test stimulus, select the **PRESENT** Button.



When a test tone is presented, the LED above the display labeled with **PRESENT** will illuminate.



When the test person is pressing the patient response switch, the LED above the display labeled with **RESPONSE** will illuminate.

Store the obtained threshold for the selected frequency by pressing the store button. The stored threshold will then show on the screen.

Please note: Previous audiometric test results can be shown on the screen while running a new test sequence. Refer to chapter 4.7.4 to learn more about how to show previous stored test results.

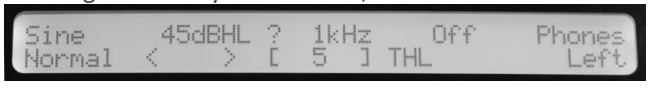
4.8.4. MASKING (PURE TONE AUDIOMETRY)

4.8.4.1. BC MASKING TRANSDUCERS

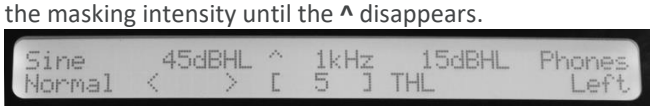
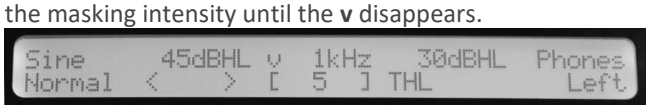
When no insert phones are used, the masking of the bone conduction might be considered challenging when it is required to place both headphones and bone conductor on the patient's head. In this case, the masking earpiece can be used to mask the contralateral ear while the bone conduction is tested.

4.8.5. MASKING INTELLIGENCE

When performing audiometry (with or without masking), the instrument will automatically help by informing the user that masking might be required and advise suggestions. These suggestions are based on the transducers used and will also be shown in the temporary storage of the test.

SYMBOL	INTERPRETATION
	Masking is active and efficient, no additional information is shown on screen. 
?	Masking is currently switched off, but advisable. 
!	Masking is active but considered too high compared to the test signal level.



^	Masking is active. However, the masking level is judged to be too little. It is recommended to increase the masking intensity until the **^** disappears. 
v	Masking is active. However, the masking level is judged to be too high. It is recommended to decrease the masking intensity until the **v** disappears. 

4.8.6. MANUAL MASKING

When the masking channel is active, the LED ring around the Channel 2 rotary control will illuminate white. To activate masking, select the **MASK** button.



Active manual masking is started by selecting **F2** (**MASK**). In this case, the user needs to increase the masking level himself, using the Channel 2 rotary control.

Pressing **F3** (**TRACKED**) activates tracked masking, which means that the control of the test signal level (Channel 1 rotary control) also increases the loudness of the masking signal. The masking signal start level can be set by using the Channel 2 rotary control.

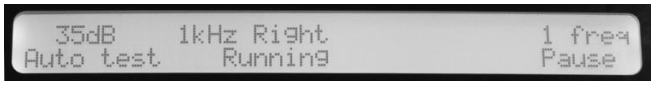
Pressing **F1** (**NONE**) will deactivate masking again. Using the option **CANCEL** will return to the previous test screen.

Please note: Masking the bone conduction can be performed by using either headphones or insert transducers.

4.8.7. AUTOMATIC TESTING (PURE TONE AUDIOMETRY)

Automatic masking can be activated by pressing the **AUTO** button. The option is given to test only one frequency on the current selected ear, all frequencies on the current selected ear or to run a full audiogram on both ears. The measurement procedure will be identical for any of the three methods as well as for AC and BC.

The test sequence will start at 30 dB and increase the level stepwise always by 5dB. When the patient response switch is pressed, the level is decreased by -10dB. While the auto test is ongoing, the **PRESENT LED** is illuminated.



Based on the test settings, the system automatically stores a threshold if the responses made to 2 out of 3 or 3 out of 5 signals are at the same hearing level. The first tone presented is never considered part a response. A valid response consists of 'no response at a level, followed by a response at the next level'. This means that first, the level where the patient cannot hear a tone will be detected before the 2 out of 3 (or 3 out of 5) method applies. It is also required, that the 2 (or 3) equal responses are made in one attempt and no inconsistent answer is given in between.

To pause an automatic test, select **F4**. From here, the test can be continued (**F3**), the current tested frequency can be skipped or the sequence can be stopped (**F4**).



On-screen, a message will show to inform about the status of the test sequence.

MESSAGE	INTERPRETATION
Auto test Running	Indicates the first round of testing. After 100dB has been reached and no response or inconsistent responses were given by the patient, the on-screen instruction will show **RETRY**.
Retry	Retry indicates, that the test is still ongoing but is in a retesting phase. When the patient doesn't respond to 100dB, the test sequence will restart at 30dB. This test will be repeated 3 times in total before **NO RESPONSE!** is shown and the test stops.
Test Finished	Auto testing has successfully finished.
No Response!	The subject did not press the patient response switch during the test phase.
Response Always!	The subject keeps on pressing the response switch at any intensity and thereby gives incorrect information.
Pattern not found	The response pattern of the subject does not meet the criteria.

4.8.8. AUTOMATIC TESTING WITH MASKING (PURE TONE AUDIOMETRY)

Auto-masking needs to be activated in the **AUTO SETTINGS** in order to be functional for the automatic test sequence. Select **MENU** and **AUTO** and activate the setting **AUTO MASK**.

Afterwards, select **AUTO** to start the automatic test sequence and the device will apply masking when needed. On screen, the wording **eMASK** will be shown to indicate that auto-masking is taking place.



4.8.9. FREEFIELD PRESENTING (TONE TESTING)

It is possible to present the air conduction test signals (sinusoid, warble, pulsed test signal) via a loudspeaker. Select the **OUTPUT** button to find your **FFIELD** option and confirm the output by pressing softkey **F3**.



Please note: When two loudspeakers are connected to the device, use **LEFT** and **RIGHT** to select the required loudspeaker.

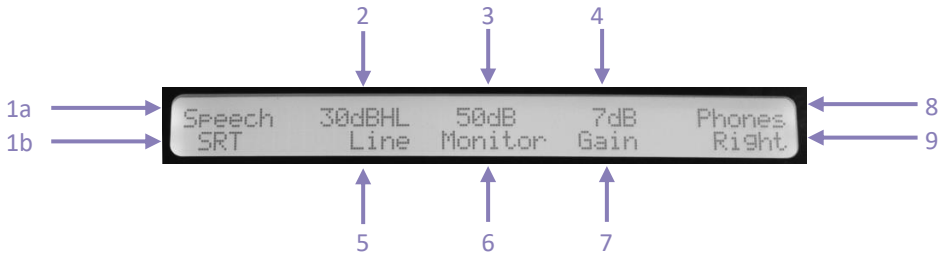
Change the test level and frequency as usual. In order to present a test signal to one loudspeaker and a noise signal to the other, select the **MASK** button and control the volume with the Channel 2 rotary control.

4.9. PERFORMING SPEECH AUDIOMETRY

4.9.1. GENERAL

The Model 270+ has audio line in/out connections (**LINE**) for CD, tape player or MP3 input (e.g. for recorded speech testing) and amplifier output (**MIC.**).

Press the **SIGNAL** button to select between **LINE** and **MIC.** output.



1a	**Module**	Speech module
1b	**SRT Test**	Select **F1** to start SRT test
2	**Test Level**	Current present level of selected ear (in this example right ear)
3	**Monitor Level**	The current monitor level of the headset for the examiner, to listen to the same test sounds as the patient. Use the frequency buttons to change the monitor level
4	**Gain Level**	Use the Channel 2 rotary control to change the gain level
5	**Line or eMic**	Current selection of either line in (e.g. CD) or external Mic (**eMic**) for presenting the speech signals. Use **F2** to change between the two.
6	**Monitor**	Level above shows the current monitor level
7	**Gain**	Level above shows the current gain level
8	**Transducer**	Phones, Insert, FField (FreeField)
9	**Test ear**	Left, Right, or Both (Speech and Special Tests)

4.9.2. TEST EAR

In speech mode it is possible to test either the left or right ear or both ears at the same time via headphones. Use the **EAR** button or the softkey **F4** to choose the presented ear.

4.9.3. MONITOR FUNCTION

Where an acoustic booth/room is used, a patient microphone is installed in the booth and connected to the Model 270+ unit. The operator can then hear the patient through the headset.



In order to adjust the monitor listening levels, the frequency control buttons can be used.

The level of the patient's responses is controlled by using the talkback function as described in chapter 4.6.3.

4.9.4. USING LIVE SPEECH (EMIC.)

Users should be aware that there is a growing body of professional opinion that Live Voice speech audiometry is generally not recommended. Select eMic. to present speech via live speech. The sound will then be presented through the microphone of your external headset.



To ensure the speech present level is set correctly, check the VU meter is set to 0dB.



⃠ VU meter does not reach 0dB line



✔ VU meter reaches 0dB line

Adjust the intensity level for the VU meter by using the Channel 2 rotary control and thereby adjust the **GAIN** level until the present level reaches 0dB. After the VU meter is set at 0dB speech testing can begin.

4.9.5. USING RECORDED SPEECH (LINE)

For recorded speech audiometry, only material with a stated relationship with the calibration signal should be used. Connect a CD, tape/MP3 player, or other sound source to the line in socket of the Model 270+.

Please note: The audiometer line input is intended for connection to audio playback devices that are able to output signals where the line level voltage amplitude is around 0.707Vrms. Using other types of output (i.e. headphone sockets, laptop audio sockets) may result in a reduction of signal level. While some compensation for a reduced level is possible using the audiometer, it is also possible to increase the signal levels of recorded speech test material by using freely available PC software. Contact your distributor for details.

To ensure the correct present level is set, play ~~the 1kHz~~ calibration tone on the recorded material and adjust the input signal such that the LEVEL dB bar graph reads 0dB; the headphone output measured in an IEC 318 ear simulator will now be 89dBSPL for a setting of 70dBHL.

To ensure the speech present level is set correctly, check the VU meter is set to 0dB.



⃠ VU meter does not reach 0dB line



✔ VU meter reaches 0dB line

The start and stop of the recorded speech material are controlled via the audio device itself, not the audiometer.

4.9.6. MEASURING THE SRT SCORE

In order to measure the SRT (speech recognition score), a counter is available. Select **F1** (SRT) to activate the counter.



For any given level of stimulus the display then shows the percentage correct alongside the total number of responses.



To use the counter the operator selects the frequency buttons: left for **YES** or right for **NO** according to the response made by the patient.

The score will be automatically calculated and shown on screen.



Pressing **F3** (**CLEAR**) clears the counter to zero. To exit from the counter mode screen press **F1** again.

The results obtained will be saved in the temporary memory to be printed or sent to the computer. The obtained SRT can also be saved using the **MENU** – **LOAD/SAVE** function. The results may be added to those already established (use **F1** to activate the counter again).

4.9.7. MASKING (SPEECH TESTING)

In some cases masking might be required to be applied to the opposite ear of the test ear. Select **MASK** and choose the preferred option of manual or tracked masking. As soon as masking is active, the light ring around the Channel 2 rotary control is illuminated and speech-weighted masking is now routed to the opposite headphone to that selected.

4.9.8. FREEFIELD PRESENTING (SPEECH TESTING)

Please note: For the following Free Field modes of operation it is essential for the Free Field calibration procedure described in Appendix A to have been performed. This aspect may also be subject to local requirements or legislation.

Ensure the external amplifier/loudspeaker is correctly connected to the audiometer. Select **OUTPUT** button, to select the transducer the test signal shall be presented to.



Select **F3** to utilise the connected loudspeakers to present the signal via **FREEFIELD**.



Ensure the intensity level of the signal presented via loudspeaker is correctly set via the VU meter display.



⃠ VU meter does not reach 0dB line



✔ VU meter reaches 0dB line

Please note: When two loudspeakers are connected to the device, use **LEFT** and **RIGHT** to select the required loudspeaker.

Change the test level and frequency as usual. In order to present a test signal to one loudspeaker and a noise signal to the other, select the **MASK** button and control the loudness with the Channel 2 rotary control.

Please note: For recorded speech play the 1kHz calibration tone on the recorded material and follow the calibration procedure in Appendix A.

4.10. PERFORMING SPECIAL TESTS

4.10.1. STENGER (TONE AUDIOMETRY)

The Stenger test is often performed to identify pseudohypacusis and malingering subjects. It is necessary to have an audiogram done before the Stenger test can be performed.



Both ears will be stimulated simultaneously but with different intensities. The patient will be instructed to press the response switch when a tone is heard. A normal hearing patient will always locate the sound in the ear, which is stimulated with higher intensities.

When Stenger was selected in the **SPECIAL** menu, **BOTH** will be shown in the ear selected and also both light rings around both Channel rotary controls will illuminate.



To start the sequence, adjust the test tone in the poorer ear to be presented at 10 to 20dB above the indicated threshold and the test tone in the better ear to be 20dB below threshold. The signals will then be presented to the subject via the **PRESENT** button. Further, the intensity in the poorer ear will be increased and presented again, until the loudness is higher in the poorer ear than in the better ear.

If the patient at that point does not respond to the test signal anymore, the test result is called a “positive Stenger”, indicating the patient is ignoring the stimulus on purpose. The Stenger test is called “negative Stenger”, when the patient is still responding to the presented stimulus in the better ear.

The test can be performed at all frequencies between 0.125 to 8kHz. Use the frequency buttons to adjust the frequency.

Please note: Selecting the **SPECIAL** button again will stop the Stenger Test and return to the Tone Audiometry Screen.

4.10.2. PERFORMING ABLB

The ABLB Test (**A**lternate **B**inaural **L**oudness **B**alance), also known as the Fowler Test, is used in subjects with a unilateral hearing loss to identify how loudness is perceived between the ears. The ABLB test is used in conductive hearing loss to detect recruitment at frequencies where recruitment is assumed. It is necessary to have an audiogram done before the ABLB test can be performed.

When ABLB was selected in the **SPECIAL** menu, **ABLB** will be shown in the ear selected.



To start the sequence, adjust the test tone in the poorer ear to be presented at 20dB above the indicated threshold. The intensity is fixed in the impaired ear and will not be changed. The level of the better hearing ear is set 5dB above hearing threshold.

A sinusoid is presented alternatively to the ears. The subject is tasked to judge the loudness of the tone presented to the better ear to match the loudness of the tone perceived in the poorer ear. This procedure is also known as loudness balance.

The test can be performed at all frequencies between 0.125 to 8kHz. Use the frequency buttons to adjust the frequency.

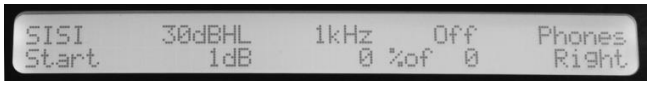
Use the Channel 1 rotary control to adjust the **Left** ear level and the Channel 2 rotary control to adjust the **right** ear signal. Pressing the **PRESENT** key interrupts the signal presented. Select **STORE** to save the measurement.

Please note: Selecting the **SPECIAL** button again will stop the ABLB Test and return to the Tone Audiometry Screen.

4.10.3. PERFORMING SISI

The SISI Test (**S**hort **I**ncrement **S**ensitivity **I**ndex) is used to detect hypersensitivity to small intensity increments, often found in patients with cochlear impairment. It is necessary to have an audiogram done before the SISI test can be performed.

When SISI is selected in the **SPECIAL** menu, **SISI** will be shown in the ear selected.



Both ears will be stimulated simultaneously and continuously.

The test can be performed at all frequencies between 0.125 to 8kHz. Use the frequency buttons to adjust the frequency. Choose the frequency where the maximum bone conduction hearing loss was found. The SISI Test is often performed at 1 and 4kHz.

Use the Channel 1 rotary control to adjust the test intensity.

Use **F1** (UP) and **F2** (DOWN) to adjust the step size between 1 and 5dB. To familiarise the patient with the SISI Test procedure 5dB increments are often used, as 5dB changes are easier to detect than discriminating 1dB increments.

Adjust the test tone to be presented at 20dB above the indicated threshold. Instruct the subject to indicate when a brief jump in the loudness is heard.

To start the test sequence with the selected step size, select **F3** (SISI) and the counter screen will be seen.

During the actual test phase, twenty 1dB increments should be presented to the subject. The continuous test tone is increased by 1dB for a period of 0.2 seconds every 4.8 seconds. Select the **PRESENT** to present the increment change. If the subject could hear the level change, select the **RIGHT FREQUENCY** button, if the change was not heard, push the **LEFT FREQUENCY** button. The Model 270+ will calculate the percentage of detected increments accordingly. To delete the displayed score, select **F3** (**CLEAR**). To return to the initial SISI display, select **F4**.

The score is expressed as a percentage of ratio of the increments heard to the delivered increments (all increments heard = 100% and no increments heard = 0%).

RESULT SISI TEST	CONCLUSION RECRUITMENT
70 – 100 %	Positive
35 – 65 %	Indifferent
0 – 30 %	Negative

Please note: Selecting the **SPECIAL** button again will stop the SISI Test and return to the Tone Audiometry Screen.

4.10.4. PERFORMING MHA

When selecting MHA, you will be taken to the Speech Module to start the hearing aid simulation.



Select **F3** to change the filter settings and to present different hearing losses to the subject. Use softkey **F2** to change the input from **LINE** to **eMic**. Use softkey **F1** to start the counter function, which can be controlled with the frequency buttons. Select **F1** again to stop the counter.

SCREEN	DEFINITION
mFLAT	No filter used
MHA6	1kHz High Pass filter 6 dB/octave
MHA12	1kHz High Pass filter 12 dB/octave
MHA18	1kHz High Pass filter 18 dB/octave
MHA24	1kHz High Pass filter 24 dB/octave
MHAHFE	1kHz High Pass filter 12 dB/octave and 2kHz High pass filter 12 dB/octave

Please note: Selecting the **SPECIAL** button will stop the MHA Test and return to the Tone Audiometry Screen.

4.10.5. PERFORMING HLS

When selecting HLS, you will be taken to the Speech Module to start the hearing loss simulation.



Select **F3** to change the filter settings and to present different hearing losses to the subject. Use softkey **F2** to change the input from **LINE** to **eMic**. Use softkey **F1** to start the counter function, which can be controlled with the frequency buttons. Select **F1** again to stop the counter.

SCREEN	DEFINITION
sFLAT	No filter used
SHL6	1kHz Low Pass filter 6 dB/octave
SHL12	1kHz Low Pass filter 12 dB/octave
SHL18	1kHz Low Pass filter 18 dB/octave
SHL24	1kHz Low Pass filter 24 dB/octave
SHL12A	1.5kHz Low Pass filter 12 dB/octave
SHL12B	2kHz Low Pass filter 18 dB/octave

Please note: Selecting the **SPECIAL** button will stop the HLS Test and return to the Tone Audiometry Screen.

4.10.6. PERFORMING DECAY

The Decay Test, also known as the Carhart Test, is used in subjects with sensitivity loss to measure fatigue. It is necessary to have an audiogram done before the Decay test can be performed.



Please note: As soon as the **DECAY** test is selected from the **SPECIAL**, the Decay Test will start immediately.

Before starting the Decay Test, select the ear to be tested, the test frequency as well as the test level. Adjust the test tone to be presented at 5dB above the indicated threshold. Instruct the patient to hold the response switch while the tone is heard and to release the switch as soon as the tone is no longer heard. Select the **DECAY** test in the menu to start the test sequence.

The test stops automatically if the patient is able to hear the tone at the same level for 60 seconds or if the level is increased for 30dB.

Please note: Selecting the **SPECIAL** button again will stop the Decay Test and return to the Tone Audiometry Screen.

4.11. TRANSFERING DATA TO PC

The Model 270+ is supplied with software to allow connection to a computer for the transfer of test results. You must use the designated USB cable supplied.

TRANSFER TO NOAH	TRANSFER TO AMPLISUITE
To transfer test results stored within the audiometer to a NOAH database the Amplivox NOAH Audilink or NOAH ampliSuite software must be installed on to a computer.	Amplivox ampliSuite allows data to be transferred to a computer and subsequently viewed, annotated & printed. This software is supplied on a USB stick which includes this operating manual.

Refer to the installation & operating instructions provided with NOAH Audilink or ampliSuite for further details on how to install and operate the PC software. It is required to have the latest USB drivers installed on the PC in order to have a working communication between instrument and computer.

Ensure the USB cable is attached to the Model 270+ and the USB port on the PC. Load the audiogram from the internal device memory so you can see the data on the screen of the Model 270+. Open ampliSuite and select download. The measurement will than show in the software.

5. ROUTINE MAINTENANCE

5.1. GENERAL MAINTENANCE PROCEDURES

The performance and safety of the instrument will be maintained if the following recommendations for care and maintenance are observed:

1. It is recommended that the instrument go through at least one annual service, to ensure that the acoustical, electrical and mechanical properties are correct. This should be carried out by an authorised service centre in order to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load that could involve damage.
3. To ensure that the reliability of the instrument is maintained, we recommend that the operator, at short intervals, for instance once a day, performs a test on a person with known data or the recommend Amplivox ER75.
4. If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always disconnect the mains power adaptor during the cleaning process and be careful that no fluid enters the inside of the instrument or accessories.
5. After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant.



CAUTION

- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilise or immerse the instrument or accessories in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessories
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use accessories

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces

5.2. CLEANING THE MODEL 270+



CAUTION

- Use caution while cleaning.
- Before cleaning, remove the Model 270+ from mains power.
- Do not allow any liquid to enter any part of the instrument or accessories.
- Do not autoclave or sterilise the instrument or any accessories.
- Do not use hard, sharp or pointed objects to clean any part of the instrument or an accessories.
- If parts have been in contact with fluids do not allow them to dry before cleaning.
- Follow local best practice and safety guidelines if available.
- Clean the instrument by wiping the outer case with a lint free cloth lightly dampened with cleaning solution. Recommended cleaning and disinfection solutions are warm water with mild, nonabrasive cleaning solution (soap) and/or Clinical wipes (for example Clinell Universal).
- If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors and seams where plastic pieces connect such as under the rubber buttons on the Model 270+. Follow the instructions on the disinfection product.

5.3. CLEANING THE ACCESSORIES

5.3.1. TRANSDUCER MAINTENANCE

Before use check the transducer cables and connectors for signs of wear and/or damage. If you find any, please replace the item immediately by contacting Amplivox or your Amplivox distributor, requesting the relevant part number.

Handle the audiometric headset, bone vibrator headset and other accessories with care. For parts that are in direct contact with the patient it is recommended that replacement parts are used or the parts are subjected to a standard disinfecting procedure between patients.

This includes physically cleaning and use of a recognised disinfectant. The specific manufacturer's instructions should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

During the cleaning process do not allow moisture to enter the earphone, insert masker, monitor or microphone grills etc. For specific accessories refer to the sections below.

5.3.2. EARPHONES

Clean the ear cushions (including those on the Audiocups, if used) with a recognised disinfectant, e.g. a “Mediswab” or “Clinell”.

5.3.3. INSERT MASKER

Never insert or in any way use the insert masker without using a new, clean and fault-free test tip. This part is for single use only - that is, each test tip is intended to be used once only for a single ear for a single patient. Do not reuse test tips as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

5.3.4. INSERT EARPHONES

The disposable foam eartips supplied with the optional IP30 insert transducers are for single use only - that is, each eartip is intended to be used once only for a single ear for a single patient. Do not reuse eartips as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

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

5.3.5. MAINS ADAPTER MAINTENANCE

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



CAUTION

DO NOT USE ANY OTHER TYPE OF MAINS ADAPTER

5.4. ACCESSORIES/REPLACEMENT PARTS

Some reusable accessories are subject to wear with use over time. We recommend that you keep stock of these replacement parts.

5.5. REPAIR

Amplivox Ltd is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons
- a 1 year service interval is maintained
- the electrical installation of the relevant room complies with the appropriate requirements, and
- the equipment is used by authorised personnel in accordance with the documentation supplied by Amplivox Ltd.

It is important that the customer (distributor) fills out a returns form and emails it to support@amplivox.com.

This should be done every time an instrument is returned to Amplivox Ltd.

When packing the instrument for shipping, please use the original shipping carton and packing materials. Place the instrument parts in plastic bags before packing to prevent dirt ingress.

5.6. WARRANTY

Amplivox gives the purchaser the following warranty;

If within 36 months from the date of dispatch, any defect in respect of material or workmanship within our control is discovered, we will make good the defect without charge, subject to the following conditions;

- Notice of the fault is given to Amplivox within the warranty period.
- The instrument is forwarded, carriage paid, to Amplivox Limited at the address on the returns form or as otherwise directed.
- Return carriage is free of charge for customers in the UK and chargeable for overseas customers.
- The responsibility of Amplivox under this warranty is strictly limited to making good the defect in the instrument itself.
- No attempt has been made to affect a repair or adjust the calibration or alter the instrument from the original build standard.
- Defects caused by abnormal conditions of use, accident or neglect are expressly excluded.
- Earphones, bone vibrator 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.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Amplivox Ltd service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Amplivox's expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Amplivox Ltd shall be at purchaser's risk.

In no event shall Amplivox Ltd be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Amplivox Ltd product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Amplivox Ltd shall not be responsible for, any loss arising in connection with the purchase or use of any Amplivox Ltd product that has been:

- repaired by anyone other than an authorised Amplivox Ltd service representative;
- altered in any way so as, in Amplivox Ltd opinion, to affect its stability or reliability;
- subject to misuse or negligence or accident, or that has had the serial or lot number altered; defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by Amplivox Ltd.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Amplivox Ltd. Amplivox Ltd does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Amplivox Ltd any other liability in connection with the sale of Amplivox Ltd products.

AMPLIVOX LTD DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

5.7. CALIBRATION AND RETURN OF THE INSTRUMENT

Amplivox recommends that the Model 270+ is calibrated annually. The date of the last calibration is displayed when selecting **MENU** and the **Frequency UP** key.

Please contact Amplivox or the designated distributor for details of calibration services.

6. TECHNICAL SPECIFICATIONS

6.1. STANDARD AND REGULATORY

Medical CE mark	The CE mark indicates that Amplivox Ltd meets the requirements of Annex II of the Medical Device Regulation.	
Class	The Model 270+ Audiometer is classified as a Class IIa device under Annex IX (Section 1) of the EU Medical Device Regulation.	
Standards and Conformance	**Safety:**	IEC 60601-1 (plus UL, CSA & EN deviations)
	EMC:	IEC 60601-1-2
	Performance:	Type 2 (IEC 60645-1:2001) Type B-E (IEC 60645-2:1993) Type 3BE (ANSI S3.6:2004)
Physical	**Display:**	2 lines of 24 characters
	Dimensions (base unit):	L x W X H: 249 x 374 x 90 mm / 9.8 x 14.33 x 3.54 inchpo (excluding connections)
	Weight (base unit):	1400g / 3.08 lbs
Power Supply	**Mains power:**	100-240Vac; 50/60Hz; 0.5A
	Warm-up period:	None at room temperature
Environmental	**Operating temperature:**	+15°C to +35°C / + 59°F to +95°F
	Operating humidity:	30 % to 90 % RH (non-condensing)
	Operating atmospheric pressure:	700 hPa to 1060 hPa
	Transport: storage temperature:	-20°C to +70°C / -4°F to +94°F
	Transport and storage humidity:	10 % to 90 % RH (non-condensing)
	Transport and storage atmospheric pressure:	500 hPa to 1060 hPa
Equipment Classification	**Type of protection against electric shock:**	Powered via SELV ClassII mains adapter
	Degree of protection against electric shock:	Type B applied part
	Degree of protection against ingress of water:	Not protected
	Mode of operation:	Continuous operation
	Equipment mobility:	Portable

6.2. GENERAL

Languages:		English, German
Database	**No. of records stored:**	10
	Data storage:	Any recording can be stored once the tone or speech audiogram was taken. Special tests cannot be stored.
	Data held:	THL, MCL, UCL threshold Speech SRT score
Printing	**Supported printer:**	Sanibel MPT-II
	Interface:	Cable supplied

	Information printed:	Tone audiogram in table format for THL, MCL, ULL (UCL) and BC for left and right ear; space for patient details to be entered.
PC Interface	**Serial Interface:**	USB Version 1.1
	Information sent:	Tone Audiometry: THL, MCL, ULL (UCL), BC, masked thresholds and SRT for speech test results for both ears,
Communication:		Integral talkover facility Talkover and talkback facility via external headset

6.3. TONE AUDIOMETRY

Transducer	**Outputs:**	Left earphone, Right earphone, Bone (L&R) Insert masking and Freefield
	Options:	AC: DD45 earphones (supplied), IP30: Insert earphones (option) BC: B-71 bone vibrator (supplied)
	Transducer types and reference levels:	DD45: ISO 389-1, Table 3 IP30: ISO 389-2, Table 1 B-71: ISO 389-3, Table 1
	Static headband force:	Headphones: 4.5N Bone vibrator: 5.4N
	Sound attenuation characteristics:	ISO8253-1, Table 3
	Airborne sound from bone vibrator:	See Br. J. Audiol. 1980, P73-75
Insert Masking Earpiece	**Calibration method:**	With 2cc coupler compliant with IEC 126
Test Signals	**Frequency:**	AC: 0.125 – 8 kHz BC: 0.25 – 8 kHz
	Frequency accuracy:	< 1 %
	Distortion:	< 2 %
	Output level range:	AC: -10dBHL to 120dBHL maximum BC: -10dBHL to 70dBHL maximum FF: Up to 90dB
	Level step size:	2 or 5dB
	Tone present:	Single, Pulsed, Warble or Continuous
Frequency Modulation	**Carrier frequencies:**	125Hz to 8kHz as per pure tones
	Modulation waveform:	Sinusoidal
	Rising and falling symmetry:	Symmetrical on linear frequency scale
	Modulating frequency:	15.625Hz
	Frequency deviation:	+/-10%
Masking	**Signals:**	Narrow bands at test frequencies
	Narrow-band noise bandwidth:	Meets IEC 60645-1; ANSI S3.6
	Speech noise bandwidth:	Meets IEC 60645-2; ANSI S3.6
	Reference levels:	Refer to ISO 389-4
	Output level range:	90dBHL max (250-4 kHz)
	Level accuracy:	Within 3dB
	Level Step Size:	2 or 5dB Synchronous channel (Track/ Lock function)

Clinic Tests/ Special Tests		SISI Stenger ABLB (Fowler) Decay (Carhart Test) MHA (Master Hearing Aid) HLS (Hearing Loss Simulation)

6.4. SPEECH TESTING

Material:		Recorded speech: Tape or CD/MP3 input Live speech: 1 x microphone input
Masking:	**Signals:**	Speech weighted noise
Monitoring Indicator:	**VU Meter:**	IEC 60268-17; ANSI S3.6:2004)
Speech Channel:	**Frequency response:**	+/- 3dB from 100Hz to 10kHz electrical
	Voltage requirement at 0dB input level setting to zero meter:	1.20Vrms at 1kHz
	Output level:	90dBSPL at 1kHz for attenuator setting of 70dBHL with level meter at 0dB

6.5. MAXIMUM HEARING LEVELS PROVIDED BY EACH FREQUENCY

FREQUENCY [HZ]	AIR CONDUCTION [DB HL]	BONE CONDUCTION [DB HL]
125	80	-
250	100	45
500	115	60
750	120	65
1000	120	70
1500	120	70
2000	120	70
3000	120	70
4000	115	70
6000	110	50
8000	100	40

6.6. EARPHONE SOUND ATTENUATION CHARACTERISTICS

FREQ [HZ]	125	250	500	1000	2000	4000	8000
ATTENUATION [DB]	2	5	7	15	25	31	23

7. EMC GUIDANCE & MANUFACTURER'S DECLARATION



CAUTION

- This instrument is suitable in hospital 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
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers 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, transducers and cables are listed in chapter 1.4.
- 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 instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTICE

- ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:
  This instrument does not have an ESSENTIAL PERFORMANCE. Absence or loss of cannot lead to any unacceptable immediate risk.
- Final diagnosis shall always be based on clinical knowledge
- There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1
  NOTICE: There are no deviations from the collateral standard and allowances uses
  NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 270+ Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Model 270+ Audiometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Model 270+ 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.
RF emissions CISPR 11	Class A	The Model 270+ Audiometer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Model 270+ Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Model 270+ 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 270+ Audiometer requires continued operation during power mains interruptions, it is recommended that the Model 270+ Audiometer be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 Model 270+ Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the Model 270+ 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 Model 270+ Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	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]
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	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 stations for radio (cellular as base /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 Model 270+ Audiometer is used exceeds the applicable RF compliance level above, the Model 270+ 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 Model 270+ 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 Model 270+ Audiometer

The Model 270+ Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 270+ Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 270+ 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** d = 1.2√P	**80 MHz to 800 MHz** d = 1.2√P	**800 MHz to 2.5 GHz** d = 2.3√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 meters (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.

APPENDIX A - FREE FIELD CALIBRATION PROCEDURE

7.1. GENERAL

The following is a brief description of the equipment and procedures to be used with the Model 270+ audiometer as a means of performing freefield calibration.

The following calibration should be performed before any freefield tests are conducted, and repeated if any changes to equipment positions or settings are made, or if there are other changes to the room (e.g. furniture moved). The procedures outlined below cover calibration for both speech and warble tone modes of audiometry. If both modes are to be used then speech calibration **must** be carried out first. If only warble mode is to be used then only the warble part of the calibration procedure may be carried out.

However, if speech mode is required later (and a speech calibration is performed) this will invalidate any previous warble calibration which would then need to be repeated. If warble tones are to be used as a means of equalising the frequency response in the speech calibration then this will invalidate any previous warble calibration which would then need to be repeated when warble tone testing is required.

7.2. ASSURANCE OF CALIBRATION

It must be emphasised that it is the responsibility of the equipment operator to ensure that correct freefield calibration has been achieved, and it is recommended that the standards for freefield & speech testing & calibration (e.g. ISO 8253-3 & ISO 389-7) and other appropriate reference works are consulted.

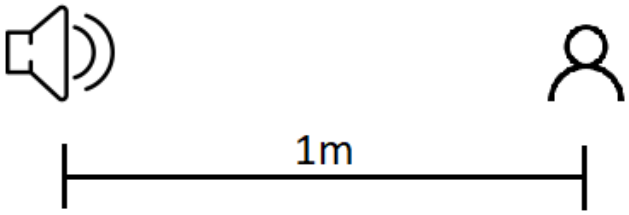
It is assumed that the room, speakers and listening position have been set up in conformance with the relevant standards and that the required calibration equipment, operating procedures and trained technical staff are available to perform this operation. Once calibrated, items should not be moved, removed, or added to the room without re-calibration.

7.3. EXTERNAL LOUDSPEAKER

The SP90A Active Loudspeaker by RadioEar is specified for use of the Model 270+ audiometer in freefield modes of operation.

7.4. CALIBRATION SET-UP

Place the speaker(s) in the desired position(s), at least 1 meter from the subject's listening (head) position. Refer to the specification for the test to be performed for correct loudspeaker and subject alignment(s).



For calibration, the measuring microphone of a sound level meter (SLM) is placed at the reference point (the point that the subject's head will be located).

7.5. FREEFIELD SPEECH CALIBRATION

7.5.1. GENERAL

The freefield speech calibration is carried out in two stages:

1. The speech channel, which contains two elements:
    - an optional equalisation phase
    - a level-setting phase
2. The competing noise channel, which may be omitted if competing noise is not required

7.5.2. CALIBRATING THE SPEECH CHANNEL: EQUALISATION (OPTIONAL)

Follow the steps described below to perform equalisation:

1. Connect an external speech source (e.g. CD or tape/MP3 player) to the audiometer.
2. Switch the device on and enter the **SPEECH** module.
3. Select the **FREEFIELD** option via the **OUTPUT** button.
4. Use softkey **F2** to select **LINE** as input signal.
5. When more than one loudspeaker is used, select the correct loudspeaker by choosing **LEFT** or **RIGHT**, pressing softkey **F4**.
6. After the selection is done, play the test signal from the speech recording, which should either be:
    - pink noise used with a third-octave spectrum analyser and the SLM
    - third-octave noise bands used with the SLM
7. Use the Channel 1 rotary control set the output to 70dBHL and adjust the external amplifier to give a reading of 90dBSPL as measured by the SLM at the reference point.

    The response should then be checked to be within the following limits (IEC 60645-2:1993 Section 10.1):

FREQUENCY RANGE [HZ]	TOLERANCE [DB]
125 to 250	+0/-10
250 to 4000	+3/-3
4000 to 6300	+5/-5

If necessary, adjustments should be made using the amplifier controls or an additional graphic equaliser to achieve this response.

As an alternative to using an external speech source, the warble-tone calibration method and controls may be used to achieve this response. Note that this will invalidate any previous freefield warble tone calibration, and this must be repeated when warble tone testing is required.

7.5.3. LEVEL SETTING

The calibration tone from the speech recording should be played and the external amplifier volume control used to give a reading of 90dBSPL for a 70dBHL instrument setting. Once set, no further adjustment should be made to the external amplifier or graphic equaliser controls (if used for equalisation).

If more than one set of test recordings is to be used then the following procedure can be used to allow for minor differences in calibration levels:

- Set up as above for the most commonly used test recording

- Measure the actual listening point level for when playing the calibration tone of each alternative set of test recordings
- For each alternative set of test recordings produce a correction table (the difference between the actual listening point level measured and 90dBSPL)
- Apply this correction to the output level of the audiometer while conducting a test to compensate for the minor difference in calibration level

7.5.4. CALIBRATING THE COMPETING NOISE CHANNEL

Identify if a warble tone calibration is not to be carried out. If warble tones are to be calibrated (or if the warble tone calibration method is used to equalise the speech frequency response) then the competing noise channel may be calibrated after the warble procedure as the instrument will already be in the appropriate display mode for this operation.

7.6. FREEFIELD WARBLE TONES CALIBRATION

7.6.1. ENTERING FREE FIELD CALIBRATION MODE

- Press **MENU,** press **F1** key to enter **Config** and move through the menu items and access the **SET FREFIELD LEVELS** screen. Select the **YES** key.
- Press Save and you are now presented with the freefield calibration screen for Warble tones.
- The audiometer will now output at 70dBHL from the Left channel.

As reference for the calibration of warble tone sound pressure levels, the values from ISO 389-7, Table 1 are used (binaural, on-axis).

FREQ [HZ]	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
DB SPL	92	81	74	72	72	70.5	68.5	64	63.5	72.5	81.5

7.6.2. CALIBRATION PROCEDURE

If a calibration of the speech channel has already been carried out:	Adjust the calibration level for the 1kHz, Left channel using the Channel 1 rotary control to reach the SPL level specified above as measured by the SLM.
If a calibration of the speech channel is not required:	The output of the external amplifier should be set in order to achieve the level specified above at 1000Hz (i.e. 72dBSPL) as measured by the SLM with the audiometer set to 0dB compensation. The amplifier's level control should **not** then be changed.

When 1kHz calibration is complete continue with the calibration of the other frequencies of channel 1:
At every other frequency the adjustment should then be made as follows to give the above values as measured by the SLM.

1. Change frequency using the frequency keys and then adjust the calibration level for the new frequency using the Channel 1 rotary control to reach the correct level as measured by the SLM
2. Repeat the above until all frequencies have been calibrated for the Left channel

To calibrate the Right channel (if required) press softkey **F3** to select **RIGHT** (do **not** change the amplifier's volume control).

1. Adjust the calibration for all of the right channel frequencies (including 1000Hz) by using the frequency keys and the Channel 1 rotary control as described above
2. To store the levels and leave Freefield calibration mode, press the softkey **F4** key
3. If required, all calibration levels can be set to a default of zero by pressing **Softkey F1** ('Zero all') while in freefield calibration mode

It is possible that, because of the characteristics of the listening room or test set-up, the calibration levels listed above cannot be achieved because the limit of adjustment is reached for one or more frequencies. Re-arrangement of the listening room may improve the situation, but if not, the following is a possible solution:

- Set all of the frequencies for which calibration can be achieved
- For frequencies where this is not possible, adjust each to be a multiple of 5dBs from the required level
- Produce a correction table for each frequency for which calibration could not be achieved to be applied to the output level of the audiometer while conducting a test to relate the instrument display to actual output level from the speakers.

7.6.3. CALIBRATING THE COMPETING NOISE CHANNEL

This part of the calibration procedure may be omitted if freefield speech calibration is not required.

1. Enter the Freefield calibration mode through the **MENU**
2. Press the **F2** softkey and the display will change to indicate the option to adjust the competing noise calibration level – the legend "Sp Mask" is used to indicate this
3. Without changing the setting on the external amplifier use the Channel 1 control to adjust the level of the competing noise to 90dBSPL as measured by the SLM using dBA settings.
4. Calibrate each channel, pressing the RIGHT and LEFT keys to switch between channels
5. If necessary it is possible to switch between speech (competing noise) and warble calibration modes by pressing SPEECH and WARBLE respectively
6. To store the levels and leave Freefield calibration mode, press the SAVE key

7.7. FREEFIELD LIVE SPEECH CALIBRATION

Note: Users should be aware that there is a growing body of professional opinion that Live Voice speech audiometry is generally not recommended. Exceptional skill and concentration are required to achieve accurate and consistent levels.

1. Connect a microphone to the **MIC1** input on the audiometer
2. Press **SPEECH** and use Softkey 2 to ensure that 'MIC' is displayed in capitals (indicating that the external microphone is selected)
3. The input signal is adjusted in 1dB steps with the Channel 2 rotary control
4. Input signal adjustment should be made to adjust for the operator's voice to peak at the 0dB point on the LEVEL dB bar graph
5. If recorded speech has been calibrated no further action is necessary
6. If recorded speech has not been calibrated, the volume control of the amplifier should be adjusted so that the SLM reads 90dBSPL at the listening point with a 70dBHL setting on the instrument; note that this is an approximate setting only, as it is not possible to produce a true calibration signal in live speech

APPENDIX B – USE WITH NON-MEDICAL ELECTRICAL EQUIPMENT

Any person who connects external equipment to signal input, signal output or other connectors has created a medical electrical system and is therefore responsible for the system complying with the requirements of clause 16 of IEC 60601-1:2005 *(General requirements for basic safety and essential performance).*

Please note that if connections are made to standard equipment like printers and networks, special precautions must be taken in order to maintain medical safety. The following notes are provided for guidance in making such connections to ensure that the general requirements of clause 16 of IEC 60601-1:2005 are met.

The following signal inputs and outputs on the Model 270+ audiometer are electrically isolated to the requirements of IEC 60601-1 in order to reduce any potential hazard associated with the use of mains-powered equipment connected to these inputs and outputs:

SOCKET LABEL	SOCKET TYPE	TYPICAL CONNECTION
DATA	6 pin mini DIN	Printer
LINE IN	3.5mm jack	CD/MP3 Player
LINE OUT	3.5mm jack	Amplifier
USB	USB Connector	Computer

External equipment intended for connection to signal input, signal output or other connectors, shall comply with the relevant IEC or international standards (e.g. IEC 60950, CISPR 22 & CISPR 24 for IT equipment, and the IEC 60601 series for medical electrical equipment).

Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in IEC 60601-1 (at least 1.5m from the patient).

The operator must not touch the connected equipment and the patient at the same time as this would result in an unacceptable hazard.

Refer to Diagrams 1 to 5 below for typical configurations of connected peripheral equipment. Refer to Amplivox Limited at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.

Diagram 1: Model 270+ used with the medically-approved mains adapter



Diagram 2: Model 270+ used with the medically-approved mains adapter and printer

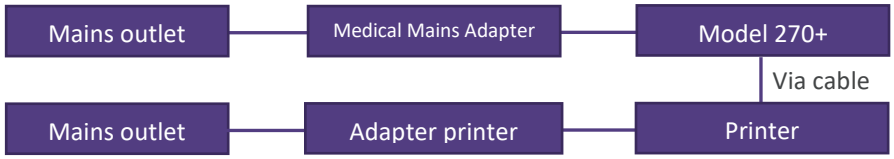


Diagram 3: Model 270+ used with the medically-approved mains adapter and PC

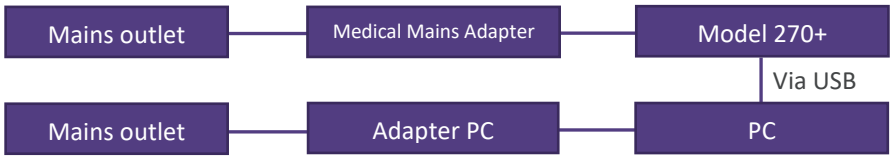


Diagram 4**:** Model 270+ used with the medically-approved mains adapter and CD/Tape player

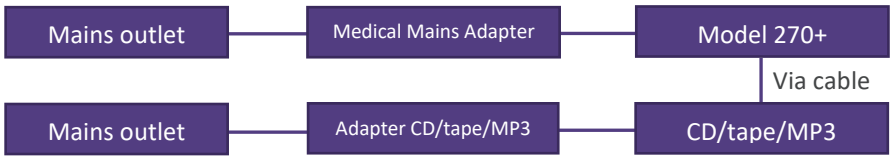
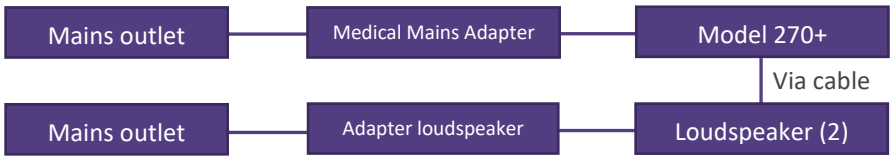


Diagram 5: Model 270+ used with the medically-approved mains adapter and external loudspeaker



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