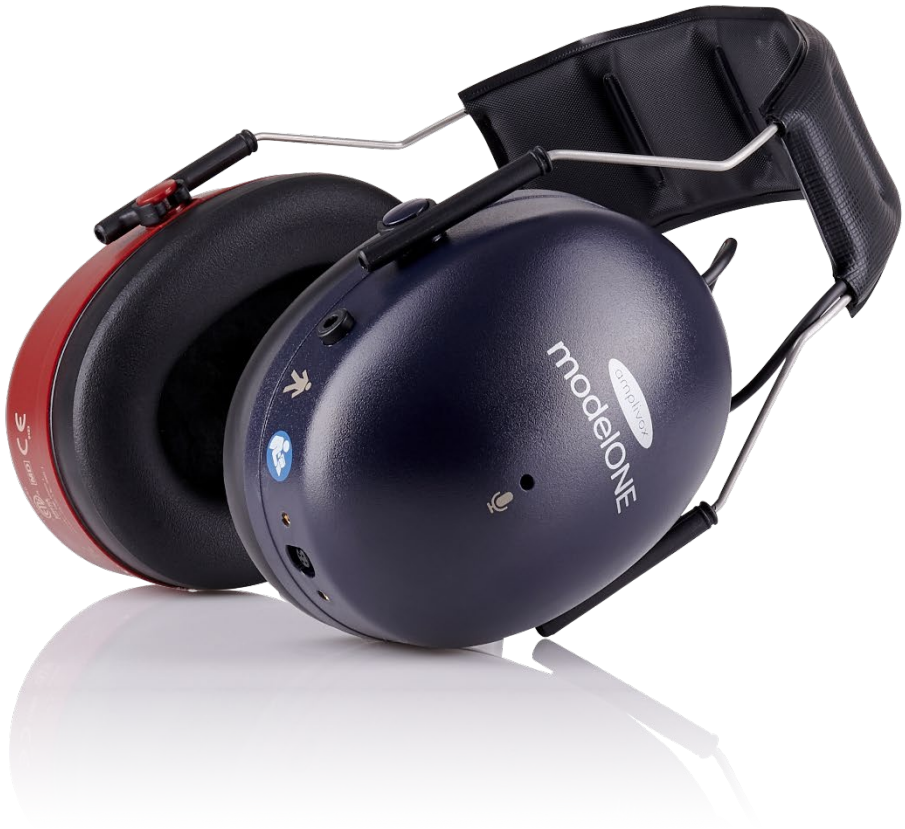
amplivox

For everyone

modelONE

Instruction for use



D-0143451-A
June 2025

About this manual

Read this operating manual before attempting to use the instrument.

This manual for the modelONE

This product is manufactured by:
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CE 0123

EC REP

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

Table of contents

1.Introduction

1.1. Thank you

Thank you for purchasing the modelONE PC-based screening audiometer. Consisting of noise-attenuating headphones, an integrated USB to PC cable and Sound Room Microphone, the modelONE provides optimal patient comfort, user confidence and superior reliability.

1.2. Intended applications

For fast, accurate and repeatable hearing tests, the modelONE is the perfect solution. Designed to provide occupational health professionals and non-audiologists with unrivalled performance, efficiency and guided testing.

The device is operated directly via a PC with our state-of-the-art audiological data management software - Amplisuite. Custom-built, Amplisuite offers users a modern and simple way to present, review and process patient test results.

The modelONE can also be used as part of Amplivox BEEP; the ideal solution for customer outreach, acquisition and next-step rehabilitation. In this instance, the modelONE connects to our Amplisuite BEEP software.

Please see Amplisuite or Amplisuite BEEP IFU for software installation and operation.

1.3. Intended patient target group

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

1.4. Contraindications

As the tests are conducted by the client themselves, information about potential outer and external auditory canal abnormalities cannot be recorded and might have an impact on the test result.

Testing might be impacted 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.

1.5. Standard and optional accessoires

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

Standard accessories			
modelONE	8531884	Carry case	8531412
USB A cable	8518617	Calibration certificate	
USB C cable	8518615		
USB-C to USB-A Adapter	8526453		

* Please contact Amplivox for further information

1.6. 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, and carriage paid to the Amplivox service department. Return carriage is free of charge for customers in the UK and chargeable for overseas customers.

1.7. 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.

1.8. Malfunction

WARNING

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has

caused, or potentially could cause such harm, it must be quarantined immediately. Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Amplivox Ltd and the local national competent authority.

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 on the device:

Symbol	Explanation
	Follow Instructions for Use
	**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, 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.
CE 0123	The CE-mark indicates that Amplivox Ltd meets the requirements of the Medical Device Regulation (EU) 2017/745. TÜV Product Service, Identification No. 0123, has approved the quality system.
SN	Serial number.
	Manufacturer
	Date of manufacture.
	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.
MD	Medical Device.
	Built-in microphone: Room monitor.
amplivox	Company Logo.

2.3. Safety instructions

2.3.1. General

The following safety precautions must be always observed. 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 organization using this instrument, the more stringent rules should take precedence.

The ModelONE is intended to be setup by hearing healthcare professionals (i.e. ENT doctors, audiologists), nurses or technicians who have been trained in the proper use of the device. In general, audiometric equipment should always be used or supervised by trained personal.

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. Defective products 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.

The 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 ModelONE. Only accessories which have been stated by Amplivox Ltd to be compatible are allowed to be connected to the device.

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 meet 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 modelONE 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.

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 5 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 modelONE in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

2.3.7. Measuring accuracy

To guarantee that the ModelONE 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 modelONE 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 must 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 functions 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 acclimatized. 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. USB operation

The audiometer modelONE is powered from the USB connection, no extra power or batteries are needed. Ensure that the USB port can provide sufficient power to ModelONE, e.g. you may need to disable power save schemes.

2.4. Connections

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 ModelONE 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. Hardware installation

2.5.1. Power

The instrument is designed for continuous operation and is powered by the USB connector. Connect the USB output to the PC USB socket to power the device.

2.5.2. Changing the USB connector in modelONE

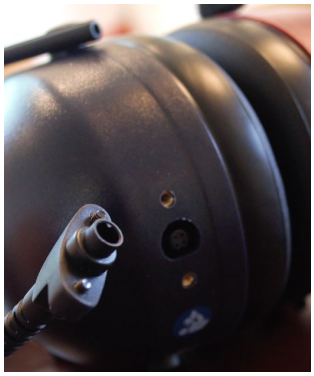
ModelONE can be used with three different USB connection: USB type A and USB type C (standard delivery) and mircro USB (optional).

The connector can be replaced in the field by the owner. Exchanging the lead does not influence product functionality nor the calibration of the audiometer.

To change the lead, follow the steps as listed below:

1. Disconnect ModelONE from the PC or tablet.
2. Unscrew the two screws on the headphone input.

3. Disconnect connector.



4. Connect other connector.
5. Screw in both screws again.

Please note: Refer to the installation & operating instructions provided with your instrument for details of the data transfer operation and errors that could possibly occur. If a fault cannot be fixed, the operator is cautioned against repeatedly restarting the instrument.

Proble	Cause	Solution(s)
Instrument doesn't connect.	• USB connection unstable	• Disconnect and then connect back the instrument • Check USB connection in both instrument and PC • Ensure cable is in good working order
Calibration error "Cal Error #16"	• You are using an uncalibrated ModelONE • Calibration data expired	• Contact your ModelONE distributor

3.Routine maintenance

3.1. 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 to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of 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.
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's examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed 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

3.2. Cleaning the ModelONE

CAUTION

- Use caution while cleaning.

- Before cleaning, remove the ModelONE from the computer or tablet.
- 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 on the ModelONE. Follow the instructions on the disinfection product.

3.3. Cleaning the accessories

3.3.1. 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 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 headphone or microphone etc. For specific accessories refer to the sections below.

3.3.2. Earphones

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

3.4. Accessories/replacement parts

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

3.5. 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.

3.6. Warranty

Amplivox gives the purchaser the following warranty;

If within 2 years 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 center 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.

3.7. Calibration and return of the instrument

Amplivox recommends that the ModelONE is calibrated annually.

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

4.Technical specification

4.1. Standard and Regulatory

Medical CE mark	The CE-mark in combination with MD symbol indicates that Amplivox Limited meets the requirements of the Medical Device Regulation (EU) 2017/745. Approval of the quality system is made by TÜV – identification no. 0123.	
Class	The ModelONE Audiometer is classified as a Class IIa device under Annex VIII of the EU Medical Device Regulation.	
Standards and Conformance	**Safety:**	BS/EN/IEC 60645-1: Electroacoustics – Audiological Equipment – Part1: Pure-tone Audiometers BS/EN/IEC 60601-1-2: Medical Electrical Equipment – Electromagnetic Compatibility: Requirements and Tests BS/EN/IEC 60601-1 and A1 2012 ANSI/AAMI ES60601-1:2005/(R)2012: Medical Electrical Equipment – General requirements for basic safety and essential performance
	Performance:	Type 4 (IEC 60645-1:2017 & ANSI S3.6:2018)
Physical	**Display:**	No
	Dimensions (base unit):	W x D X H: 19.1 x 9.3 x 13.4 cm/ 7.5 x 3.6 x 5.3 inch (excluding connections)
	Weight (Headphones):	389g / 0.86 lbs
Power Supply	**Mains power:**	15V, 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
	Storage temperature	0°C /32°F to 50°C /122°F
	Transport 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 Class II 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

4.2. Audiometry

Transducer	**Outputs:**	USB A or USB C
	Transducer types and reference levels:	DD65v2A: ISO 389-1, Table 3
	Static headband tension:	Headphones: 10 +/-0.5 N
	Sound attenuation characteristics:	ISO8253-1, Table 3
Test Signals	**Frequency:**	AC: 125Hz, 250Hz, 500Hz, 750Hz, 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz
	Frequency accuracy:	< 1 %
	Distortion:	< 2 %
	Output level range:	AC: -10dBHL to 120dBHL maximum
	Level step size:	5 or 10dB
	Tone present:	Continuous

4.3. Maximum hearing levels provided by each frequency

Frequency [hz]	Air conduction [db hl]
125	85
250	105
500	115
750	115
1000	120
1500	120
2000	120
3000	120
4000	120
6000	105
8000	100

4.4. Earphone sound attenuation characteristics

FREQ [HZ]	125	250	500	1000	2000	4000	8000
ATTENUATION [DB]	8.3	15.5	26.1	32.4	43.6	43.8	45.6

5. 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 ModelONE Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the ModelONE Audiometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ModelONE 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 ModelONE 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 ModelONE Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the ModelONE 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 ModelONE Audiometer requires continued operation during power mains interruptions, it is recommended that the ModelONE 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 modelONE Audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the modelONE 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 ModelONE 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.			

Guidance and manufacturer's declaration – electromagnetic immunity (2)
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 ModelONE Audiometer is used exceeds the applicable RF compliance level above, the ModelONE 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 ModelONE 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 modelONE audiometer

The modelONE Audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ModelONE Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ModelONE 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** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 D - 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 ModelONE 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	Socket type	Typical connection
USB socket	USB A, C or micro	Computer, laptop or tablet

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 Diagram 1 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: modelONE used with the PC