RA660

PC based group audiometer

RA660 Operation Manual

Model: RA660 – Operation Manual

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All available operation manuals can be found in the download center on the MAICO homepage:

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Compliance

MAICO Diagnostics GmbH is an ISO 13485 certified corporation.

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

Trademark Notice

Windows is a registered trademark of Microsoft Corp.

Table of Contents

1 Introduction

This section offers you important information about:

- **the intended purpose of the device**
- **indications and contraindications of use**
- **the intended operator**
- **features and benefits**
- **a description of the device**

1.1 Intended Purpose

This audiometer is designed to quantitatively measure and monitor an individual's hearing threshold across different frequencies.

1.2 Indication for Use Statement

There are no medical indications for this device.

1.3 Patient Population

The target patients are adults.

1.4 Contraindications of Use

A discharging ear, acute external auditory canal trauma, discomfort (e.g., severe otitis externa) or occlusion of the external auditory canal, or if the patient is sick or uncooperative to perform the tasks.

1.5 Intended Operator

The RA660 is intended to be used by trained audiologists, occupational health practitioners, and medical personnel responsible for assessing and managing the hearing health of employees.

1.6 Features and Benefits of the RA660

The RA660 offers the features and benefits listed in Table 1.

Table 1 Features and Benefits

FEATURES	BENEFITS
Computer Controlled	USB Computer interface. Allows multiple audiometers to be controlled by a single PC.
Auto-Subject Instruction	Automatically instructs the subject in multiple languages insuring accurate testing with reduced operator involvement.
Integrated Bio-acoustic Simulator	Automatically preforms Daily Calibration and Listening Checks
Automatic Retest	Automatic retest of suspect HTLs insures valid tests. Retest failed frequencies. Retest shifts from baseline >15 dB. Retest on Contralateral differences ≥ 40 dB. Retest on excessive levels ≥ 90 dB, or > 30 dB at 250 or 500 Hz.
Sound Room Monitor	Verifies that test room sound levels meet OSHA requirements
Inclusive Test Display	Allows the operator to view the progress of the hearing test and comparison to the baseline.
Storage for audiograms	Allows storage for large hearing conservation programs.
Reports	Reports to help manage your hearing conservation program. Who has been tested and is due for testing Who has an STS / possible OSHA Recordable Daily Biological Log List subjects.
Export Data Capabilities	Enables complete data transfer to backup and interface to data management software.
Headphones or Insert Earphones	Allows testing with headphones or insert headphones.
Test Integrity, Configuration	The RA660 verifies before each hearing test that the audiometer is properly configured adding additional test validity.
Test Integrity, Daily Biological	The RA660 maintains a Pass/Fail log of the Daily Biological test (calibration verification) and listening / performance check.
Test Integrity, ID Earphones	Patented features insure that the test results are valid. Earphones are uniquely and electronically identified to insure that they were calibrated with the correct RA660.
Test Integrity, Reminders	The RA660 reminds operator when a Daily Biological test and calibration a needed.

1.7 Description

The RA660 is a 1-channel screening audiometer with an integrated acoustic simulator and a real-time room monitor option. The output and specificity of this type of device are based on the test characteristics defined by the user and may vary depending on environmental and operating conditions.

It determines pure tone hearing threshold levels using the proven Hughson-Westlake Test Paradigm, which allows the operator to screen subjects for shifts in hearing acuity. The audiograms obtained from the RA660 may be used to maintain records for the subject and for the company administering the test. This helps the health care professional evaluate and prevent major hearing problems.

The RA660 is a modular system allowing up to 8 audiometers to be connected to a single USB port using an interface box. Each RA660 audiometer has an integrated bio-acoustic simulator that is used for daily calibration verification. Each audiometer has an input for an optional room monitor microphone to verify that ambient sound levels meet testing requirements.

1.8 Medical Disclaimer

Testing, as referred to in this operation manual, is the screening procedure used to establish thresholds (hearing levels) and is not an attempt to diagnose, monitor, or treat any medical problem, disease, or injury. If a problem is suspected, the subject should be referred to an audiologist, physician, or ENT for evaluation.

2 Warnings and Cautions

This section offers you important information about:

- **how to read the operation manual**
- **where to spend special attention**
- **the customer responsibility**
- **the explanation of all regulatory symbols used**
- **important cautions and warnings that have to be considered during the whole time handling and operating your device**

2.1 Reading this Operation Manual

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS DEVICE!

In this manual the following two labels identify potentially dangerous or destructive conditions and procedures.

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

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

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during device operation.

2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

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.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this device, the more stringent rules should take precedence.

This product and its components 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 snug and 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 MAICO.

NOTE: Customer responsibility includes proper maintenance and cleaning of the device (see sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see sections 2.3 and 3.1).

NOTE: In the unlikely case of a serious incident, inform MAICO as well as the competent authority in the country where the user is established.

2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

2.4 Regulatory Symbols

The following Table 2 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 2 Regulatory Symbols

SYMBOL	DESCRIPTION
SN	Serial Number
	Date of Manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to Authorized Representative, Special Disposal Required
REF	Reference Number
MD	Medical Device
(01)04260176127444 (11)201020 (21)MA0123456	UDI information: (01) GTIN (Global Trade Item Number), (11) Date of manufacture, (21) Serial number
	Type B Applied Part according to IEC60601-1
	Refer to operation manual (mandatory)
	Keep Dry
	Transport and Storage Temperature range
	Transport and Storage Humidity limitations
	Transport and Storage Atmospheric pressure limitations
	Voltage Transformer
	Do not reuse
CE 0123	CE label with notified body ID
	Non-ionizing electromagnetic radiation
	Direct Current (DC)
ETL CLASSIFIED Intertek	ETL listed mark
TREMETRICS	Logo
MAICO	Logo

2.5 General Precautions

Before starting a measurement make sure, that the device works properly.

Use and store the device indoors only. For operation, storage and transport conditions see table in Section 6.1.

Do not open the case of the RA660. Refer servicing to qualified personnel.

Do not modify this equipment without authorization of the manufacturer.

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

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

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

Calibration of the device: The audiometer and the transducers complement each other and share the same serial number (i.e. MA1234567). Therefore, the device shall not be used with any other transducer prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

Uncalibrated devices may lead to faulty measurements and sometimes even damage the hearing of the examinee.

2.6 Electrical and Electrostatic Safety

This icon indicates that applied parts of the device conform to IEC 60601-1 Type B requirements.

In Case of Emergency

In case of emergency, disconnect the device from the computer.

In Case of Emergency

In case of emergency, disconnect the device from power supply.

Position the device in such a way that it can be easily disconnected from the power supply at any time.

Do not use the device if the power supply unit and/or the plug is damaged.

To transfer data to a PC, establishing a PC connection via USB is required.

See section 4.2.6 on how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop.

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 shall 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 – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e., at least 1.5 m from the patient support or shall be supplied via a separation 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 the requirements. If in doubt, contact qualified medical technician or your local representative.

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

If the device is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601-series.

Do not touch the contacts of the device and the patient at the same time.

If the device is connected to a PC (IT equipment forming a system) do not touch the patient and the IT equipment at the same time.

The consequence of not following this warning could be a too high leakage current to the patient.

The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.

To avoid the risk of electric shock, this equipment must only be connected to the medical power supply originally delivered by MAICO. Using another power supply can also lead to electrical damage on the device.

Prevent cable breakage: cables must not be bent or buckled.

The device is not intended to be used in environments exposed to fluid spills. Ingress of any fluids is considered single fault condition. No means specified for fluid protection (not IP classed).

2.7 Electromagnetic Compatibility (EMC)

This device 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.

The device fulfills the relevant EMC requirements. 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.

Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device 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 can be found in the Section 6.5 of this operation manual.

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 the RA660, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

2.8 Cyber Security and Data Protection

To ensure data protection it is essential to follow common practice in terms of cyber security. This involves:

1. Ensure operating systems are security patched.
2. Keep your software up to date.
3. Install only apps and software from trusted sources.
4. Install an antivirus protection and anti-malware software and a firewall from a trusted vendor and keep them up to date.
5. Utilize the tablet/PC password settings and use safe passcodes.
6. Ensure secure physical and network access to computers with local data storage.
7. Implement an appropriate backup policy.
8. Do not use public WiFi.
9. Learn about phishing scams: Be very suspicious of e-mails and calls.

2.9 Device Control

The user of the device should perform a subjective device check once a day.
For performing the automatic Daily Biological in order to verify the audiometer calibration using the integrated bio-acoustic simulator see section 5.9.

3 Warranty, Care & Maintenance

This section offers you important information about:

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **accessory and replacement parts**
- **recycling and disposal of the device**

3.1 Warranty

3.1.1 General

The MAICO device is guaranteed for at least 1 year. Ask your authorized local distributor for more information.

This warranty is extended to the original purchaser of the device by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of at least one year from date of delivery to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the device case will void the warranty.

In the event of repair during the guarantee period, please enclose evidence of purchase with the device.

3.1.2 Ownership, Warranty and Disclaimer (Software)

Ownership

The HearCon RA660 Software (hereinafter the “SOFTWARE”) are solely owned by MAICO Diagnostics GmbH, Sickingenstr. 70-71, D-10553 Berlin, Germany. By purchasing the SOFTWARE the buyer is entitled the right of usage, but not ownership of the SOFTWARE. The SOFTWARE is to be used in accordance to the agreed terms of usage provisioned by MAICO.

Copyrights

MAICO’s ownership of the SOFTWARE covers worldwide and is therefore, protected against any unauthorized copying of the SOFTWARE. Non conformity of use of the SOFTWARE is strictly prohibited.

Restrictions

You may not:

Reverse engineer or attempt in any manner to discover the source code of the SOFTWARE.

Attempt to defeat any mechanisms in the SOFTWARE, including those mechanisms responsible for password protection of data and limiting the number of concurrent users.

Rent, lease, sublicense or in any manner, copy or transfer (except as permitted above) the SOFTWARE.

Obscure or obliterate any MAICO copyright or trademark notices which appear on the SOFTWARE, the documentation, the screen-display, or otherwise in connection with the SOFTWARE.

MAICO specifically calls your attention to the fact that, any violation or infringement of above restrictions will result in legal action.

The SOFTWARE can be used by any number of users, on any number of computers, and in any place, provided but not on more than one display screen at the same time.

Limited Warranty

MAICO warrants that any physical media and physical documentation provided by MAICO are free of defects in materials and workmanship. This limited warranty is effective for a period of ninety (90) days from the original purchase date.

If MAICO receives notification within the warranty period of defects in materials or workmanship and determines that such notifications are correct, MAICO will replace defective media or documentation.

Do not return any product until you have obtained authorization to do so from your supplier. The entire and exclusive liability and remedy for breach of this limited warranty shall be limited to replacement of defective media or documentation supplied by MAICO, and shall not include or extend to any claim for or right to recover any other damages, including but not limited to, loss of profit, data, or use of the SOFTWARE, or special, incidental or consequential damages, or other similar claims, even if MAICO has been specifically advised of possibility of such damages. In no event will MAICO’s liability for any damages to you or any other person ever exceed the lowest list price or the actual price paid for the license to use the SOFTWARE, regardless of the form of the claim.

Disclaimer

MAICO covers; including but not limited to; all warranties, representations and terms and conditions, either expressed or implied; under specified terms of use and application of the SOFTWARE for its specific purpose. All other terms and conditions shall not apply.

Furthermore, MAICO does not guarantee that the SOFTWARE or Documentation is free of bugs, or fulfill the relevant standards, requirement or needs of a user. In this case, all the warranties, guarantees and terms and conditions on all MAICO delivered physical disk and documentation shall be limited to the 90 days warranty period.

MAICO is not liable for any third party's product, disks, SOFTWARE or documentation that is used in conjunction with MAICO's SOFTWARE or programs, but is not directly manufactured or supplied by MAICO.

General Terms and Conditions

Any change made to this Agreement shall be notified in writing, agreed and signed between both parties, namely the purchaser of the SOFTWARE and a representative of MAICO.

In the event that the essential purpose of the above remedy (limited warranty) is not fulfilled, all other limited liability including the liability limits and exclusions of damage claims shall continue to apply.

This SOFTWARE License Agreement shall be interpreted and construed according to, and governed by, the laws of Jurisdiction of Federal Republic of Germany.

In the event that any legal or commercial dispute or controversy arising out of, or relating to this agreement; provided MAICO is in all case violated of the rights, to the SOFTWARE or other intellectual property protection right related to the SOFTWARE; shall be presented under the Jurisdiction of Federal Republic of Germany in the court of Berlin.

The SOFTWARE is protected under both Copyright Law and the International Copyright Treaties. Copying of the SOFTWARE is strictly prohibited except for copies made of the SOFTWARE for backup purposes to protect data loss.

3.2 Maintenance

To ensure that the device works properly, it has to be checked and calibrated at least once every 12 months.

The service and calibration must be performed by your distributor or by a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing when returning the device.

3.3 Cleaning and Disinfection Recommendations

It is recommended that parts (device and accessories like headphones, ear cushions) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients.

Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

If there is not a high infection potential, MAICO recommends:

- Before cleaning always switch off and disconnect the device from the power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the RA660 and its accessories by wiping the surfaces with disinfectant wipes. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious diseases

To avoid damage of the device and its accessories, please mind the following:

- Do not autoclave or sterilize.
- 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 device should not be used until deemed safe by a MAICO certified service technician.

Do not use hard or pointed objects on the device or its accessories.

3.4 Disposables

Use only the Sanibel Supply disposable supplies that are supplied with your RA660 system.

Foam eartips are intended for single-use only. These should be discarded after use. They cannot be cleaned.

In case of re-use of the single-use disposables, you enhance the risk of cross contamination!

3.5 Accessories and Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep these replacement parts available (as appropriate for your RA660 device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.6 Recycling and Disposal

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment-related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all your respective local laws and regulations for the proper disposal of batteries and any other parts of this device.

Non-European countries

Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

4 Unpacking and Hardware Orientation

This section offers you important information about:

- **unpacking the system**
- **components**
- **becoming familiar with the hardware inclusive connections**
- **how to store the device**

4.1 Unpacking the Device

Check Box and Contents for Damage

- It is recommended that you unpack your RA660 carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing list included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration (see section 3.2).

Components

The RA660 comes with different components (see Table 2). The availability of configurations with the following components is country specific. Contact your local distributor for more information.

Components

Item	
RA660 Audiometer	
Patient Response Switch*	
Transducers***	
	AC Headphones DD45*
	AC Headphones TDH39*
	IP30 Insert Earphones*
Wall Mount Kit RA660	
Interface Cable	
Interface Box	
Power Supply UES65-240250SPA3	
Power Mainscable	
USB Cable	
Talk Forward Microphone	
Microphone Room Monitor	
USB Flash Drive with PC Software	
Operation Manual**	
Quick Guide**	

***Applied part according to IEC/EN 60601-1**
****As download from the download center – see accompanying leaflet**
*****Selection of transducer at time of purchase**

Table 3 Replacement Parts and Disposables

Item
Foam Eartips***+

*****+Only for use with Insert Earphones.**

4.2 Hardware Orientation

4.2.1 RA660 Front View

Figure 1 shows the device in the front view with the following features:

1. Color LCD touch screen display
2. Right coupler for bio-acoustic simulator
3. Left coupler for bio-acoustic simulator

Figure 1

4.2.2 RA660 Back View

The RA660 connections on the back of the device are labeled for configuration (Figure 2 and Table 4).

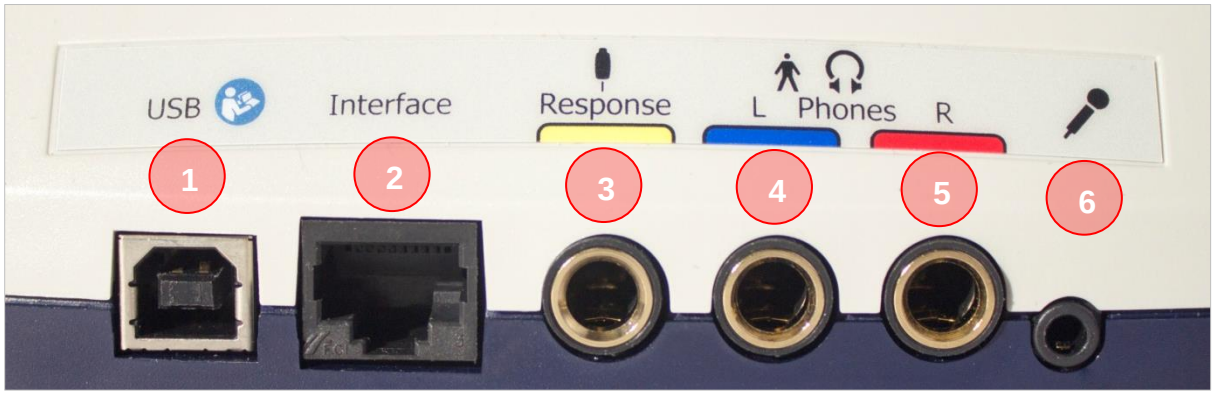


Figure 2

Table 4 Connections (Back View)

Connections (Back View)		
1	USB Device	Connection to a PC for calibration using calibration software. The USB port is not used durring normal operation.
2	Interface	Connection to Interface Box.
3	Response (yellow)	Connection for the patient response switch.
4	Phones L (blue)	Connection for the blue headphone plug for the left ear.
5	Phones R (red)	Connection for the red headphone plug for the right ear.
6	Microphone	Connection for room monitor microphone.

4.2.3 RA660 Interface Box Front View

Figure 3 shows the RA660 Interface Box connections (front view) with connections for up to 8 audiometers.

Figure 3

4.2.4 RA660 Interface Box Back View

WARNING

This device is intended to be connected to a specific power supply unit. Use only the model specified in the technical specifications section 6.1. Nonconformity with this requirement can result in risk of electrical shock for operator or patient.

The RA660 Interface Box connections are labeled for configuration (Figure 4 and Table 5).

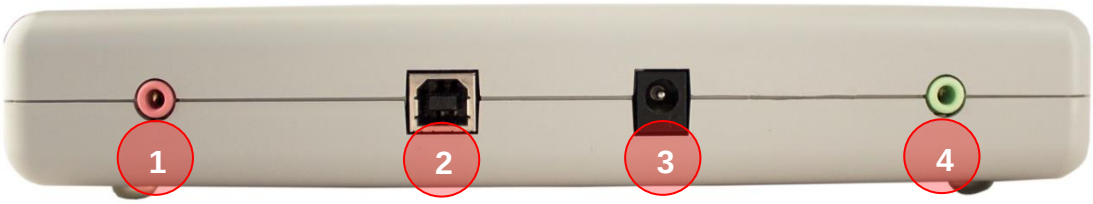


Figure 4

Table 5 RA660 Interface Box Back View

RA660 Interface Box Back View		
1	Mic In	Talk forward microphone input
2	USB In	USB connection to computer
3	Power	Power input 24 VDC
4	Line In	Talk forward line input. Alternate talk forward input for a line level signal. Not implemented in current software.

4.2.5 RA660 Interconnect Diagram

Connect all the components as shown below. Do not plug in the line cord until all the components are properly connected, and you are instructed to do so in the software installation instructions.

See the RA660 Interconnect Diagram (Figure 5).

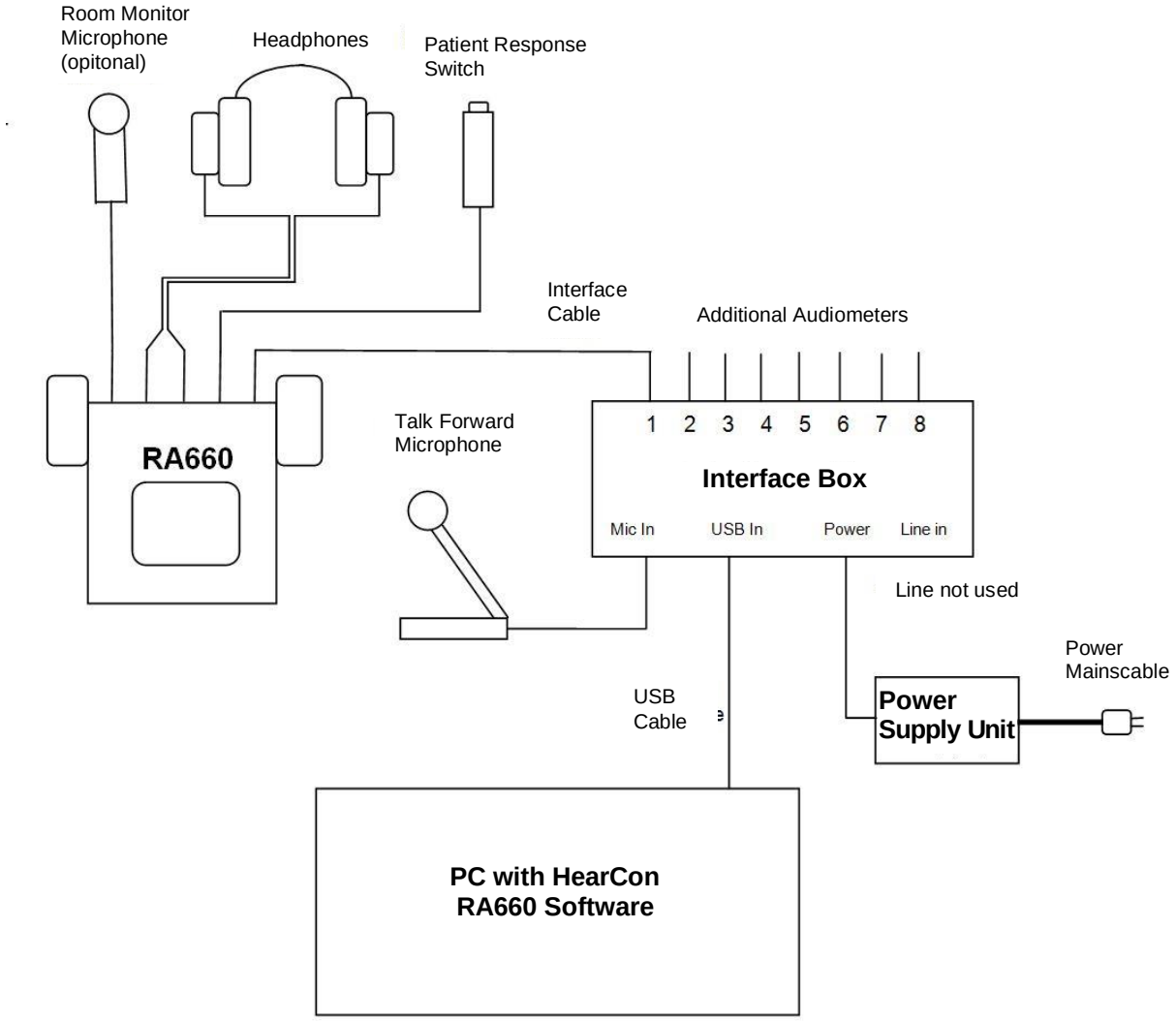


Figure 5

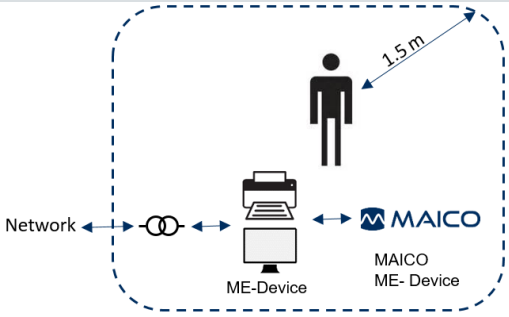
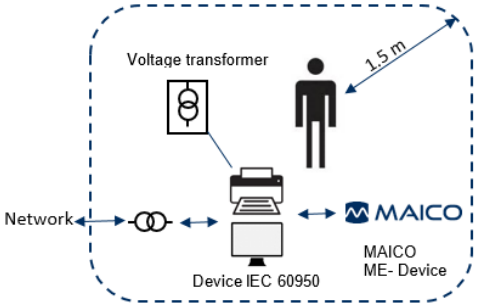
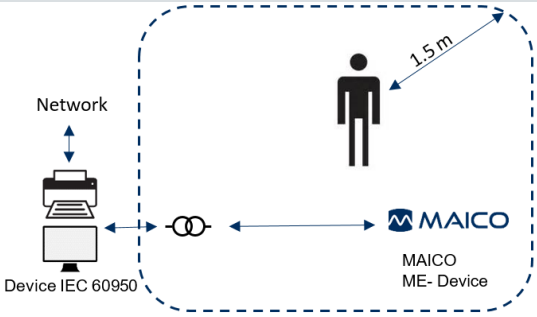
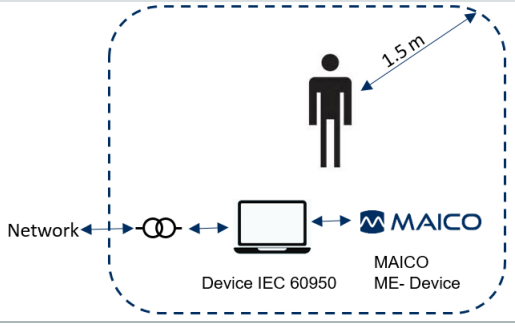
4.2.6 Establishing a PC Connection

To transfer data to a PC, establishing a PC connection via USB is required. If the RA660 is used with office equipment that is not a medical device itself (see Table 6), make sure to establish the PC connection in one of the following ways (see Table 6, PC Connection 2, 3 or 4).

WARNING

Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop is used).

Table 6 PC Connections

PC CONNECTIONS	
PC Connection 1: Medical device – Medical Device	PC Connection 2: Medical device – Non-Medical Device
	
PC Connection 3: Medical device – Non-Medical Device	PC Connection 4: Medical device – Laptop (battery-driven)
	

4.3 Software Installation

The HearCon RA660 Software supports Windows® 7 and 10. Software installation requires installation of the USB drivers and the RA660 application. Once all the components are connected as shown in the Interconnect Diagram above, plug in the line cord to power up the system. Windows® should automatically locate the required USB driver and install it. A dialog will appear to indicate this and that the device has been installed and is ready to use.

The HearCon RA660 Software now needs to be installed. The HearCon RA660 Software is supplied on the same USB memory stick that this manual is supplied on. Use Windows® Explorer to locate the file ***Setup.exe*** on the USB memory stick. Double click on this file to start the installation. A popup box should appear displaying the installation process. Once the installation is complete the RA660 opening screen will appear.

To verify that the RA660 audiometers are properly connected and operating click on the ***Audiometrics*** tab (Figure 8) on the top left of the screen and then the ***Audio Testing*** icon in the drop-down menu that appears.

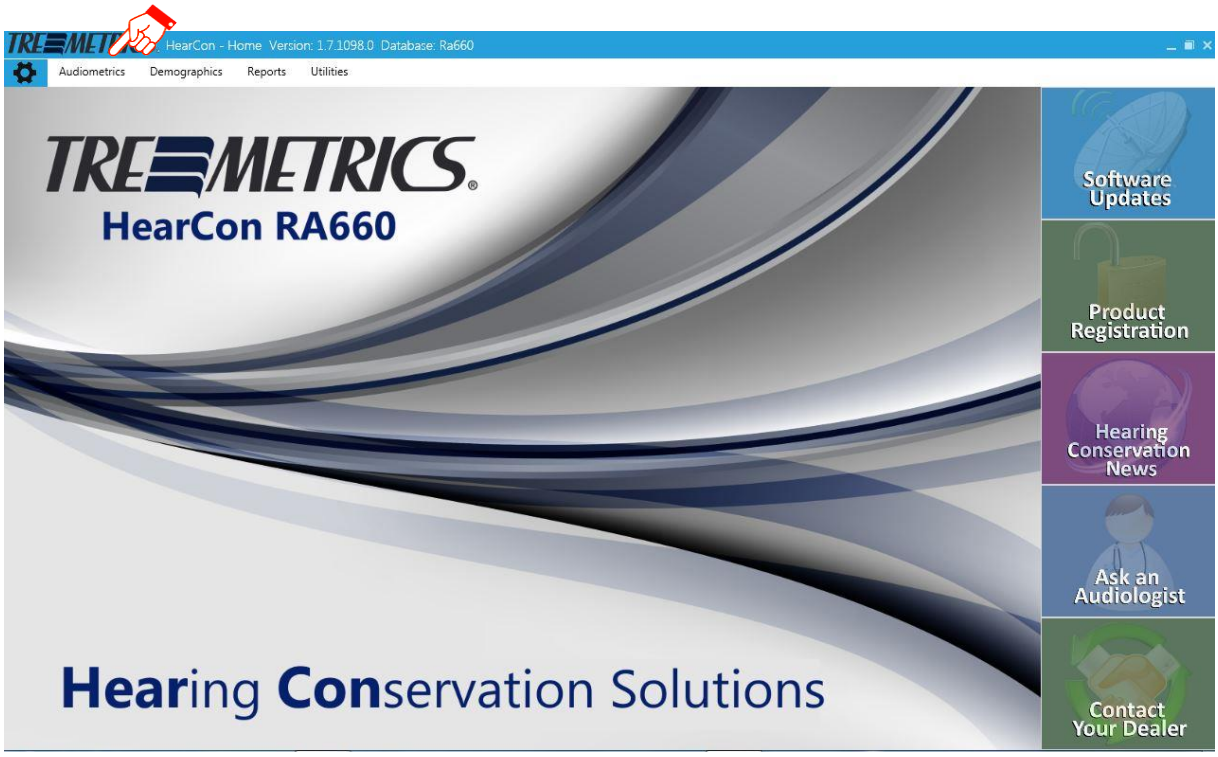


Figure 6

The ***Audiometrics*** Overview screen will appear showing all the connected RA660 audiometers and the status of each. The example in Figure 9 shows 8 connected audiometers. All the booths are active. An audiometer can be made Active or Inactive be clicking on the checkbox in front of the text.

Figure 7

The RA660 installation is complete and ready to use.

4.3.1 Wall Mount Kit

The wall mount kit allows for easy mounting of the RA660 on the sound room wall. The wall mount base plate bolts to the wall and the RA660 can then be snapped on to the base plate standoffs (Figure 6). The kit also includes a holder for the patient response switch and headphones (Figure 7). The holder can be mounted to the left or right of the audiometer or left off.

Figure 8

Figure 9

4.4 Storage

When the RA660 is not in use, store it in a location where it will be safe from damage to the sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in Section 6.1.

5 Operating the Device

This section offers you important information about:

- **how to get started with the device**
- **the device layout**
- **preparing the patient for testing**
- **performing Tone Audiometric testing**
- **changing settings**
- **managing the test results**

5.1 Use of Equipment After Transport and Storage

Make sure the device is functioning correctly before use. If the device has been stored in a colder environment (even for shorter time) allow the device to become acclimatized. This can take a long time depending on the conditions (like environmental humidity). You can reduce the condensation by storing the device in its original packaging. If the device is stored under warmer conditions than the use conditions, no special precaution are required before use. Always ensure proper operation of the device by following routine check procedures for audiometric equipment.

5.2 Where to Setup

The RA660 should be operated in a quiet room, so that the audiometric examinations are not influenced by outside noises. Ambient sound pressure levels in an audiometric test room shall not exceed the values specified in the norm ISO 8253-1:2010 or ANSI S3.1-1999.

Devices, which emit strong electromagnetic fields (e.g., cellphones, microwaves, or radiotherapy devices), can influence the function of the audiometer. Therefore, it is not recommended to use these devices near the audiometer as it may lead to incorrect test results.

The test room must be at a normal temperature, usually from 15° C/59° F to 35 °C/95° F, and the device should be switched on approximately 10 minutes before the first measurement. For further information on use after transport and storage see section 6.1.

Place the device on a stable counter or table. Connect all accessories with the appropriate sockets as shown in Section 4.2. Plug the power cord into a grounded outlet.

5.3 Preparing for Testing

5.3.1 Placement of Headphones (for Testing with Headphones)

Figure 10

Eliminate any obstructions which will interfere with the placement of the ear cushions on the ear (i.e. hair, eyeglasses).

Ensure that the headphones (Figure 10) are positioned correctly: red phone on the right ear, blue phone on the left ear. Adjust the headband of the headphones so that the headphones are positioned at the correct height (i.e., the sound output grid exactly facing the ear canal).

5.3.2 Placement of Foam Eartips (for Testing with Insert Earphones Only)we

The insertion of the insert earphones into the ear canal without an eartip can scratch the ear canal.
Always apply a foam eartip before inserting the insert earphones into the ear canal.

Figure 11

First, place the foam eartip securely on the adapter at the end of the insert earphone tubing. To prepare the foam eartip for insertion in the ear canal, you must compress the foam by rolling it in your fingers to narrow its diameter (Figure 11). Check to be sure that the foam does not obstruct the opening of the black sound tube.

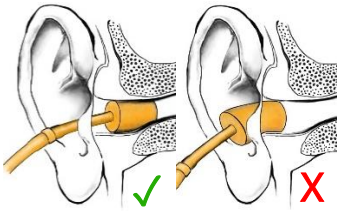


Figure 12

Quickly, while the foam is still compressed, grasp the patient's ear, and gently pull it up and back to open and straighten the ear canal. While holding the canal open, slide the compressed foam eartip into the ear canal. The foam should be completely surrounded by the canal with virtually none of the foam sticking out of the canal (Figure 12).

5.3.3 Removal of Eartips

After the screening, the eartips should be removed from the subject and discarded. These disposables are intended for single-use only.

5.4 Starting the HearCon RA660 Software

The installation software placed a shortcut to the HearCon RA660 Software on your desktop. To start the program, double-click the shortcut (Figure 13).

Figure 13

The startup screen for the RA660 will open (Figure 14).

Figure 14

5.5 Turning Off the RA660

The RA660 ist turned off by closing the HearCon RA660 Software and unplugging the device.

5.6 Enter a Company and Plant

The first thing that needs to be done to start using the RA660 is to create at least one Company and Plant in the database. From the opening screen select the ***Utilities*** tab at the top of the screen and then select the ***Organization Levels*** icon (Figure 15).

Figure 15

The ***Organization Structure*** screen will open . Click on the **+** to the right of Company. Fill in the company information fields that open and select the save icon to the right of Company. The Plant information fields will open, fill them in and select the save icon to the right of Plant.

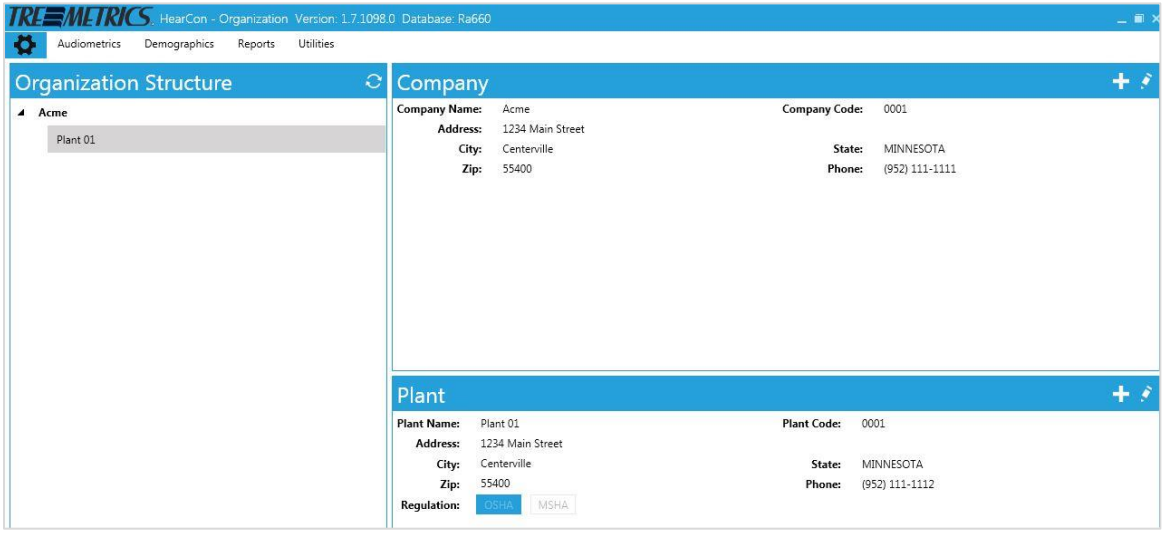


Figure 16

5.7 Enter Examiners

The next thing that needs to be done is create a list of examiners for this location. Select the ***Examiners*** Icon at the top of the screen.

Figure 17

The Examiners pop up box will open. Enter the examiner name and click the ***Save*** box. Repeat for each examiner. When complete select one of the names and click the ***Set Default*** box to designate that examiner as the default. When finished select ***Save*** and ***Close*** (Figure 18).

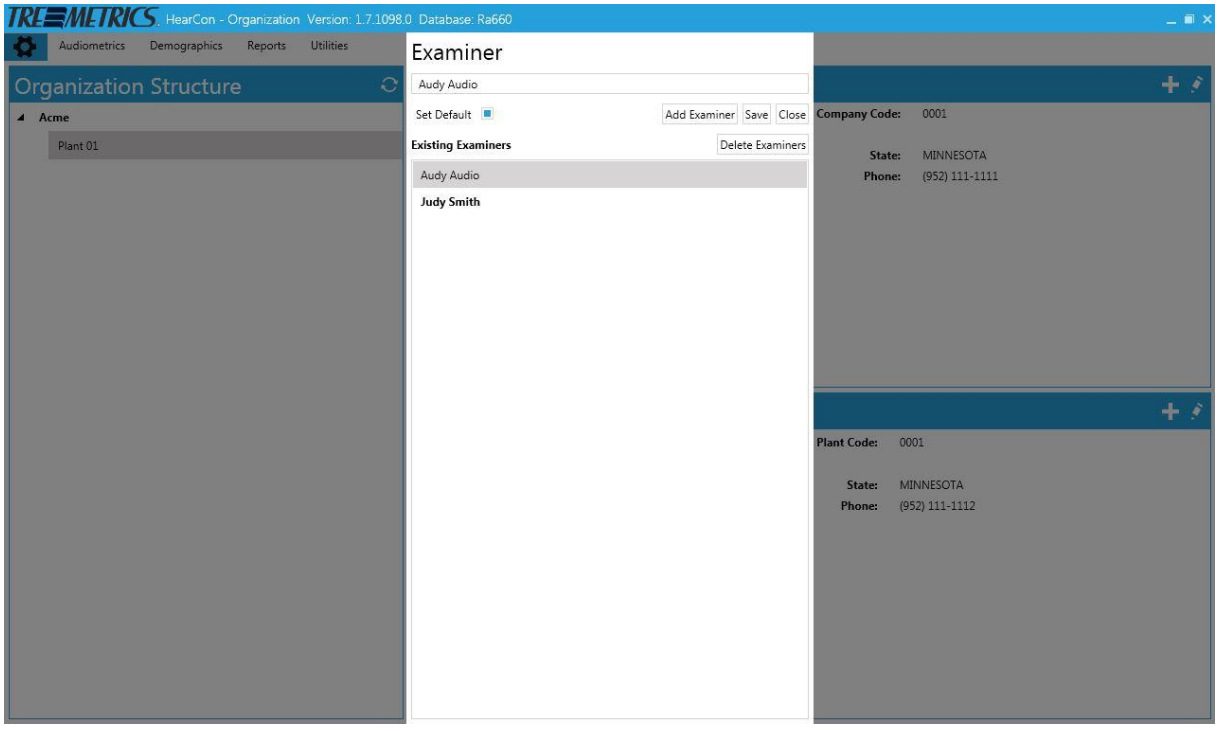


Figure 18

5.8 Enter Employees

To enter an employee, select the ***Demographics*** tab at the top of the screen (Figure 19).

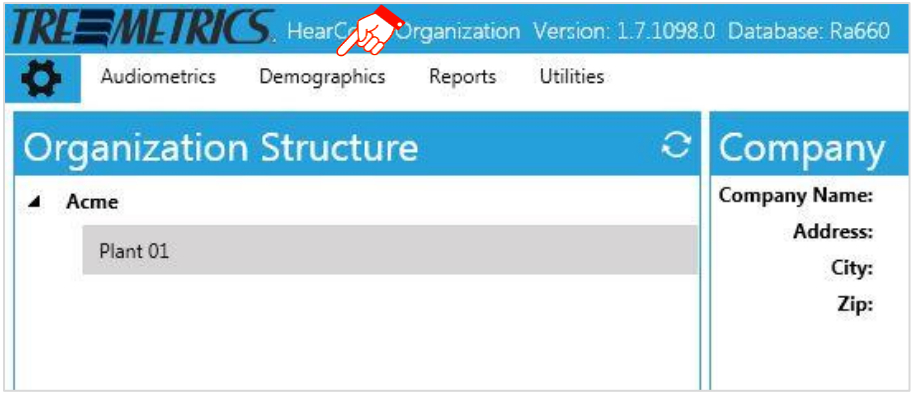


Figure 19

The Demographics screen will open. Enter the employee's information in the Personal Info fields. The minimum information required to enter a new employee are ***Employee Number, Birthday, First Name, Last Name*** and ***Sex***. When complete select ***Save*** at the bottom right side of the screen (Figure 20).

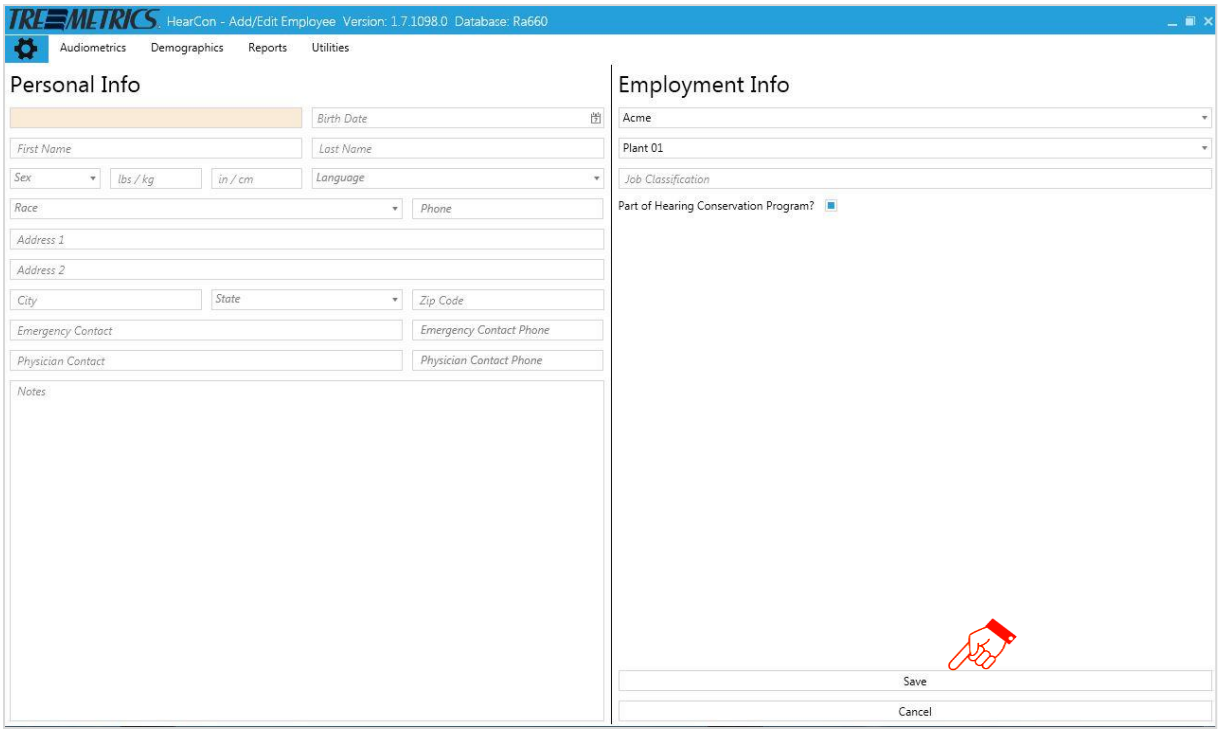


Figure 20

5.9 Run a Test

5.9.1 General

To run a test, select the ***Audiometrics*** tab at the top left of the screen and then click on the ***Audio Testing*** icon that appears in the drop-down window (Figure 21).

Figure 21

The audiometer ***Overview*** screen will open (Figure 22). It is possible to run tests from this ***Overview*** screen or from the audiometer ***Details*** screen. This example will use the ***Details*** screen. Click on the maximize icon for the booth to select.

Figure 22

5.9.2 Run a Test From the Details Screen

The ***Details*** screen of the selected booth will open (Figure 23). Click on ***Select an Employee*** to select an employee that is already in the database. If the employee is not in the database, click ***Add New Employee*** and enter the employee information.

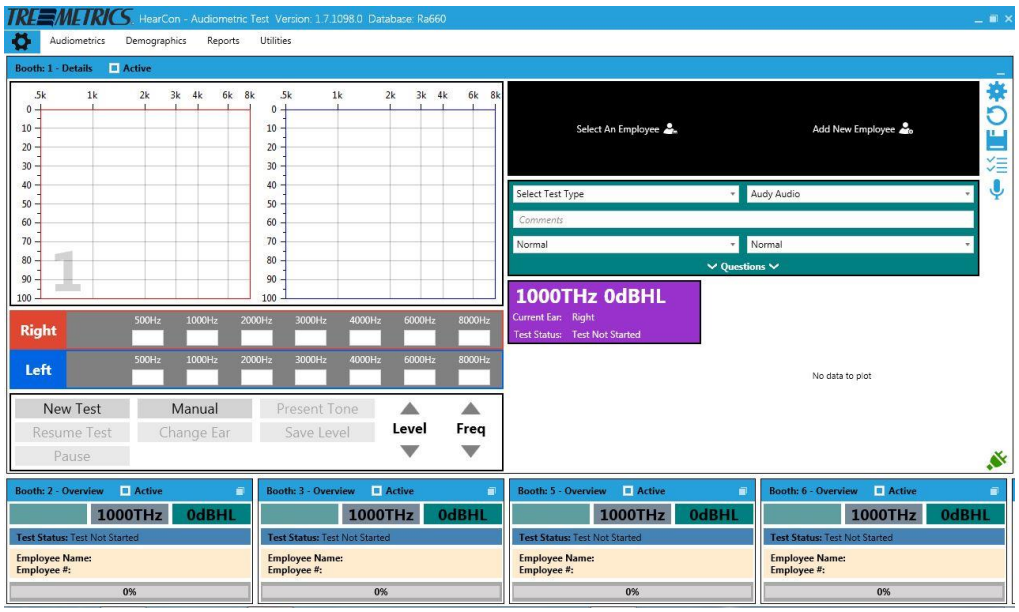


Figure 23

The ***Employee*** window will open (Figure 24). Enter the employee to be tested and click on ***Select***. The ***Employee*** window will close.

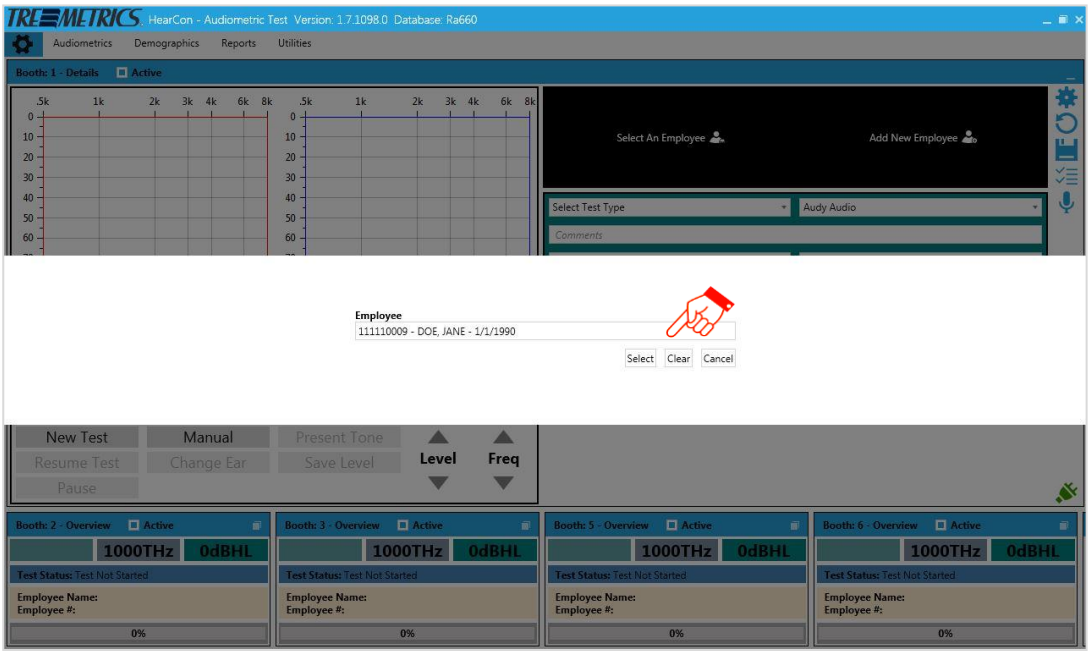


Figure 24

To start the test, select ***New Test***. The automatic test will begin. The test will continue automatically, after about four minutes the test will complete. The test results will be displayed on the left and right audiograms and in the table below them. Select the ***Save*** icon to save the test results (Figure 25).

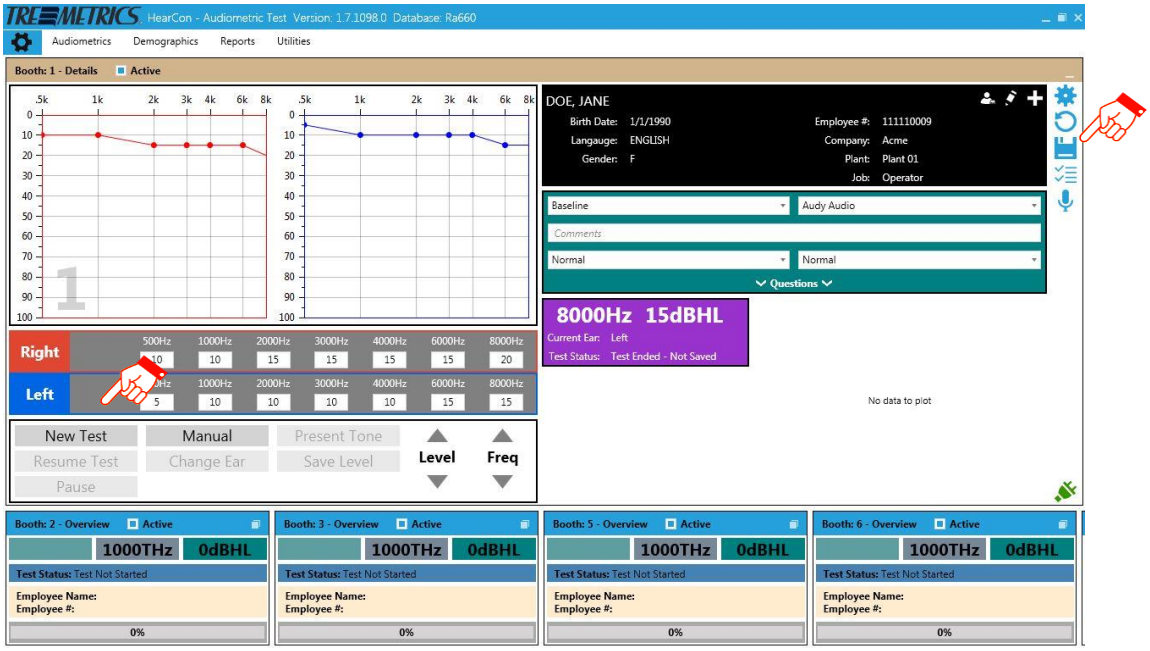


Figure 25

Error Codes

If the automatic test is unable to establish a threshold at a frequency it will record and error code instead of a threshold. Some error codes are immediate warnings, including both an onscreen visual and auditory signals. Some error messages have an audio feedback message played to the subject. A list of error codes is shown below.

Table 7 Error Codes

Error Code	Description
NR	No response at 1 kHz. Did not obtain a subject response for the first ear tested at 1 kHz.
	Audio Feedback***: "Listen carefully, and make sure you hear the tone. Then quickly press and release the handswitch."***
2ND	1 kHz 20 Presentations No HTL No validation at 1000 Hz. There is no validation for the first test ear response at 1000 Hz. This occurs if too much time has elapsed or 25 presentations without achieving threshold validation.
	Audio Feedback***: "As soon as you hear the tone even it is very faint, quickly press and release the handswitch."***
RF	1 kHz Retest Error. Failed 1 kHz validity. The first ear fails the 1000 Hz retest. This validity check is performed by testing each ear twice at 1000 Hz. The thresholds must agree ± 5 dB. If the RA 660 cannot get at 5 dB agreement the operator is notified by a beep or error message.
	Audio Feedback ***"As soon as you hear the tone, even it is very faint, quickly press and release the handswitch."***
SNR	Handswitch Not Released Error Re-instruct and restart
	Audio Feedback***: "The handswitch button must be released quickly. Press and release the handswitch button as soon as you hear the tone."***
RNT	Response No Tone. Responding when no tone is present.
	Audio Feedback ***"Be sure you hear the tone, then press and release your patient response switch quickly."***
MAX	Error for Second Time. No validation on one or two frequencies. The retest did not validate the HTLs at the required one or two frequencies. A maximum of 25 tone presentations or 60 seconds are allowed at each test frequency. Failed for a second time.
	Audio Feedback: None
	Switch to manual mode and administer a manual test at the missed frequencies.
NR3	Maximum Failed Frequencies. Failed to establish thresholds.
	Audio Feedback: None

5.9.3 Run a Test From the Overview Screen

It is also possible to run tests from the Overview screen instead of the Details screen. Click ***Audiometrics*** > ***Audio Testing*** to get to the Overview screen. Right-click in the Employee Name and number field of the audiometer to be selected. A drop-down menu will appear.

From this drop-down menu it is possible to start an individual audiometer with ***New Test*** or all the audiometers with ***Start/Resume All*.**

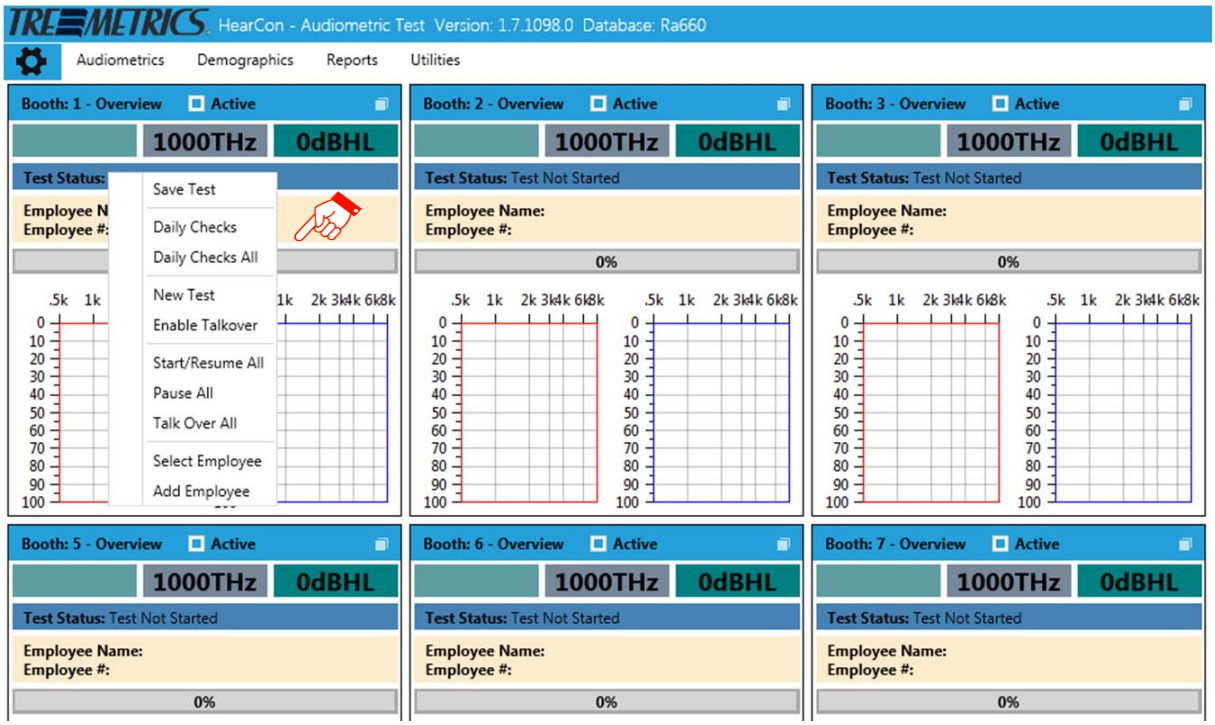


Figure 26

5.9.4 Talkover Function

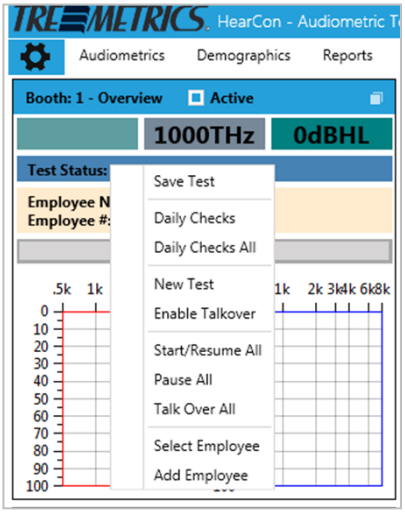
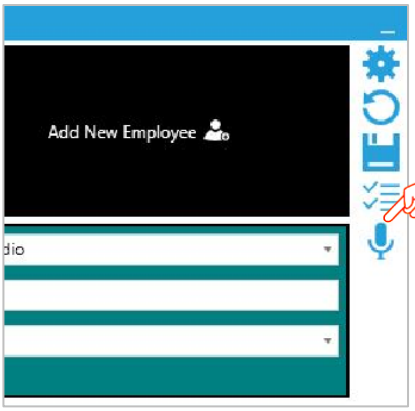


Figure 27

The RA660 audiometers have a talkover function that allows the operator to talk to one or all the employees being tested.

From the ***Overview*** screen, talkover is activated from this drop-down menu (Figure 27).



Enable Talkover activates talkover only to the selected audiometer.

Talk Over All activates talkover to all audiometers.

From the ***Details*** screen, talkover is activated with the icon.

Only talkover for the selected audiometer can be activated in the ***Details*** screen.

Figure 28

5.9.5 Plug Status

The RA660 headphones, response switch and room monitor microphone have an identification circuit that allows the RA660 audiometers to determine if the proper accessories are connected to the correct jacks. If everything is correct, the plug icon on the details screen is green (Figure 29). If there is a connection error the plug icon is red (Figure 30).

Connections Correct

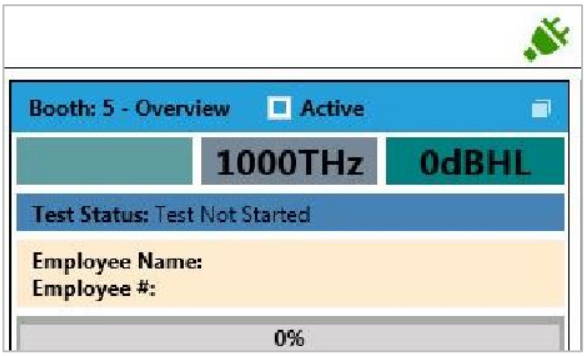


Figure 29

Connection Error

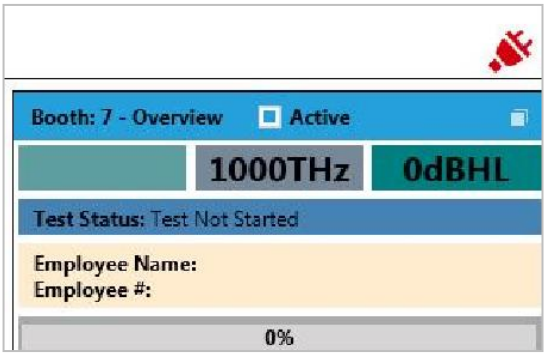


Figure 30

A plug connection error will not prevent operation of the device, but it does indicate a potential problem that shall be investigated. If an accessory need to be changed the identification circuit can be reset by right-clicking on the plug icon. You will be prompted for a password before the identification can be reset.

5.10 Perform a Daily Biological

5.10.1 Integrated Bio-acoustic Simulator

The RA660 has an integrated bio-acoustic simulator which is an OSHA acceptable substitute for a human subject for performing the Daily Audiometer Calibration Check. The process, often referred to as the Daily Biological, is intended to verify the audiometer calibration and cannot be used to perform the annual audiometer calibration. Also, the RA660 implements the equally important ***Listening Check*** by guiding the test administrator through the process of confirming tone stimulus quality. The Daily Biological should be performed at the start of each day of testing.

5.10.2 The Automated Daily Biological

1. Place the audiometer headphones on the RA660 with the **red right** earphone in the **red** coupler) and the **blue left** earphone in the **blue** coupler. Be sure that the earphone cushions are seated properly as show below and fully inside the couplers. The cushions should be replaced if they do not fit inside the couplers.

Figure 31

2. From the ***Audiometrics*** Overview screen, select the audiometer to be tested. Select the ***Daily Checks*** button as shown below.

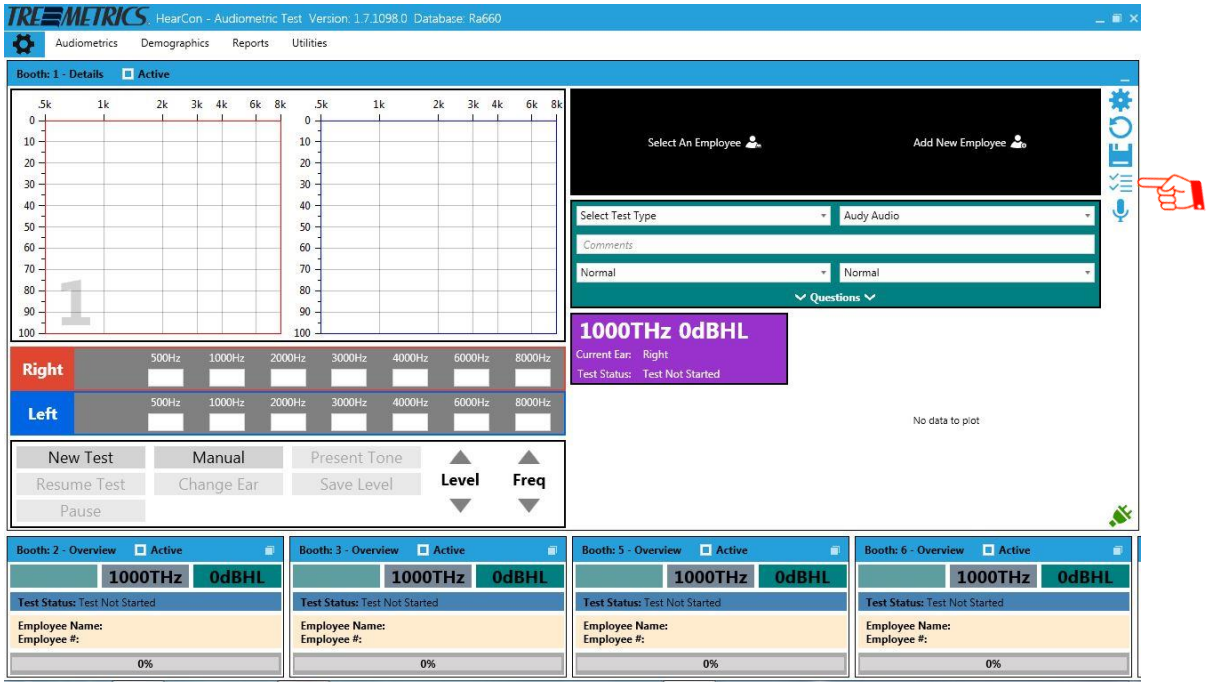


Figure 32

The Daily Biological window will open. Select ***Start Daily Biological*** (Figure 33). The Daily Biological test will start.

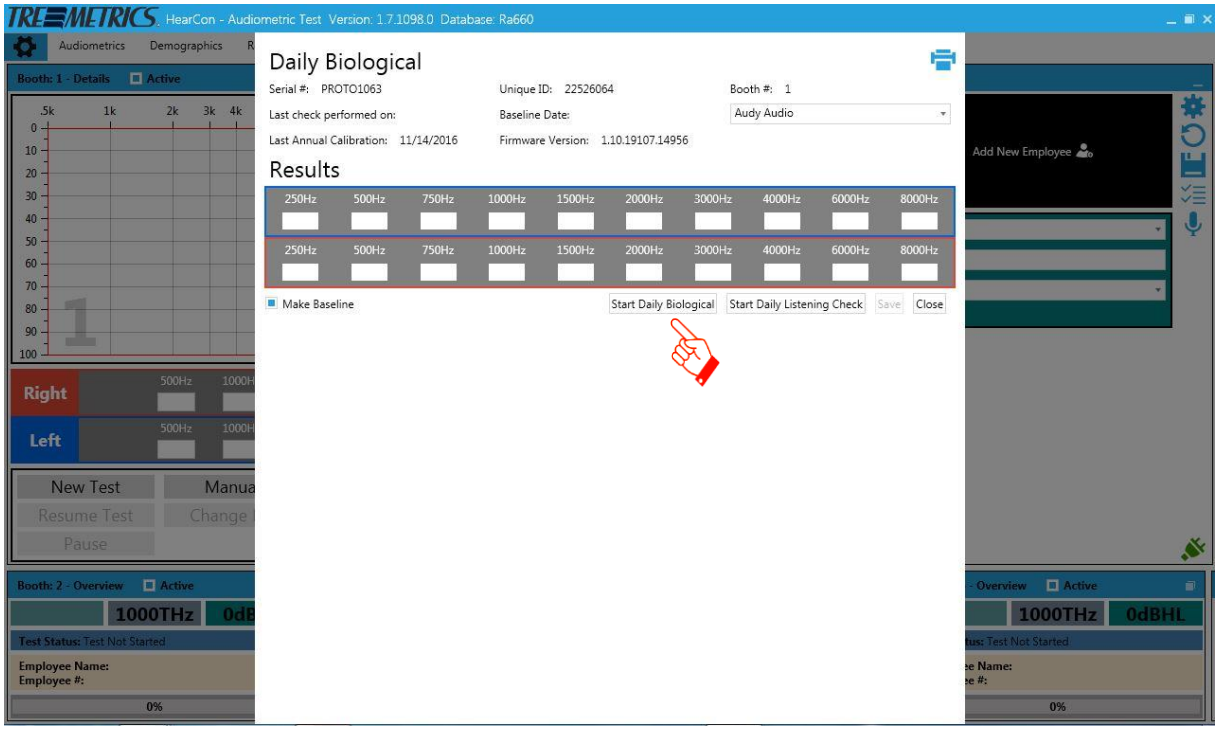


Figure 33

As the test executes the thresholds will be recorded in the boxes. When all the thresholds have been recorded, the test is complete. If this is the first Daily Biological test for this RA660, it will automatically be made the baseline for this RA660. Future tests will be compared against this baseline. There should be no more than ±5 dB difference between the baseline and the current test. If the difference is greater than 5 dB there will be an error message displayed. In this case, reseat the headphones and rerun the test.

5.10.3 The Listening Check

The second, and equally important part of the Daily Biological Test, is the listening check. The listening check allows the operator to listen to the audiometer tones in both earphones and verify that there are no clicks, pops, static or crosstalk. The operator should also confirm that the earphone cords are not frayed or broken, the cushions are not worn or cracked, and that the headband is undamaged.

1. Select ***Start Daily Listening Check***.

2. The actual Daily Listening Check is performed at the RA660. Go to the RA660 being tested and follow the instructions on the RA660 display (Figure 34 to Figure 37).

RA660 Daily Listening Check Screens

Figure 34

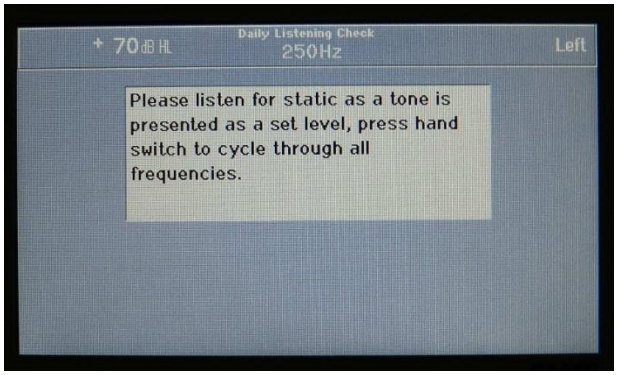


Figure 35

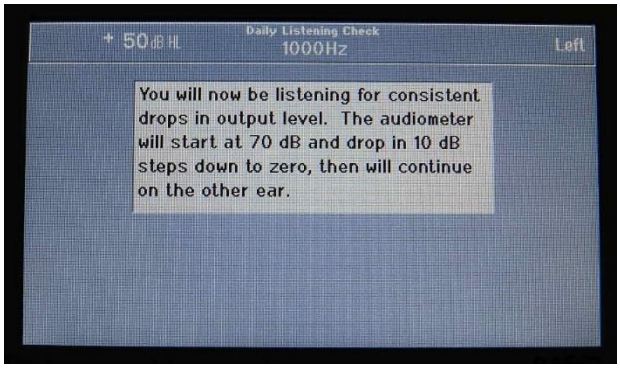


Figure 36

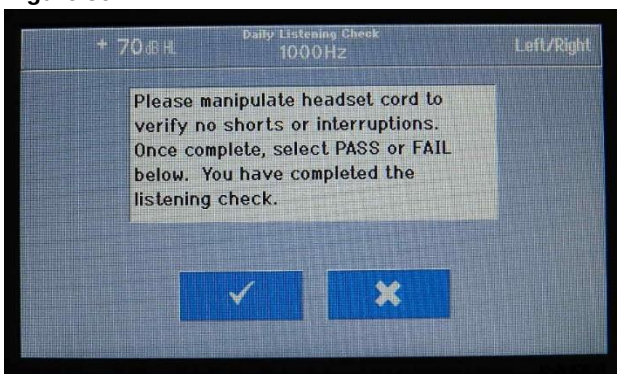


Figure 37

3. Back at the PC select ***Save*** and ***Close*** on the Daily Biological window. The ***Daily Biological*** window closes, and the Daily Biological is complete (Figure 38).

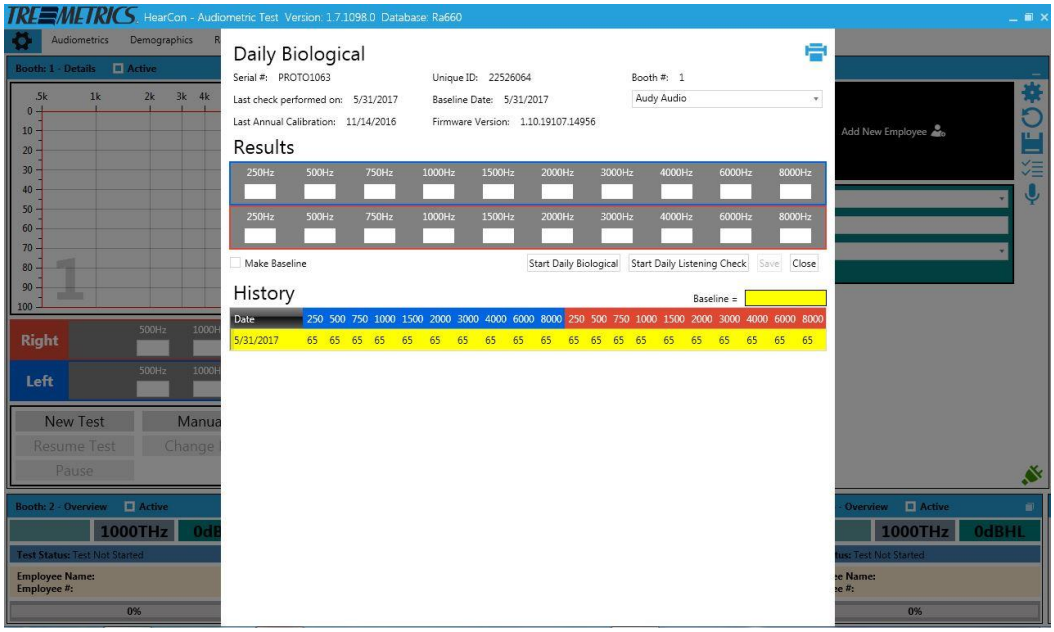


Figure 38

5.10.4 Run a Daily Biological from the Overview screen

It is also possible to run a Daily Biological from the Overview screen instead of the Details screen. Click ***Audiometrics > Audio Testing*** to get to the ***Overview*** screen. Right-click in the ***Employee Name*** and ***Employee #*** field of the audiometer to be selected. A drop-down menu will appear (Figure 39).

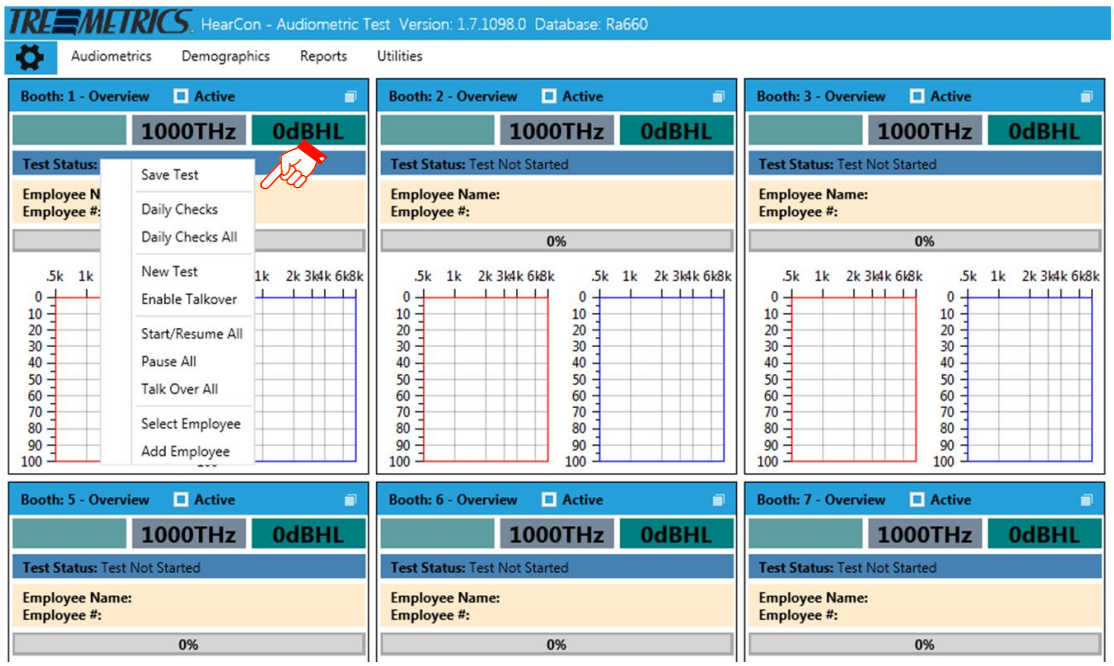


Figure 39

From this drop-down menu it is possible to start a Daily Biological on an individual audiometer with ***Daily Checks*** or all the audiometers with ***Daily Checks All*.**

5.11 Test Configuration

5.11.1 General

The HearCon RA660 Software allows customization of the automatic test and other software parameters. To access these options, select the ***Settings*** icon at the top left of the screen (Figure 40. The settings menu will open.

Figure 40

5.11.2 Test Parameters

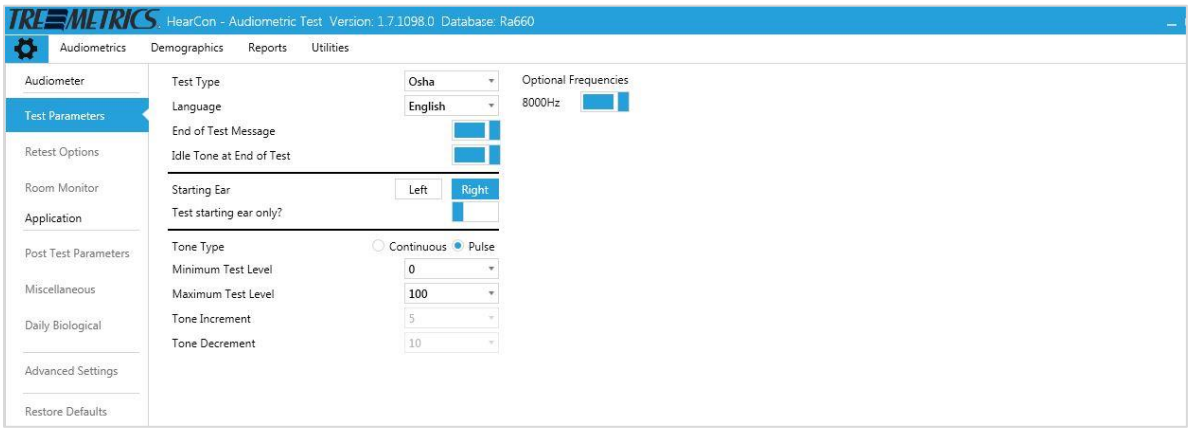


Figure 41

1. ***Test Type*** OSHA – selects test parameters based on OSHA requirements.
   Other – allows custom test parameters.
2. ***Language*** - Selects language for voice prompts.
3. ***End of Test Message*** – Turns on the End of Test voice prompt.
4. ***Idle Tone at End of Test*** – Continues to present test tones to the employee after completing the test until everyone being tested is finished.
5. ***Starting Ear*** – Selects the ear to test first.
6. ***Test starting ear only?*** – Selects testing only the selected Start Ear.
7. ***Tone Type*** – Selects continuous or pulsed tone presentation.
8. ***Minimum Test Level*** – Selects 0 or -10 dB HL as the lowest level tested.
9. ***Maximum Test Level*** – Selects 90, 95, or 100 as maximum level tested.
10. ***Tone Increment*** – Selects the automatic intensity increase.
11. ***Tone Decrement*** - Selects the automatic intensity decrease.
12. ***Optional Frequencies*** – Allows frequencies to be turned off.

5.11.3 Retest Options

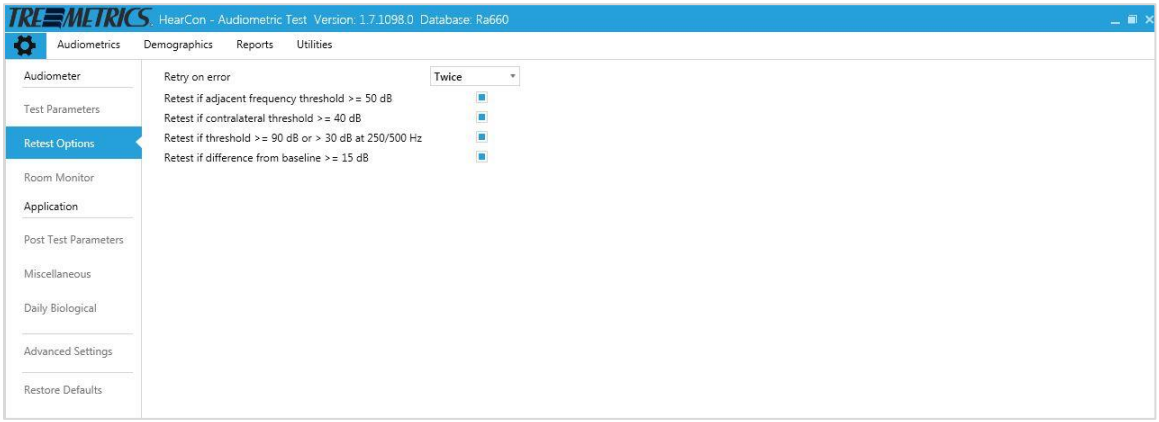


Figure 42

The RA660 will go back and retest frequencies for any of the enabled conditions below:

1. ***Retry On Error*** – Selectes how many times (Once, Twice or Always) the conditions below will be retested before stopping the test.
2. ***Retest if adjacent frequency threshold >= 50 dB*** – If the current threshold is 50 dB greater than the threshold at the previous frequency a retest will occur.
3. ***Retest if contralateral threshold >= 40 dB*** – If the threshold is 40 dB or more than the opposite ear a retest will occur.
4. ***Retest if threshold >= to 90 dB or > 30 dB at 250 or 500 Hz*** – If the threshold at any frequency is 90 dB or greater or the threshold is greater than 30 dB at 250 or 500 Hz a retest will occur.
5. ***Retest if difference from baseline >= 15 dB*** – if a baseline is present and the current threshold differs by 15 dB or more a retest occurs.

5.11.4 Room Monitor

Figure 43

Pause Testing If Over Limits – If enabled the test will automatically pause if the octave band sound level exceeds the theshold level entered for each frequency in the boxes below.

Add New Zone – See Section 5.9 Room Monitor.

5.11.5 Miscellaneous

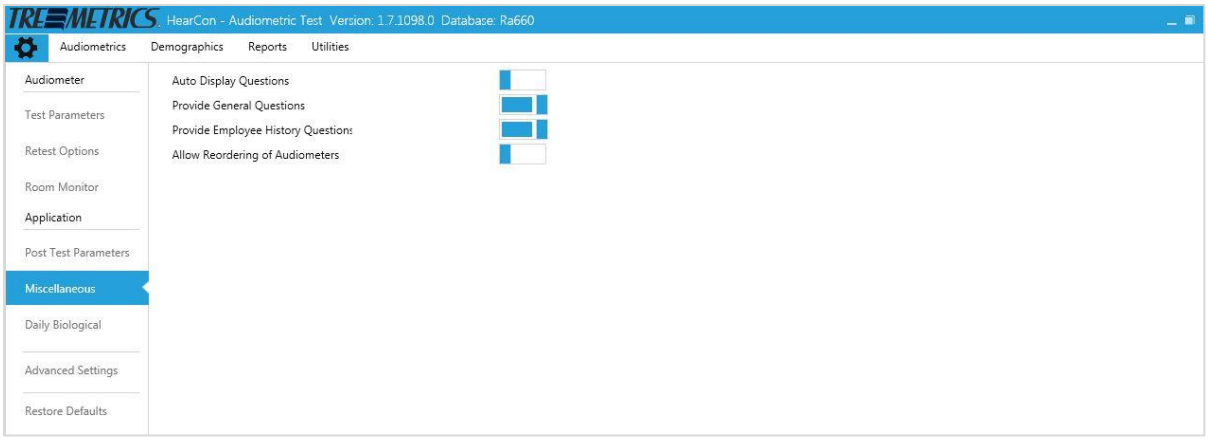


Figure 44

1. ***Auto Display Questions*** – Automatically opens the questions window at the start of a test.
2. ***Provide General Questions*** – Enables general employee questions.
3. ***Provide Employee History Questions*** – Enables employee history questions.
4. ***Allow Reordering of Audiometers*** – Allows reordering the audiometers on the overview screen by dragging and dropping the audiometer to the desired location.

5.11.6 Daily Biological

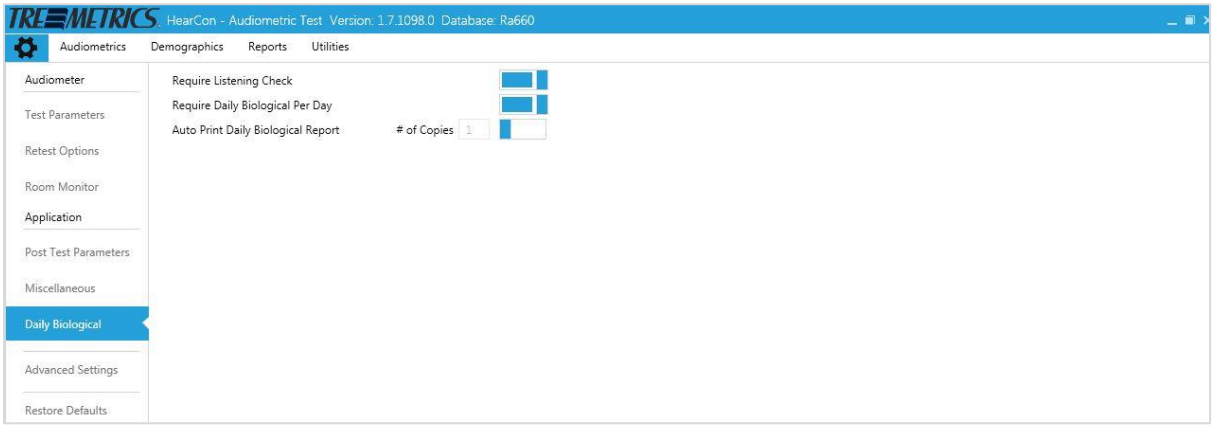


Figure 45

1. **Require Listening Check** – When enabled, a Listening Check is required as part of the Daily Biological test.
2. **Require Daily Biological Per Day** – When enabled a Daily Biological Test must have been completed in the past 24 hours to begin a new test.
3. **Auto Print Biological Report** – Enables automatically test printing at the completion of a Daily Biological Test and allows multiple copies.

5.12 Reports

The RA660 can generate several reports based on tests stored in its data base. To access the reports, select the ***Reports*** tab at the top of the screen. Then select the type of report from the drop-down menu (Figure 46).

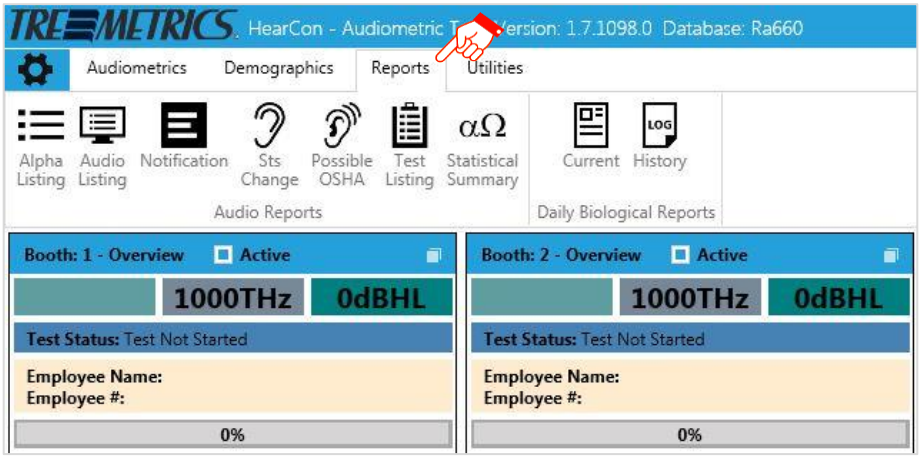


Figure 46

Available tests are:

1. ***Alpha Listing*** – a listing in alphabetical ordered of all tested employees
2. ***Audio Listing*** – a list of tests for the selected employee
3. ***Notification*** – current test report for the selected employee
4. ***STS Change*** – a list of employees with a Standard Threshold Shift.
5. ***Possible OSHA*** – a list of employees exhibiting a 10 dB average change.
6. ***Test Listing*** – a list of all employees and their tests
7. ***Statistical Summary*** – a statistical summary of the current database
8. ***Daily Biological Current*** – a list of the most recent Daily Biological tests
9. ***Daily Biological History*** – a list of all Daily Biological tests

5.13 Room Monitor

The RA660 can continuously monitor room noise in seven octave bands from 125 – 8000 Hz. This requires a Room Monitor Microphone which plugs into the back of the RA660 audiometer (Figure 47).

Figure 47

The room monitor feature also requires a Room Monitor License. This license key is entered into the RA660 the room monitor microphone is plugged into. The microphone must be plugged into the RA660 with the license key, but the sound room levels can be displayed on and used to control multiple RA660 audiometers. This is done with the room monitor zoning feature.

Before using the room monitor feature one or more room monitor zones need to be setup from the ***Settings*** > ***Room Monitor*** menu.

Click on the ***Add New Zone*** box, then click on the drop-down menu box and select the RA660 audiometers to be in the zone. One of the RA660 audiometers in the group must have a room monitor microphone plugged in and licensed. To create additional zones, click on the ***Add New Zone*** box (Figure 48).

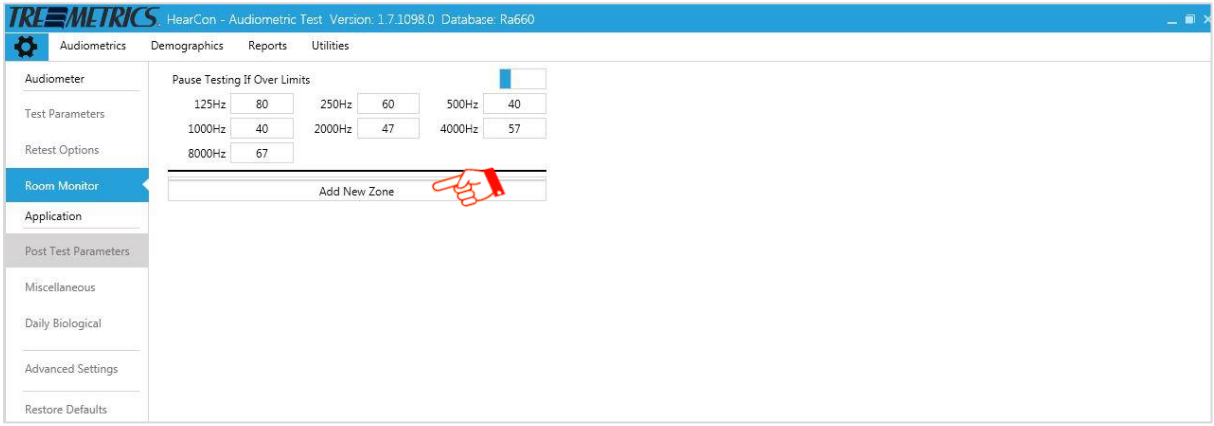


Figure 48

Each zone must have a RA660 with a room monitor microphone (Figure 49, example of 2 zones ZONE 1 RA660 1 – 4 ZONE 2 RA660 5 – 8 in Figure 14)

Figure 49

The measurement results are displayed on the ***Details*** screen of each RA660 in the zone. The results are displayed as a bar graph on the right side of the screen (Figure 50).

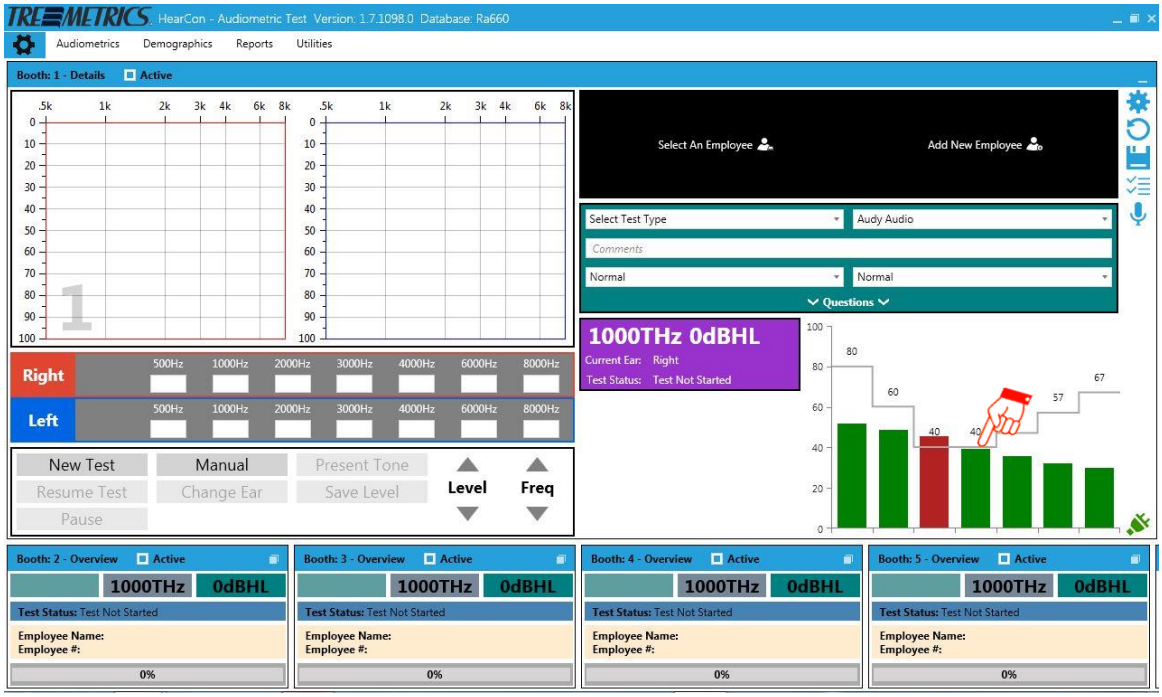


Figure 50

A green bar indicates that octave band is below the defined limit, a red bar indicates that octave band is above the defined limit. The gray line above the bars indicates the limit for each band. The numbers above the gray line are the same limit values displayed numerically.

The limit for each band is set in the ***Settings*** > ***Room Monitor*** screen. Also on this screen is the ***Pause Testing If Over Limits*** switch. If this switch is on, the audiometers will automatically pause the test if the room noise exceeds the set limit and automatically restart when the noise drops below the limit.

5.14 Exporting and Importing Data

5.14.1 General

The HearCon RA660 Software can export or import its database to an XML or CSV format file. This allows the HearCon RA660 Software to interface with third party hearing conservation programs. To use this feature, select the ***Utilities*** tab (Figure 51).

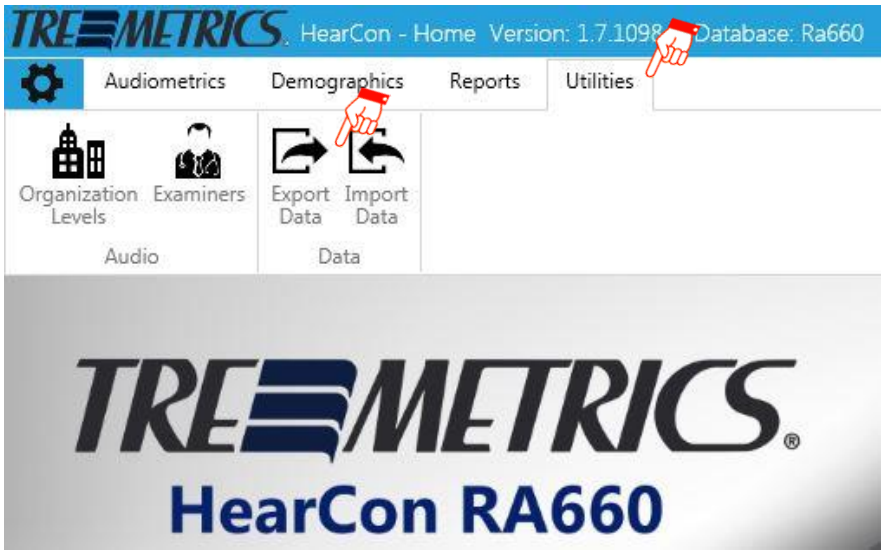


Figure 51

5.14.2 Exporting Data

To export the database, select ***Utilities*** > ***Export Data***. The export data screen will open and populate with the current database information. It will display the ***Record Count*** and ***Employee Count*** for verification of the data (Figure 52).

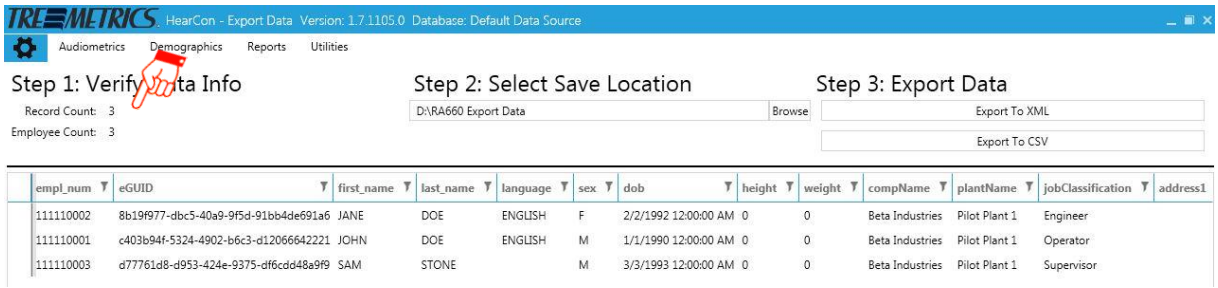


Figure 52

Under Step 2: Enter a location to export the data. The ***Browse*** button can be used to find a location.

Under Step 3: Select ***Export To XML*** or ***Export To CSV***. A file named export of the type selected will be created in the selected location containing the exported data. See Section 6.6.1 for the export data format.

5.14.3 Importing Data

To import a database, select ***Utilities*** > ***Import Data***. The ***Import Data*** screen will open (Figure 53).

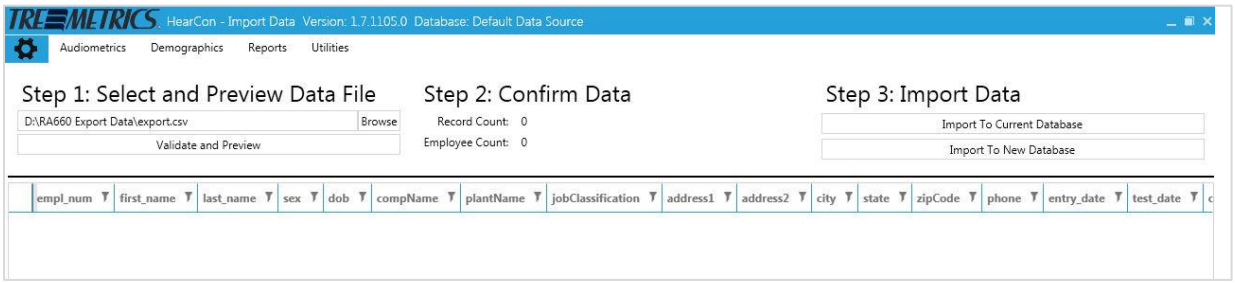


Figure 53

Under Step 1: enter in the box the data file to be imported. Then click on the ***Validate and Preview*** button to load the data.

Under Step 2: the record count and employee count can be used to verify all the data has correctly loaded.

If the data counts look correct go to **Step 3**: and click on ***Import to Current Database*** or ***Import to New Database*** to import the data. See Section 6.6.2 for the import data format.

6 Technical Specifications

This section offers you important information about

- **the RA660 hardware specifications**
- **connections**
- **the pin assignment**
- **calibration values and maximum levels**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated standards**

6.1 RA660 Hardware and Software

CE 0123

The RA660 audiometer is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

General Information About Specifications

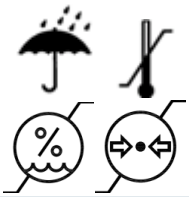
The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least once every 12 months.

MAICO Diagnostics puts diagrams and service manuals at the disposal of authorized service companies.

STANDARDS	
Electrical Safety Standards	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) AAMI ES 60601-1:2005/A12012 CSA-C22.2 No. 60601-1:14 Class I, Type B Applied Parts
EMC Standard	IEC 60601-1-2:2014
Audiometer Standards	IEC 60645-1:2012/ANSI S3.6-2010Type 4
Calibration	ISO 3I d89-1:2017

DEVICE SPECIFICATIONS		
Power supply unit UES65-240250SPA3 Fuhua Electronic	Consumption	60 W max.
	Input	100-240 VAC ± 10 %, 50/60 Hz, 2.0 A
	Output	24.0 DC, 2.5 A max.
Mode of Operation	Continuous	

DEVICE SPECIFICATIONS

Environment Conditions 	**Operation**	+15 °C to +35 °C /+59 °F to +95 °F Humidity: 30 % to 90 %, non-condensing Air pressure: 80 kPa to 104 kPa
	Storage	0 °C to +50 °C / +32 °F to +122 °F Humidity: 10 % to 95 %, non-condensing
	Transport	-20 °C to +50 °C / -4 °F to +122 °F Humidity: 10 % … 95 %, non-condensing
Dimensions	Audiometer: W x D x H: 170 mm x 170 mm x 100 mm Interface Box: W x D x H: 210 mm x 110 mm x 35 mm	
Weight	Audiometer: 0.5 kg Interface Box: 0.4 kg	
Display	4.3”, color LCD touch screen, 480 x 3 (RGB) x 272	
User Interface	LCD touch screen, PC screen and/or keyboard	
Language Settings	User interface: English Voice prompt: English, Khmer, French, German, Italian, Spanish, Vietnamese	
PC Connection	USB; up to 8 audiometers can be connected to a single PC via the interface box and operated simultaneously in the HearCon RA660 Software.	
Warm-up Time	Less than 1 min after power on (incl. boot-up time)	
Patient Communication	Talkforward	
Inputs	Tone, Pulse Tone (modulation: 200 mS on 200 mS off)	
Accuracy	Frequency: 2 %, Level ± 3 dB	
Precision	5 dB HL steps	
Outputs	Left, Right	
Special tests/test battery	Automatic-recording audiometer according ISO 8253-1 Auto threshold: Hughson-Westlake Time window for patient response: 1.8 s from presentation of tone	
Test Frequencies	250 Hz to 8000 Hz	
Levels	-10 dB HL to 100 dB HL	
Subject Response	Handheld patient response switch	
Stimulus Functions	Tone Presenter	
Bio-acoustic Simulator	Response at 65 dB HL ±10 dB at 250 Hz to 8000 Hz	
Room Monitor	Octave band measurements 125 Hz to 8000 Hz	
Calibration	Calibration information and instructions are located in the RA660 Service Manual.	
Air Conduction	DD45	RadioEar Standard Values
	IP30	ISO 389-2, ANSI S3.6
	TDH39	ISO 389-1:1998, ANSI S3.6-2010
Transducers – Headband tension	DD45	Headband Static Force 4.5 N ± 0.5 N
	TDH39	Headband Static Force 4.5 N ± 0.5 N
PC Requirements (HearCon RA660 Sofware)	Windows® 7 or Windows® 10	

6.2 Connections and Pin Assignment

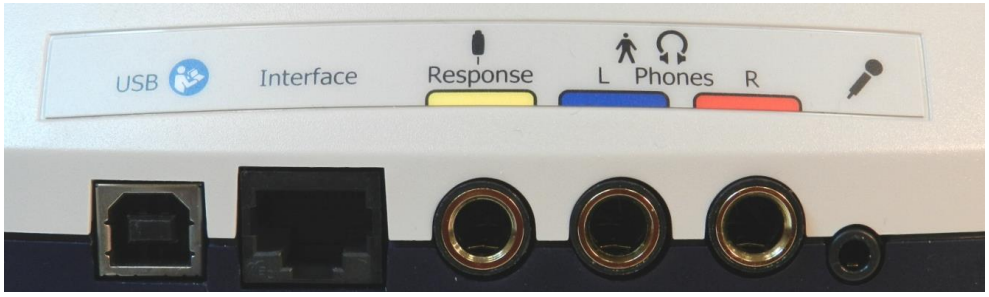
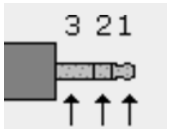
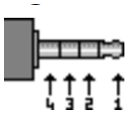
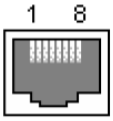
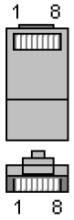


Figure 55

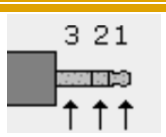
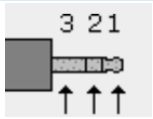
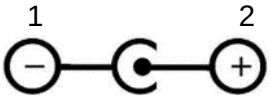
CONNECTION SOCKETS	SPECIFICATION
USB in	USB 2.0
Interface	Custom
Subject response switch (Response)	R_I = 330 Ω V = 3.3 VDC
Phone left	Z_A =10 Ω U_A = 3 V_{eff}
Phone right	Z_A =10 Ω U_A = 3 V_{eff}
Microphone input	Z_I = 3 k Ω U_I = 0.5 - 50 mV_{eff}

SOCKET	CONNECTOR	PIN 1	PIN 2	PIN 3	PIN 4
Phone Left Phone Right Subject response	 6.3 mm Stereo	Signal	One Wire ID	Ground	
Room Monitor Microphone	 3.5 mm Stereo	Signal	Bias	One Wire ID	Ground
USB In		+5 VDC	Data -	Data +	Ground

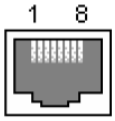
INTERFACE		
 RJ45 Socket	 RJ45 Cable Plug	1 TX - Transmit Data - 2 TX + Transmit Data + 3 RX + Receive Data + 4 Audio In + 5 Audio In - 6 RX - Receive Data - 7 Power + 8 Ground

Interface Box Connections

CONNECTION SOCKETS	SPECIFICATION
Mic In	Z_I = 3 k Ω, U_I = 0.5 - 50 mV_{eff}
USB in	USB 2.0
Power In	UES65-240250SPA3
Line In	Z_I = 10 k Ω, U_I = 50 - 500 mV_{eff}
Audiometer 1 - 8	Custom

SOCKET	CONNECTOR	PIN 1	PIN 2	PIN 3	PIN 4
Mic In	 3.5 mm Stereo	Signal	Bias	Ground	
Line In	 3.5 mm Stereo	Signal	Signal	Ground	
USB In		+5 VDC	Data –	Data +	Ground
Power In		Ground	+24 VDC		

AUDIOMETER 1 – 8



RJ45 Socket

RJ45 Cable Plug

1	RX - Receive Data -
2	RX + Receive Data +
3	TX + Transmit Data +
4	Audio Out +
5	Audio Out -
6	TX - Transmit Data -
7	Power +
8	Ground

6.3 Calibration Values and Maximum Levels

Headphones DD45

Coupler IEC 60318-3, PTB Report 2009, DTU Report 2010

Frequency (Hz)	Tone RETSPL dB re 20µPa	Max Tone [dB HL]	Sound Attenuation [dB] with MX41/AR or PH51 Cushion ISO 4869-1
250	27.0	100	5
500	13.0	100	7
750	6.5	100	-
1000	6.0	100	15
1500	8.0	100	-
2000	8.0	100	26
3000	8.0	100	-
4000	9.0	100	32
6000	20.5	100	-
8000	12.0	100	24

Headphones TDH39

Coupler IEC 60318-3, ISO 389-1:1998 or ANSI S3.6-2010

Frequency (Hz)	Tone RETSPL dB re 20µPa	Max Tone [dB HL]	Sound Attenuation [dB] with MX41/AR or PH51 Cushion ISO 4869-1
250	25.5	100	5
500	11.5	100	7
750	7.5	100	-
1000	7.0	100	15
1500	6.5	100	-
2000	9.0	100	26
3000	10.0	100	-
4000	9.5	100	32
6000	15.5	100	-
8000	13.0	100	24

Insert Earphones RadioEar IP30

Coupler IEC 60318-5, ISO 389-2:1994 or ANSI S3.6-2010

Frequency (Hz)	Tone RETSPL DB re 20µPa	Max Tone [dB HL]	Sound Attenuation [dB] ISO 4869-1
250	14.0	100	34.5
500	5.5	100	34.5
750	2.0	100	-
1000	0.0	100	35.0
1500	2.0	100	-
2000	3.0	100	33.0
3000	3.5	100	-
4000	5.5	100	39.5
6000	2.0	90	-
8000	0.0	90	43.5

6.4 Electromagnetic Compatibility (EMC)

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE.
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

This device is in compliance with IEC 60601-1-2:2014, 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.

Portable and mobile RF communications equipment can affect the RA660. Install and operate the RA660 according to the EMC information presented in this section.
The RA660 has been tested for EMC emissions and immunity as a standalone RA660. Do not use the RA660 adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by MAICO as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *RA660* is intended for use in the electromagnetic environment specified below. The customer or the user of the *RA660* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***RA660*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***RA660*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *RA660*.			
The ***RA660*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***RA660*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***RA660*** as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
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 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***RA660*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***RA660*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+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 residential 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 residential environment.
Voltage dips, short interruptions and voltage variations on power supply 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***RA660*** requires continued operation during power mains interruptions, it is recommended that the ***RA660*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) 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 residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***RA660*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***RA660*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***RA660,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***RA660*** is used exceeds the applicable RF compliance level above, the ***RA660*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***RA660.*** **b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

ITEM	MANUFACTURER	MODEL
Power supply unit	FUHUA	UES65-240250SPA3
Audiometric Headphones	Telephonics	TDH39
Audiometric Headphones	RadioEar	DD45
Insert Earphones	RadioEar	IP30

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened/Unscreened
Mains Cable	2.0 m	Unscreened
USB Cable	5.0 m	Screened
Interface cable	10.0 m	Unscreened
Insert Earphones	2.0 m	Screened

6.5 Appendix Export / Import Formats

6.5.1 Export Data Format

Data Export Fields			
Name	Type	Max Length	Valid Values / Examples
empl_num	string	15	'12345678', '1234567A'
eGUID	Guid		c8596441-c6aa-4a1e-a2dd-b13a4ebcea2b
first_name	string	50	
last_name	string	50	
language	String	20	
sex	string	1	'M' or 'F'
dob	dateTime		'010117', '01/01/2017'
height	int		
weight	int		
compName	string	50	
plantName	string	50	
jobClassification	string	30	
address1	string	50	
address2	string	50	
city	string	30	
state	string	2	'NC', 'SC', 'VA'
zipCode	string	5	'27409'
phone	string	20	
notes	string	1000	
test_id	int		
tGUID	Guid		c8596441-c6aa-4a1e-a2dd-b13a4ebcea2b
entry_date	dateTime		'010117', '01/01/2017'
test_date	dateTime		'010117', '01/01/2017'
comments	string	MAX	
q1	string	1	'Y', 'N'
q2	string	1	'Y', 'N'
q3	string	1	'Y', 'N'
q4	string	1	'Y', 'N'
r250	int		
r500	int		
r750	int		
r1000	int		
r1500	int		
r2000	int		
r3000	int		
r4000	int		
r6000	int		
r8000	int		
l250	int		
l500	int		
l750	int		
l1000	int		
l1500	int		
l2000	int		
l3000	int		
l4000	int		
l6000	int		
l8000	int		
audiometerMake	string	10	'Tremetrics'
audiometerModel	string	10	'RA660'
audiometerSerial	string	10	'PROTO1234'
audiometerCalibration			'010117', '01/01/2017'
examinerName	string	50	

6.5.2 Import Data Format

Data Import Fields			
Name	Type	Max Length	Valid Values / Examples
empl_num	string	15	'12345678', '1234567A'
first_name	string	50	
last_name	string	50	
sex	string	1	'M' or 'F'
dob	dateTime		'010117', '01/01/2017'
compName	string	50	
plantName	string	50	
jobClassification	string	30	
address1	string	50	
address2	string	50	
city	string	30	
state	string	2	'NC', 'SC', 'VA'
zipCode	string	5	'27409'
phone	string	20	
entry_date	dateTime		'010117', '01/01/2017'
test_date	dateTime		'010117', '01/01/2017'
comments	string	MAX	
q1	string	1	'Y', 'N'
q2	string	1	'Y', 'N'
q3	string	1	'Y', 'N'
q4	string	1	'Y', 'N'
r250	int		
r500	int		
r750	int		
r1000	int		
r1500	int		
r2000	int		
r3000	int		
r4000	int		
r6000	int		
r8000	int		
l250	int		
l500	int		
l750	int		
l1000	int		
l1500	int		
l2000	int		
l3000	int		
l4000	int		
l6000	int		
l8000	int		
audiometerMake	string	10	'Tremetrics'
audiometerModel	string	10	'RA660'
audiometerSerial	string	10	'PROTO1234'
audiometerCalibration			'010117', '01/01/2017'
examinerName	string	50	

6.6 Electrical Safety, EMC and Associated Standards

1. IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint), AAMI ES 60601-1:2005/A12012, CSA-C22.2 No. 60601-1:14: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests
3. General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
4. 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
5. DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Specifications are subject to change

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