GE Healthcare

MRIaudio

COMFORT THROUGH SOUND

Installation and User Guide

Models 1505 and 1506

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MRIaudio
COMFORT THROUGH SOUND

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Patient Comfort through Sound

DEVICE DESCRIPTION

The MRIaudio Sound System is an MRI conditional audio solution that provides MRI patients with music, direct communication from the technologist and 29 dB hearing protection.

WARNINGS AND CAUTIONS

Please read this manual and follow its instructions carefully. The words, **WARNING**, **CAUTION** and **NOTE** carry special meaning and should be carefully reviewed:

WARNING: Indicates risk to the safety of the patient or technologist. Failure to follow warnings may result in injury to the patient or technologist.

CAUTION: Indicates risk to system equipment. Failure to follow cautions may result in product damage and void warranty.

To avoid potential serious injury to the user and the patient and/or damage to this device, please note the following warnings:

- Check for any obvious damage prior to installing or using equipment. If damage is detected, refer to the standard warranty.
- The wishbone, In-Ear Headset is much louder than the Over-Ear Headphones. Volume level should not exceed 40%.
- Test the volume level prior to giving a patient the headphones. Prolonged exposure to loud noises can cause hearing damage.
- The voltage within the device may have sufficient magnitude to cause electric shock. Therefore, it is dangerous to make any kind of contact with any part inside the device.
- The foam ear-tips on the In-Ear Headphones must be fully inserted into the ear canal to achieve 29 dB of noise attenuation, or NRR (Noise Reduction Rating).
- Do not remove the cover on any of the equipment as there are no user serviceable parts inside.

- Do not modify this equipment in any way.
- Never use the system in the presence of flammable or explosive gases.

It is critically important that only MR Safe and MR Conditional components be taken into and installed in the MRI suite. When installed correctly, the MRIaudio Sound System is MRI-compatible and will produce high-quality audio for patients undergoing MRI scans.

INDICATIONS FOR USE

The MRIaudio Sound System is intended to provide audio entertainment and facilitate patient communication in MRI environments up to, and including, 3.0 Tesla. The product is not intended for medical diagnosis or treatment. Technologist control units are intended to be used outside of the MRI scan room.

WARNING: Portable RF communications equipment including peripherals such as antenna cables and external antennas should be used no closer than 12 inches (30 cm) to any part of the MRIaudio Sound System or cables. This could result in a performance degradation of the system.

WARNING: Use of accessories, cables, and other equipment not specified or provided by MRIaudio could result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment and result in improper operation.

WARNING: Use of system equipment adjacent to or stacked with other equipment should be avoided. This could result in improper operation. If this scenario is necessary, the equipment should be observed to verify the system is operating normally.

NOTE: The emissions characteristics of this system equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The technologist might need to relocate or re-orient the equipment.

CLEANING

Device components can be cleaned with a dampened small cloth with rubbing alcohol or hand sanitizer. Do a quick wipe over the surface of the devices as well as the wires. For the Over-Ear Headphones, clean the ear cups with a sanitizing wipe. To avoid patient cross contamination, replace the headphone cloth covers after each scan session. For the In-Ear Headphones, clean the entire plastic wishbone with a sanitizing wipe. Replace the foam ear tips after each scan session.

EMERGENCY PROCEDURE

In the unlikely event that either the MRIaudio Sound System or any component creates smoke, sparks, or if the patient requires emergency assistance:

- Stop the scan immediately if one is in progress.
- Remove the headphones from the patient.
- Remove the patient from the scan room if medical treatment is needed.

REPORTING INCIDENTS

Contact MRIaudio immediately to report an incident and/or injury to a patient, operator or maintenance employee that occurred while using the MRIaudio Sound System. Do not operate the equipment until an investigation is conducted.

SYSTEM COMPONENT CLASSIFICATIONS

MR SAFE

This device is classified as completely nonmagnetic, non-electrically conductive and non-radio frequency reactive. This eliminates all primary and potential risks during MRI scanning.

MR CONDITIONAL

This system component may contain magnetic, electrically conductive or radio frequency-reactive parts. These are safe for operation in proximity to the MRI, provided the conditions for safe operation are defined and observed (both for the MRI scanner and the device itself).

MR UNSAFE

These objects are classified as MRI unsafe. They are significantly ferromagnetic and pose a clear and direct threat to persons and equipment within the magnet room.

MR UNSAFE COMPONENTS

WARNING: These system components are **NOT MR SAFE** and should never be taken into the MRI Suite.

**Optional*

iPad Mini w/ Mount

iPad Mini P/N 620
Mount P/N 630

Digital Amplifier

P/N 600

Technologist Speakers

P/N 670

100' DB9 Cable

DB9 Cable P/N 201

AutoVoice Adapter

25 pin P/N 680
15 pin P/N 685

6' RCA to 35mm Cable

P/N 625

MRI SAFE COMPONENTS

These system components are **MR SAFE** and can be used within the MRI bore during a scan.

In-Ear Headphones

P/N 320

Over-Ear Headphones

P/N 330

Headphone Covers and Ear Tips (optional)

Cloth Covers P/N 326
Foam Ear Tips P/N 325

9' Pneumatic Tubing

P/N 220

MRI CONDITIONAL COMPONENTS

WARNING: These system components are **MR CONDITIONAL** and can be placed within the MRI Suite near or next to the bore. These components should be kept at a minimum of 3 feet away.

Sonic Transducer

P/N 101

45' RF Shielded Cable

DB9 Cable P/N 210

SYSTEM COMPONENT DESCRIPTIONS AND PART NUMBERS

PRIMARY COMPONENT SPECIFICATIONS				
NAME	**PART #**	**GE PART #**	**DIMENSIONS (L x W x H - IN.)**	**WEIGHT (LBS.)**
Digital Amplifier	600	5759312	9 x 6 x 3.5	3.2
Technologist Speakers	670	N/A	3.5 x 6 x 7.5	3.3
Sonic Transducer	101	5759309	7 x 5 x 5	7
iPad and Mount	620 / 630	5759314 / 5759316	8 x 6 x 10.5	2.6

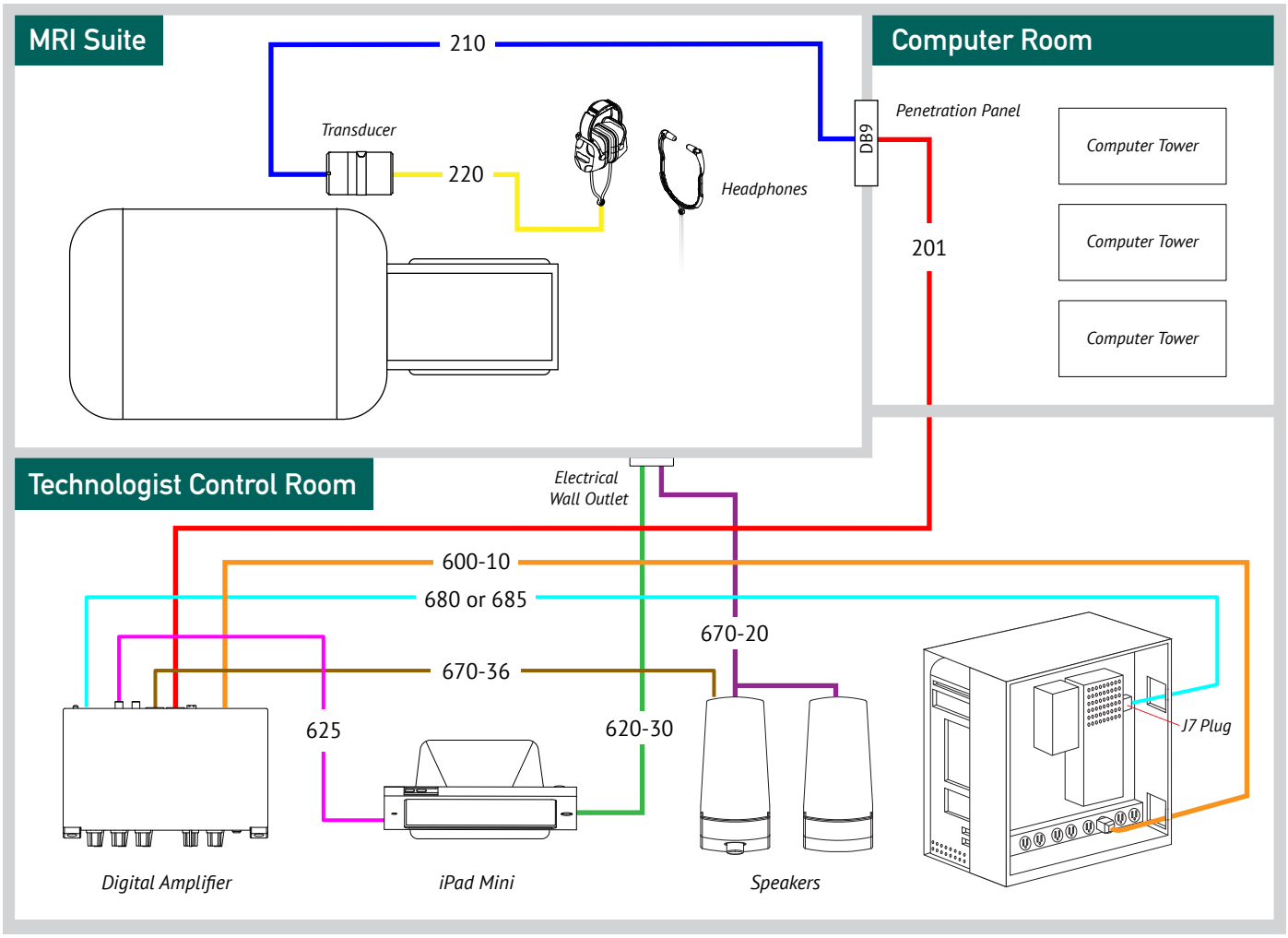
NAME	PART #	GE PART #	DESCRIPTION
Sonic Transducer	101	5759309	Component has a BNC input and is 1.5 / 3 Tesla tested. Can be mounted under MRI or to the side of the patient table.
100' DB9 Cable	201	5759308	Connects Digital Amplifier to the penetration panel in computer room.
45' RF Shielded DB9 Cable	210	5759308	Connects penetration panel to the Sonic Transducer inside the MRI suite.
9' Pneumatic Tubing	220	5759307	Connects patient headphones to Sonic Transducer. Features one Sonic Transducer connection end and one standard two-prong headphone connection end.
Disposable Headphone Cloth Covers	326	N/A	Replacement sanitary cloth covers for Over-Ear Headphones.
Disposable Headphone Ear Tips	300 (250 pairs) 325 (500 pairs)	E8823NC (250 pairs) E8823ND (500 pairs)	Replacement foam ear tips for In-Ear Headphones. Rated for 29 decibels noise attenuation. Bio-compatibility tested for patient safety.
In-Ear Headphones	320	5759310	Slim, wishbone design fits inside all MRI coils. Provides 29 dB NRR (Noise Reduction Rating) when used with MRIaudio ear tips.
Over-Ear Headphones	330	5759311	Audio headphone features over size ear cups that a provides 29 dB NRR (Noise Reduction Rating). The 4' long tubing connects to 9' Pneumatic Tubing and Sonic Transducer.
Digital Amplifier	600	5759312	Sends audio signal from input device (iPad or other) to Sonic Transducer and Technologist Speakers. Allows direct patient communication through technologist microphone. Includes front panel volume, bass, and treble controls.
Universal Power Adapter	670-10	N/A	Intended to adapt power cords for use outside of the US and Canada. Adapters for China, Europe, UK, Australia, and New Zealand.
Amplifier Power Supply	600-10	5759318	24V DC/2A output, 100-240V AC input, Energy Star level 5 compliant. Connects Digital Amplifier's power supply to wall outlet or GOC. 6' power cord, type B (US/Canada).
iPad Mini (optional)	620	5759314	Customized 16 GB iPad Mini with Wi-Fi and music streaming apps.

SYSTEM COMPONENT DESCRIPTIONS AND PART NUMBERS

NAME	PART #	GE PART #	DESCRIPTION
iPad Charging Kit	620-30	5759315	3' lightning cable to charge iPad Mini. Type B (US/Canada) USB power adapter includes 6' USB extension cable.
6' RCA to 3.5mm Cord	625	5759315	Connects any music source with a 3.5mm port to the Digital Amplifier.
iPad Locking Mount	630	5759316	Locking mount stand for iPad Mini.
Technologist Speakers	670	N/A	Pair of Bose desktop speakers that allow the technologist to listen to the same music as the patient. Independent volume control included on master speaker.
Speaker Power Supply	670-20	5759319	Power supply for Technologist Speakers. 5' 8" cord, type B (US/Canada).
Speaker Amplifier Cable	670-36	N/A	Connects Technologist Speakers to Digital Amplifier.
AutoVoice Adapter (25-pin)	680	5759317	Integrates AutoVoice features with MRIaudio system. Connects to control computer with Digital Amplifier. 12' cable has 25-pin connector. For GE MRI models: Discovery™
AutoVoice Adapter (15-pin)	685	5762069	Integrates AutoVoice features with MRIaudio system. Connects to control computer with Digital Amplifier. 12' cable has 15-pin connector. For GE MRI models: SIGNA Explorer/Creator, SIGNA Pioneer (ver. 25 hardware).

For MRIaudio Premium Sound System Model #1505 and 1506 using AutoVoice Adapter.

The map diagram below provides an installation overview of the system that utilizes the 15 or 25-pin AutoVoice Adapter. The system is designed within the expected MRI and operator environments.



MAP LEGEND		
PART NUMBER	**PRODUCT DESCRIPTION**	**CABLE LENGTH (FT.)**
201	100' DB9 Cable	100'
210	45' RF Shielded DB9 Cable	45'
220	9' Pneumatic Tubing	9'
600-10	Amplifier Power Supply	11'
625	RCA to 3.5mm Cable	6'
670-20	Technologist Speakers Power Supply	5' 8"
670-36	Technologist Speakers Amplifier Cable	3'
680 or 685	AutoVoice Adapter (15-pin or 25-pin)	12'

1. 100' DB9 CABLE INSTALLATION

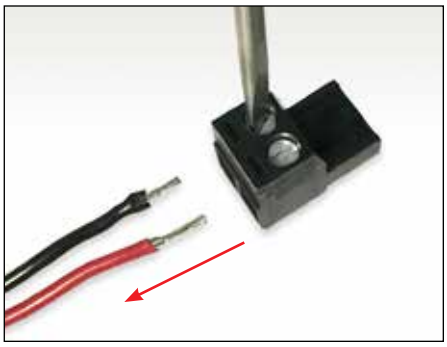
The following steps will walk you through the process for running the 100' cable from the Digital Amplifier to the penetration panel in the computer room.

100' DB9 Cable

1.1 Using a mini screwdriver, loosen, then remove the 2-pin terminal clip attached to the pigtail end of the 100' cable (Fig. 1). Set the pin aside for now. ***NOTE:*** *The terminal pin may arrive already detached.*

1.2 Locate the conduit pipe that begins in the control room and ends in the computer room. Look for both sides of an existing cable as a guide.

In the control room, the conduit is usually located under the main technologist desk. In the computer room, the conduit is usually located on the ceiling or high up on the same wall as the penetration panel. In older facilities, it may be located underneath the floor panels.

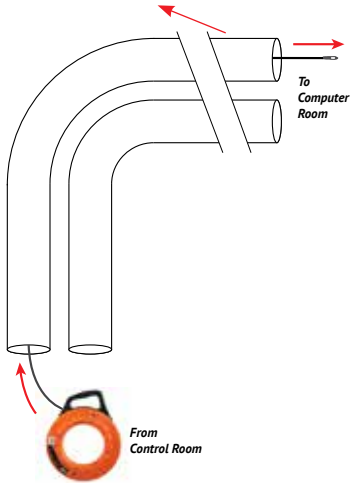


(Fig. 1)

1.3 To run the cable through the conduit, there will be two scenarios:

A) If you already have an older audio system in place, there will be an existing cable inside the conduit. You can utilize the old cable to pull the new cable through.

B) For a new cable install, you will need to run a fish tape through the conduit to pull the new cable through (Fig. 2). Starting in the control room, feed the fish tape through the conduit until it emerges in the computer room. This will require periodic checking of the conduit in the computer room.



(Fig. 2)

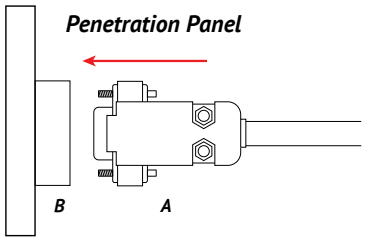
1.4 Using electrical tape, wrap the pigtail end of the new DB9 cable onto the end of the fish tape (or the old existing cable). Make sure to wrap it tightly and thoroughly in order to prevent detachment or snags when pulling the fish tape back through.

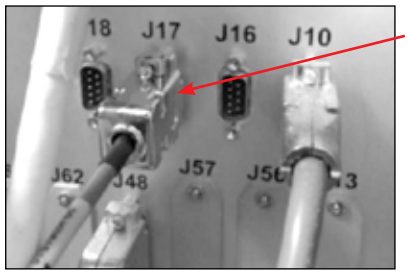
1.5 Once the cable is securely affixed, return to the control room. Begin to pull the fish tape/old cable through the conduit until the cable emerges in the control room. Pull out about 5' to 6' of cable into the control room for slack.

On rare occasions, you may not be able to get the fish tape past an obstruction in the conduit, no matter what you attempt. In this scenario, you will have to run the cable above the ceiling tiles from the control room to the computer room. This will require a large ladder, zip ties, and the fish tape to help get the cable past the drywall. Every facility's architecture is different and this process will require a bit of trial and error.

2. CONNECT 100' DB9 CABLE TO PENETRATION PANEL

2.1 In the computer room, connect the DB9 end (A) to J16, J17, or J18 (B) on the penetration panel (Fig. 3). Record the port used, as you will be connecting the 45' RF cable to the same port on the opposite side. Take up the slack in the 100' cable, coil it and secure to existing cables with zip-ties.





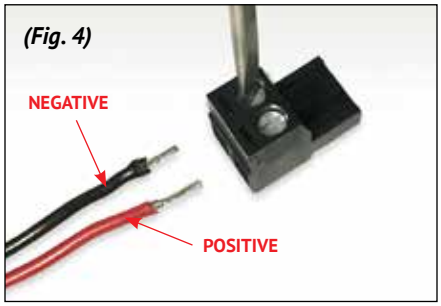
(Fig. 3)

3. CONNECT 100' DB9 CABLE TO DIGITAL AMPLIFIER

Once the cables are connected in the computer room, head back to the control room to finish the installation of the 100' cable.

3.1 Feed the pigtail end of the cable through any necessary troughs, cord concealers or desk grommets to get it up to the Digital Amplifier on the technologist desk.

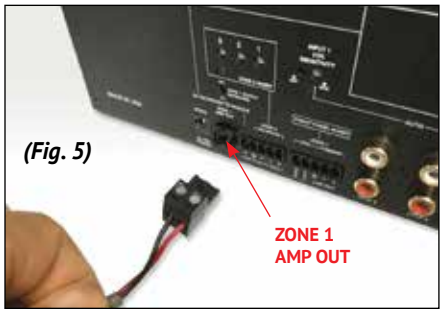
3.2 Using a mini screwdriver, reattach the 2-pin terminal clip that you removed earlier to the pigtail end of the cable (Fig. 4). The black wire is **NEGATIVE** and the red wire is **POSITIVE**.



(Fig. 4)

3.3 Connect the terminal pin into the back of the Digital Amplifier in the plug labeled **ZONE 1 AMP OUT** (Fig. 5).

3.4 Take up the slack in the cable directly in front of the conduit pipe, coil it, then zip-tie. Leave enough slack to move the Digital Amplifier, around the desk if necessary. Stuff the zip-tied cable up into the conduit and re-fasten any access panels.

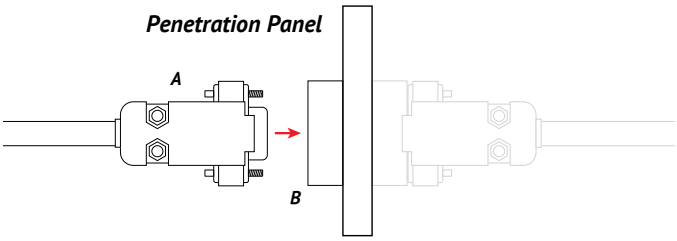


(Fig. 5)

4. CONNECT 45' RF CABLE TO PENETRATION PANEL

4.1 Before entering the MRI suite, ensure that you have no ferrous items (tools, keys, phone, etc.) on your person. In the MRI suite, connect the 45' RF cable (A) to the same DB9 port used in step 2.1.

4.2 Once the 45' cable is connected to penetration panel, run the other end to the magnet through cable raceway above the ceiling, along the floor, or through any available cable troughs (Fig. 6). It is recommended that you follow the existing cables that run from the penetration panel to the magnet. For aesthetics, you may run the cable inside the shell of the magnet, depending on the model.



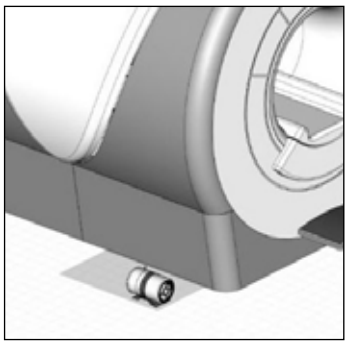
(Fig. 6)

5. INSTALL SONIC TRANSDUCER

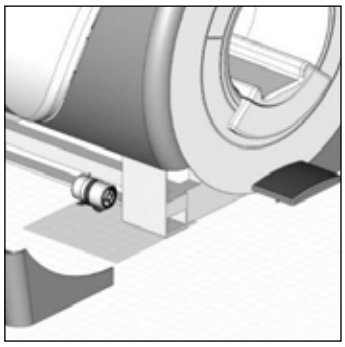
WARNING: The Sonic Transducer is **MR CONDITIONAL** and must be kept at least 3' away from the bore at all times. Exercise extreme caution when handling it until it is mounted.

5.1 Mounting Option 1.
The most common area to mount the transducer is on the floor near the front left or right side of the magnet. This should be on the opposite side of the injector (Fig. 7). Wipe floor clean, remove sticker tabs from bottom of transducer and place where desired.

5.1 Mounting Option 2. Remove the lower side panel on one side and mount the transducer under the magnet (Fig. 8). Wipe floor clean, remove sticker tabs from bottom of transducer and place where desired. Feed Pneumatic Tubing through opening in machine base (Fig. 9).

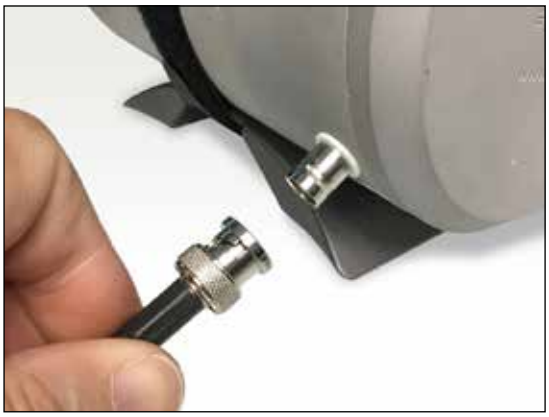


(Fig. 7)



(Fig. 8)

(Fig. 9)



(Fig. 10)

5.2 Connect the 45' cable to the BNC port on the transducer (Fig. 10). Pull any excess cable back toward the penetration panel leaving enough slack if the transducer needs to be adjusted. Ensure that there are no coils in cable. Coils are **NOT MR SAFE**. Collect the cable slack at the penetration panel, coil it, flatten and zip-tie (Fig. 11). Stuff as much excess cable as possible back into conduit.

5.3 Insert the male end of the 9' Pneumatic Tubing into the end port of the transducer. (Fig. 12). Make sure it is fully inserted. If mounted inside MRI machine, carefully close panel, leaving enough space for tubing (Fig. 13).

(Fig. 11)

(Fig. 12)

(Fig. 13)

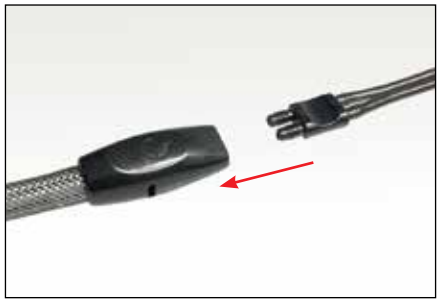
Pneumatic Tubing

6. MOUNT HEADPHONES

6.1 Remove the sticker backing on the Over-Ear Headphone mount. Attach to the side of MRI machine approximately 4-5 feet off ground (Fig. 14). Remove the sticker backing on the In-Ear Headphone hanger and attach under Over-Ear mount. Clamp the two headphones as shown (Fig. 15).

6.2 To connect to music system, plug the appropriate headphone set into Pneumatic Tubing (Fig. 16).

(Fig. 14)



(Fig. 16)

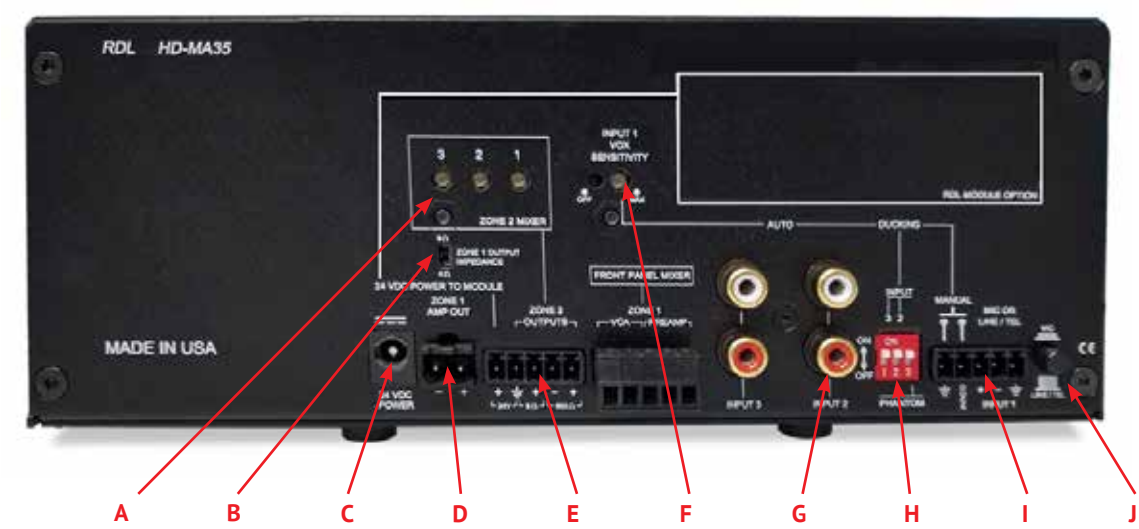
(Fig. 15)

7. DIGITAL AMPLIFIER ASSEMBLY

Before installing, inspect each component for visible damage. If components are damaged, do not proceed with installation and contact MRIaudio.

7.1 In the control room, connect the Digital Amplifier (600), Technologist Speakers (670) and the iPad (620) charger (if equipped) to electrical wall outlet. If necessary, use the Universal Power Adapter (670-10) to adapt the power cords to your locality.

If installing on a GE magnet, connect the Digital Amplifier power supply or Universal Power Adapter to the power strip inside the GOC.



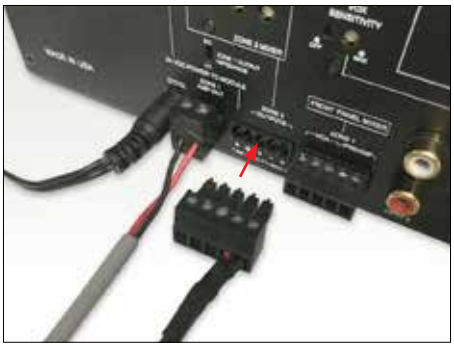
A. Zone 2 Mixer
B. Zone 1 Output Impedance
C. Power Supply
D. 100' DB9 Cable
E. Bose Speakers
F. VOX Sensitivity
G. RCA Cord
H. Phantom Switches
I. AutoVoice Adapter
J. Mic or Line/Tel Button *(should be out and set to LINE/TEL)*

7.2 The Digital Amplifier will arrive pre-configured. **DO NOT** change the settings unless the system is not working correctly. Check the back of the amplifier to ensure proper functionality.

- **ZONE 2 MIXER** - Dials 2 and 3 should be turned 75% clockwise. Dial 1 should be turned fully counterclockwise.
  NOTE: *Dials are plastic and should be turned with very little torque.*
- Input **PHANTOM** switches are in the "On" position.
- The **VOX SENSITIVITY** dial is turned fully clockwise.
- The **ZONE 1 OUTPUT IMPEDANCE** is set to the "8 ohm" position.
- Confirm that the **MIC OR LINE/TEL** button is out and set to the **LINE/TEL** position.

8. CONTROL ROOM COMPONENT ASSEMBLY

8.1 The power cord for the amplifier has two bayonet-style prongs. Line up the prongs with the hole labeled **24 VDC POWER**. Insert the cord plug and twist to lock into place. If you are unable to pull straight out, the cord is connected correctly.



8.2 Plug the Bose Speakers terminal clip (670-10) into the slot labeled **ZONE 2 OUTPUTS.**

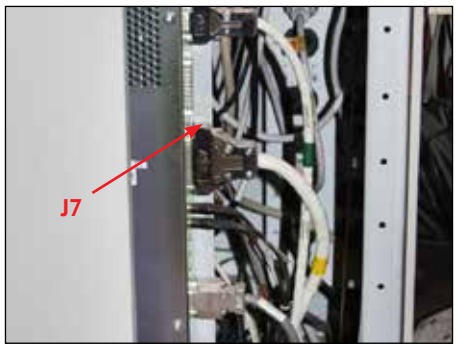
8.3 Plug the other end of the Bose Speakers connection cord into the slot labeled **AUX IN.** Plug the power cord from the wall outlet into the middle slot labeled **POWER**. Plug the secondary speaker cord (670-36) into the bottom slot labeled **LEFT SPEAKER**.

8.4 Plug the RCA cord into the slots labeled **INPUT 2**. The white marked cord should go in white slot. The red marked cord should go in red slot.

8.5 Plug the RCA cord audio jack into the left bottom audio port on the iPad.

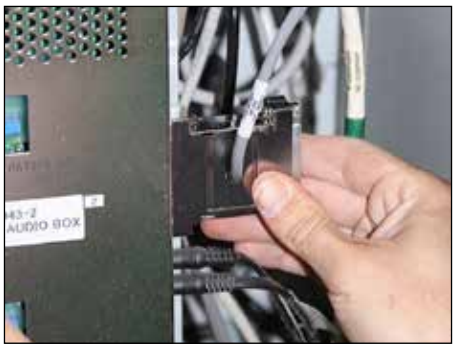
9. AUTOVOICE ADAPTER CONNECTION

Depending on the MRI machine model, you will be installing a 15-pin (685) or 25-pin (680) AutoVoice Adapter in the machine's console PC.



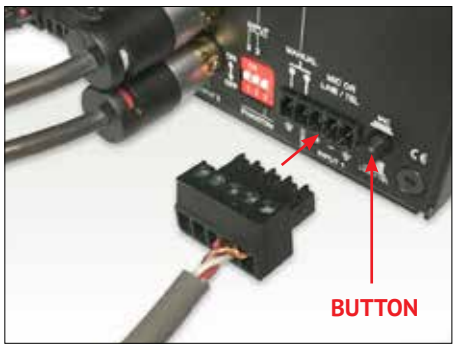
9.1 Open the case of the console PC. Locate the 25-pin DSUB AUDIO BOX or the 15-pin DSUB connector attached to the port labeled J7.

9.2 Using a small screwdriver, detach the existing pin connector.



9.3 Before installing, run the AutoVoice Adapter cable through the opening in the computer panel. Connect the new adapter back into the J7 port.

9.4 Re-connect the original pin connector into the back side of the AutoVoice Adapter. Tighten all screws until snug. Close panel and run cable up to Digital Amplifier.



9.5 Plug AutoVoice Adapter terminal clip into **INPUT 1** of the Digital Amplifier**.** Button should be set to **LINE/TEL** and pushed out.

iPad INTERFACE

The iPad Mini arrives pre-configured and is ready to use right away. Slide the iPad into the locking mount and secure in place. Lock combo is 0000. Ensure that the 3.5mm jack leading to the amplifier is connected to the iPad at all times. It is recommended to keep the charger (lightning port) connected at all times to ensure constant battery life.

iPad SETTINGS

CONNECT TO INTERNET
Go to iPad SETTINGS. Select WiFi in left column (A). Turn on WiFi (B). Find your facility's network and select (C). Enter password and connect.

USERNAME AND PASSWORD
Go to iPad SETTINGS. The username* for all apps will be listed under title (D). The password for all apps is **MRIaudio10**

**If you lose the original box or forgot your username, it can be found on the back of the iPad or in the Settings.*

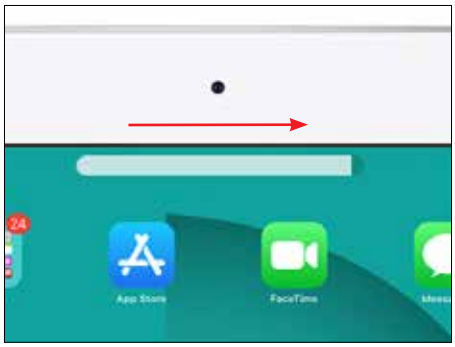
SUPPORT

FACETIME AND MESSAGES
For any support questions or troubleshooting, contact us through the FaceTime app for visual assistance.

10. HOW TO USE SYSTEM

10.1 POWER ON THE SYSTEM
Depress the power button on the lower right of the Digital Amplifier. A green light will illuminate to indicate the system is on. The blue light will always glow whether the amplifier is on or off.

10.2 SELECT STREAMING SERVICE
Have the patient select a streaming app, then choose their favorite music genre or podcast. Hit play.



10.3 ADJUST iPAD VOLUME
In order for the audio to work properly, the volume on the iPad must be maxed out. Slide volume control all the way to right.

10.4 CLOTH COVERS AND EAR TIPS
To prevent cross-contamination, put new cloth covers or foam ear tips on the headphones for each new patient.

10.5 PLACE HEADPHONES
For Over-Ear Headphones: Adjust the head band for size and place onto patient. Ensure the ear cups are covering entire ear. *For In-Ear Headphones:* Gently insert foam tips into patient's ears covering the entire ear canal.

10.6 ADJUST HEADPHONE VOLUME
Using the **MUSIC INPUT 2** knob on the Digital Amplifier, adjust the volume for the patient's headphones.

10.7 COMMUNICATE WITH PATIENT
Before beginning the scan, utilize the SCIM intercom to check with patient and adjust headphone sound volume.

10.8 MIC AND AUDIO CONTROL KNOBS
The knob **MIC INPUT 1** controls the technologist microphone to the patient. The knob **MUSIC INPUT 2** controls the patient's headphone volume. Both knobs have a green indicator light when in use.

10.9 ADJUST BOSE SPEAKER VOLUME
The technologist has the option of listening to the same audio as the patient. To adjust volume in control room, turn knob on main speaker.

TROUBLESHOOTING

The MRIaudio Sound System is easy to install and use. However, some issues may occur. Below are some of the most common operating problems.

Digital Amplifier is not powered:

If the blue indicator light is dark, the amplifier has no power. Check that the power cord in back is pushed all the way in, twisted and locked into place. You should not be able to pull it out. Press the power button. Both the blue and green light should be lit.

No sound in the headphones or technologist speakers:

- Check that the iPad or other media device is connected to the Internet.
- The volume on the iPad or other media device should be maxed out.
- The volume knob on the Digital Amplifier should be turned up and the input light is green.
- The music app should be playing (not paused) on the iPad.
- Check all connections on the back of the amplifier (see page 15).

Still no sound:

- Check that the headphones are fully plugged into the Pneumatic Tubing.
- Check that the Pneumatic Tubing is fully plugged into the Sonic Transducer.
- There should be no kinks or crimps in the Pneumatic Tubing or headphone tubing.
- Check cable connections on the penetration panel in both the computer room and MRI suite.
- Check that the excess cable has been flattened and zip tied (not coiled).

FREQUENTLY ASKED QUESTIONS

Does MRIaudio create noise or artifacts?

The MRIaudio system is designed from the ground up to eliminate the likelihood of artifacts or noise through the use of specialized components made specifically for compatibility in the MRI environment. This has been proven through rigorous third party testing and vetted by the U.S. Food and Drug Administration.

Are MRIaudio systems OEM compatibility?

MRIaudio systems are compatible with all OEMs, including GE, Siemens, Philips, Hitachi, and Canon (formerly Toshiba) MRIs.

What is the Noise Reduction Rating?

Tested by an ISO 17025 laboratory, both the Over-Ear and In-Ear headphones provide 29 decibels of hearing protection, satisfying the OSHA requirement for sustained excessive noise levels.

Is the MRIaudio system a medical device?

The FDA considers MRI sound systems to be medical devices; the MRIaudio system was tested and cleared as a class II medical device.

Does MRIaudio, Inc. have liability Insurance?

MRIaudio carries a 3 million dollar liability insurance policy.

How do you clean the MRIaudio system?

The headphones are the only system component which the patient will contact. Clean with sanitizing wipes or a cloth with alcohol. MRIaudio's disposable headphone foam ear tips and cloth covers are highly recommended.

Does MRIaudio offer a warranty on its systems?

All MRIaudio products come standard with a one year limited warranty. We also offer additional coverage through MRIaudio Care.

EMC INFORMATION

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The MRIaudio Sound System is intended for use in the electromagnetic environment specified below. The customer or the user of the MRIaudio Sound System should assure that it is used in such an environment.

EMISSIONS TEST & STANDARD	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated RF Emissions CISPR 11	Group 1	The MRIaudio Sound System 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.
Conducted RF EMISSIONS CISPR 11	Class A	The MRIaudio Sound System 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 distortion IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

IMMUNITY TEST AND STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles, @ 0°	0 % UT; 0,5 cycle, @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles, @ 0°	Main power quality should be that of a typical commercial or hospital environment. If the operator requires continued operation during power interruptions, it is recommended that the system be powered from an uninterrupted power supply or a battery.
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
Rated power freq. magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz repetition frequency	Main power quality should be that of a typical commercial or hospital environment
Surges (Line-to-line) IEC 61000-4-5	± 0.5 kV, ±1 kV	± 1 kV	Main power quality should be that of a typical commercial or hospital environment.
Surges (Line-to-ground) IEC 61000-4-5	± 0.5 kV, ±1 kV, ±2 kV	± 2 kV	

EMC INFORMATION

IMMUNITY TEST AND STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 0,15 – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MRIaudio Sound System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. *Recommended separation distance:* - 80MHz to 800 MHz - 800MHz 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*, should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**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 MRIaudio Sound system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MRIaudio Sound system.*

***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 MRIaudio Sound System.

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

PATIENT COMFORT THROUGH SOUND

Founded by Spencer Howe in 2010, MRIaudio is fully dedicated to providing the absolute best in MRI patient comfort equipment and customer service for diagnostic imaging professionals and their patients worldwide.

MRIaudio has seen exceptional growth in recent years, with annual sales growing nearly 100x, thanks to our **core values** and our incredible team. Each of our team members contributes to our success; together, we produce a team that is greater than the sum of its parts, culminating in first-rate **teamwork.** We believe that achievements deserve to be **celebrated** and that **positivity** is critical to success.

We are a dynamic, quick-moving company that always aims to go above and beyond, heeding the voice of the customer at every step. Working directly alongside MRI technologists, MRIaudio consistently utilizes their feedback to improve our products, as evidenced by the suite of customer-suggested features that have been included in the third generation of the MRIaudio system. Our president and CEO, Spencer Howe, believes that **simplicity** and ease of use are paramount - the simplest solutions are typically the best ones and the easier a product is to use, the more it will be used. Our goal for every one of our customers is to make their life as easy as possible - we believe that every deal should be a **win/win.**

MRIaudio
COMFORT THROUGH SOUND

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