

OPERATORS MANUAL

T-250 MRI Sound System

Troyka Med Inc IOSB Sitesi 2284. Cad No: 48 ANKARA-TURKIYE Tel: +90 5325128580- info@troykamed.com – www.troykamed.com MRI Sound System Op. Man. Pub. 022018 Pub. No: 0 Rev:0





MRI CONDITIONA TO 3 T.0 TESLA



Introduction

Thank you or purchasing the T-250 MRI :Sound System. This product is manufactured and tested to the highest standards and is guaranteed MR Conditional up to 3 Tesla.

This product is manufactured by Troyka Med Inc. at our factory based is Ankara, Turkey, to BS EN ISO 13485:2016

To ensure that you obtain maximum benefit from the T-250 MRI Sound system, please take a few minutes to read the enclosed information regarding operation, service and maintenance. After reading this manual, store it in a safe place for future reference.

If you have any problems in the meantime or would like any advice about this or any other MR products from the Troyka Med range, Please contact us at the following address

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溇	Protect from direct sunlight	Ĵ	Protect from rain and humidity	MR	MRI conditional up to 3 Tesla
i	Read user manual		Manufacturer	CE	ISO13485 ISO 9001 Class L medical devises

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1 Safety Information

1.1 MRI Safety Definition for MRI As Defined By International Standards ASTM F2503-13

MR	MR SAFE An item that poses no known hazards resulting from exposure to any MR environment MR SAFE items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic.
MR	MR CONDITIONAL An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific conditions of the item, may be required. Supplementary marking – additional information that, in association with marking as " MR CONDITIONAL " states via additional language the
MR	conditions in which as item can be used safely within the MR environment. MR UNSAFE An item with poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

1.2 General Safety Information and Intended Use

The MRI sound system must only be operated by personnel property trained in MRI safety.

The MRI Sound system must only be operated by personnel properly trained in identifying interference problems such as artifacts, streaks and distortions in image data. It is required that as personnel handling the MRI Sound System are familiar with the safety instructions given in the manual and other documentation provided to ensure safe operation of the Sound System and associated equipment.

The system comes with a one year warranty on all parts and labor, and a shelf life on two years starting from the day of its original installation. Troyka Med Inc. suggest a maintenance call every six months after the one year original warranty period to check up on frequently used items such as the patient audio headset and the Interface Unit. This way you will make the best use of this system for your facility and your patients.

1.3 Health Concerns

Avoid using the audio headset on patients at high volume. Hearing expert's advice against continuous loud and extended audio play. If your patients experience ringing in their ears, reduce the audio volume or discontinue use the system use until the patient feels comfortable.

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Warning!

If any of the components becomes damaged, stop using the headset immediately and notify Troyka Med Inc. customer service for assistance. Use of broken components can cause injury to the clinician or the patient.

1.4 Electrical safety

Warning! Contain electric components in the device require several hundred volts to operate properly. In order to prevent potentially lethal electric shock it is essential to disconnect the device from its power source during installation, and prior to servicing or repair. Some capacitors will remain charged with dangerous voltage levels even after the power is off. In order to prevent any possible electric shock, please wait several minutes for all capacitors to become completely discharged before proceeding.
Warning! Do not operate the device near the water, where it can become moist, or near excessive heat. Operation under such conditions could result in failure of the Sound System, possible electric shock, or fire. Don't handle the power cable with wet hands. High voltages present could cause lethal electric shock.
Warning! Should any foreign substances enter the device such as liquid, metal chips or dust, immediately turn off power to the Interface Unit. Under no circumstances shall tools or foreign objects be inserted into the device, as this could result in failure of the device, electric shock or fire.
Warning! If smoke, noxious odors or unusual noise should come from the device, immediately turn off power to the Sound System and contact your local distributor or Troyka Med service team.
Warning! Do not damage the power cable of the device. Do not attempt to modify the power cable should it malfunction. Should the power cable become damaged or frayed, it must be replaced.
Warning! Do not operate the Sound System if any cables are damaged.





Warning! Switch off and unplug the Sound System if it not be in use for 1 days or more.
Warning! To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
Warning! Self-heating of cables due to improper cable routing! Injury to equipment and/or operating personnel. Cables should not be looped crossed inside MRI room .

1.5 Warnings for MRI

CAUTION	Caution! Installation of materials inside the MRI must be done with extreme caution.
CAUTION	Caution! Take care that ferromagnetic materials be kept at least three meter away from the magnet and that no installation shall be done near the filter panel if a scan is in progress.
CAUTION	Caution! In addition, no persons with ferromagnetic prosthetic devices, such as pacemakers or joints replacement, should enter the MRI suite at any time. Extreme, high magnetic fields inside the magnetic room have the potential to dislodge items at high velocities and can result in serious injury, or death.
CAUTION	Caution! For questions regarding installation procedures or technical support, call Troyka Med Service team or contact via email at info@troykamed.com.
CAUTION	Caution! Only system components explicitly designed for use inside the MRI suite should be placed inside the magnet room. Components not designed for MRI use may present a projectile hazard and can become airborne, causing serious injury, damage or death.





2 General Information

2.1. Inspection of Delivered Goods

Each of Sound System has been thoroughly tested prior to deliver and is ready for immediate use. Upon receipt, please report any transportation damage or massing accessories immediately. Troyka Med can only accept liability for such damages if it is claimed prior to initial operation. In case of transportation damage, please contact the Troyka Med service department. For faster support please have ready all shipment details Sound System seral number and damage description. It is recommended to keep and store the original crate/box used to ship the Sound System for all future transportation needs.

2.2 Power Connection Information

The MRI Sound System operates on the line voltages 90-250V AC and 50/60 Hz. It is not necessary to double check line voltages or change any fuses. The equipment should be near the power outlet in the technical room of MRI and the outlet should be easily accessible.

Stabilizing circuits ensures satisfactory performance within supply variations specified. If the supply voltage in your location is not 90-250V AC, please consult your Troyka Med Sales or Service office.

Always use the power supply card supplied in the original shipping carton.

If the enclosed power card could not be used due to a different standard in your country, use a power card that conforms to the fallowing regional standards:

United States (UL)	United Kingdom (BASEC/BS)
Germany (VDE)	Switzerland (SEV)
Canada (CSA)	Japan (MITI)

In other regions, please use an AC power card that complies with the country's safety regulations.

In order to prevent electrical hazard, the cord set must use a three-core cable of at least 6A/0.75mm², and have an earth ground contact on both the free socket and the plug. If the main cord is damaged, use only an original replacement cable.





3 System Overview and Installation Guide

3.1 Parts Included

1	MRI Sound Control Unit	HHHHH = o
2	Microphone with 4 m cable	
3	MRI speaker box with 12 m cable	
4	MRI pneumatic headset with 4m pneumatic cables	
5	MRI compatible statoscope type headset and hoses	Q
6	Electrical sound cable 30 m with connector	
7	MRI Filter: 9 Pin D-Sub LPF with EMI gasket	
8	Power cable	Contraction of the second seco
9	USB disk with MRI music	0
10	AUX cable	Q

Table 1: MRI Sound System list of components





3.2 System Overview

The T-250 MR Sound System is designed to be MR Conditional and is manufactured and tested to the highest standards according (Fig. 1). The Sound System is designed to be used with all MRI scanners up to 3 Tesla magnetic field strength.

MRI Sound Control Unit: Through easy and accessible controls, the Sound Control Unit (Figure 1-1) offers one-way patient communication and full flexibility of audio settings. Thanks to its two input channels, it allows to connect a wide variety of audio devices through 3,5 mm mini jack. Onboard MP3 circuit allow technician directly play MP3 and control audio records from USB disk easily switch the audio input source. There are two embedded speakers on the sound control unit which allows the technicians to hear the sound/music given to the patient. MRI room's sound level and technician room's sound level can be controlled separately and simultaneously. There is a MUTE circuit in the amplifier to stop the music automatically and allow the patient to hear the technician's instructions given via microphone when the technician turns the microphone on (Figure 1-2). MRI computer can be connected to the sound amplifier which provides the patient listen to the MRI auto voice commands and after the auto voice commands music continues to play.

Slim Headphones: The slim headphone, which is approximately 20mm wide fit perfectly even in a 32 channel head coil. The headphone provides approximately 28 dB noise isolation.

Designed for fMRI: Designed specifically for fMRI, the superior sound quality and increased noise isolation provides a more precise audio stimulation to the patient, which yields a more robust BOLD response than traditional. Designed with reliability and durability in mind, the headphones are incredibly robust and suited for daily use in a busy clinical environment.



Figure 1: Picture of MRI sound system.





3.3 Technical Specification

Sound Control Unit		
Power	60 W	
Onboard Speakers	2x10 W	
Inputs	2x Aux, Microphone, USB disc	
MUTE Circuit	Yes	
Dimensions	31x26x10 cm	
Microphone		
Characteristics	Uni-direction	
Frequency bandwidth	80-12000 Hz	
Impedance	$600\Omega \pm 30\%$	
Sensitivity	-72dB ± 3dB	
Cable Length	4m	
Weight	811 gr	
MRI speaker		
Power	100 W	
Frequency bandwidth	800 Hz – 20kHz	
Mean Sensitivity	93dB @ 1m/1W	
Typical impedance	0,8 μf	
Weight	214 gr	





3.4 Installation

A representative drawing showing the layout plan of the MRI compatible sound & music system is given at Figure 2. The white wooden box containing the two speakers is placed in front of the MRI scanner, right next to the MRI bed (Figure 2-3). Following the patient wearing the MRI compatible stethoscope type or headphone type headset, acoustic sound system is completed by connecting the pneumatic male connectors located at the tips of the sound hoses, to the pneumatic female connectors of the white wooden box. One end of the sound transmission cables shown at Table 1-6 is connected to the speaker box, and the other is connected to the 9 pin D SUB-B LPF located at the penetration panel. The filter shown at Figure 2.7 has a male and a female connector. Female end connects to the penetration panel, facing the MRI room and filter body staying within the MRI room. Male end is connected such that it goes outside of the MRI room through the filter jack at the penetration panel (Figure 2.7).

Electrical sound cable shown at Table 1-6 connects to the male end of the filter. The 9 pin D SUB-B female edge connects to the male end of the filter, whereas the 6 mm jack connects to the MRI Sound Control Unit as shown at Figure 2-1. 6 mm jack at the end of the MRI microphone connects to the microphone input at the back panel of the MRI Sound Control Unit (Figure 2-2). Through the power cable shown at Table 1-8, Sound Control Unit is connected to the AC and the system is ready to be used.



Figure 2: T250 MRI sound system installation diagram.





3.5 Sound Control Unit Connection Diagram

Located on the back panel of the MRI Sound Control Unit are three 6mm input jacks. Top jack is dedicated for the electrical sound cable indicated at Table 1-6, which is responsible for transmitting the voice signal over to the MRI room. Middle jack is the backup AUX input, whereas the bottom jack is the microphone input. Located on the right panel of the MRI Sound Control Unit is the power connector, which contains a 6 A glass fuse. The power cable shown at Table 1-6 connects the MRI Control Unit to 220 VAC. Located on the front panel of the MRI Sound Control Unit, there is the main AUX connector input (Figure 3-10), which an exterior sound source could be connected to. Right above the AUX input is the USB Drive input.



Figure 3: Connection schematic of MRI Sound Control Unit





4 Adjustment of Sound Control Unit

General stricture of the Sound Control Unit is given on Figure 3. There are 6 slide pots for the sound control on the front face of the Sound control unit. These pots are:

- 1. MIC: Adjust sound level of microphone
- 2. VOL Main: this pot allows adjustment of sound level off all audio inputs simultaneously.
- 3. VOL MR: Adjust sound level delivered to the patent inside MRI scanner.
- 4. VOL Tech: adjust sound level in technical room.
- 5. TREBLE: Adjust TREBLE of sound delivered to the patient.
- 6. BASS: Adjust BASS of the sound delivered to the patient.
- 7. AUX Input: This Aux input allows a connection of the MRI sound system to external audio source like PC, Ipod, ext.
- 8. Play button: Play the MP3 audio from USB disk.
- 9. Backward button: Rewind the audio on USB disk.
- 10. Forward button: Forwarding the audio on USB disk.
- 11. M button: Switch the sound system between USB input and Aux audio input.
- 12. On/off: Switch the main power of the system power on and off.
- 13. MP3 circuit
- 14. Onboard speaker: 2x10 W onboard speaker



Figure 4: Adjustment schematics of MRI Sound Control Unit





5. Contact

If you have any questions or problems, please contact us through any of the fallowing routs.

If you purchased your system through one of our international distributors, please contact the distributor first especially if the system is under warranty.

In all other cases, please contact <u>info@troykamed.com</u> if you have any questions or to get assistance with technical problems.

For sales related questions, please contact your local distributor, or contact us at sales@troykamed.com

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