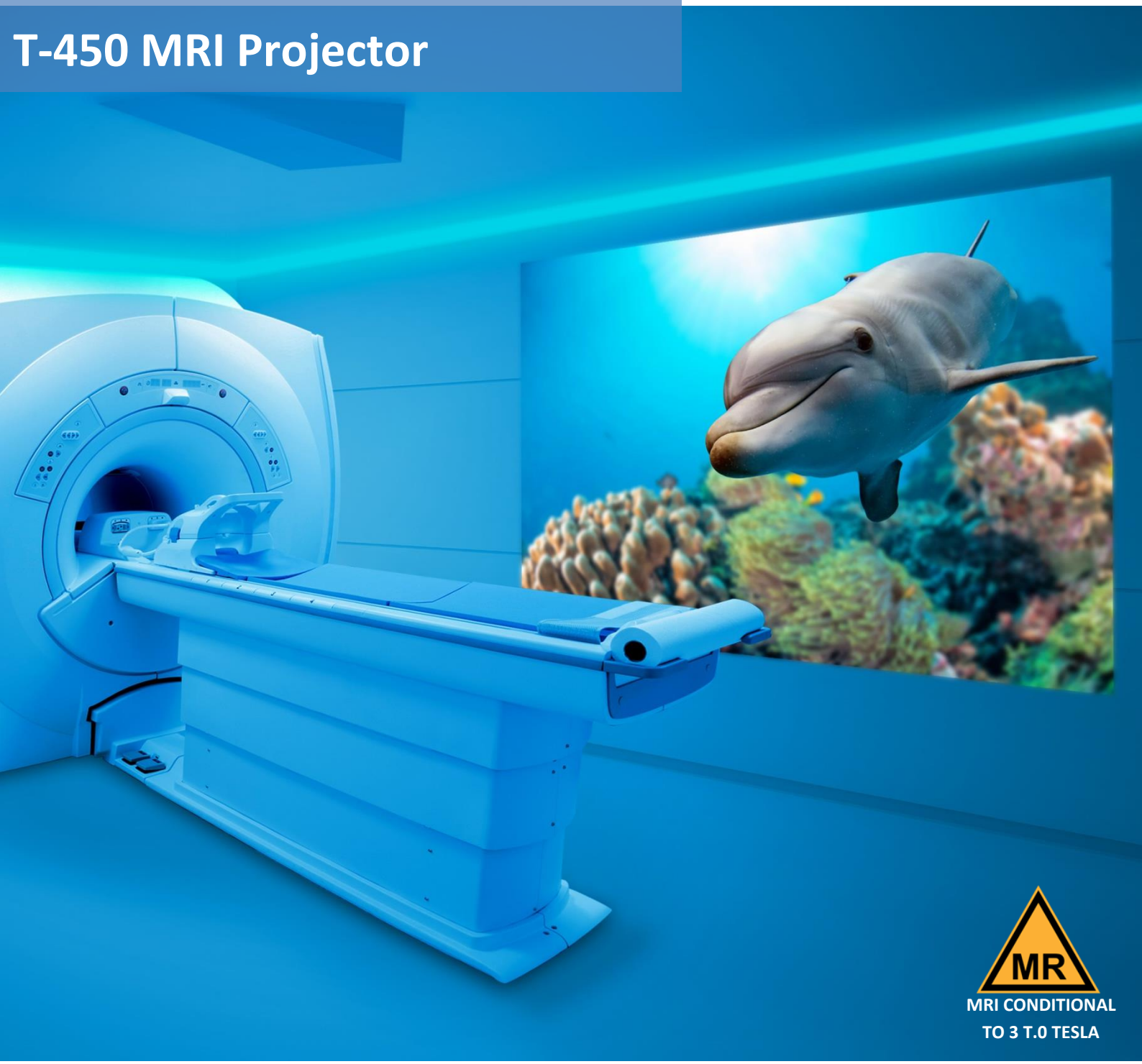
OPERATORS MANUAL

T-450 MRI Projector



MR

MRI CONDITIONAL
TO 3 T.0 TESLA

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CE
ISO 13485:2016

Introduction

Thank you or purchasing the T-450 MRI Projector. 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-450 MRI Projector, 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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	Protect from direct sunlight		Protect from rain and humidity		MRI conditional up to 3 Tesla
	Read user manual		Manufacturer		ISO13485 ISO 9001 Class I medical devises

1 Safety Information

1.1 MRI Safety Definition for MRI as Defined by International Standards ASTM F2503-13

	**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 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 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 Projector must only be operated by personnel property trained in MRI safety.

The MRI Projector 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 Projector are familiar with the safety instructions given in the manual and other documentation provided to ensure safe operation of the Projector and associated equipment.

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

1.3 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 Projector 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 system. Under no circumstances shall tools or foreign objects being 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 projector if any cables are damaged.
	**Warning!** Switch off and unplug the projector if it is not in use for 1 day or more.
	**Warning!** To avoid the 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.

1.4 Warnings for MRI

	**Caution!** Installation of materials inside the MRI must be done with extreme caution.
	**Caution!** Take care that ferromagnetic materials be kept at least three meters away from the magnet and that no installation shall be done near the filter panel if a scan is in progress.
	**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!** For questions regarding installation procedures or technical support, call Troyka Med Service team or contact via email at **info@troykamed.com.**
	**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 Projector System has been thoroughly tested prior to delivery and is ready for immediate use. Upon receipt, please report any transportation damage or missing 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 projector serial number and damage description. It is recommended to keep and store the original crate/box used to ship the projector for all future transportation needs.

2.2 Power Connection Information

The MRI Projector 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 cord supplied in the original shipping carton.

If the enclosed power cord could not be used due to a different standard in your country, use a power card that conforms to the following 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 cord 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/0.75mm^2 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 Projector**  Presentation of visual stimuli and video materials inside the MR room. To avoid any accidents, the MRI-Projector should be kept no closer than 0.5 Tesla field from the magnet.	
2	**Table with entertainment software**  A wireless tablet with the real-time media integration playback offers patient amazing experience during the scan. The entertainment software includes over 250 animation, videos, and images that patient can choose to watch during the MRI scan.	
3	**HDMI – Fiber Transmitter**  Converts video signal into an optical signal for transmission to MR room. Contains ferromagnetic materials, keep out of the Magnet Room	
4	**Fiber Cable**  The connection between the HDMI – Fiber Transmitter and the MRI-Projector through an available waveguide. Standard Length 30 m. Contact Troyka Med for other length options. This cable is fragile. Maximum bending radius is 10 cm	
5	**Power Cable**  The power cable delivered with your system may vary depending on your type of mains outlet and may come in a dual configuration. Power Cable contains ferromagnetic materials and must be kept at the safe distance from the MR scanner (outside the 40mT (400 Gauss) line).	
6	**HDMI Cable**  The connection of the Fiber Transmitter with the stimulus presentation PC. Contains ferromagnetic materials, keep out of the Magnet Room.	
7	**Remote Control**  The control contains some slightly ferromagnetic materials and must be kept at the safe distance from the MR scanner (outside the 40mT (400 Gauss) line).	

Table 1: MRI projector system list of components

3.2 System Overview

The T-450 MRI-Projector System is designed to be MR conditional and is manufactured and tested to the highest standards according. The Projector system is designed to be used with all MRI scanners up to 3 Tesla magnetic field strength.

MRI Projector: Through easy and accessible controls, the MRI projector (Figure 1) offers one-way patient video and audio experience with full flexibility. Thanks to advanced projection technology, the projector provides 300-inch image with incredible color contrast even in the bright environment. At the back side of the projector, there are two 20 W speakers which provides incredible sound inside MRI room (Figure 1-1). Power on and all the futures of the projector are provided by remote control. The projector comes with 7000-hour lamp life. After final positioning of the project inside MRI room, optimum image quality is achieved by sensitive adjustment of focus and zoom using adjustment tools given in figure 1-3.

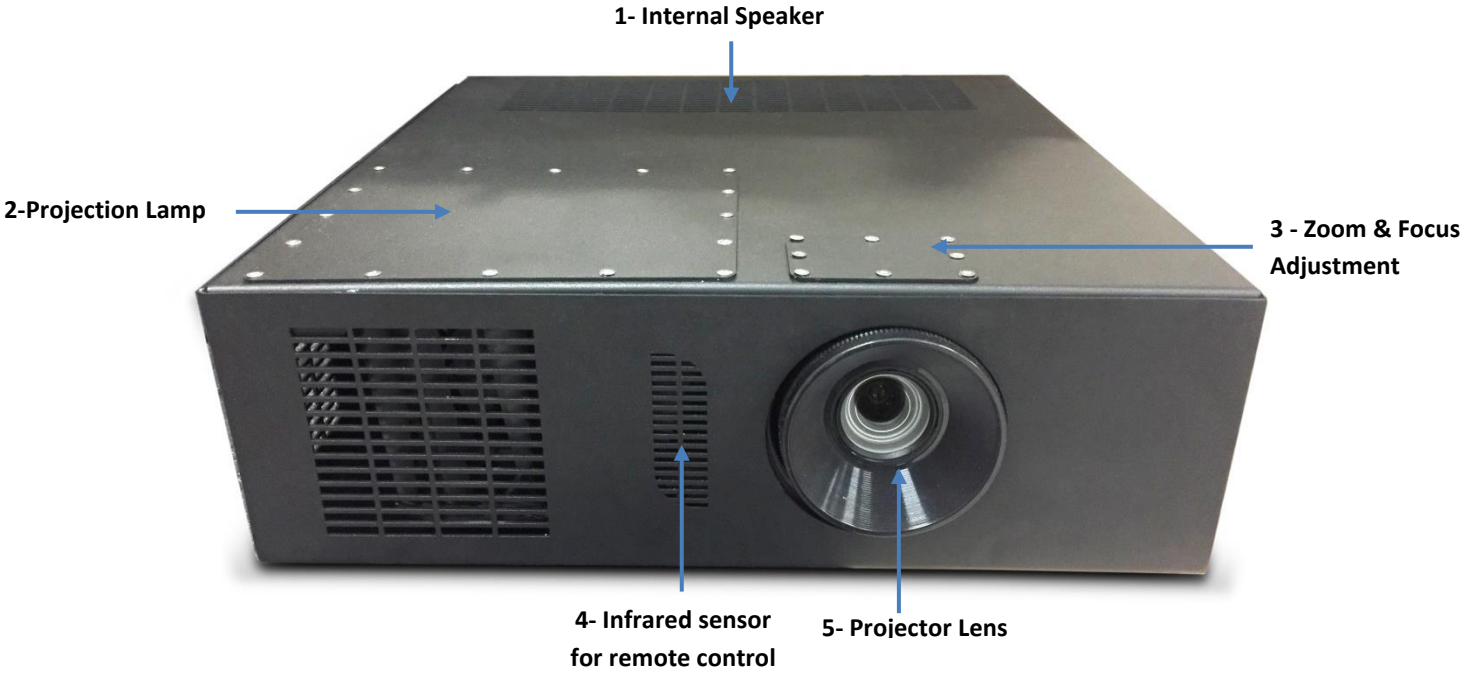

Figure 1: Picture of MRI Projector

Patient Entertainment System

A wireless tablet with the real time media integration playback offers patient amazing experience during the scan. The entertainment software includes over 250 animations, videos and images that patient can choose to watch during the MRI scan. When patient choose the desired video, the video is transmitted through the wireless communication network to the monitor and the audio signal goes to the MRI sound system for the complete patient experience.

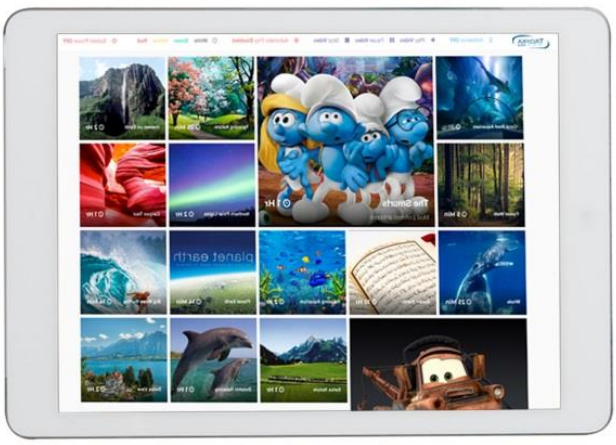

Figure 2: Patient entertainment tablet

3.3 Technical Specification

Patient Control Software	
Real-time media integration playback	
Over 250 animations, videos and images to choose.	
Run LED monitor, projector, room ambient sound, headset sound and LED lights dynamically by the click of the button of touchscreen.	
Custom developed media software and hardware	
The wireless tablet interface for easy patient interaction	
Integration with DVD and other media streaming devices.	
Real-time streaming of patient experience content	
The software runs algorithm which real-time analyze the video on the screen, find the main RGB color code and stream it to the LED RGB light.	
Projector	
Brightness (Lumens):	3200 lumen
Resolution Type:	1080p
Resolution:	1920x1080 Full HD
Color Contrast:	30.000:1
Throw Distance:	4.5 – 5.1 ft
Throw Ratio:	1.2~1.6
Display Size (in.):	30 - 300 in.
Aspect Ratio:	16:9
Connection:	Fiberoptic (LC Type)
Power:	100~240VAC (Auto Switching), 50-60Hz
Light Source Life, Normal (hours):	4500
Light Source Life, Eco-Mode (hours):	7500
Internal Speakers	2x20 W
Patient Entertainment Table	
Screen size	10,1 inch
Display	AMOLED
Resolution	2560x1600
Flash Memory	16 GB
REM Memory	3 GB

3.4 Installation

3.4.1. Installation Diagram of MRI Projector in MRI Room

A representative drawing showing the layout plan of the MRI projector is given in Figure 3. The MRI projector is placed as is shown in figure 3-1. There must be 220V power outlet near the projector. Power cable given in table 1-5 must be connected the projector to power outlet Figure 3-3. One end of the fiber-optic cable sown on Figure 3-4 must be connected to the projector and the other end must be connected to the HDMI- Fiberoptic converter shown in figure 3-5. The HDMI-fiberoptic converter must be placed next to the PC which will be used for transmission of the video content (Figure 3-7). The HDMI-fiberoptic transmitter must be connected to the power outlet using 5V DC adapter. The HDMI-fiberoptic converter must be connected to the PC using HDMI cable given on table 1-6. The wireless tablet could be placed as is shown on figure 3-8 or could be placed in any available location.

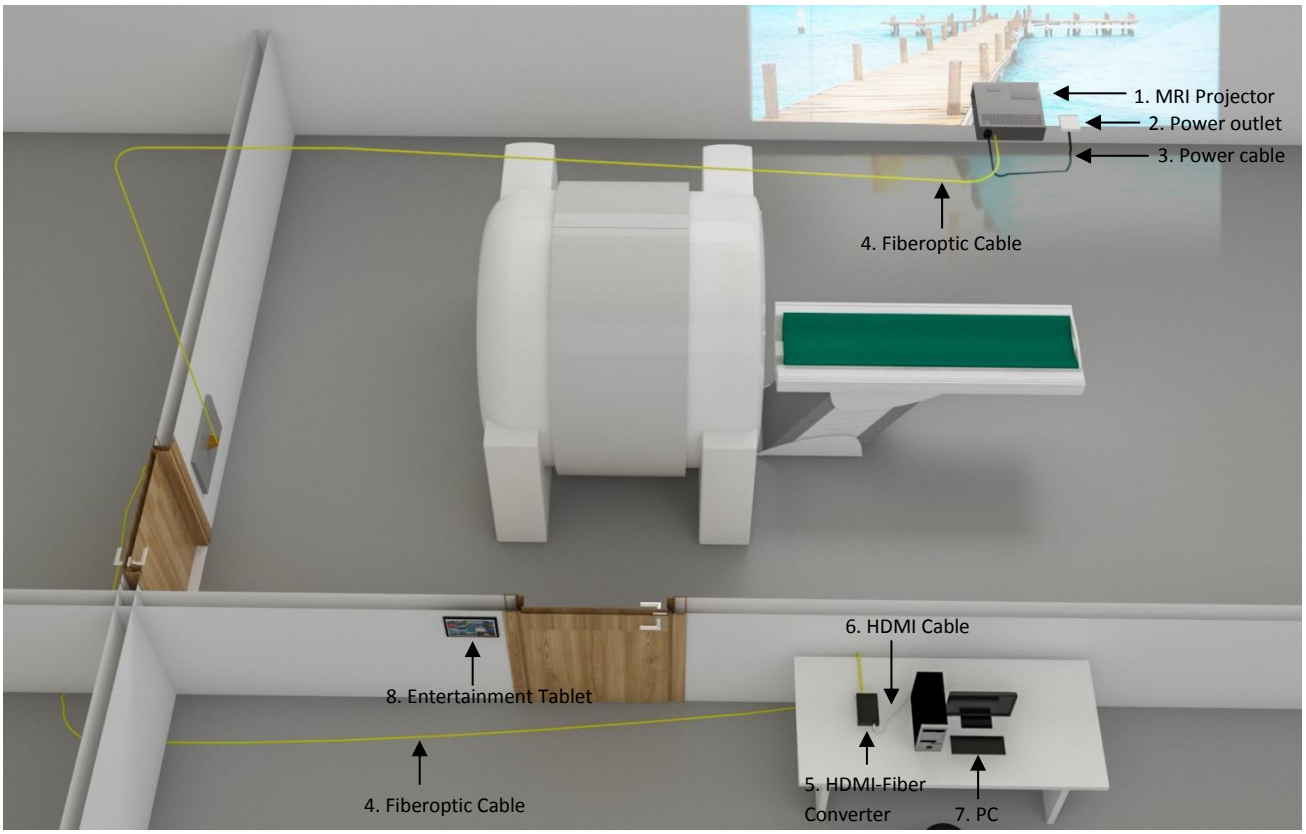

Figure 3: T-450 MRI projector installation diagram.

3.4.1. Installation Diagram of MRI Projector

The installation diagram of the projector is given in figure 4. The projector ceiling bracket must be chosen according to MRI room ceiling specifications. For the most suitable option please contact Troyka Med service team or your local distributor.

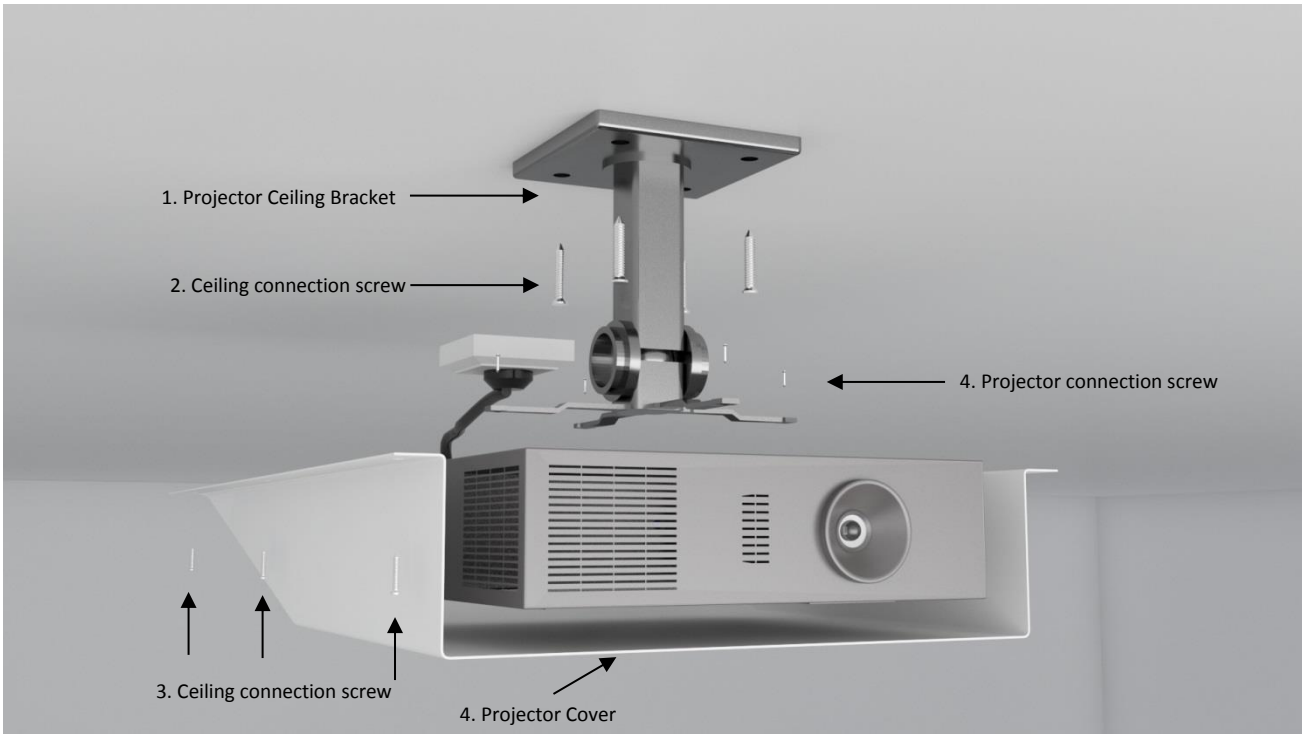

Figure 3: Installation diagram of MRI projector