



OPERATORS MANUAL

EP-500 MRI Ear Plug



MRI SAFE

Troyka Med Inc
IOSB Mah. 2284. Cad. No: 48 Yenimahalle Ankara TURKEY
Tel: +90 3122650096- info@troykamed.com – www.troykamed.com
MRI Ear Plug Op. Man. Pub. 022018 Pub. No: 0 Rev:0



ISO 13485:2016

Introduction

Thank you for purchasing the EP-500 MRI Ear Plug. This product is manufactured and tested to the highest standards and is guaranteed MR Conditional up to 3 Tesla.

To ensure that you obtain maximum benefit from the EP-500 MRI Ear Plug, 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

Troyka Med Inc.

Tel: +90 312 2650096

E-mail: info@troykamed.com

Website: www.troykamed.com

	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 devices

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1 Safety Information

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

	<p>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.</p>
	<p>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.</p> <p>Supplementary marking – additional information that, in association with marking as “MR CONDITIONAL” states via additional language the conditions in which an item can be used safely within the MR environment.</p>
	<p>MR UNSAFE An item with poses unacceptable risks to the patient, medical staff or other persons within the MR environment.</p>

1.2 Warnings for MRI

	<p>Caution! Installation of materials inside the MRI must be done with extreme caution.</p>
	<p>Caution! Screws in the package are not MRI compatible. They should be used to hang the ear plug station outside of the MRI room.</p>
	<p>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.</p>
	<p>Caution! For questions regarding installation procedures or technical support, call Troyka Med service team or contact via email at info@troykamed.com.</p>



2 General Information

2.1. Inspection of Delivered Goods

Each of Ear Plug Station 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 and damage description.

3 System Overview and Installation Guide

3.1 Installation

You will receive a station with 500 pairs ear plugs, a wall hanger and screws. You can use the screws to mount the hanger on the wall or you can use a double-sided tape to mount the hanger in the MRI room. Be sure that you have a strong double-sided tape and it sticks well both on hanger and the wall. The hanger should be mounted max 110 cm height from the floor to the bottom part of the hanger. After mounting the hanger on the wall, place the station with ear plugs over the hanger gently (Fig. 1). After that the station will be ready to use. Whenever you turn the lock of the station you will get some ear plugs in your hand.

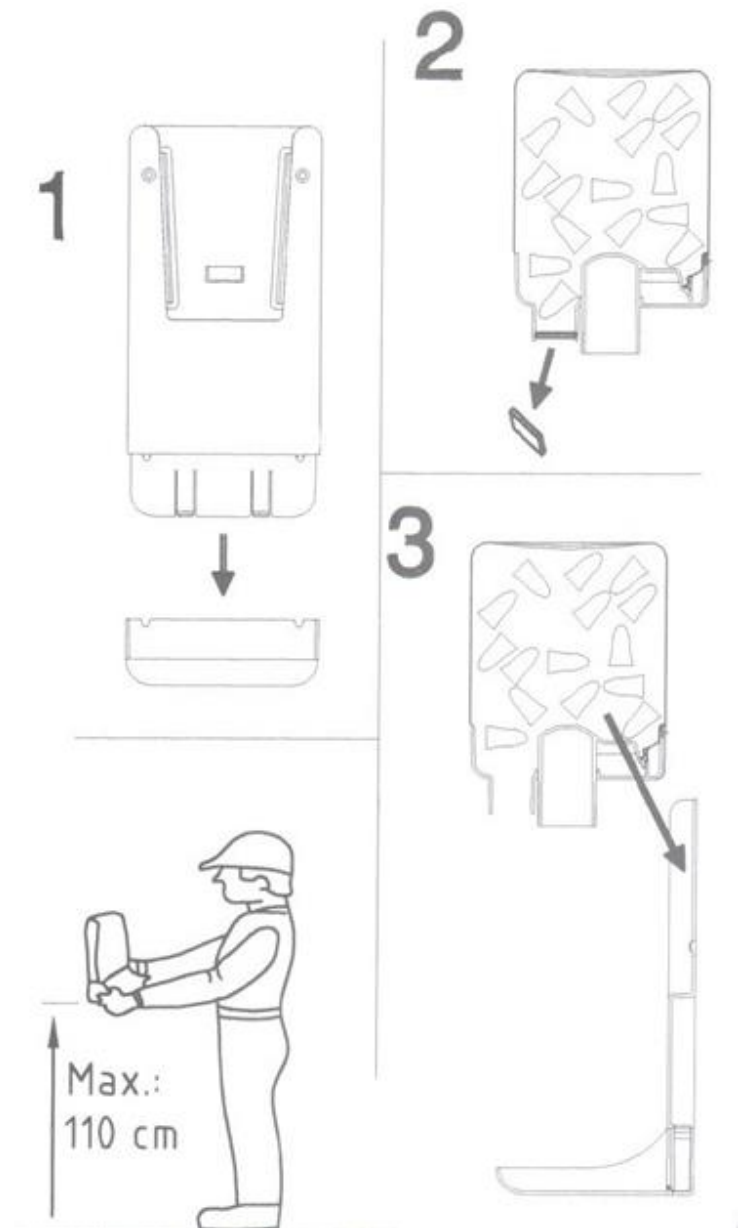


Figure 1. Ear Plug Station Mounting Steps



3.2 System Overview

The EP-500 MRI Ear Plug is manufactured and tested to the highest standards according to. The ear plug is designed to be used with all MRI scanners up to 3 Tesla magnetic field strength.

3.3 Technical Specification

Tested according to ANSI Specs S3.19-1974 Michael & Assoc., State College, PA.

ATTENUATION DATA											
Frequency (Hz)	125	250	500	1000	2000	3150	4000	6300	800		
Mean Attenuation (dB)	42,3	43,7	46,6	40,9	38,6	44,7	46,9	49,3	48,3	NRR	CSA
Standard Deviation (dB)	5,0	6,0	5,8	4,2	2,8	3,2	3,3	4,2	3,6	33	AL

