Anexa 14 la Formularul Specificații tehnice

Detector de metale compatibil IRM 3Tesla

Parametri solicitati	Parametri oferiti, model MD-100 (Troyka Med Inc.,
	Turcia)
Detector de metale compatibil IRM 3Tesla	Detector metale compatibil IRM 3Tesla.
Ușor de utilizat – prin simpla apăsare a comutatorul ON	Commutator ON/OFF, pag. 5
pentru a detecta toate obiectele metalice periculoase.	Alerta vizuala si audio, pag. 4
Alertă vizuală și audio.	Buton de eliminare a interferentelor, pag. 5
Sensibilitate reglabilă pentru zonele cu interferențe,	Banda de prindere de incheietura, pag. 5
suprafață mare de scanare, avertizare de baterie scăzută și	
prindere confortabilă.	Anul producerii minim 2023.
Cerințe:	Termen de garanție nu mai mic de 24 luni din momentul
Anul producerii minim 2023.	instalării.
Termen de garanție nu mai mic de 24 luni din momentul	Instalare, darea in exploatare, instruirea de către
instalării.	participantul câștigător - obligatoriu
Instalare, darea in exploatare, instruirea de către	Training pentru utilizatori la instalare și la solicitare -
participantul câștigător - obligatoriu	obligatoriu.
Training pentru utilizatori la instalare și la solicitare -	Documente confirmative:
obligatoriu.	Prezentarea certificatelor care confirmă compatibilitatea
Documente confirmative:	IRM 3T
Prezentarea certificatelor care confirmă compatibilitatea	Manual de utilizator în limba engleză se ataseaza.
IRM 3T	Manualul in Rom va fi prezentat la livrare.
Manual de utilizator în limba română și engleză	



OPERATORS MANUAL

MD-100 MRI Handheld Metal Detector



Troyka Med Inc







Introduction

Thank you for purchasing the MD-100 Handheld MRI Metal Detector. 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 MD-100 Handheld MRI Metal Detector, 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

誉	Protect from direct sunlight	#	Protect from rain and humidity	MR	MRI conditional up to 3 Tesla
(i	Read user manual		Manufacturer	CE	ISO 9001







1 Safety Information

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



MRI SAFE

An item that poses no known hazards resulting from exposure to any MRI environment MRI SAFE items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic.



MRI CONDITIONAL

An item with demonstrated safety in the MRI 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 "MRI CONDITIONAL" states via additional language the conditions in which an item can be used safely within the MRI environment.



MRI UNSAFF

An item poses unacceptable risks to the patient, medical staff, or other persons within the MRI environment.

1.2 General Safety Information and Intended Use

The Handheld Metal Detector is a product that is MRI room compatible, and it can be used up to 60 cm distance from the MRI machine. But the metal detector cannot be used inside the MRI scanner in-bore due to the battery of the product can be damaged.

The metal detector must only be operated by personnel properly trained in MRI safety and identifying interference problems such as artifacts, streaks, and distortions in image data. It is required that as personnel handling the metal detector 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.

1.3 Health Concerns



Warning!

If any of the components become damaged, stop using the headset immediately and notify Troyka Med Inc. customer service for assistance.







1.5 Warnings for MRI



Caution!

Take care that metal detector should be kept at least three meters away from the magnet since it is MRI unsafe



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 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 metal detector 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. It is recommended to keep and store the original crate/box used to ship the metal detector for all future transportation needs.

3 System Overview and Installation Guide

3.1 System Overview

The MD-100 Handheld MRI Metal Detector is designed to be used for pre-MRI scans and is manufactured and tested to the highest standards. The metal detector is designed to be used before all MRI scans.

The metal detector - with both audible and silent vibrating alarm options - offers outstanding performance stability and extreme sensitivity in detecting the smallest objects when used properly. Its state-of-the-art digital circuitry allows instant operation with no operator adjustment required.







3.2 Components / Function

3-Way Power Switch

Has two "On" positions and a central "Off" position. When the Power Switch is pressed forward, the detector will sound an audible alert upon detection of any metal and the red-Light Alert will appear. When the switch is pressed backward, the detector will vibrate upon detection of any metal and no sound will be heard even though the red-Light Alert will appear. Power is turned off when the switch is in the central position.

Light Alerts

The rear green light illuminates whenever the detector is operating. The red light, forward most of the three lights, illuminates whenever metal is detected. The center amber light illuminates when battery power becomes low, and the battery should be recharged or replaced.

Audio Alert

The speaker provides a clearly audible sound whenever metal is detected. The Audio Alert sounds only when the Power Switch is pressed forward.

Vibrating Alert

The vibration mode is activated when the Power Switch is pressed backward. The unit's handle will vibrate, and the red light will alert the operator whenever metal is detected.

Interference Elimination Button

The detector is factory set for a high level of sensitivity to detect the smallest of items. This high level of sensitivity may produce alarms when approaching a floor containing rebar. Press and hold this button to decrease sensitivity to a level that does not respond to the rebar. Release button and detector returns to normal sensitivity.

Safety Sling

Used to assist the operator in convenient handling of the Super Scanner.

3.3 Technical Specification

Sound Control Unit		
Voltage	9 V standard battery	
Power	270 mW	
Frequency	22 KHz	
Currency	<50 mA	
Net weight	409 g	
Dimensions	41 x 8,5 x 4,5 cm	







3.4 Service Information

Battery Replacement

Slide back the battery cover (do not attempt to remove it), tilt the detector and the battery will slip out. Replace it with a fresh battery. Because the battery cover will not slide back if the battery is inserted improperly, never force the cover. When the metal detector is to be stored more than 30 days, remove the battery.

Internal Sensitivity Adjustment

Some applications may require a sensitivity setting other than the nominal factory setting. This may be achieved by choosing an appropriate test target and utilizing the Internal Sensitivity Adjustment as follows:

Turn on the metal detector. Roll back the grip cover just below the nameplate. Insert a small screwdriver into the potentiometer located within the exposed hole. Rotate the potentiometer counterclockwise to decrease sensitivity, or rotate the potentiometer clockwise to increase sensitivity, until the desired detection of the test target is achieved. An excessive sensitivity setting may result in unstable operation (chatter) and excessive detection of surrounding metal. Note: this sensitivity adjustment pot is set to the nominal center (12:00 o'clock) position at the factory.

CAUTION:

Always verify that the metal detector is set to the desired sensitivity level by testing with appropriate targets anytime the sensitivity adjustment is changed.







Declaration

27.05.2023

To Whom It May Concern,

We, as **Troyka Med Tibbi Sistemler Danişmanlık Sağ. Turz. Elk. A.Ş.** located at *İOSB Mah, 1371. Sk. No:7/1, 06378 Yenimahalle, Ankara, Turkey* hereby declare that the **MRI Compatible Handheld Metal Detector MD-100** is not needed any preventive maintenance.

Sincerely yours,

TROYKA MED TIPAI SISTEMLER DAN. SAĞ. TURZ ELK. A.Ş.
I.O.S.B. Man. 1311 CARA No: 7/1
Yenimahatle Ankara Tic. Sic. No: 241171
Little Vergi Dalresi: 859 052 1837

Nikolay V. Viskuşenko CEO

Troyka Med Tıbbi Sistemler Danışmanlık Sağ. Turz. Elk. A.Ş.