Anexa 5 la Formularul Specificații tehnice

Set Laringoscop compatibil cu IRM 3Tesla

Parametri solicitati	Parametri oferiti, model LY-5B (Troyka Med Inc., Turcia)
Set Laringoscop compatibil cu IRM 3Tesla Lamele laringoscop: Iluminare prin fibră optică Lame tip Miller (sau Macintosh) – mărimea 0,1, 2,3,4 Mâner laringoscop cu baterii (2 seturi de baterii compatibile IRM) Trusă de păstrare/depozitare a setului. Cerințe: Anul producerii minim 2023. Termen de garanție nu mai mic de 24 luni din momentul instalării. Instalare, darea in exploatare, instruirea de către participantul câștigător - obligatoriu Training pentru utilizatori la instalare și la solicitare - obligatoriu. Servicii de mentenanță preventivă pe perioada de garanție. Pe perioada garanției timpul de intervenție în caz de defecțiune minim 24-36 ore. Documente confirmative: Prezentarea certificatelor care confirmă compatibilitatea IRM 3T Manual de utilizator în limba română și engleză	Set Laringoscop compatibil IRM Set LY-5B, compatibil cu IRM 3Tesla. Lamele laringoscop: Iluminare prin fibră optică Lame tip: 5 lame (MAC-1, MAC-2, MAC-3, MILL-0, MILL-00). Trusa contine: 1 maner 1 baterie 1 trusa de depozitare Anul producerii minim 2023. Termen de garanție nu mai mic de 24 luni din momentul instalării. Instalare, darea in exploatare, instruirea de către participantul câștigător - obligatoriu Training pentru utilizatori la instalare și la solicitare - obligatoriu. Servicii de mentenanță preventivă pe perioada de garanție. Pe perioada garanției timpul de intervenție în caz de defecțiune minim 24-36 ore. Documente confirmative: Prezentarea certificatelor care confirmă compatibilitatea IRM 3T Manual de utilizator engleză se ataseaza.In rom va fi prezentat la livrare.

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ULUSAL MANYETİK REZONANS ARAŞTIRMA MERKEZİ

28/10/2017

Evaluation of Magnetic Field Interactions and Displacement Force at 3-Tesla for the MRI Non-Magnetic Laryngoscope produced by Troyka Med Inc.

Presented to: **V. Nikolay Viskuşenko**
Troyka Med Dan. Sağ. Tur. Elk. A.Ş.
IOSB Mah. 2284 Cad. No 48 Yenimahalle Ankara / Turkey

Summary:
The magnetic field interactions and displacement forces related with the "MRI Non-Magnetic Laryngoscope'' (Troyka Med Inc.) in a 3 Tesla MRI (Siemens, Magnetom Trio A Tim System) scanner has been tested in a compliance with ASTM 2052 MRI compatibility testing standard. ASTM 2052 covers the measurement of the displacement force produced by the static magnetic field on the medical devices and the comparison of that force to the weight of the medical devices. Based on the testing results with the 3T MRI system given in the ASTM 2052 standard, the maximum measured deflection angle for the test objects was 24°. ASTM F2052, recommendation states; ***"If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to the gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field."*** Hence, the devices that underwent testing passed the ASTM acceptance criteria for deflection angle with respect to exposure to the 3 Tesla MR Scanner used in this evaluation.

- Attachment: Test Report

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National Magnetic Resonance Research Center, 2017
Üniversiteler Mahllesi Bilkent 1606. Cadde (6. Cadde) No:7
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Test Report

The Magnetic Field Interactions and Displacement Force related with the "MRI Non-Magnetic Laryngoscope" (Troyka Med Inc.) in a 3 tesla MRI (Magnetom Trio A Tim, Siemens Medical Solutions, Erlangen, Germany) scanner has been tested in compliance with the ASTM F2052-02 MRI compatibility testing standards.

The standard covers the measurement of the magnetically induced displacement force produced by the static magnetic field on medical devices and the comparison of that force to the weight of the medical devices. This test is also known as "deflection angle test".

In order to determine the presence of ferromagnetism for the metallic components or parts, the laryngoscope was thoroughly tested using a powerful hand-held magnet, before to exposure to the MRI environment.

The device was hanging on a wooden test setup shown in Figure 1. The test fixture consisted of a sturdy structure capable of holding the device in position without movement and contained a protractor with 1°- graduated markings, rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically.

The test objects were tied with a string and hanged to the test setup. The length of the string was 20 cm, which was long enough so that each device could be suspended from the test fixture. The weight of the string was less then %1 of the test object. There were no other materials, such as tape, used to attach the test object to the setup.

Measurement of deflection angle was obtained at the position that produced the greatest magnetically induced deflection. This location was determined by using gauss line plots, measurement, calculations and visual inspections. This point was determined where the spatial magnetic field gradient was the greatest.

Firstly the handle and blades of the laryngoscopes were tested individually and then blades (Miller: 00, 0 and Macintosh: 1, 2, 3) were tested attached to the handle one by one. Mean deflection angle was calculated as mean of 3 deflection angle measurements of each test object.

The following scale was applied to the results:

Scale	Description
0	**No magnetic field interaction**
1	**Mild magnetic field interactions:** The device slowly changed orientation or moved relative to the magnetic field.
2	**Moderate magnetic field interactions:** The device moved gradually relative to the magnetic field and moved into the bore of the MR system
3	**Strong torque:** The device showed rapid and forceful move towards the magnetic field and moved into the bore of the MR system.
4	**Very strong torque:** The device showed very rapid and very forceful movement relative to the magnetic field and moved into the bore of the MR system

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The presence of eddy currents was assessed for the object by carefully moving it around the entrance of the bore of the MR system. The following scale was applied.

Scale	Description
0	No eddy currents
1	Mild Addy currents
2	Moderate eddy currents
3	High Addy currents

RESULTS AND DISCUSSION

The results of the test performed to determine magnetic field interaction of the MRI Laryngoscope are listed in Table 1.

Product Name	Results	Eddy Current
Handle	22 degrees , no torque	0
Miller 00	19 degrees , no torque	0
Miller 0	19 degrees , no torque	0
Macintosh 1	22 degrees , no torque	0
Macintosh 2	23 degrees , no torque	0
Macintosh 3	20 degrees , no torque	0
Handle and Miller: 00	19 degrees , no torque	0
Handle and Miller: 0	18 degrees , no torque	0
Handle and Macintosh 1	22 degrees , no torque	0
Handle and Macintosh 2	24 degrees , no torque	0
Handle and Macintosh 3	23 degrees , no torque	0

Table 1: Deflection angle test results.

The maximum mean deflection angle measured for the test objects was 24°. The findings for translational attraction for these devices should be considered in view of the deflection angle measurement recommendation provided by the ASTM F2052, which states:
"If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to the gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field." Hence, the devices that underwent testing passed the ASTM acceptance criteria for deflection angle with respect to exposure to the 3 Tesla MR Scanner used in this evaluation.

MRI LABELING INFORMATION

MRI-Conditional

The "MRI Non-Magnetic Laryngoscope" was determined to be MRI conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, Wet Conshohocken, Pennsylvania, 2005:

Non-Clinical testing demonstrated that this product is MRI Conditional and can be used in the MRI environment according to the following conditions. Static magnetic field 3-Tesla or less.

Important Note: **This product is intended for use inside of the MRI environment (e.g., in the MR system room, close to the scanner). However, they should not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), itself.**

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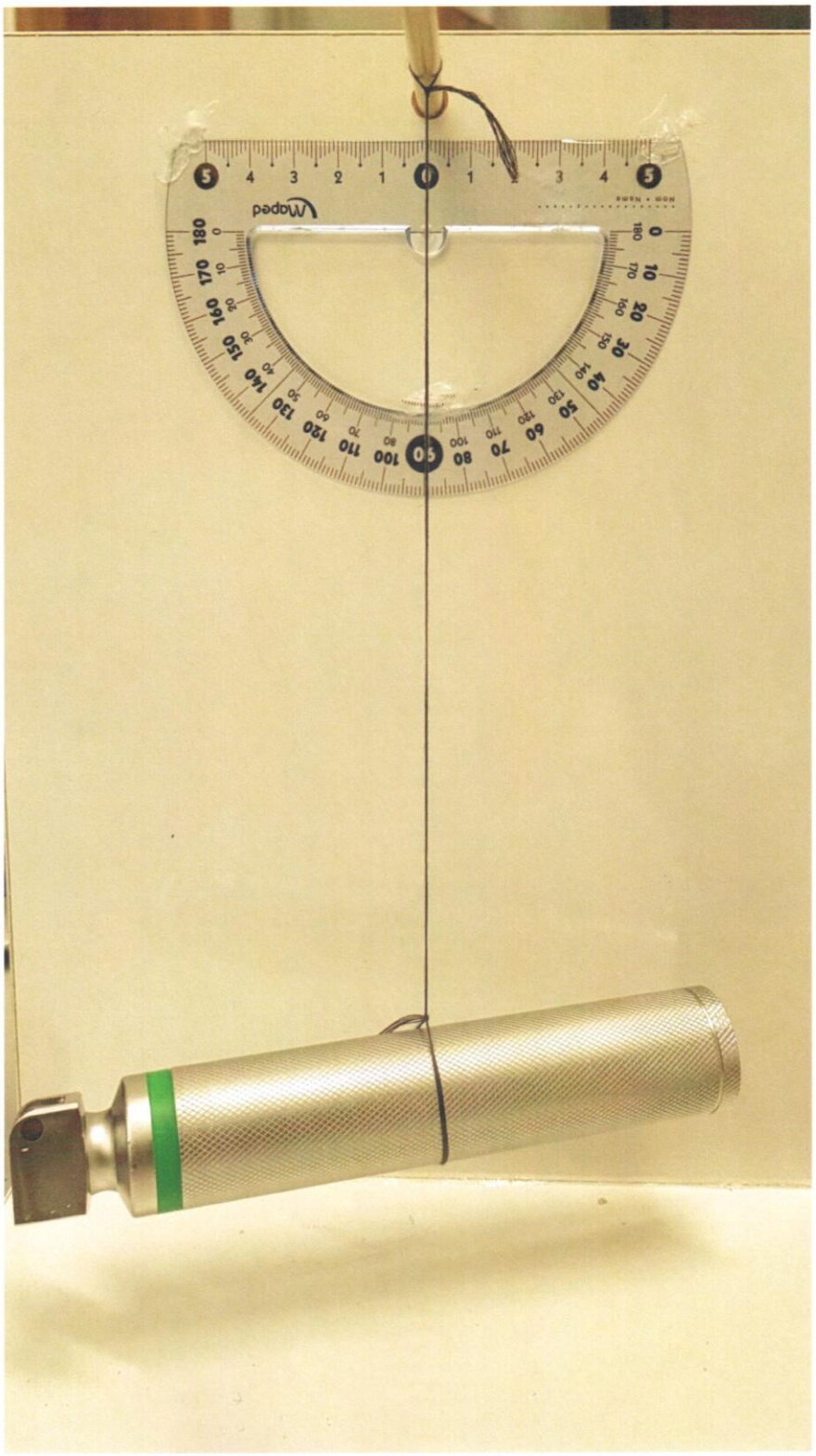

Figure 1: Photograph of handle of MRI Non-Magnetic Laryngoscope hanged to the test setup. The test setup is located outside the MRI room

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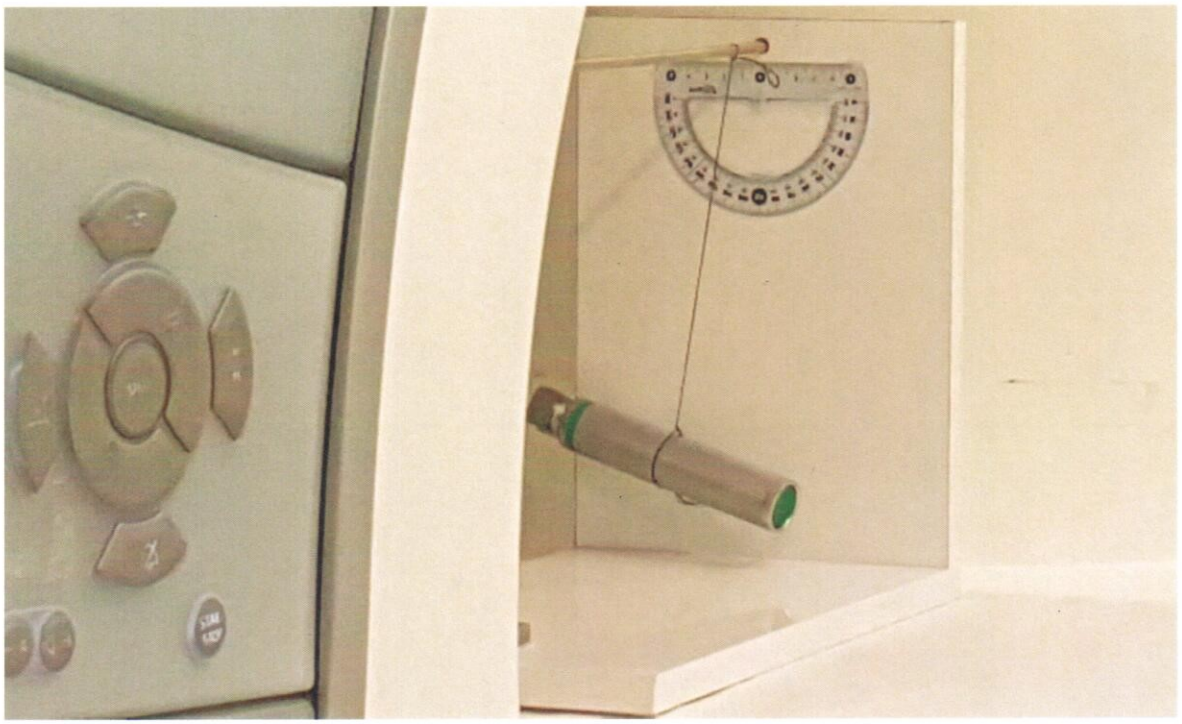

Figure 1: Photograph of handle of MRI Non-Magnetic Laryngoscope hanged to the test setup during exposure to a 3-Tesla MR system.

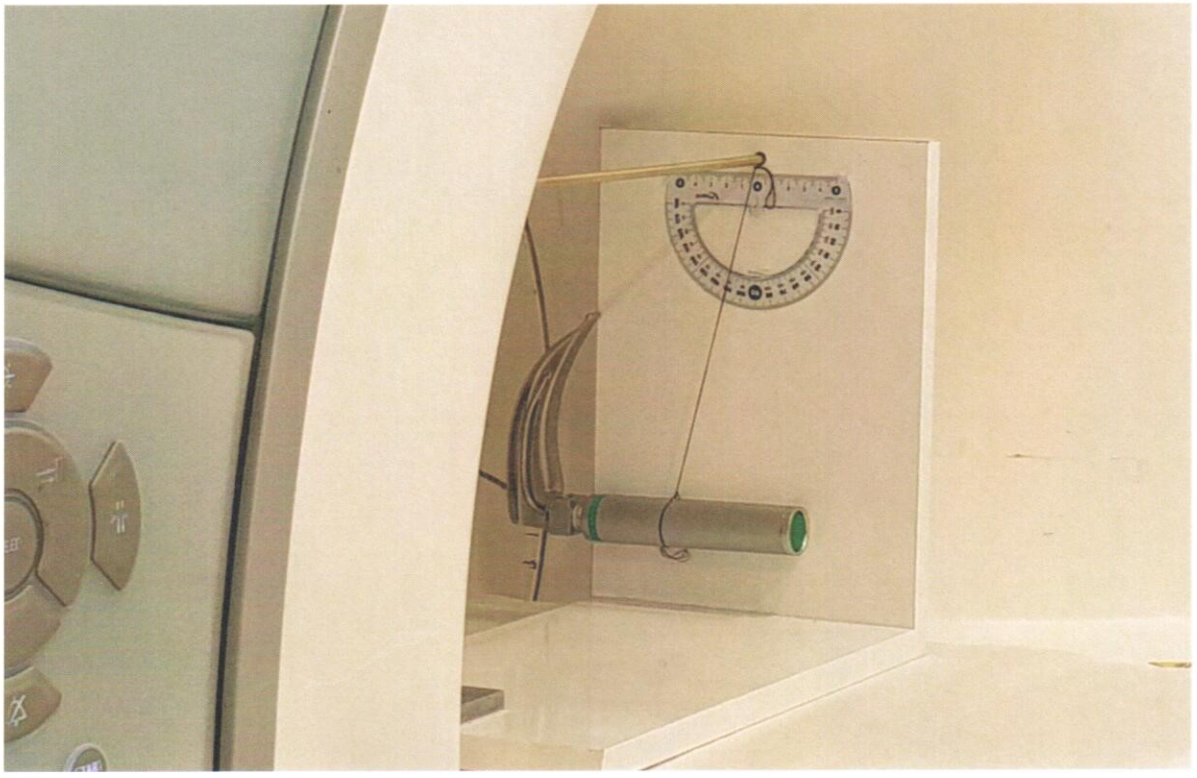

Figure 2: Photograph of handle with attached Macintosh 3 blade exposure to a 3-Tesla MR system.

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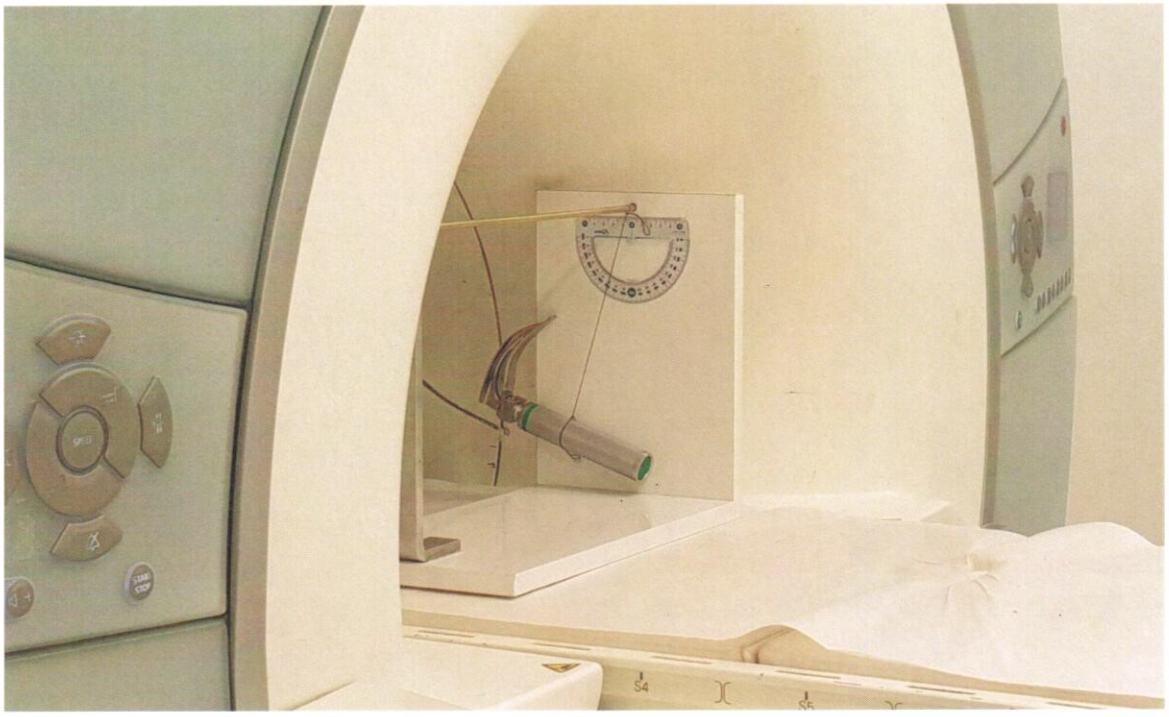

Figure 3: Photograph of handle with attached Macintosh 2 blade exposure to a 3-Tesla MR system.

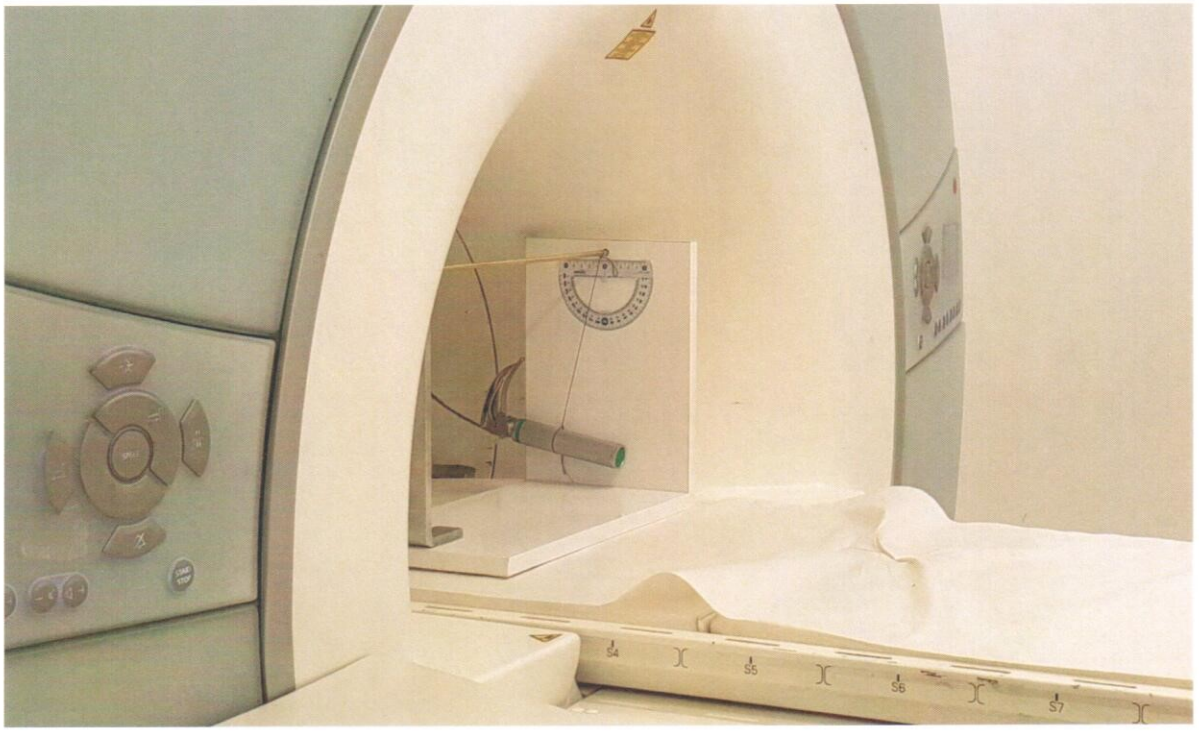

Figure 4: Photograph of handle with attached Macintosh 1 blade exposure to a 3-Tesla MR system.

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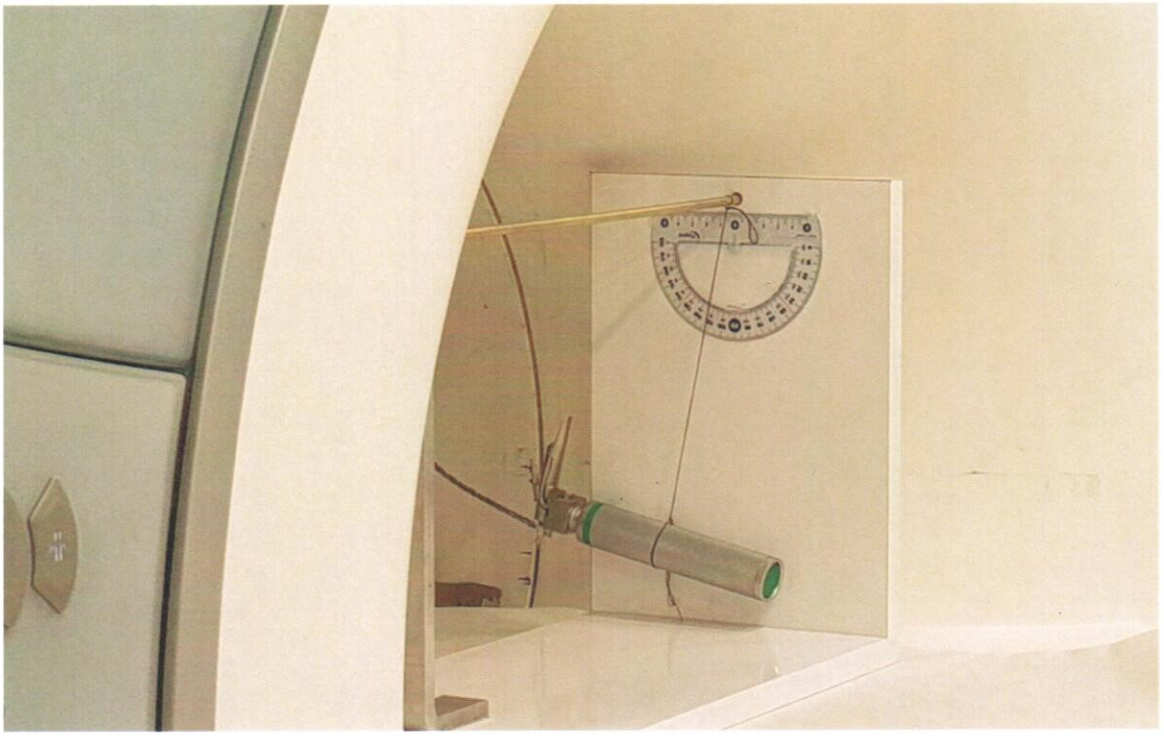

Figure 5: Photograph of handle with attached Macintosh 1 blade exposure to a 3-Tesla MR system.

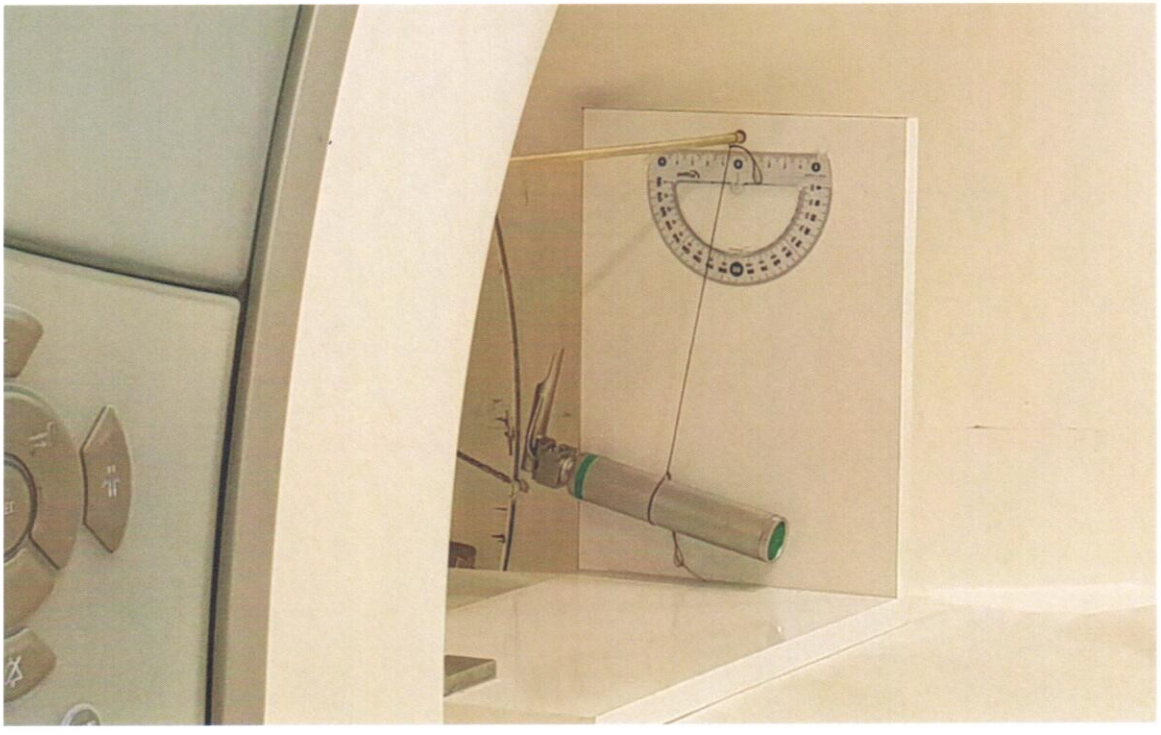

Figure 6: Photograph of handle with attached Macintosh 1 blade exposure to a 3-Tesla MR system.

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OPERATORS MANUAL

LY-5B MRI Laryngoscope Set

MRI CONDITIONAL
TO 3 T.0 TESLA

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

ISO 13485:2016

Introduction

Thank you or purchasing the LY-5B MRI Laryngoscope Set. 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 LY-5B MRI Laryngoscope Set, 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 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 an 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 laryngoscope 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 MRI laryngoscope 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 of two years starting from the day of its original installation.

1.3 Health Concerns

	**Warning!** If any of the components become damaged, stop using the laryngoscope set immediately and notify Troyka Med Inc. customer service for assistance. Use of broken components can cause injury to the clinician or the patient.

	**Warning!** Laryngoscope handles and blades must be reprocessed after each use.
	**Warning!** The reprocessing procedure and the equipment and materials described must be followed and conducted by persons trained and familiar with medical device reprocessing.
	**Warning!** Consult cleaning and disinfecting agent manufacturer instructions for their proper preparation and use.
	**Warning!** Repeated reprocessing may degrade elements of the handle. Follow inspection procedures to assure damage has not occurred to the handle.
	**Warning!** High level disinfection and/or sterilization are not achieved by these methods.
	**Warning!** Discard any component that shows evidence of damage or deterioration.
	**Warning!** Do not modify this equipment. Any modification of this equipment may lead to patient injury. Any modification of this equipment voids the product warranty.
	**Caution!** Failure to follow these instructions may cause damage to this handle.
	**Caution!** Do not immerse/soak handle, damage to handle may occur.

	**Caution!** If the device will be unused for several months or longer, remove the battery prior to storing the device.

1.4 Reprocessing instructions

These reprocessing instructions refer to procedures for cleaning and intermediate level disinfection. Laryngoscope handles must be reprocessed prior to first use and between each use using the following method as outlined in this document:

• Cleaning and intermediate level disinfection

The laryngoscope was validated the above instruction as being capable of preparing these laryngoscope handles for re-use. The user must ensure that the reprocessing as actually performed by the user's personnel, with the user's equipment and materials, achieves the desired result. This may require validation and routine monitoring of the user's actual process NOTE: The main handle and bottom cap components of handles marked “AUTOCLAVE” are compatible with the autoclave methods identified which are provided for facilities who wish to autoclave after cleaning and intermediate level disinfection.

1.4 Cleaning and Intermediate Level Disinfection Instructions

Point of use:

1. Separate blade assembly from handle and place handle into suitable containment for subsequent reprocessing per figure 1. Do not place handle with sharp devices.

2. Prevent the handle

Preparation for decontamination:

1. Select an appropriate quaternary ammonium isopropanol based germicidal cleaner labeled suitable for use on healthcare equipment and capable intermediate level disinfection. Reference EPAregistered disinfectants: http://www.epa.gov/oppad001/chemregindex.htm Outside of the U.S., please consult applicable regulatory body for equivalent quaternary ammonium isopropanol germicidal cleaner.

2. Remove the battery per figure 3.

Figure 1

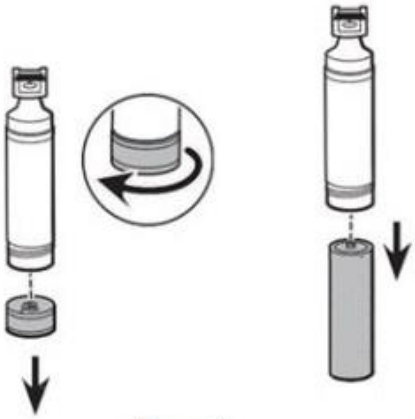

Figure 2

Cleaning and intermediate level disinfection:

1. Follow the germicidal wipe manufacturer’s instructions to clean all exposed surfaces of the handle and end cap.

2. If necessary, brush with a dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil.

3. After all visible soil is removed, re-wipe to wet all surfaces and allow adequate contact time for disinfection as directed by the germicidal wipe manufacturer.

CAUTION: Only use quaternary ammonium isopropanol based germicidal wipes.

Drying:

1. Allow components to air dry.

Maintenance, Inspection and Testing:

1. Inspect each component area (per figure 3) for damage or deterioration.

WARNING: Discard any component that shows evidence of damage or deterioration.

2. Reassemble the battery into handle per figure 4 with new or a battery in known good condition.

3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that:

- Blade assembly engages and locks onto handle.
- Blade assembly deploys into its locked position on handle AND lamp illuminates.
- Light output is satisfactory.

If the lamp fails to light or output is low, check or replace the battery.

Storage:

1. Store handle per facility practice to allow device to remain clean, dry, and ready for service.

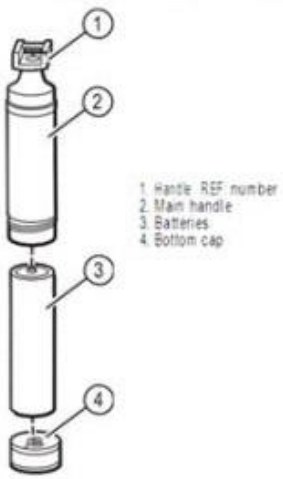

Figure 3

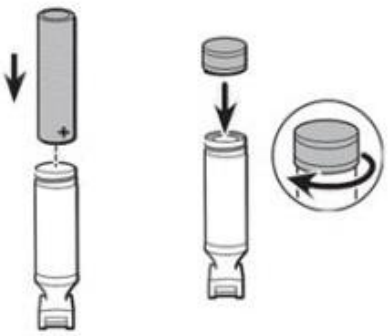

Figure 4

1.5 Autoclave Instructions

NOTE: The main handle and bottom cap components of handles marked “AUTOCLAVE” are compatible with the autoclave methods identified which are provided for facilities who wish to autoclave **after cleaning and intermediate level disinfection.**

Disassembly:

Remove the battery per figure 2 and set aside.

After battery removal, select **ONE** of the following autoclave methods below for the main handle and bottom cap (only):

Gravity autoclave: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment. Gravity autoclave settings are as follows:

- Temperature: 132 C (270 F)
- Exposure time: 3 minutes (unwrapped)
- Minimum dry time: 1 minute

Pre-vacuum autoclave: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment. Pre-vacuum autoclave settings are as follows:

- Temperature: 132 C (270 F)
- Exposure time: 3 minutes (unwrapped)
- Minimum dry time: 1 minute

Maintenance, Inspection and Testing:

1. Inspect each component area per figure 3 for damage or deterioration.

2. Reassemble the battery into handle per figure 4.

3. Attach handle to a clean and disinfected test blade assembly in known working condition. Verify that:

- Blade assembly engages and locks onto handle.
- Blade assembly deploys into its locked position on handle AND lamp illuminates.
- Light output is satisfactory.

If the lamp fails to light or output is low, check or replace the battery.

Storage:

Store handle per facility practice to allow device to remain clean, dry, and ready for service.

1.6 Warnings for MRI

	**Caution!** Installation of materials inside the MRI must be done with extreme 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!** 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 of laryngoscope sets 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 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.

3 System Overview

3.1 Parts Included

No	Quantity	Items
1	1	Laryngoscope Blade Miller 00
2	1	Laryngoscope Blade Miller 0
3	1	Laryngoscope Blade Macintosh 1
4	1	Laryngoscope Blade Macintosh 2
5	1	Laryngoscope Blade Macintosh 3
6	1	Laryngoscope Handle
7	1	MRI Compatible Battery
8	1 or 2	Back Up MRI Compatible Battery (Optional)

Table 1: MRI Laryngoscope Packing List3.4 Installation