

Endoscopic Ultrasound Training Phantoms User Guide

Models GIETP, TEUTP, & TEUS-B



SUN NUCLEAR
A MIRION MEDICAL COMPANY

Endoscopic Ultrasound Training Phantoms User Guide

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1 Introduction

The endoscopic ultrasound training phantoms provide low cost, practical, hands-on, easy-to-use devices. These products give the user the opportunity to learn and refine the skills required to master the techniques of ultrasound endoscopic procedures.

The target structures or spheres are contained within a soft, rubber-based, tissue-mimicking material. The number, placement, and contrast of these spheres vary between the three models offered.

These training phantoms are semi-disposable. During normal usage, each needle puncture creates a track within the phantom. Ultimately, the number of tracks will interfere with the ability to obtain a clear image.

See *Specifications* on page 4.

Instructions for Use

The endoscopic training phantoms are semi-disposable. They are designed to provide a simple means of training the user in the techniques required to guide the flexible endoscope into a tissue-mimicking channel, identifying simulated target structures and insertion of a biopsy needle.

2 Support and Maintenance

Hardware Maintenance

Inspection

Periodically inspect the phantom and accessories for damage. If damage is visible, if any mechanical or electrical degradation is suspected, or if errors are suspected, discontinue use and contact Sun Nuclear Support. See *Contacting Sun Nuclear Support*.

Repair

The phantom and the parts provided with the phantom cannot be repaired by the user. If there are problems with any of the devices, contact Sun Nuclear Support.

Cleaning

Following each training session, flush the channel with clean tap water in a sink. Using a foam applicator, gently remove any debris which maybe clinging to the channel wall. Clean the phantom housing with warm water or alcohol. Avoid using products containing petroleum solvents as they may adversely react with the rubber-based material.

Storage and Shipping

Cover the end(s) of the phantom to avoid introduction of dust or packing material if they are to be shipped to other sites.

Disposal and Recycling



Do not discard unit as waste. Recycle the components in accordance with local regulations.

Contacting Sun Nuclear Support

You may request support in two ways:

- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
 - U.S.A.: +1 321-259-6862, Option 3
 - Netherlands: +31 20 399 90 41, Option 1
 - Germany: +49 61 02 50 49 500, Option 2




Support Website

- 1** Open an internet browser and navigate to sunnuclear.com/support.
- 2** Enter your email address and password and then click **Login**.

- To download product information, click **Products and Devices**, select the product, and then select the download type.
- To open a Support request, click **Open New Case**, complete the form, and then click **Create Case**.

3 Specifications

Product Specifications

			
	Model GIETP GI Endoscopic Ultrasound Training Phantom	Model TEUTP Tracheal Endoscopic Ultrasound Training Phantom	Model TEUS-B Tracheal Endoscopic Ultrasound Training Phantom with Bifurcation
Overall Dimensions*	400 x 100 x 100 mm 15.75 x 4 x 4 in	219 x 118 x 79 mm 8.62 x 4.65 x 3.11 in	238 x 154 x 114 mm 9.4 x 6.0 x 4.5 in
Weight*	5.9 kg (13 lb)	2.1 kg (5 lb)	3.5 kg (7.75 lb)
Scan Channel Diameter	25 mm (1 in)	20 mm (0.78 in)	23 mm (0.90 in)

*Nominal dimensions

Echogenic & Anechoic Target Structures

Characteristic	Specification
Diameter	10 & 20 mm
Target Pattern	360 degrees around the central scanning channel

Appendix A: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Sun Nuclear Corporation Symbols

The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.



WARNING: This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)



CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)



CAUTION: This symbol indicates a pinch hazard. (EN ISO 7010, W024)



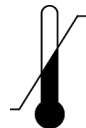
Note: Important or supporting information.



Manufacturer's Identification (name and address). (EN ISO 15223-1, 5.1.1)



Date of Manufacture. (EN ISO 15223-1, 5.1.3)



Temperature limitation. (EN ISO 15223-1, 5.3.7)



Humidity limitation. (EN ISO 15223-1, 5.3.8)



Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)



Serial Number. (EN ISO 15223-1, 5.1.7)



Catalog Number. (EN ISO 15223-1, 5.1.6)



Consult instructions for use. This equipment must be used in accordance with the instructions in this manual. Read all instructions and safety labels before use. (EN ISO 15223-1, 5.4.3)



Do not throw in trash; dispose of in an environmentally friendly way. (EN 50419)

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator is solely responsible for the accurate setup and use of the phantom.

Reporting Health or Safety Related Issues or Concerns

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

Modifications to Equipment

Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.

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