Liver Phantom Product Guide

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WARRANTY

THE PHANTOM LABORATORY INCORPORATED ("Seller") warrants that this product shall remain in good working order and free of all material defects for a period of one (1) year following the date of purchase. If, prior to the expiration of the one (1) year warranty period, the product becomes defective, Buyer shall return the product to the Seller at:

By Truck By Mail

The Phantom Laboratory, Incorporated The Phantom Laboratory, Incorporated

2727 State Route 29 PO Box 511

Greenwich, NY 12834 Salem, NY 12865-0511

Seller shall, at Seller's sole option, repair or replace the defective product. The Warranty does not cover damage to the product resulting from accident or misuse.

IF THE PRODUCT IS NOT IN GOOD WORKING ORDER AS WARRANTED, THE SOLE AND EXCLUSIVE REMEDY SHALL BE REPAIR OR REPLACEMENT, AT SELLER'S OPTION. IN NO EVENT SHALL SELLER BE LIABLE FOR ANY DAMAGES IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT. THIS LIMITATION APPLIES TO DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, DIRECT OR INDIRECT DAMAGES, LOST PROFITS, OR OTHER SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, WHETHER FOR BREACH OF CONTRACT, TORT OR OTHERWISE, OR WHETHER ARISING OUT OF THE USE OF OR INABILITY TO USE THE PRODUCT. ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTY OF MERCHANT ABILITY AND FITNESS FOR PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED.

WARNING

This product has an FH3-4 mm/min flame rating and is considered to be flammable. It is advised not to expose this product to open flame or high temperature (over 125° Celsius or 250° Fahrenheit) heating elements.

Medical device labeling

Manufactured by: The Phantom Laboratory, Incorporated

2727 State Route 29

Greenwich, NY 12834 USA

EU Representative: Raförninn ehf

Suðurhíð 35

IS-105 Reykjavík ICELAND

Product: Liver Phantom

Model: CCT288

UDI:



(01)00812266030581

Device Class: 1





This device is intended for use under direction of a trained medical physicist. Please refer to your machine manufacturer documentation and regulatory guidance for information on intended use.

A sample of this product has been assessed against the Essential Requirements of the EU Medical Device Regulation (MDR). The above mentioned product is deemed in compliance with MDR 2017/745 EU.

A risk assessment was conducted to the following standard: EN ISO14971 This declaration of conformity is the result of testing and evaluation performed by The Phantom Laboratory, Incorporated.

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Liver Phantom CCT288

Introduction

The Liver phantom was developed in collaboration with physicists from ImTECH at Oslo University Hospital for use in scientific evaluation of CT scanners and their protocols and post processing reconstructions.

We do not make recommendations on how to configure this phantom or the applications for this product.

Labeling

This phantom and components are intended to be used by medical physicists or scientists.

Design

The hybrid design of the Liver Phantom enables use of quantitative test objects in an anthropomorphic phantom. The unique design is ideal for the evaluation of different imaging protocols and post reconstruction algorithms. The phantom has seven (7) 5cm diameter holes. Four (4) located in the liver section and three (3) in adjacent RANDO® material. The phantom has solid liver and RANDO® rods that can fill the 7 holes. Depending on the imaging characteristics that are being evaluated there are a selection of test objects with defined features which can be positioned in the 5cm holes.

Contact information

If you have any additional questions please contact Phantom Laboratory at:

Phone: 518-692-1190

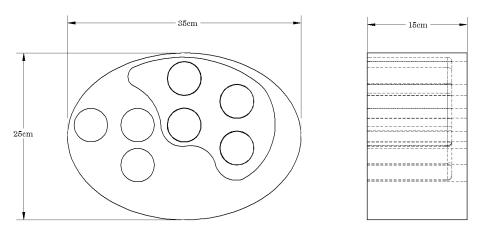
email: info@phantomlab.com

Additional product information is available at: www.phantomlab.com

The current pdf version of this manual can be found in our library: www.phantomlab.com/library

Components

Phantom body MCP062



The phantom is a simplified representation of a human torso with a 25cm x 35cm oval shape and a length of 15cm. The phantom body is cast from RANDO® tissue simulating material and contains simplified liver and bone structures. The liver is cast out of a higher density tissue material and the vertebrae and ribs are cast from simulated bone materials. The phantom has seven 5cm diameter holes for holding insert rods. Three holes pass through the RANDO® material and four holes pass though the liver.

RANDO® material rods MCP046-1 (3)

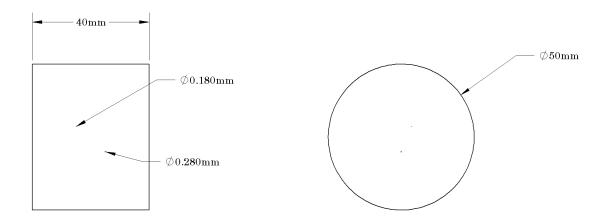
 $5 \mathrm{cm}$ diameter x $15 \mathrm{cm}$ long rods cast from RANDO® material to fill holes when not occupied by test objects.

Liver material rods MCP046-3 (4)

5cm diameter x 15cm long rods cast from RANDO® material to fill holes when not occupied by test objects.

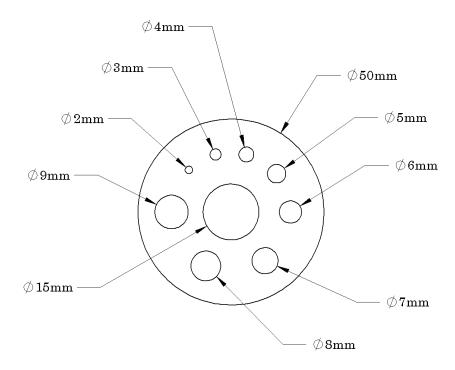
Liver phantom cases

The Liver phantom comes with two cases. One for the phantom body and the second for the extra inserts. The phantom body does not have to be removed from the case for scanning. To remove the case, both sides can be unzipped making it easier to push the phantom. The rectangular insert case has extra space to accommodate for additional or custom inserts.



An MTF bead insert with 0.18mm and 0.28mm tungsten carbide beads.

CCT253

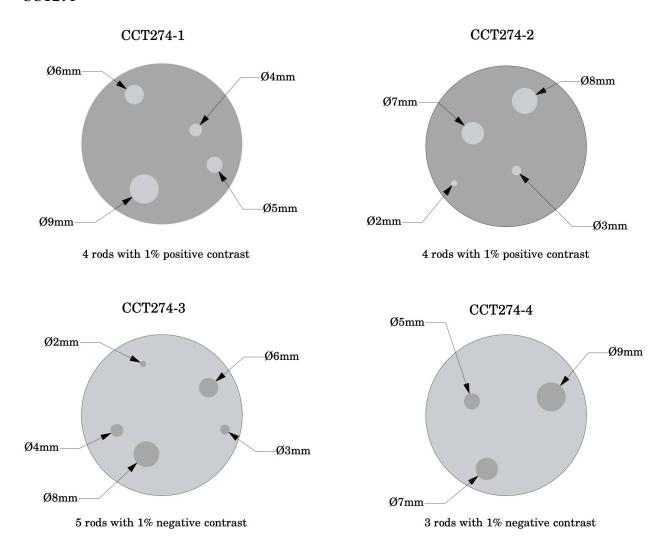


CCT253-1

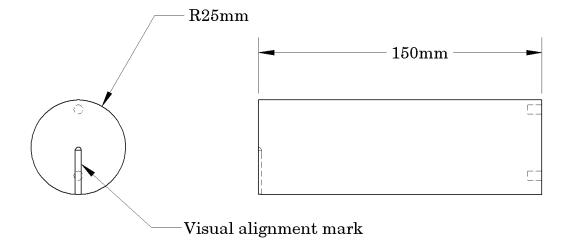
Low Contrast insert with 2, 3, 4, 5, 6, 7, 8, 9, and 15 mm diameter 1% low contrast rods.

CCT253-I2.5

Iodine Contrast insert for dual energy systems with 2, 3, 4, 5, 6, 7, 8, 9, and 15 mm diameter 1 mg/ml iodine.

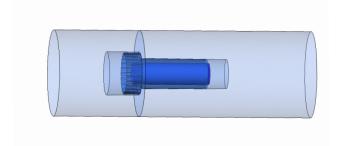


Set of 4 Low Contrast Rods designed for receiver operating characteristic curve (ROC) assessments.



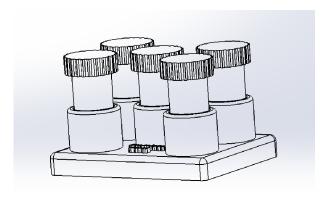
Set of 4 rods that can connect with the CCT274 to assist in positioning. The rod has 2 holes that align with the pins in the CCT274 inserts.

MCP091

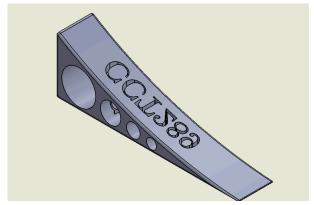


Metal Artifact insert holder.

CTP748



Metal artifact insert set including 12.7mm and 6.35mm diameter rods made from stainless steel and titanium.



Liver phantom stabilization wedges (2 pcs) can be used on flat tables to stabilize the phantom.