

T h e P h a n t o m L a b o r a t o r y

CCT189 and CCT191 MITA CT IQ Low Contrast 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

The Phantom Laboratory, Incorporated
2727 State Route 29
Greenwich, NY 12834

By Mail

The Phantom Laboratory, Incorporated
PO Box 511
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.

CCT189
CCT191

6/October/2021

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: MITA IQ Low Contrast Phantom

Model: CCT189

UDI: 
(01)00812266030567

Model: CCT191

UDI: 
(01)00812266030574

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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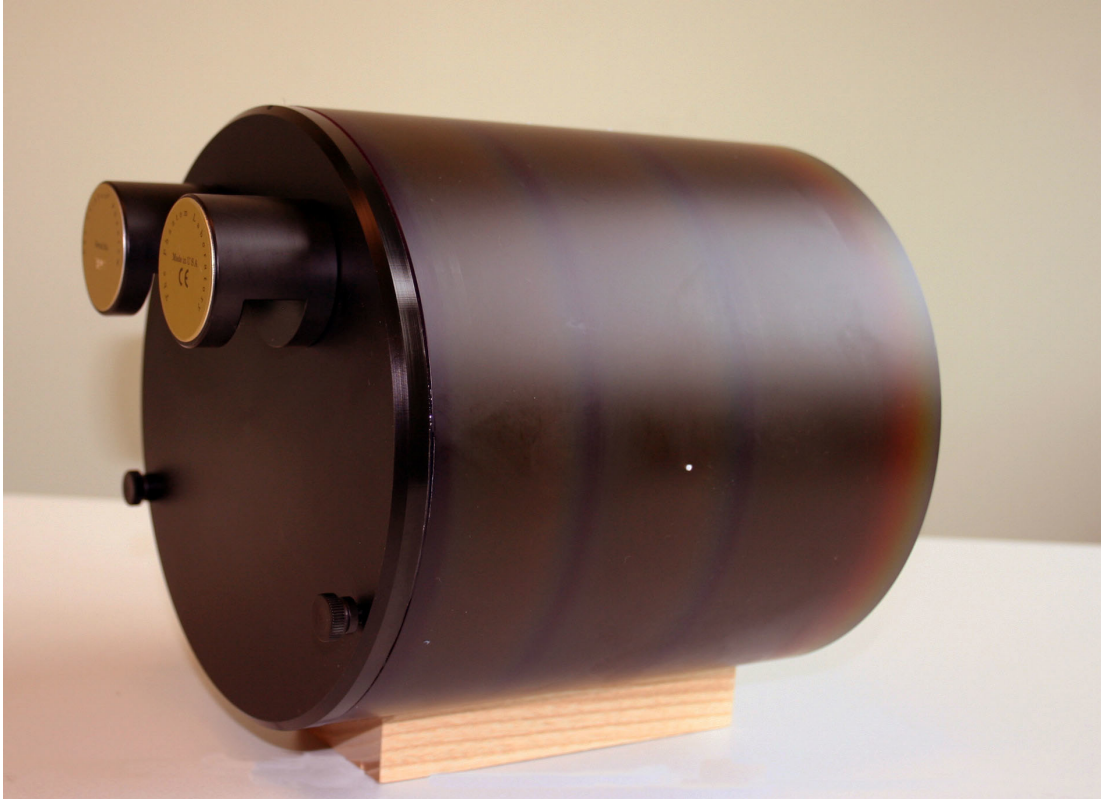
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Indications for Use

The CCT189 and CCT191 MITA IQ LC Phantoms are designed for performing low contrast measurements as defined by the MITA CT IQ Task Group. The CCT189 is designed for body imaging low contrast evaluations and the CCT191 is designed for head imaging low contrast evaluations.



Introduction

The Phantom Laboratory, Incorporated developed the CCT189 and CCT191 Phantom to address the design criteria presented by the MITA CT IQ Task Group in 2013. These designs were selected by the MITA committee to replace the CCT183 phantom.

If you have questions about the CCT189 and CCT191 Phantoms please contact The Phantom Laboratory at the following address:

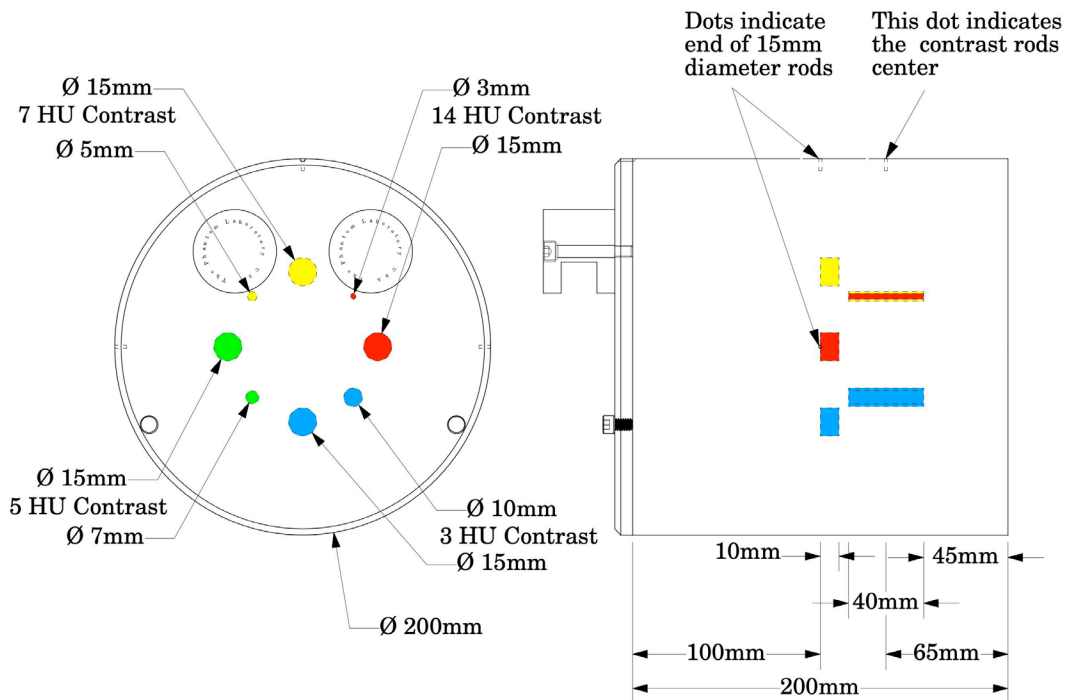
The Phantom Laboratory, Incorporated
PO Box 511, Salem NY 12865 USA
Phone: 800-525-1190 or 518-692-1190
Fax: 518-692-3329
Email: info@phantomlab.com

Schematic Drawing CCT189 Low Contrast Body Phantom

The CCT189 Phantom has eight contrast rods. Four of the contrast rods are 40mm long, and each of these rods have different diameters and nominal contrasts. Samples from each selected batch of contrast rods are tested with multiple scans on our in house CT scanner. The scans of the contrast rods are analyzed through automated analysis. While these contrasts are measured to be within .05% of target values for more precise evaluation of your phantom we recommend averaging of multiple scans.

The nominal contrast values and diameters are 14HU contrast with 3mm diameter, 7HU contrast with 5mm diameter, 5HU contrast with 7mm diameter and 3HU contrast with 10mm diameter (HU referring to Hounsfield Units or CT numbers). For each 40mm long contrast rod there is a corresponding 10mm long, 15mm diameter contrast rod. To assure contrast consistency the 40mm rods and the 10mm rods of each contrast come from the same casting batch.

The phantom has four alignment dots which are helpful in positioning the phantom. There are three dots that define the plane aligned with the mount end of the 10mm long, 15mm diameter contrast rods. One of these dots is on the top and the other two are on the sides of the phantom. The fourth dot is also on the top of the phantom and aligns with the center of the 40mm contrast rods.



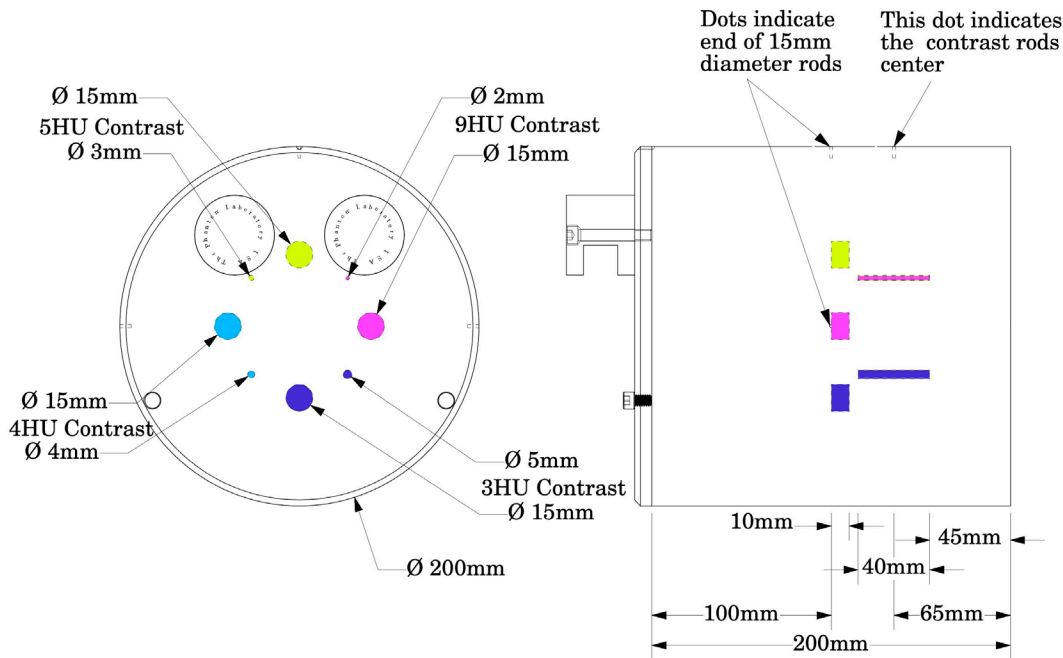
CCT189 Low Contrast Body Phantom Sketch

Schematic Drawing CCT191 Low Contrast Head Phantom

The CCT191 Phantom has eight contrast rods. Four of the contrast rods are 40mm long, and each of these rods have different diameters and nominal contrasts. Samples from each selected batch of contrast rods are tested with multiple scans on our in house CT scanner. The scans of the contrast rods are analyzed through automated analysis. While these contrasts are measured to be within .05% of target values for more precise evaluation of your phantom we recommend averaging of multiple scans.

The nominal contrast values and diameters are 9HU contrast with 2mm diameter, 5HU contrast with 3mm diameter, 4HU contrast with 4mm diameter and 3HU contrast with 5mm diameter (HU referring to Hounsfield Units or CT numbers). For each 40mm long contrast rod there is a corresponding 10mm long, 15mm diameter contrast rod. To assure contrast consistency the 40mm rods and the 10mm rods of each contrast come from the same casting batch.

The phantom has four alignment dots which are helpful in positioning the phantom. There are three dots that define the plane aligned with the mount end of the 10mm long, 15mm diameter contrast rods. One of these dots is on the top and the other two are on the sides of the phantom. The fourth dot is also on the top of the phantom and aligns with the center of the 40mm contrast rods.



CCT191 Low Contrast Head Phantom Sketch

Note:

The manufacturing of these phantoms follows a complex process with numerous casting steps. There are several CT inspections to verify the area surrounding the posts are free of interface or air bubbles. Small imperfections and seams away from the long contrast rods are considered acceptable since that material is only providing extra attenuation or scatter and will not affect the ability to visualize rods in their immediate background.

Scanning Alignment

The CCT189 and CCT191 Phantoms are equipped with a Catphan® case and mount. Place the phantom case on the gantry end of the table with the box hinges away from the gantry. It is best to place the box directly on the table and not on the table pads.

Open the box, rotating the lid back 180°. If you are using an annulus, additional weight will need to be placed in the box to counterweigh the phantom. The patient straps can be used for additional stability.

Remove the phantom from the box and hang the Catphan® from the gantry end of the box. Make sure the box is stable with the weight of the phantom and is adequately counterweighed to prevent tipping.

Use the level and adjusting thumb screws to level the Catphan®. Once the phantom is level, slide the phantom along the end of the box to align the section center dots on the top of the phantom with the x axis alignment light.

Use the table height and indexing drives to position the phantom.

