Corgi® 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: Corgi® Phantom

Model: CGI014

UDI:

(01)00812266030529

Model: CGI023

UDI:

(01)00812266031236

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.

Phantom Laboratory

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CGI014 Corgi™ phantom

Introduction

The Corgi® phantoms are based on cone beam CT phantom development done by John Boone, Ph.D. and Jeffrey Siewerdsen, Ph.D. They have collaborated with The Phantom Laboratory to develop the production models of the Corgi® phantom and the automated analysis.

This phantom has a modular design allowing it to be configured differently for different cone beam systems. The phantom is designed to be used with the Smári Analysis service. This manual will give basic information on set up configurations and review the output from the Smári analysis service.

We do not make specific recommendations on the content of your quality assurance program as each medical imaging facility has its own unique set of requirements. A sample program is provided to give you ideas for possible program content. We suggest a review of local governing regulations, manufacturers' specifications, and the needs of your radiologists and physicists before developing your CT quality assurance program.

Labeling

The Corgi® phantoms are designed to be used by, or under the supervision of a person trained in CT physics.

Contact information

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

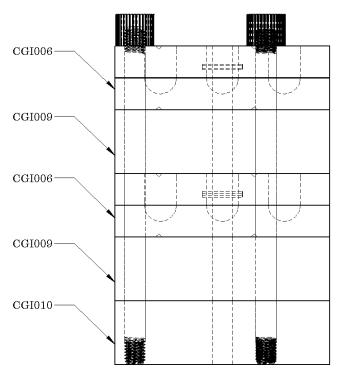
Phone: 518-692-1190

email: info@phantomlab.com

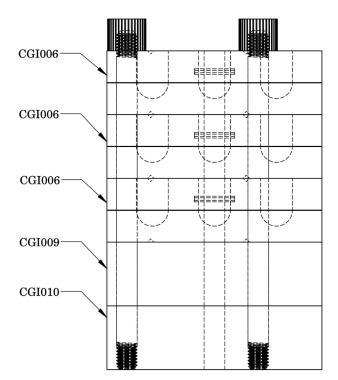
Additional product information is available at: www.phantomlab.com

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

Corgi® phantoms CGI014 and CGI023



CGI014 contains: 2 CGI006, 2 CGI009 and 1 CGI010 modules.

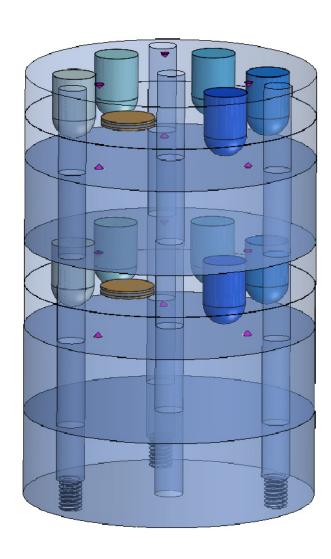


CGI023 contains: 3 CGI006, CGI009 and 1 CGI010 modules.

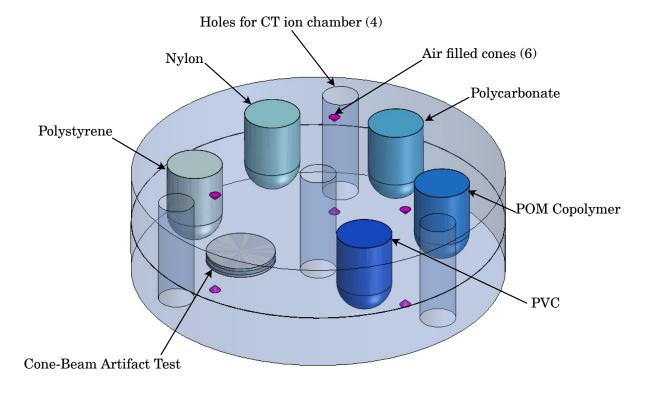
Phantom tests

Image uniformity
Noise
Spatial resolution
Axial plane
Voxel resolution
Cone beam artifact
Sensitometry
Geometric accuracy:
Axial plane
Z direction

Dose



Corgi® phantom modules



CGI006 Sensitometry and CB Test Module

The $Corgi^{TM}$ phantom contains 2 CGI006 modules. They include 5 sensitometry 20mm diameter insert rods with a hemisphere at one end. They are made from Polystyrene, Nylon, Polycarbonate, POM Copolymer and PVC.

Sensitometry material information:

Material	Formula	Density(g/cc)	Mass Electron Density(e/g) Volum	Volume Electron Density(e/cc)		
PVC	C2H3Cl	1.33	3.08E+23	4.01E	E+23		
POM Copolymer	C6H12O5	1.41	3.23E+23	4.55E	2+23		
Nylon	C18H34N2	2O2 1.06	3.34E+23	3.54E	E+23		
Polycarbonate	C15H16O2	1.19	3.22E+23	3.83E	E+23		
Polystyrene	C8H8	1.03	3.24E+23	3.34E	2+23		
Material Relative Electron		lectron Density	Zeff Measured		*		
				$100 \mathrm{kVp}$	$140 \mathrm{kVp}$		
PVC	1.	199	13.86	1255	958		
POM Copolymer	1.	362	6.83	355	342		
Nylon	1.	058	5.95	13	31		
Polycarbonate	1.	146	6.09	85	101		
Polystyrene	0.	998	5.7	-48	-27		

Notes on material information:

For standard sensitometry inserts, The Phantom Laboratory purchases a multiple year supply of material from a single manufacturing batch.

Chemical formulas are from our best information, either standard or obtained from the manufacturers. The actual formulas may differ due to limited imformation or manufacturing variations.

Zeff, the effective atomic number, is calculated using a power law approximation.

Relative Electron Density is the volume electron density of the material divided by the volume electron density of water.

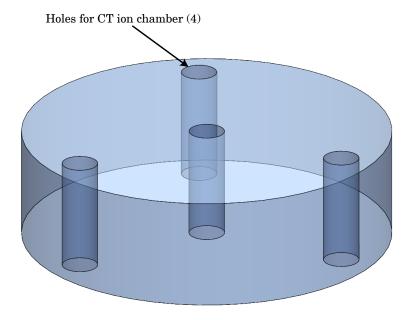
*Measured HU were taken on a Neurologica Ceretom scanner. Measured HU can vary widely depending on the scanner and the details of the scanning protocol, even when scanned at the same energy. These values are included as an example.

Higher Zeff tends to increase attenuation at lower energies. That is why the HU of PVC and POM Copolymer, materials with higher Zeff, increase at 100kVp vs. 140kVp, while the HU of the other materials decreases.

The sensitometry inserts are also used for spatial resolution measurements in terms of an edge spread function (ESF) and modulation transfer function (MTF). Both in-plane and out-of-plane spatial resolution can be evaluated by using the sensitometry insert edges in the x-y plane or rotating the edge 45° on the hemispherical end to get x-y-z spatial resolution.

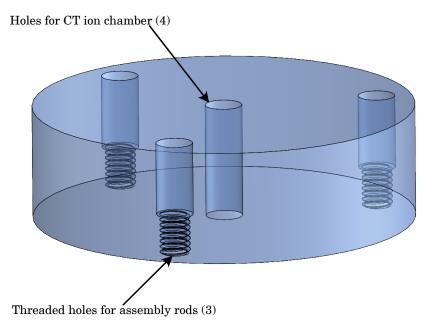
To quantify the magnitude of cone beam artifact two Teflon disks, 25mm in diameter and 1mm thick, are separated by 1.5mm. By analyzing the image in the region of the disks near the central plane and at the edge of the volumetric field of view, the "cone-beam" sampling effects can be mathematically evaluated.

Geometric accuracy in the x, y and z directions is evaluated with 6 cone shaped voids that are precisely machined on the top and bottom of the test modules.



CGI009 Blank uniformity module

The Corgi® CGI009 modules are used for measurement of image uniformity, noise, and dose. The central hole and 3 peripheral holes will accept an ionization chamber - for example, a 0.6 cc (Farmer) air ionization chamber common for measurement of dose in cone beam CT. Connecting rods are easily removed enabling peripheral dose measurements in any of the locations.



CGI010 Blank uniformity base (end) module

The Corgi® phantom contains 1 CGI010 module for measurement of image uniformity, noise, and dose. This module has a central hole which will accept an ionization chamber (similar to the CGI009 module). The 3 peripheral holes are threaded on the bottom end to accept the connecting rods.

Configuring the modular Corgi phantom



The above photos show standard 3 and 5 module configurations

The Corgi® phantom is shipped in the standard 5 module format with the CGI011-1 long assembly rods threaded into the CGI010 base module. The modules are held together by the assembly rods and the plastic thumb nuts at the top. On the side of each module is the phantom serial number followed by a -1, -2, ... showing their standard positions.

If the phantom is positioned so the central CGI006 module is near the center of the x-ray beam where there is minimal divergence, the tests in the top CGI006 will be 8 cm in the z axis direction away from the central module resulting in greater divergence. This way, the variation in image quality from center to off-center can be better evaluated.

Depending on the actual geometry of the system being evaluated, other configurations may be more appropriate. To set up a custom configuration choose either a 3 module (12cm z length) or 5 module (20cm z length) configuration. For the 3 module configuration, mount the 3 short CGI011-2 assembly rods (which are attached to the outside of the Corgi® case) into the CGI010 base module. Make sure the threaded side of the CGI010 is on the bottom and the rods are threaded down through the top. The remaining modules can then be slid over the rods in any order. For other configurations, custom length rods are available. Modules from multiple Corgi® phantoms can also be used with custom rods to make configurations longer than 20cm (z).

Please note for QA constancy, testing the same phantom configuration and positioning needs to be used so performance over time can be monitored.



The Corgi® phantom is designed to be evaluated with the Smári automated analysis service. The Corgi purchase includes 2 years of the Smári analysis service.

To register for the service, go to the Smári page at our website: phantomlab.com



You will need your phantom serial number to register, which is located on each module's label. In the example above the serial number is CGI0143.

Once we receive your information, The Phantom Laboratory support team will contact you and set up your account.

Smári provides cloud-based automated analysis of your Corgi® phantom and tools such as longitudinal history and user specified alerts.

Dose measurements

The Corgi® phantom is designed to work with the standard CT dose probes for example, a 0.6 cc (Farmer) air ionization chamber as common in dose measurement for cone beam CT.. To perform a dose measurement in the center of the phantom simply slide the probe into the central hole. To measure the dose in one of the 3 peripheral holes, select a hole and remove the assembly rod. Then insert the assembly rod into the center hole and the ionization chamber into the open peripheral hole. It is good practice to ensure that all holes (other than the hole containing the ionization chamber) contain a rod.

Corgi™ options

16cm OD Clear urethane Corgi® annulus CGI019

20cm OD Urethane Corgi® annulus is compatible with Catphan® body annuli CGI020 To reduce the air-gap between the Corgi® phantom and annulus pressing the Corgi® into and out of the 20cm annulus will require some force. To reduce friction a water based lubricant may be used.

Annuli that are compatible with the CGI020 are listed on the Catphan® Annulus Datasheet in the library at phantomlab.com

Assembly rods for: 2, 4, 6 and longer Corgi® phantom configurations. Please note that configurations greater than 5 modules will require modules from multiple Corgi phantoms.

Bibliography

Principles for the Corgi® phantom and analysis draw in part from the following scientific journal article:

"Cone-beam CT dose and imaging performance evaluation with a modular, multipurpose phantom," J. H. Siewerdsen, A. Uneri, A. M. Hernandez, G. W. Burkett, and J. M. Boone, Med Phys 47(2): 467-479~(2020) https://doi.org/10.1002/mp.13952