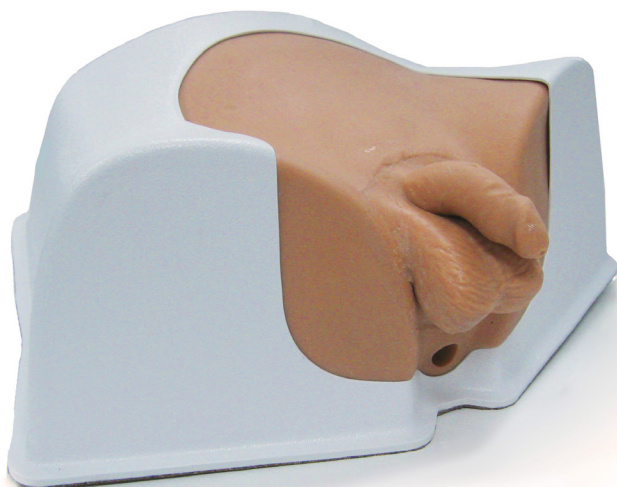


Multi-Modality Pelvic Phantom

Model 048A



USER GUIDE

CIRS

2428 Alameda Avenue Suite 316 • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765
WWW.CIRSINC.COM

OVERVIEW

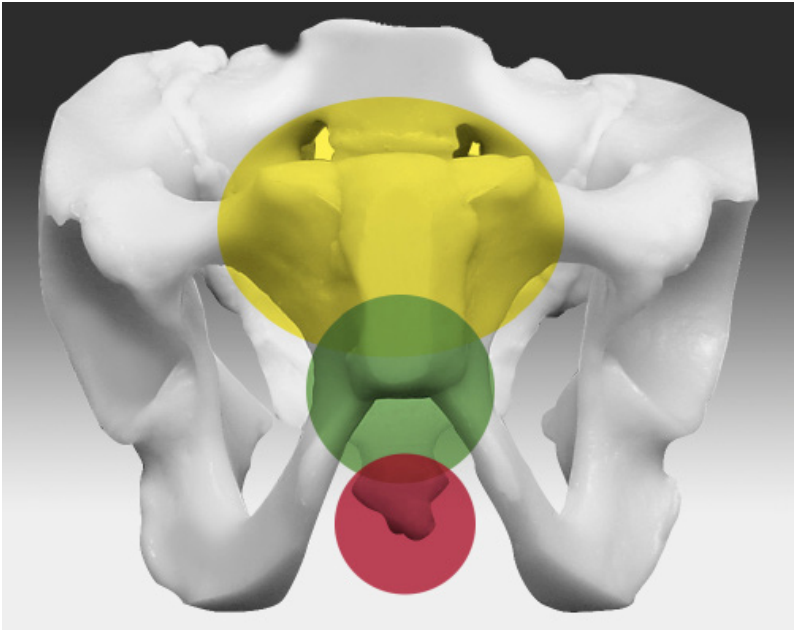
The Multi-Modality Male Pelvic Phantom was designed for realistic abdominal and transrectal ultrasound scanning of the bladder and prostate. The phantom includes pelvic bones, anechoic bladder, prostate, urethra, seminal vesicles and rectum enclosed in a pelvic-shaped plastic housing with a Z-Skin™ membrane. The self-healing qualities of Z-Skin make this design ideal for the demonstration of biopsies and other image-guided procedures.

The phantom is made from materials that can be imaged under ultrasound, MRI and CT making the phantom useful for applications that require multiple modalities such as radiation treatment planning. The phantom is provided with certified prostate and bladder volumes to enable assessment of volumetric measurement accuracy. Modifications are available such as permanently embedded brachytherapy “dummy” seeds or gold fiducial markers for demonstration of target visualization.

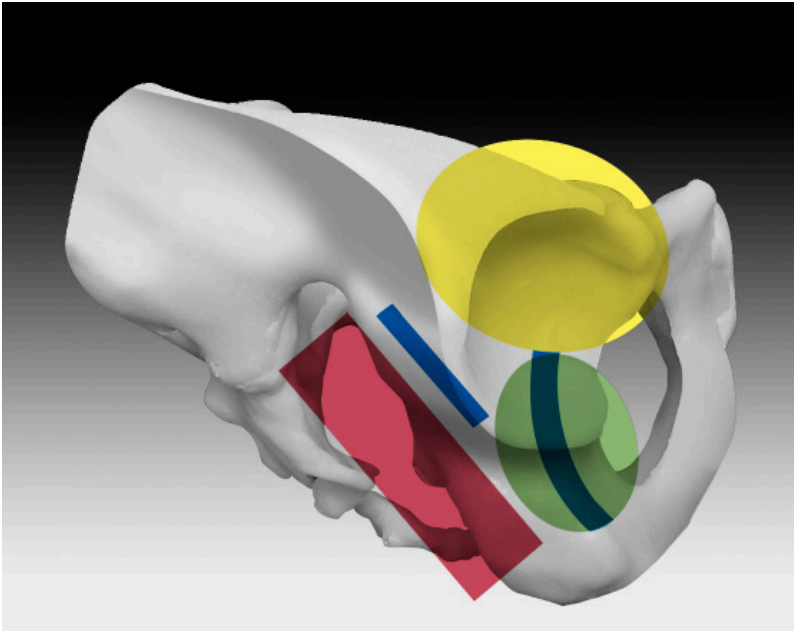
Each phantom is sold with a certificate of compliance.

CIRS is certified to ISO 9001:2008 standards. We have an in-house test facility to measure acoustic properties of speed, attenuation and relative contrast. In addition, two ultrasound systems are used to visually inspect each phantom. As a result, every ultrasound phantom is subjected to rigorous testing both during manufacture and upon completion. A Certificate of Compliance is issued with each phantom.

FRONT AND SIDE VIEW OF MODEL 048A



Front View



Side View

SPECIFICATIONS

DIMENSIONS:	15 cm W x 11 cm L x 11 cm H
PHANTOM WEIGHT:	16 lbs. (5.9 kg)
BACKGROUND:	Zerdine® (1)
URETHRA:	Zerdine Ultrasound Contrast: Anechoic Diameter: ¼"
SEMINAL VESICLES:	Zerdine Ultrasound Contrast: Isoechoic to prostate Diameter: ¼"
RECTUM:	Zerdine Ultrasound Contrast: Isoechoic to prostate Diameter: 32mm
PELVIS:	Tissue Equivalent epoxy resin Attenuation: Highly attenuating will cast shadows
BLADDER:	Zerdine Ultrasound Contrast: Anechoic at 15 dB Volume: 177cc
PROSTATE:	Zerdine Ultrasound Contrast: Hypoechoic Volume: 45cc
PHANTOM HOUSING:	ABS shell, thermoformed to pelvic shape Membrane: Z-Skin

(1) See page 5 for more information

MODEL 048A INCLUDES

QTY	COMPONENT DESCRIPTION
1	Multi-Modality Pelvic Phantom
1	User Guide
1	Certificate of Compliance
-	6-Month Warranty

NOTES

All dimensions without tolerances are nominal

All measurements made at $22^{\circ}\text{C} \pm 1^{\circ}\text{C}$

All speed of sound and attenuation measurements made with 5 MHz focused transducer

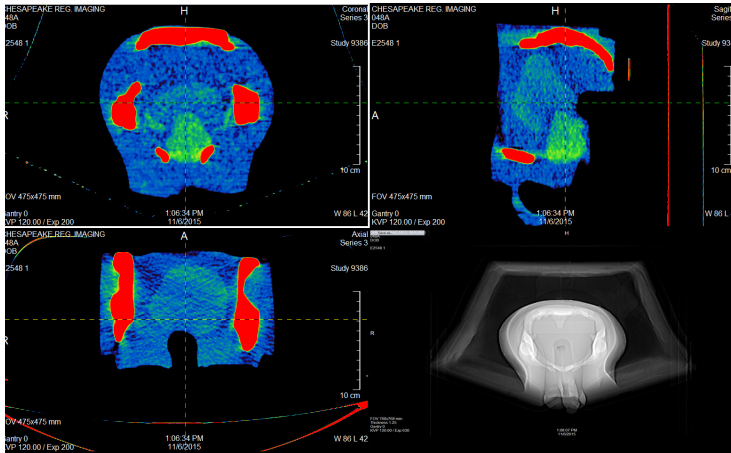
SAMPLE IMAGES



Sample Ultrasound Image of 048A



Sample Ultrasound Image of 048A



Sample CT and SCOUT image

ZERDINE®

The Model 048A is constructed from a patented, solid elastic material developed at CIRS called Zerdine. Zerdine, unlike other phantom materials on the market, is not affected by changes in temperature. It can be subjected to boiling or freezing conditions without sustaining significant damage. Zerdine is also more elastic than other materials and allows more pressure to be applied to the scanning surface without subsequent damage to the material. At normal room temperatures, Zerdine will accurately simulate the ultrasound characteristics found in human liver tissue. Specific proprietary fabrication procedures enable close control over the homogeneity of Zerdine and the reliability of its acoustic characteristics from batch to batch.

The speed of sound in Zerdine can be adjusted between 1430 and 1650 meters per second. The acoustic attenuation can be adjusted between 0.05 dB/cm-MHz and 1.50 dB/cm-MHz. The relation between the acoustic attenuation, A , and the acoustic frequency, F , is of the form $A = A_0 F^n$ with values of the power coefficient, n , in the range of 0.8 to 1.10, indicating the proportional increase of the acoustic attenuation with frequency. Backscatter characteristics can be adjusted through the addition of predetermined amounts of calibrated scatter material. Zerdine can be molded into very intricate shapes, and the material can be cured in layers allowing the production of “multi-tissue” phantoms. Zerdine, like most other phantom materials, will desiccate if unprotected; thus, all phantoms must be stored properly. If stored in the case provided, your phantom should last many years.

HANDLING PRECAUTIONS AND END OF LIFE DISPOSAL

Clean by hand using water and mild dish washing liquid. Rinse thoroughly and allow to air dry. Solvents may damage the abdomen. Do not expose the phantom to extreme temperatures or direct sunlight and store at normal room temperature. To maximize phantom lifetime and minimize dessication, phantom may be stored in re-sealable plastic bag.



At least once a year, weigh your phantom and compare to original weight noted on certificate of compliance. If phantom has lost or gained more than 1% of its original weight and you notice a difference in vertical distance measurements, or the scan surface appears depressed, call CIRS at (800) 617-1177.



This product contains Zerdine, a non-flowing water-based, polyacrylamide material which is fully sealed within the phantom housing. Zerdine contains trace amounts of residual monomer acrylamide CAS#79-06-1. There are no known hazards when the phantom is used and stored as intended. Zerdine is fully cured and will not leak from the housing. Damage to the integrity of the housing may expose the user to Zerdine containing trace monomer acrylamide below levels necessary to cause adverse health effects. Nonetheless, it is advised to wear protective gloves if handling exposed Zerdine gel. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.



Regulations regarding disposal of materials with trace acrylamide monomer vary by locality. Contact your local authority for instructions. If assistance is desired in the proper disposal of this product, including accessories and components, after its useful life, please return to CIRS.



Note: Each phantom is individually hand crafted and as such will have minor variations and anomalies. Our QA system has established processes to review these various anomalies to ensure they do not jeopardize the utility of the phantom. Microbubbles, creases or mold seams on phantom surface, as in the photos above, will not adversely affect ultrasonic scans.

WARRANTY

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

NON-WARRANTY SERVICE

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

RETURNS

If you are not satisfied with your purchase for any reason, please contact Customer Service prior to returning the product. Call 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or "customized" products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and/or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

WITH RMA NUMBER, ITEMS MAY BE RETURNED TO:

CIRS
Receiving
2428 Alameda Avenue Suite 218,
Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD
Model 048A - Multi-Modality Pelvic Phantom	6 Months

