# Brachytherapy QA Phantom Model 045B



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# **OVERVIEW**

The Model 045B is sturdy, reliable phantom for testing the imaging performance of side-fire and bi-plane probes used for transrectal ultrasound imaging in prostate brachytherapy seed implantation. The Model 045B phantom offers a complete solution for implementing a brachytherapy QA program as recommended by AAPM Task Group 128.<sup>1</sup>

The phantom is supplied with a water tank for vertically coupling a transducer to the scanning membrane. Brachytherapy needle grid QA can be accomplished using the space available inside the water tank as specified by Goldstein et al.<sup>2</sup> The tank

# Consistency Measurements with the Model 045B

- Uniformity
- Depth of Penetration
- Vertical distance measurement accuracy
- Horizontal distance measurement
  accuracy
- Electronic Grid Accuracy
- Stepping Mechanism Accuracy
- Volume Measurement Accuracy
- Needle Alignment Testing

has two angled slots to allow the phantom to be positioned at a 30° angle which simplifies use with floor-mounted TRUS systems. When testing table-mounted TRUS systems, the phantom membrane can be oriented vertically. (See page 2 and 3 for images.)

The Model 045B has a series of monofilament targets that will appear as bright dots or lines on the ultrasound image. These targets are made from monofilament nylon wire with a diameter of 0.4 mm and a positional accuracy of  $\pm 0.2$  mm. There are also three volumetric targets. These targets are made from Zerdine that has a different contrast relative to the background material.

CIRS is certified to ISO 13485:2016 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.

For further guidance on establishing a quality assurance program, you may want to reference the accreditation programs established by the ACR and AIUM. You can access this information at www.acr.org or www.aium.org. If additional information is required, please call CIRS technical service at 1-800-617-1177.

1. Pfeiffer, Douglas, et al., AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems. Med. Phys., vol. 35 (12), pgs. 5471-5489, December 2008.

2. Goldstein, A., Yudelev, M., Sharma, R.K. and Arterbery, E. (2002), Design of Quality Assurance for Sonographic Prostate Brachytherapy Needle Guides. Journal of Ultrasound in Medicine, 21: 947-954. doi:10.7863/jum.2002.21.9.947 Phantom is placed vertically in water tank for testing. Tank needs to be filled with water prior to use.





Phantom can be positioned at 30-degrees for compatibility with floor mounted brachytherapy systems.





# **INSTRUCTIONS AND USE**

#### HANDLING AND CARE

With proper care, the Model 045B will withstand years of normal use. Below are some guidelines to follow.

The scanning surface is the most important item on the phantom to protect. It can withstand normal scanning pressure but DO NOT press on the scanning surface with your fingernails or any other sharp objects. If the scanning surface becomes damaged, seal the phantom in an airtight container and IMMEDIATELY contact CIRS for return authorization. Call 800-617-1177, email at rma@cirsinc.com or fax RMA Request form to 757-857-0523.

The phantom may be cleaned with mild soap and water ONLY. Avoid solventbased, alcohol-based, or abrasive cleaning agents.

For longest life, the phantom should be cleaned after each use and stored at room temperature in the provided zip-lock bag. The primary concern is gel desiccation due to loss of water vapor through the membrane. In addition, the thermal stresses associated with a freeze/thaw cycle may cause the gel to crack or damage the housing integrity, while extreme heat may accelerate water vapor transmission through the membrane. To minimize desiccation, always store the phantom in a sealed zip-lock bag or an equivalent air-tight, sealed container.

Inspect your phantom regularly for signs of damage and weight loss. If any noticeable changes to the phantom are detected, return the phantom IMMEDIATELY for repair or replacement.



At least once a year, weigh your phantom and compare to original weight noted on certificate of compliance. If the phantom has lost or gained more than 1% of its original weight and you notice a difference in vertical distance measurements, or if 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 the 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 trace amounts of acrylamide monomer. The amount is not sufficient to pose an acute health risk, but it is still advised to wear protective gloves if handling exposed Zerdine gel due to the potential long-term hazards of the monomer. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.

### HANDLING AND CARE (CONTINUED)



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.

#### **GENERAL GUIDELINES FOR PERFORMING MEASUREMENTS**

It is recommended that all measurements be performed at the most frequently used imaging arrangements. The importance of these tests is to make sure that system performance remains constant over an extended period of time. Measurements may also be used to compare the performance of various setups of the same machine or to compare different machines in a quantitative manner.

The following are general steps for imaging all targets:

- Some wires will appear as short lines rather than dots. When using the electronic calipers, always take measurements from a point on one echo to the same point on the next (i.e., center to center). Otherwise, errors may be introduced.
- When assessing vertical distance measurements, DO NOT press on the scanning surface. Pressure on the scanning surface causes the wires to become temporarily displaced, making vertical distance measurements inaccurate.
- When assessing horizontal distance accuracy, ensure that the scan plane is perpendicular to the horizontal target group. Rotation of the probe will result in inaccurate distances.
- Always be sure the phantom is scanned while at room temperature. A phantom just received may be colder or hotter than room temperature depending on where it was stored during shipping. Temperature affects the speed of sound and, ultimately, the perceived measurements. The phantom should be stored at room temperature for at least 24 hours before use to ensure its core temperature is correct.
- The most accurate measurements will be made with the phantom 22°C  $\pm$  1°C (70°F–73°F).

#### **ESTABLISHING A BASELINE**

Before performing routine quality assurance measurements, establish:

#### 1. System settings for each measurement:

System setup can have a dramatic impact on the results obtained from quality assurance measurements. You must establish and record what system settings should be used for each of the quality assurance tests. These same settings should be used each time the test is performed. If not, then the conclusions drawn may not be valid. CIRS recommends that you use the most commonly used settings for the type of probe tested- i.e. the brachytherapy preset values which are called a "normal" technique in the sections that follow.

#### 2. Baseline measurements:

The first set of measurements taken will be the baseline measurements for the combination of system settings and phantom. Record the system settings and phantom serial number used to acquire each measurement along with your measurement results. On subsequent scans, refer to the baseline results to determine if the ultrasound system has drifted to an unacceptable level. It is each facility's responsibility to establish the magnitude of drift allowed before corrective action is warranted.

#### 3. Allowable deviation from baseline measurements:

The difference between the original baseline measurements and subsequent measurement should be calculated and recorded. At some point the difference will be large enough that some action is required (call service, replace system, etc.). Each facility needs to determine the action level for each test. You should refer to the user's manual of your ultrasound scanner and note the stated accuracies of the system's general imaging measurements. These stated accuracies may greatly influence the conclusion made when evaluating the ultrasound system. For example, if the measurement accuracy for your system is 10% for distances up to 2 cm, the scanner may detect 2.0 cm as being any where from 1.8 cm to 2.2 cm and still be functioning properly. The user is responsible for establishing action levels.

#### 4. Frequency of system assessment:

How often each system is evaluated is also up to each facility to determine. CIRS recommends at least annually.

Reference the accreditation programs established by the ACR and AlUM at www.acr.org or www.aium.org for further guidance on establishing a QA program.

# **TEST PROCEDURES**

The following sections outline procedures for performing routine quality control tests with the imaging targets contained within the Model 045B. The water tank should be filled with water and phantom placed inside the tank when performing test procdures. See the following references on page 7 for further test procedure details: Pfeiffer, Douglas, et al., AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems. Med. Phys., vol. 35 (12), pgs. 5471-5489, December 2008.

Goldstein, A., Yudelev, M., Sharma, R.K. and Arterbery, E. (2002), Design of Quality Assurance for Sonographic Prostate Brachytherapy Needle Guides. Journal of Ultrasound in Medicine, 21: 947-954. doi:10.7863/jum.2002.21.9.947

#### UNIFORMITY

Uniformity is defined as the ability of the machine to display echoes of the same magnitude and depth with equal brightness on the display. This is a good test to ensure all crystals within the transducer are functioning. Uniformity testing is performed as follows:

- 1. Position the transducer on the scanning surface in a region with a minimum number of targets.
- 2. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 3. Align the probe so that the targets are maximized.
- 4. Freeze the image and obtain a hard copy.
- 5. Observe the general appearance of the phantom. Note if all regions at the same depth are displayed with the same intensity across the width of the image.
- 6. Record your observations.

#### **DEPTH OF PENETRATION TESTING**

Depth of penetration, also called maximum depth of visualization or sensitivity, is the greatest distance in a phantom for which echo signals caused by scattering in the background material can be detected on the display. The depth of penetration is determined by the frequency of the transducer, the attenuation of the medium being imaged and the system settings. It is measured with the aid of the "N" group wire targets, as follows:

- 1. Position the transducer above the "N" Group and perpendicular to the wires. (The wires should appear as dots, not lines).
- 2. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 3. Align the probe so that all the vertical targets are displayed at their maximum intensity level.
- 4. While actively scanning, look to see where the scatterers within the background material disappear. Be careful not to confuse electronic noise with the back ground scatterers. Electronic noise will move; scatterers will remain stationary.
- 5. Freeze the image.
- 6. With electronic calipers measure the distance between the scanning surface and the last identifiable echo due to scattering. Note: The wires may be visible even though the scatterers are not. Remember to measure the distance to the scatterers not the last visible wire.

7. Record this distance on a record sheet and compare with baseline depth.

## VERTICAL AND HORIZONTAL DISTANCE ACCURACY- USING ELECTRONIC CALIPERS

If the displayed grid does not line up with the N-shaped target group or you want a more precise measure of distance accuracy, electronic calipers may be used. Vertical distance is defined as the distance along the axis of the beam. Horizontal distance is defined as the distance along the length of the transducer. Distances are used to measure areas, volumes, depths, and sizes of objects. The vertical array of targets at column B and F on the phantom diagram allow one to assess the accuracy of the vertical measurements while the horizontal array of targets at row 1 through 5 assess horizontal measurement accuracy. For bi-plane probes, the crossing wires in the z-axis can also be used for horizontal measurements and provide spacing from 0.5 cm to 5.0 cm.

- 1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 2. Align the probe so the N-shaped target group is maximized.
- 3. Freeze the image.
- 4. Using electronic calipers, measure the distances between two wires at various depths or align the echoes to the ultrasound system display markers for comparison.
- 5. Record measurements.
- 6. Compare measured values with baseline distances.
- 7. Repeat steps using horizontal targets in N-shaped group.

#### VERTICAL AND HORIZONTAL DISTANCE ACCURACY

Vertical distance is defined as the distance along the axis of the beam while horizontal distance is defined as the distance along the length of the transducer. Distances are used to measure areas, volumes, depths, and sizes of objects. Using the "N" target group, the vertical array of targets at column B and F on the phantom diagram allow one to assess the accuracy of the vertical measurements while the horizontal array of targets at row 1 through 5 assess horizontal measurement accuracy. For bi-plane probes, the crossing wires in the z-axis can also be used for horizontal measurements and provide spacing from 0.5 cm to 5.0 cm.

For the most precise assessment of vertical and horizontal distance measurement accuracy, used the electronic calipers as follows:

- 1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 2. Align the probe so the N-shaped target group is maximized.
- 3. Freeze the image.

# VERTICAL AND HORIZONTAL DISTANCE ACCURACY (CONTINUED)

- 4. Using electronic calipers, measure the distances between two wires at various depths or align the echoes to the ultrasound system display markers for comparison.
- 5. Record measurements.
- 6. Compare measured values with baseline distances.
- 7. Repeat steps using horizontal targets in N-shaped group.

# **ELECTRONIC GRID ACCURACY**

One important aspect for any brachytherapy procedure is accurate placement of seeds within the prostate. An integral part of seed placement and treatment planning is the accuracy of the distances measured. By aligning this grid to the "N" target of the phantom, users can perform a quick check vertical and horizontal distance accuracy as follows:

- 1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 2. Align the probe so the N-shaped target group is maximized.
- 3. Secure your transducer and position the stepping/stabilization unit accordingly. For ease of alignment you may want to place the front surface of the phantom in contact with the needle template. Adjust the probe/phantom position until the targets are aligned with the displayed grid. It may be easiest to align the center target with the center-displayed target and then try to align the rest of the grid.
- 4. Proper alignment is achieved when the displayed grid is superimposed on wire target echoes. The wires may appear larger or smaller than the displayed grid dots. If the targets appear larger, try to align the centers of the targets with the displayed grid dots. Depending on the manufacturer of your brachytherapy system and ultrasound machine, Row 1 on the phantom may or may not represent Row 1 on the displayed grid. If you have difficulty aligning the targets with the displayed grid, you can assess horizontal and vertical distance accuracy by using the electronic calipers.
- 5. Record results.

#### STEPPING MECHANISM ACCURACY

Just as vertical and horizontal distance measurements are important for accurate seed placement in the x-axis and y-axis, the condition of the stepping mechanism is critical to accurate seed placement in the z-axis. Perpendicular to the N-shaped target group are five wires all at the same distance from the transducer, but separated by 0.5 cm and 1.0 cm in the z-axis.

#### **STEPPING MECHANISM ACCURACY (CONTINUED)**

- 1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 2. Align the probe so targets are maximized.
- Insert the transducer towards the back of the scanning cavity and align the beam with the crossing wire number 6 as indicated on the side of the phantom. This target will appear as a short line in row 4 above the transducer. Once this target is visualized, secure the stepping mechanism in place.
- 4. The next crossing wire (#5) is exactly 1.0 cm from wire #6 in the z-axis. Using the stepping mechanism, retract the transducer by 1 cm (in most cases this is two "clicks" on the stepping mechanism). Wire #5 will now be visible if the mechanism is working. If no wire is visible, the stepper has either retracted the transducer too much or too little. Manual manipulation of the transducer forward and backward to the target may give you some approximation as to the degree of error. Note: The accuracy of this assessment is dependent on the width of the ultrasound beam.
- 5. Record results.
- 6. Repeat for various retraction distances as specified in your QA plan.

#### **VOLUME MEASUREMENT ACCURACY**

Dose mapping is heavily dependent on accurate assessment of prostate volume. The Model 045B contains three different calibrated test objects specifically designed to assess volume measurement accuracy. The volume of each test object is physically measured with a tolerance of  $\pm$  0.5cc using Archimedes Principle before insertion within the phantom. The volumes are recorded on the accompanying certi-fication sheet. Perimeters which are estimated from the measured volume with the equations listed below, are also provided. Perimeters stated in the certifications are only intended to be used nominally. The small and medium volumes are spherical, but the large volume is egg shaped as seen in figures 1 and 2.

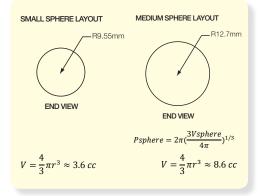


Figure 1 Sphere volumes and perimeters (see certification sheet for actual values in your phantom)

#### **VOLUME MEASUREMENT ACCURACY (CONTINUED)**

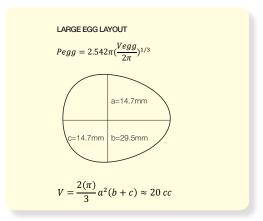


Figure 2 Egg volume and perimeter (see certification sheet for measured values in your phantom)

Volume measurements are performed as follows:

- 1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
- 2. Align the probe so targets are maximized.
- 3. Retract the probe as far as possible. If the probe is still within the phantom, move the phantom away from the needle template until only the tip of the transducer is inside the cavity.
- 4. Rotate the probe 60 degrees clockwise or counterclockwise depending on what size mass you wish to visualize.
- 5. Step the transducer forward until the mass is in view.
- 6. The volume of each test object should be computed using the methods/software provided with the ultrasound system or as performed on a patient.
- 7. Record measurements.
- 8. Repeat steps for each volume within phantom.

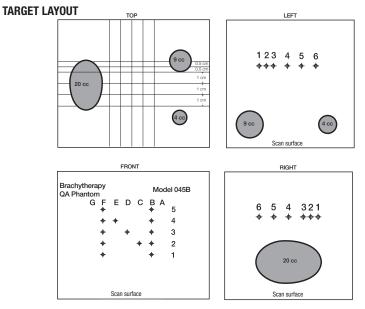
### **NEEDLE ALIGNMENT TEST**

Needle alignment testing of the brachytherapy system is important to ensure potential accuracy in guiding radioactive seeds respective of the overlay grid on the sonographic image.

- 1. Fill the water tank with water. Remove the phantom from the water tank or position the transrectal probe into an area that only images the water bath.
- 2. The transrectal probe needs to be arranged vertically so that needles are held parallel to the probe's long axis.
- 3. Adjust the system settings as for a "normal" technique. Record these settings to use on subsequent testing.
- 4. Place brachytherapy needles through the brachytherapy template grid. The needles should pass into the water bath.
- 5. Measurements are performed to assess the displacement between echoes of the needles and the on-screen grid. Use the caliper tools on the imaging system to measure the difference between the template position indicated on the sonographic image and the needle "flash" or echo.
- 6. Record measurements. Record template grid positions of needles to use on subsequent testing.
- 7. Compare measured values with baseline or clinically acceptable deviations.

# **SPECIFICATIONS**

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Front view shows the N wire target group while the side views show the Cross Axis wire targets.

Volumes are rounded to the nearest cubic centimeter. Please refer to phantom certification for measured volume.

<b>PHANTOM HOUSING</b> Material Outer Dimensions	1/4" White PVC 14 x 11 x 7.5 cm
SCANNING SURFACE Material	Saran-based laminate
WATER TANK Material	3/16" White ABS
BACKGROUND MATERIAL Material Speed of Sound Other	Zerdine 1540 m/s Compatible with harmonic imaging
<b>WIRE TARGETS</b> Material Diameter	Nylon monofilament 0.10 mm

<b>"N" GROUP</b> Number of targets Depth range Vertical distance between targets Horizontal distance between targets	13 2.0 cm to 6.0 cm 10.0 mm 10.0 mm
<b>CROSS-AXIS GROUP</b> Number of targets Depth Horizontal distance between targets	5 Row 3 5.0 mm, 10.0 mm
CALIBRATED VOLUMES Material Speed of Sound Attenuation Coefficient Contrast Nominal Volumes	Zerdine 1540 m/s 0.5 dB/cm-MHz ~+9 dB 4 cc (S), 9 cc (M), 20 cc (L)

#### ACCESSORIES

Certificate of Compliance, Water Tank Model 045B User Guide & Technical Information, QA Worksheet

#### NOTES

All dimensions without tolerances are nominal All measurements made at 22°C  $\pm$  1°C

### **ZERDINE<sup>®</sup>**

The Model 045B 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  $A = A_o F^n$  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.

# 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 or your local distributor prior to returning the product. Visit https://www. cirsinc.com/distributors/ to find your local distributor. 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 900 Asbury Ave, Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD		
Model 045B - Brachytherapy QA Phantom	48 Months		

# **APPENDIX 1: QUALITY ASSURANCE RECORD FOR MODEL 045B**

#### MODEL 045B

**BRACHYTHERAPY QA PHANTOM** 

#### QUALITY ASSURANCE RECORD

Name:	Date:	Phantom Info:
Baseline	System I.D	
Date:	Transducer I.D	
System Settings Overall Gain:	Post Processing:	Depth of
Field:		
TGC Settings:	Dynamic Range:	
	Power:	
Focal Points:	Preprocessing:	
	Other	

Parameter	Actual Value	Baseline Value	Measured Value	Drift	Corrective Action	Comments
Uniformity						
Depth of Penetration						
Small Volume						
Vertical and Horizontal Distance						
Electronic Grid Accuracy						
Stepping Mechanism						
Volume Measurement Accuracy						
Needle Alignment Test						

#### **Miscellaneous Checks**

Check for damage on the following items: (space provided for comments)

Transducer (cord, housing, & face)\_
 System (cord, knobs, wheels)\_\_\_\_\_

Clean the following items: (Space provided for comments)

- Transducer\_
- Monitor
- Keyboard & Knobs Π
- Air filters П Misc.

Directions for Use:

- Use this form to plan and record your quality assurance program.
  Use one form for each transducer.
  For Baseline measurements fill out system settings and baseline measurements.
  Use comments section to indicate changes in system settings for a particular measurement and other observations.
- 5. Use a photocopy of baseline form for subsequent test results (one for each test date).



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#### www.cirsinc.com

Technical Assistance 1.800.617.1177

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Computerized Imaging Reference Systems, Inc. has been certified by UL DQS Inc. to **(ISO) 13485:2016**. Certificate Registration No.10000905-MP2016.