NEMA SCA&I Cardiovascular Fluoroscopic Benchmark Phantom

Model 901

DISCONTINUED

DESIGNED TO MEET NEMA XR 21

USER GUIDE

CIRS

900 Asbury Ave • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765 • **WWW.CIRSINC.COM**

Model 901 Advanced Features

- Designed to meet NEMA XR 21
- Simulates coronary arteries for infant through large adult
- Evaluate spatial resolution, motion unsharpness and exposure for the entire imaging system

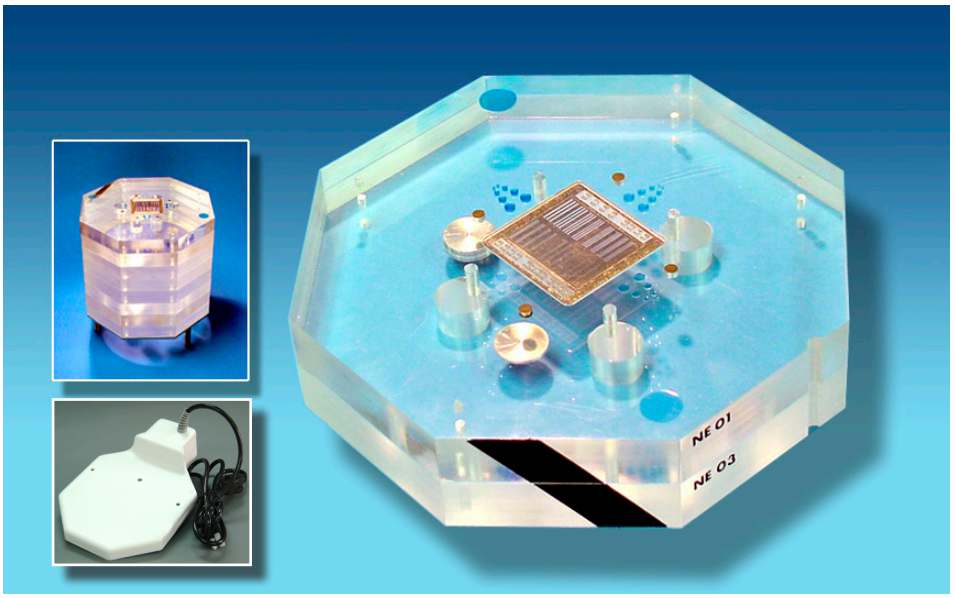
Overview

The CIRS Model 901 NEMA SCA&I phantom was designed to evaluate and standardize catheterization image quality. It is the result of collaborative efforts between the Society for Cardiac Angiography and Interventions and the National Electric Manufacturers Association.

The Model 901 is manufactured from PMMA with X-ray absorption properties similar to soft tissue at diagnostic energies. It contains a variety of static and dynamic test targets for objective assessment of resolution, motion unsharpness and radiation exposure. The sectional design allows for configuration in a wide range of thicknesses from 5 to 30 cm simulating PA thicknesses from infants to large adult patients.

The phantom is ideal for routine assessment of the entire imaging system.

Table of Contents



Model 901-01, 901-03, and 901-13 Shown
Model 901-13 Rotating Spoke Target is included with phantom, but can also be purchased separately.

DIMENSIONS:	40.6 cm x 25.4 cm x 25.4 cm (16" x 10" x 10")
PHANTOM WEIGHT:	20.4 kg (45 lb)
MATERIALS:	PMMA

MODEL 901 INCLUDES

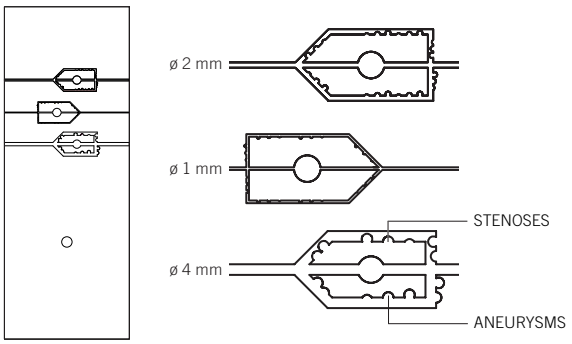
QTY	PART NUMBER	DESCRIPTION
1	901-01	Central Target Assembly
1	901-02	Working Thickness Range (WTR) Plate A
1	901-03	WTR Plate B
1	901-04	WTR Plate C
3	901-05	WTR Plate D
1	901-06	WTR Plate E
4	901-07	Blank Plate with alignment parts
1 (ea.)	901-08/ 08A	Field Size Plate
1	901-09	Alignment Target for Test Stand
1	901-10	Alignment Cross for Test Stand
1	901-11	Alignment Target for small base
1	901-12	Alignment Cross for small base
1	901-13	Rotating Spoke Target (115 VAC 60 Hz)
1	901-14	Test Stand
1	901-15	Small Base
1	901-16	3 mm thick lead plate with laminate
1	901-17	2 mm thick copper plate with laminate
1	901-CS	Carry Case
34	-	Alignment Pins

OPTIONAL ACCESSORIES

PART NUMBER	COMPONENT DESCRIPTION
901-C	Step Down Transformer (220V)
901-19	Optional Artery Slot Block for Model 901
903-06*	Artery Block with Iodine (15 mg/ mL)
903-07*	Artery Block with Iodine (150 mg/ mL)

*Must purchase Model 901-19 Optional Slot Block to use this accessory with Model 901 NEMA SCA&I Phantom.

ARTERY BLOCK WITH IODINE (903-06 & 903-07)



Instructions for use*

1. Introduction

NOTES:

The test procedures described below are primarily intended for cardiac imaging systems equipped with an isocentric stand.

The phantom may be directly used for other isocentric fluoro systems.

These instructions may be adapted for non-isocentric fluoro systems.

The primary tests described in this procedure are performed using the phantom configured to its 20 cm thickness and imaged using a normal 15 - 17cm field of view (FOW). Certain tests are performed using other combinations of thickness and FOV

Depending on clinical use of the phantom, it may be desirable to perform primary tests using another combination of phantom thickness and FOV. The necessary adaptions may be made using this document as a starting point. However, mechanical and functional construction of a particular type of equipment may preclude the use of certain combinations.

1.1. Notice

The NEMA X21 Phantom, and its associated test procedures are NOT DESIGNED OR INTENDED to directly validate compliance with FDA or other regulatory requirements. Therefore, additional procedures and measurements (outside the scope of this document) may be needed for such purposes.

1.2. Image Receptors

This Procedure is applicable to fluoro (combined Fluoroscopic and fluorographic) systems.

A typical system composed of an x-ray image intensifier equipped with a video system for fluoroscopy and one or more fluorographic cameras. The fluorographic cameras may be either optical (direct recording of the output of the image intensifier) or by electronic recording of the output of the video system. Electronic recording may be either by analog or digital means.

The CIRS model 901 and this procedure are applicable to direct digital (flat panel) systems.

1.3. Mechanical Stands

Two forms of phantom support are included in the standard these are the ‘SMALL BASE’ and the ‘TEST STAND’. Either of these supports may be used for testing. This document illustrates the use of the ‘SMALL BASE’.

1.4. Qualifications of Testers

The test procedures require subjective assessment of the visibility of certain features of the phantom. It is recommended that new users of the phantom gain proficiency from training offered by experienced users. All users should maintain their proficiency by performing an appropriate number of evaluations each year.

*Adapted from NEMA XR 21 provisional operating instructions, May 1, 2003 revision.

2. System and Phantom Configuration for Performance and Dose Measurements

2.1. Configure the imaging system for normal use according to the manufacturer's instructions and local laboratory policy. The laboratory's 'most common' fluoroscopic and cinefluorographic modes are selected. Record appropriate technical factors associated with the selected modes.

2.2. The phantom is designed so that the test objects are at or near its center. The phantom's center is placed at the imaging system's isocenter. Thus, both the focal spot and the image receptor will contribute to image unsharpness.

2.3. The 20 cm and 30 cm configurations are used in all adult laboratories. The 10 cm configuration is used when more than 25% of the patients are below 50 kg. These thickness have been chosen to drive the imaging system to a working level typical of the clinical situation.

2.4. Use the General Setup and Alignment instructions each time the phantom configuration is changed. This ensures correct alignment for all tests.

2.5. The spatial resolution plate is angled at approximately 45 degrees from the anodecathode axis of the X-ray tube. (see Figure 2)

3. General Setup and Alignment Instructions (GSAI)-SMALL BASE

3.1. Configure the imaging system with the beam vertical.

3.2. The image receptor radiographic grid is either in or out in accordance with laboratory policy. Record the presence or absence of the grid.

3.3. Configure the phantom for the required thickness of PMMA as shown in Figure 1
Photographs of various phantom configurations are shown in Figure 2
Record the configuration used

Note: The most common initial configuration for adult cardiac labs is 20 cm

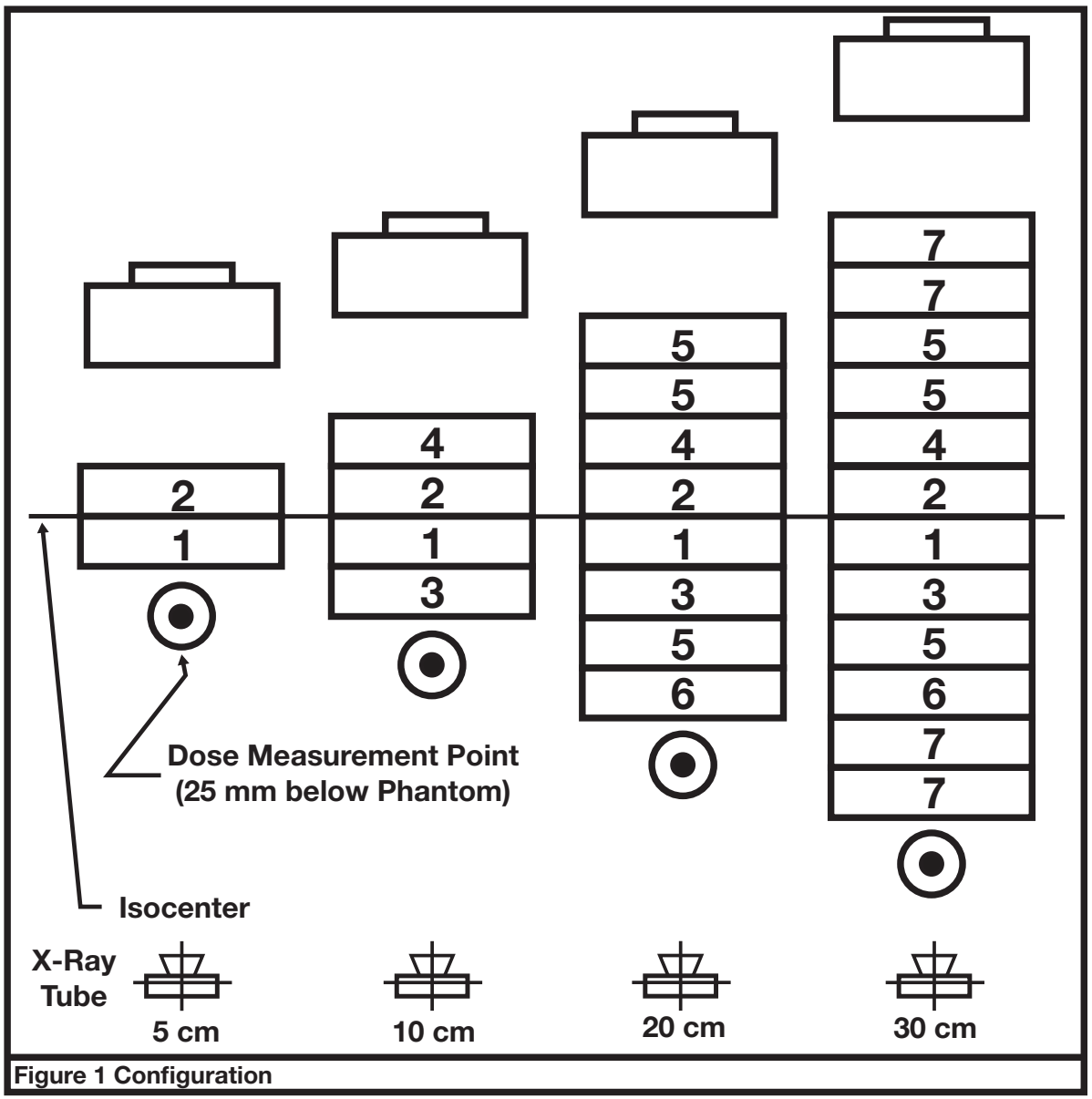
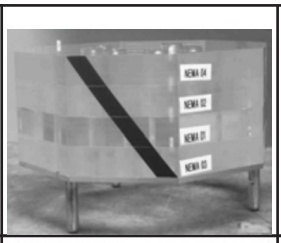
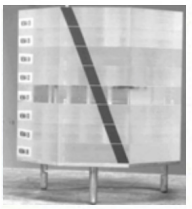


Figure 1 Configuration

5 cm



10 cm

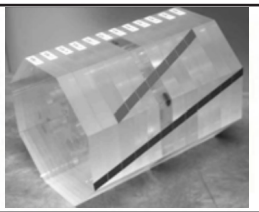


20 cm

Schematic with test plate at Phantom center

30 cm

Align Grooves and pins



Phantom may be assembled on its side
(Note locally added configuration stripes)

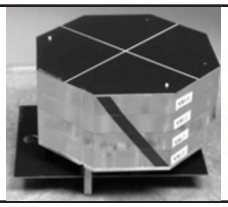
Figure 2 Configuration Photographs

3.4. Place the phantom on a 'thin' portion of the patient support. Remove any accessories such as the mattress.

Note that the patient support and accessories such as mattresses may significantly attenuate the X-ray beam. Under most circumstances, the beam enters the patient after passing through the support. Thus, support attenuation will have little effect on patient entrance dose. However, the additional system loading due to patient support and mattress attenuation may affect imaging performance.

3.4.1. Place the upper and lower alignment tools in position (Figure 3)

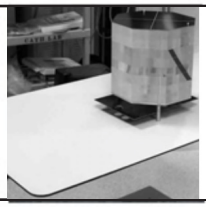
3.4.2. Orient the phantom so that the grooved side is toward the right side of the patient's head. The grooved side makes a 45 angle with the axis of the table the orientation of the line pair test plate is as shown (Figure 4)



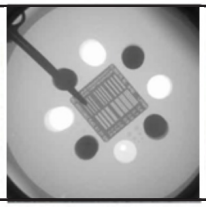
Alignment tools in place

Schematic of Alignment Tools

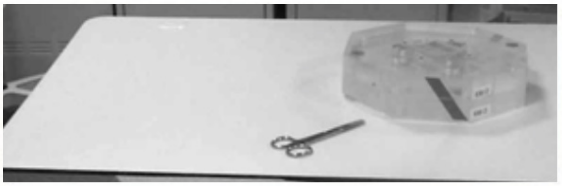
Figure 3. Alignment tools



Phantom with alignment plates placed on table



Relation of groove, lp plate, and table



Groove aligned to scissors
Note alignment table

Figure 4. Placement of phantom on table

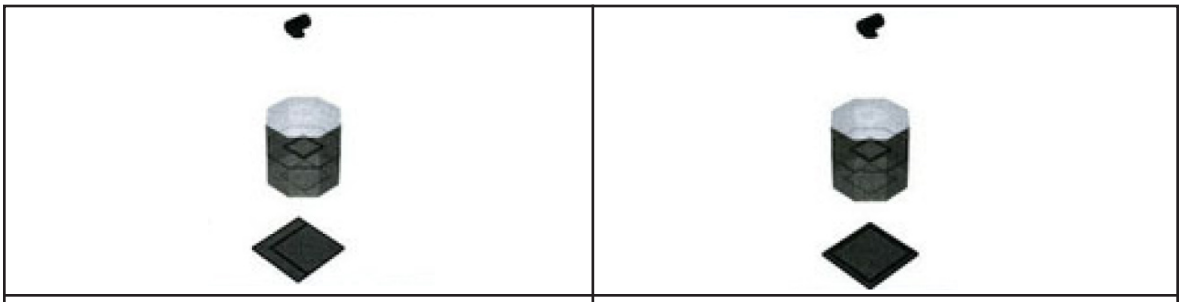


Figure 5. Preliminary centering using spatial resolution target

3.5. Verify that the center of the spatial resolution target is at isocenter.

3.5.1. Verify that the beam is vertical.

3.5.2. Select the smallest available FOV.

3.5.3. Select the lowest available dose-rate fluoroscopic mode.

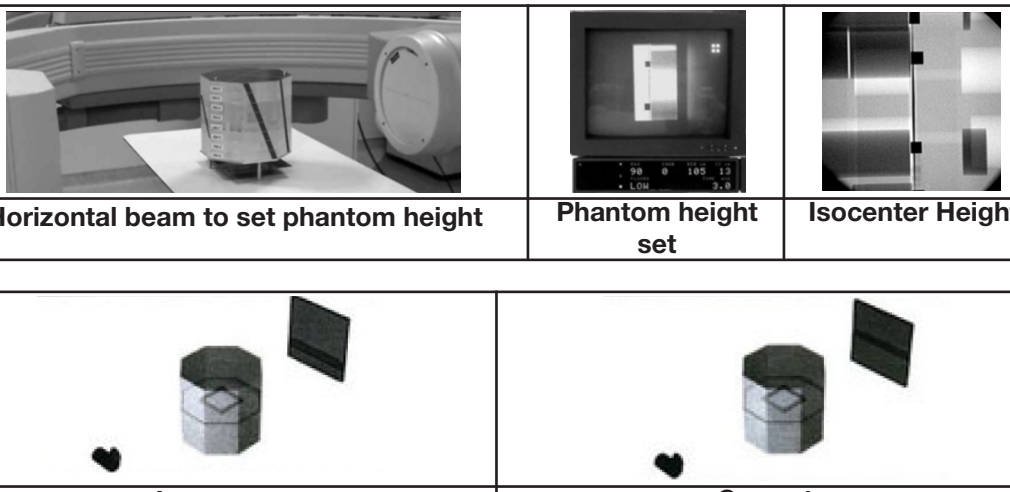
3.5.4. Collimate the beam to just encompass the resolution plate. All four corners of the resolution plate should be visualized.

3.5.5. Adjust the position of the phantom so that the resolution plate is approximately in the center of the field of view. (Figure 5)

3.5.6. Rotate the beam to a horizontal direction.

3.5.7. Adjust the table height so that the edge of the resolution target is centered in the beam. Make a short acquisition run to document this position. (Figure 6)

3.5.8. Return the beam to a vertical direction.



Horizontal beam to set phantom height | Phantom height set | Isocenter Height

Incorrect | Correct

Figure 6-Isocenter height setup

3.6 Verify that the phantom and beam are aligned

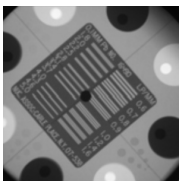
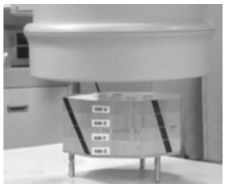
3.6.1. Verify that the beam is approximately vertical and that the smallest FOV is selected.

3.6.2. Adjust the gantly angles until the cross wires approximately intersect the center of the circular alignment target. (Figure 7) The wires should also intersect the center of each side of the resolution plate.

3.6.3. Make a short fluorographic run to document alignment.

3.7. Adjust the image receptor so that there is a normal 5 cm gap between the exit surface of the phantom and the entrance surface of the image receptor assembly.

3.8. Remove the alignment tools without disturbing the phantom.

				
Beam vertical to set alignment (note maximum SID)	**Incorrect**	**correct**	**Properly centered**	**Space set to 5cm gap**
Figure 7 Centering and alignment				

4. Data Recording and Database

4.1. An optional Microsoft Access database has been developed for use with this phantom. The current version of this database is available at www.scai.org.

4.2. Optional worksheets for graphically recording the visibility of test objects in the phantom are attached to this document.

4.2.1. A separate worksheet is recommended for each set of test conditions.

4.2.2. Instructions for use of the worksheet and database are included in the following sections.

5. Static Spatial Resolution, Dynamic Range and Iodine Detectability

5.1. Select the fluoroscopic of fluorographic mode to be tested.

5.2. Use the in-room monitor to observe the image.

5.3. Standardize monitor and image settings. Once this is done, these settings shall not be changed for the remainder of this procedure.

5.4. Testers should be at the normal clinical position of the primary operator. The monitor position can be positioned according to the tester's preference.
Note: this simulates the clinical accessibility of images

5.5 The following observations shall be made using the same monitor settings and observer position.

Electric fuorographic images are evaluated in the laboratory using loop-playback (if available).

Film fluorographic images are evaluated after processing using a clinical film viewer.

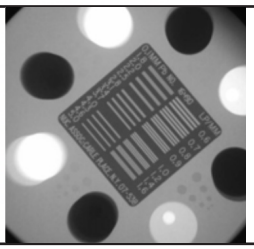
5.5.1. Fluoroscope or fluorograph the phantom. Figure 8 illustrates typical fluorographic results.

Note: Figure 9 shows contrast modified fluorographs for illustrative purposes. Evaluate the targets using the same monitor settings used for spatial and contrast resolution.

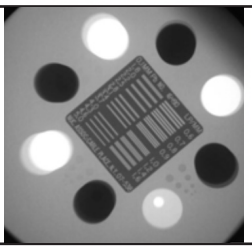
5.5.2. Record the limiting spatial resolution seen on the test plate. (Sample: Figure 10)

5.5.3. Record the number of iodine targets seen in each group

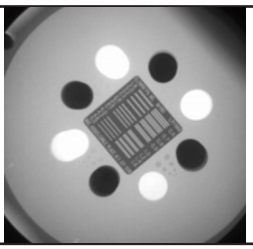
5.5.4. For the (nominal) 17 cm FOV and the 10 or 20 cm phantom configurations: Record the presense of absence of each dynamic range target.



13 cm FOV

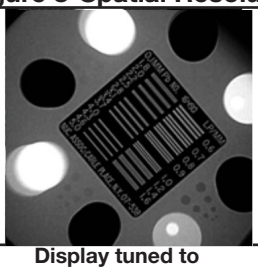


17 cm FOV

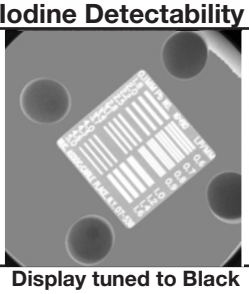


23 cm FOV

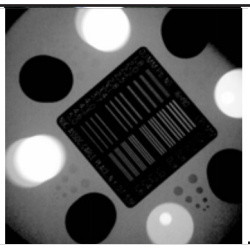
Figure 8-Spatial Resolution and Iodine Detectability



Display tuned to Iodine

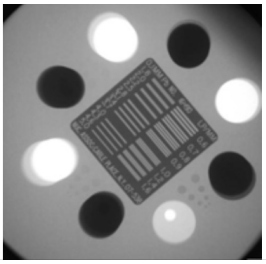


Display tuned to Black
White areas were masked

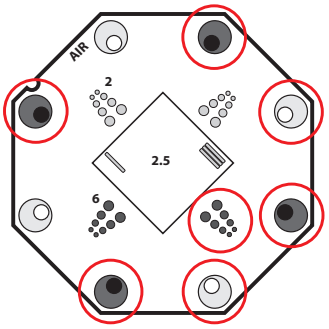


Display tuned to White

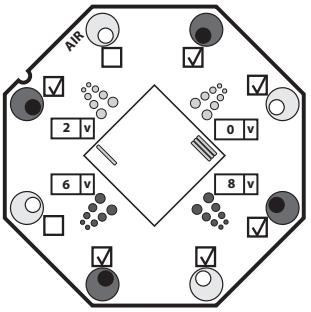
Figure 9-Working Thickness Range Evaluation



Image



Scoring Form



Data Entry

Figure 10-Sample Data Entry

6. REVERVED

7. Congruence of irradiated and visualized Fields

7.1. Without disturbing the alignment of the phantom to the X-ray beam, remove all of the phantom plates located above the isocenter.

7.2. Remove plate 1 and replace it with the field size test plate. (Figure 11)

7.3. Set the system to a 100 cm SID and a vertical X-ray beam.

7.4. The copper attenuator plate may be used to reduce beam intensity if necessary.

7.5. For each available field-of-view:

7.5.1. Open the radiographic collimators as far as the FOV permits. Remember to retract all 'dodging' blades.

7.5.2. Obtain a fluorographic image.

7.5.3. If an unirradiated margin is seen, the visualized FOV (at isocenter) is determined by inspecting the fluorograph.

7.6. PROCEDURE if no unirradiated margin is seen

7.6.1. Place a radiographic image receptor (of appropriate size) on top of the phantom

7.6.2. Fluoroscope long enough to produce an optical density between 1.0 and 1.5 on the radiographic image. (This may take some degree of trial and error.)

7.6.3. The visualized FOV is determined by inspecting the fluorographic image obtained in step 7.5.2.

7.6.4. The irradiated FOV is determined by inspecting the radiographic image obtained in step 7.6.2.

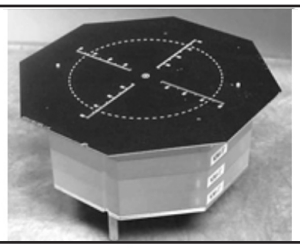


Photo of setup

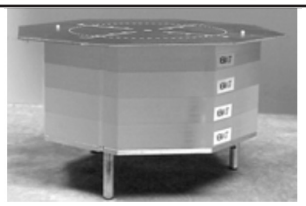
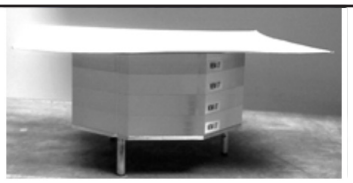
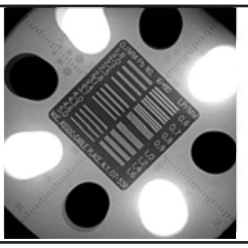


Photo of setup



Setup with film



Fluorograph with scale

Figure 11-Field size Measurements

8. Moving Wire Targets

This test is performed using all relevant thickness and FOV's

8.1. Replace plate 1 with the moving wire tool (12. All of the other test plates for that phantom thickness are used.

8.2. Repeat the GSAI to verify alignment.

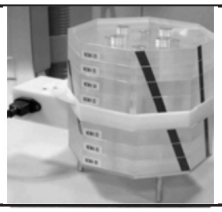
8.3. (optional) Note the smallest detectable wire with the tool stationary. Position wires by manually rotating disk (Use both fluoroscopy and flyorography)

8.4. Start the tool rotating. The motor disc should turn about 30 revolutions per minute at 110v/60 hz. Note: It will be less for 220V and 50hz

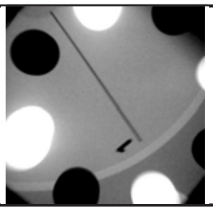
8.5. The device contains five steel wires of different diameters (0.022, 0.016, 0.012, 0.009 and 0.005 inches or 0.56, 0.41, 0.30, 0.23, 0.13 mm. Note the smallest detectable wire in each wire zone. (Use both fluoroscopy and fluorography)

Scoring is accomplished:
Estimate the fraction of each wire visible
< 1/3 ; 1/3 - 2/3 : 2/3 - 3/3 : Full
In the schematic shown on the left portion of figure 11:
#1 Full; #2 Full; #3 2/3 - 3/3; #4 1/3 - 2/3; #5 < 1/3

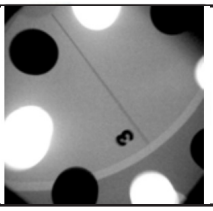
8.6. Record the number of visible lead dots in the images used for 8.5.



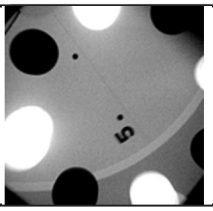
Rotor replaces plate 1



Wire 1



Wire 3



Wire 5
with Edge Enhancement

Figure 12-Rotating Wires

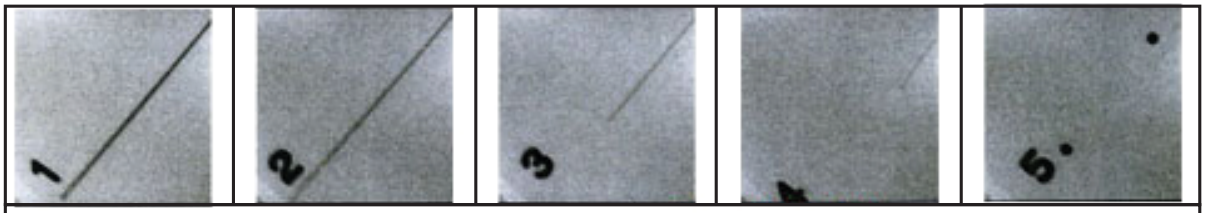
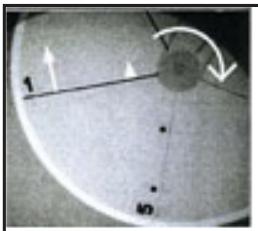
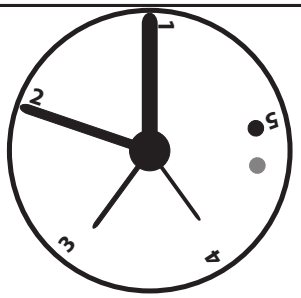


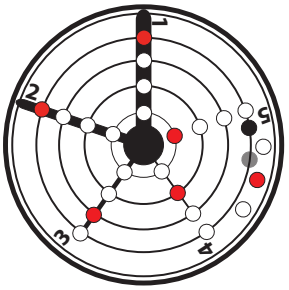
Figure 13-Sample wire images for scoring example



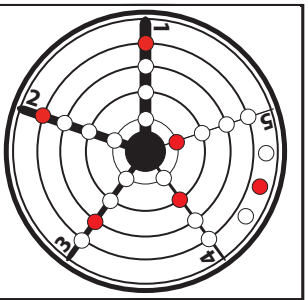
Example eith Lag



Schematic Image



Score sheet
superimposed



Data entry

Figure 14-Data Recording: Rotating Wires

9. Phantom Entrance Exposure Measurements

Note:
To improve readability, the term ‘exposure’ to an air kerma measurement when working with SI units.

(REPEATED FOR EMPHASIS) The NEMA X21 phantom, and its associated test procedures are NOT DESIGNED OR INTENDED to directly validate compliance with FDA or other regulatory requirements. Therefore, additional procedures and measurements (outside the scope of this document) may be needed for such purposes.

Perform these measurements for all relevant combinations of phantom thickness and FOV.

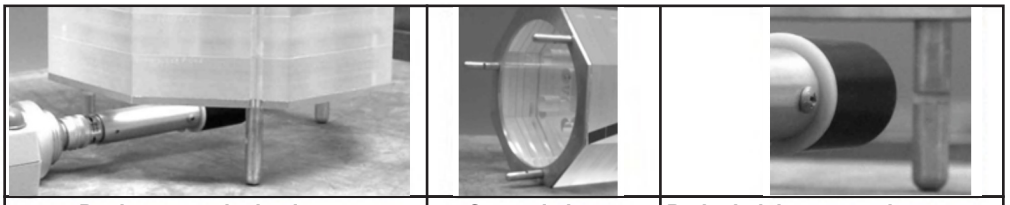
9.1. The same system settings are used for the dose measurements as for the image quality measurements performed above. This can be verified by inspecting available system readouts (e.g., kVp) during corresponding dose and image quality configurations.

9.2. Position the dosimeter probe so that the center of its active volume is centered on the axis of that phantom and 25mm below the entrance surface of the phantom. (Figure 15)

9.3. Determine the fuloroscopic entrance exposure rate (R/min or mGy/min) and the fluorographic entrance exposure per frame (mR/frame or mGy/frame) at the measuring point. (this is a measurement related to the patient’s entrance skin dose.)

9.4. Place the lead attenuator plate on top of the phantom. Repeat the previous measurement for fluoroscopy and fluorography for the medium FOV

9.5. Optional: Place the mattress on top of the X-ray collimator (between the tube and the dosimeter). Record the output with the mattress in place. The ratio of this value and that obtained in 9.4 represents the minumum attenuation of the mattress.



Dosimeter probe in place	Cutout in base	Probe height centered on groove

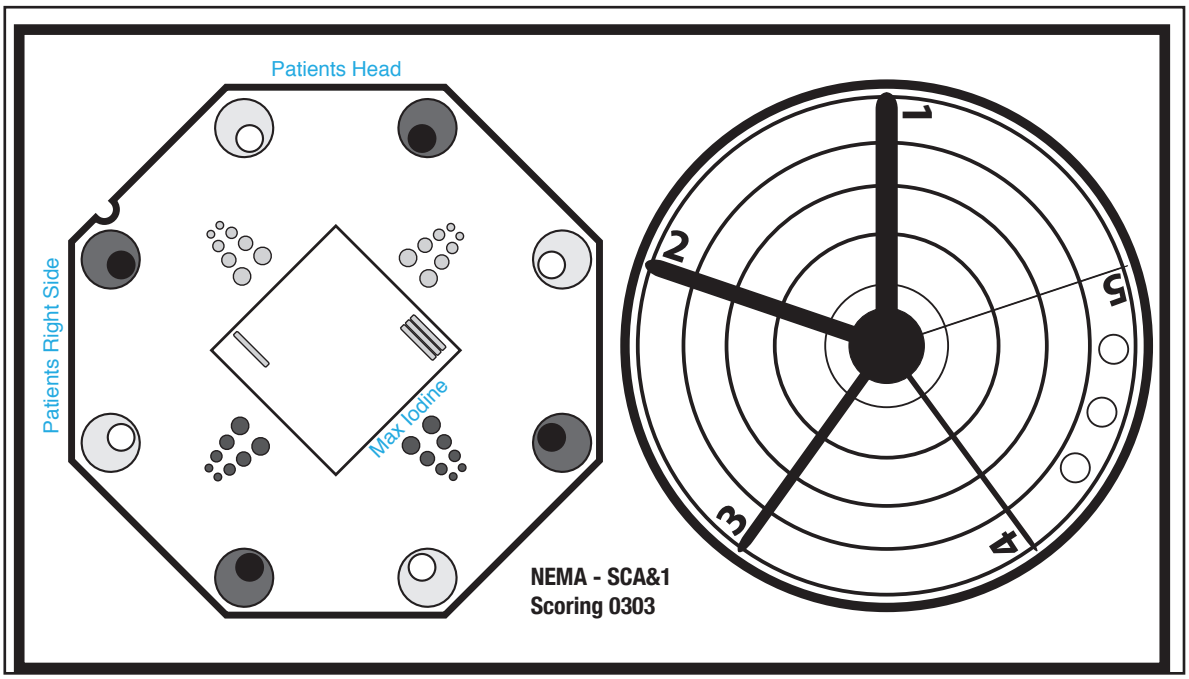
Figure 15-Dosimetry setup

10. Sample Graphic Data Recording Form

Use one of these forms to record observations for each FOV - Phantom Thickness Combination

Differentiate between fluoroscopy and acquisition observations

Equipment identification and description shall be maintained as required



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.

Product	Warranty Period
Electrical Products & Dynamic Phantoms	24 Months

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 your local distributor prior to returning the product. Visit https://www.cirsinc.com/distributors/ to find your local distributor. If you purchased your product direct through CIRS, call Customer Service at 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 prepaid.

With RMA number, items may be returned to:

CIRS
Receiving
900 Asbury Ave,
Norfolk, Virginia, 23513 USA

COMPUTERIZED IMAGING
REFERENCE SYSTEMS, INC.
900 Asbury Ave
Norfolk, Virginia 23513 USA

Toll Free: 800.617.1177
Tel: 757.855.2765
Fax: 757.857.0523
Email admin@cirsinc.com

www.cirsinc.com

Technical Assistance
1.800.617.1177

Publication: 901 UG 072220

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