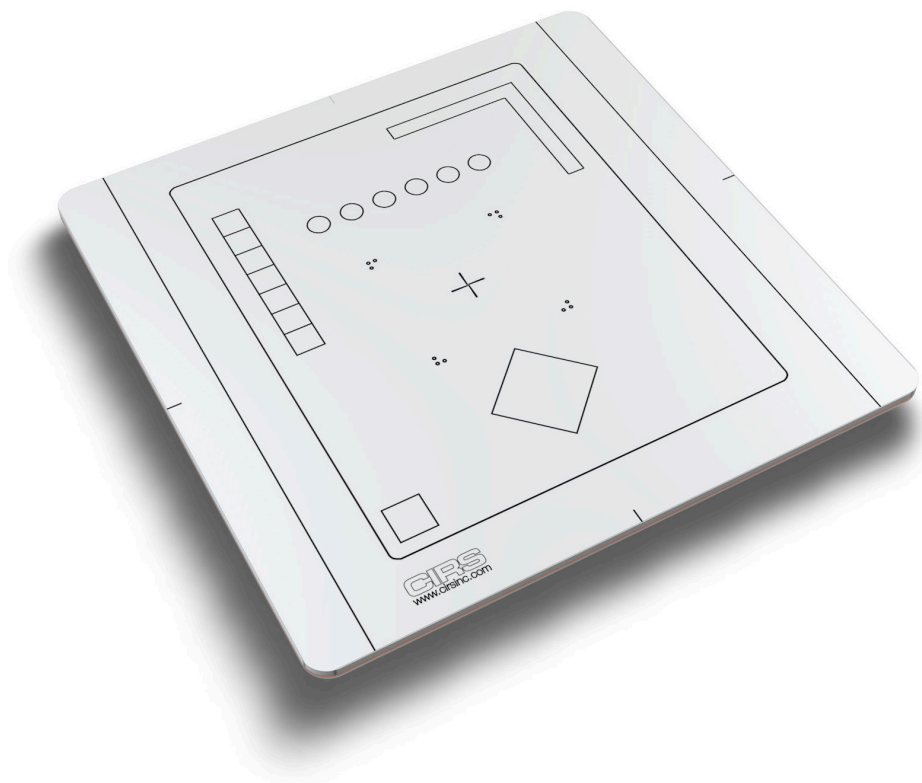


DR QC Phantom

Model 139702



USER GUIDE

CIRS

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PHANTOM DESCRIPTION

The CIRS DR QC Phantom allows comprehensive quality assurance testing for DR Detectors and associated software.

The phantom enables seven quality assurance assessments for monthly and semi-annual evaluation, including exposure linearity and sensitivity, high and low contrast reproducibility, artifact and residual image detection, image resolution, collimator beam alignment, measurement tool accuracy, and display jitter QA testing. The linepair target, 0.10 mm Pb thickness, allows for more comprehensive high contrast resolution assessment.

The CIRS DR QC Phantom measures 17" x 17" x 0.5" and allows for quick checks on 14"x 17" or 17" x 17" DR systems. Lead content has been minimized to meet European regulations.

The phantom includes standard suggested testing parameters, QC report forms, padded soft case and 60-month warranty.

SPECIFICATIONS

DIMENSIONS:	17"x17"x~1/2"
WEIGHT:	8 lb
MATERIALS:	PMMA, Copper, Aluminum

MODEL 139702 INCLUDES

QTY	COMPONENT DESCRIPTION
1	DR QC Phantom
1	Padded Soft Case
1	User Guide
-	60 Month Warranty

TESTING FREQUENCY

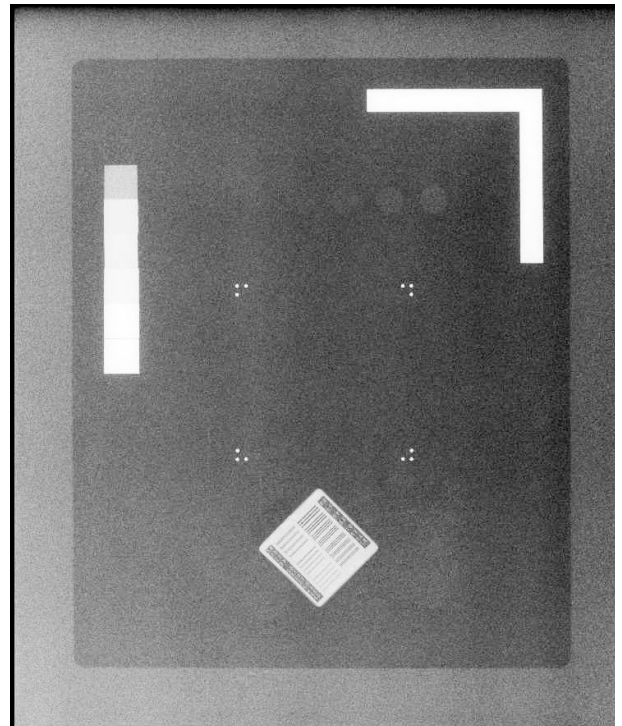
Perform QC testing on a routine basis at fixed intervals. The testing frequency depends on the type of test performed, per the following recommendation:

Monthly Testing:

- Test 1 - Exposure linearity and sensitivity
- Test 2 - Tracking contrast reproducibility high and low contrast
- Test 3 - Checking for artifacts and residual images
- Test 4 - Image resolution

Semi Annual Testing:

- Test 5 - Collimator beam alignment
- Test 6 - Accuracy of measurement tools
- Test 7 - Display Jitter Evaluation



QC TESTING PARAMETERS

Perform these QC tests with the following settings (unless otherwise directed):

- Fixed SID of 40 Inches (100 cm)
- 72 kVp, 100 mA
- Small Focal Spot
- Non Grid

The collimated areas will vary depending on the QC tests and mAs will vary to achieve specific Exposure Index (EXI) numbers or Sensitivity (S) values depending on the test. Do not use the variable time or mA settings for these tests, due to variation in mA settings for some generators.

QC Test Phantom user will need to set up four test menus associated with this QC testing program. These menus should include views for a reference image, high-mAs image, low-mAs image and collimator/beam alignment image.

These menus may be based on a high contrast, non-grid view such as an AP Ankle View. Please note that Window and Level adjustments or algorithm adjustments might be required for each view created to access the test tools embedded in the QC Test Phantom. Make sure to record these settings for future testing.

QC TEST PROCEDURES AND ACCEPTANCE CRITERIA

TEST 1 – EXPOSURE LINEARITY AND SENSITIVITY

This test verifies uniform exposure results from one test cycle to the next, for three different mAs settings. Perform this test monthly.

The first cycle this procedure is run sets baseline values, against which subsequent test results are compared. Retain the first-cycle images obtained in this procedure to use with subsequent test cycles, to reduce the number of exposures needed for the entire test suite.

1. Set the QC phantom on the detector
2. Place a coin (quarter) on the Coin Artifact area on the phantom. Note: For accurate results, use the same coin, on this same spot, for each monthly test.
3. Open the collimator to cover the entire size of the DR panel (either 17x17 or 14x17) and center the collimator over the phantom center (+).
4. Place an L marker or R marker in the appropriate lower corner of the phantom.
5. Set exposure settings to the following:
 - Fixed SID of 40 inches (100 cm),
 - 72 kVp
 - 100 mA,
 - Non-grid
 - Small focal spot.
 - mAs: baseline for Initial Image; if first cycle, use mAs = 14.
6. First cycle only: Make a test exposure and note the EXI (Exposure Index) value or Sensitivity (S) Value. The target EXI or Sensitivity (S) values can vary depending on the detector manufacturer. Be sure to use the manufacturer's recommended center or target point.

7. First cycle only: If the EXI value or S value is close to the target, continue to the next step. Otherwise, adjust the mAs setting accordingly and make another exposure. Repeat this until you have a satisfactory EXI value or S value.
8. First cycle only: The image that approximates the target is your Initial Exposure for this test cycle. Save the image, and record the EXI or S number and the mAs value.
9. Regular test cycle only (if not the first cycle): Set mAs to the recorded baseline Initial Image value recorded and make an exposure. Record the EXI value or S value.
10. Set mAs to 2 times the value for the initial exposure and make another exposure. This is your high-mAs Image. Save the image and record the EXI number or S number. The EXI value or S value should be approximately double that of the Initial or Reference Image.
11. Remove the coin from the QC phantom. Set mAs to 0.5 times (half) the value or the initial exposure and make another exposure. This is your low-mAs Image. Save the image and record the EXI number or S number. The EXI value or S value should be approximately half that of the Initial or Reference Image.
12. If this is the first test for this system, record all EXI numbers or S numbers as baseline values. These values will be used in future test cycles.
13. If this is not the first test for this system, divide each EXI or S number by its corresponding baseline numbers to determine percent deviation. These values must be within $\pm 15\%$ of the baseline values, otherwise corrective action is required.

Note: Variations of EXI or S numbers from the baseline could be due to X-ray component calibration or scintillator issues with the detector. Contact your dealer to address this.

TEST 2 – HIGH AND LOW CONTRAST REPRODUCIBILITY

This test verifies uniform contrast performance from one test interval to the next, for high contrast and low contrast. Perform this test monthly. The first time this procedure is run sets baseline values, against which subsequent test results are compared.

1. If the application software for the DR system has the ability to measure pixel values or visible density values, load the initial exposure from Test 1 (the exposure with the median EXI value or S value).
2. Measure the pixel value or the density value for the High Contrast Wedge Step 2 then make (3) pixel value readings or density value readings for this step then average the (3) readings for an average pixel value or density value for each step. Repeat for high contrast steps 4 & 6.
3. Display and note the pixel values or density values for Low Contrast Discs 1 and 4, using the same process as noted in step # 2.
4. After calculating an average pixel value or density value from the reference image for each wedge step and each disc reading. Record these average values
5. If this is the first test for this system, record all average pixel values or density values as baseline values. These values will be used in future test cycles.
6. If this is not the first test cycle for this system, divide all pixel values or density values by the baseline pixel values or density values to determine percent deviation. These values must be within $\pm 15\%$ of the baseline values, otherwise corrective action is required.

TEST 2 – HIGH AND LOW CONTRAST REPRODUCIBILITY (CONT)

Note: If the application software for the DR Detector cannot record either density or pixel value then the test results will need to be evaluated visually only. Perform this visual evaluation by estimating whether the current images vary from the baseline images by more than 15%. The Report Form offers a separate Test 2 Alternative Results section for this evaluation.

TEST 3 – ARTIFACTS, NOISE, AND RESIDUAL IMAGES

This test checks for imaging artifacts, noise and residual images produced by the DR detector or the application software. These artifacts may include lines, dark/light densities, graininess, and residual images. Perform this test monthly.

1. Compare the low-mAs and high-mAs images from Test 1. On the low-mAs image, there should be no residual image of the coin (which was removed for that exposure).
2. Examine the images for any artifacts or noise other than the QC phantom test objects. Artifacts may take the form of large grid lines, single lines, partial lines, or darkened areas. Noise may take the form of grain, and may be present even if the EXI or S numbers are proper. Refer to the example image included with this QC program (shown below).
3. Record any artifacts, noise and residual images found. Any artifacts, noise or residual image are considered a test failure. It may be necessary to perform a detector calibration or other corrective actions.

TEST 4 – IMAGE RESOLUTION

This test measures line-pair or pixel resolution from one test cycle to the next. Perform this test monthly, or more frequently as needed. The first test cycle sets baseline values, against which subsequent test results are compared

Overall image resolution is influenced by overall detector and display characteristics. Pixel/ line-pair resolution can vary by display and detector manufacturer, or by focal spot size, but should remain consistent over time.

1. Load the Initial Image from Test 1 and zoom it to full magnification, or select the 1:1 magnification setting on the DR application software display. Use the ROI magnification tool to observe greater magnified values if available.
2. Adjust the display so that the entire Line-pair Resolution test pattern is visible in the display.
3. Determine where the lines appear to merge and are no longer separate. Use the test pattern scale to record the perceived line pair resolution. For most DR detectors, this should be around 3.0 to 3.7 line pairs per millimeter.
4. If this is the first test cycle for this system, record your findings as baseline values. These values will be used in future test cycles.
5. If this is not the first test cycle for this system: If the recorded line-pair resolution degrades to a level below 6 pixels/mm (3 lp/mm) or declines gradually over a three to four-month period, consider this a test failure and report it to your dealer for corrective action.

Note: The term “line-pair resolution” typically defines image resolution for screen/film imaging. “Pixel resolution” is used for digital imaging resolution. One line pair is equal to two pixels when referring to digital pixel resolution. Example: 3 line pairs/ mm = 6 pixels/ mm of resolution.

TEST 5 – COLLIMATOR BEAM ALIGNMENT AND NUMERIC INDICATION

This test verifies the alignment of the collimator light field with the actual exposure radiation field. This test also verifies collimator light field control knob accuracy. Perform this test semiannually.

1. Set the collimated light field to the 10 cm x 10 cm area on the QC phantom (identified by 4 corners, with 3 small circles [BBs] per corner).
2. Place an L marker or R marker in the appropriate lower corner of the collimated area on the QC phantom.
3. Set exposure settings to the following:
 - Fixed SID of 40 inches (100 cm),
 - 72 kVp
 - 100 mA,
 - Non-grid
 - Small focal spot.
 - mAs = 14
4. Make an exposure and compare the collimator light field BB corners to the edges of the radiation field.
5. If the edges of the radiation field are either inside or outside of the designated collimation field of the QC phantom, measure and record the deviation, and record whether the radiation field is larger or smaller. If deviation is greater than 1.5% or approximately 3/8", then the test has failed and corrective action is required.
6. Open the collimator light field to cover the area indicated as 14" x 17" (35cm x 43cm) on the QC phantom
7. Verify that the vertical and horizontal numeric indicators match the light field size of 14" x 17" (35cm x 43cm)

Note: If the collimator numeric indicators do not match the light field, the test has failed. Contact your dealer for collimator calibration.

TEST 6 – LINEAR MEASUREMENT TOOL ACCURACY

This test verifies the accuracy of the Line Measurement tool associated with the DR Modality application. The test does not require an additional exposure. Perform this test semiannually.

The Line Measurement tool is typically used for measurements of anatomical areas. The tool is not used for making a diagnostic determination, and measurements are not typically transferred to a PACS as part of the patient image record.

1. Load the low-mAs image from Test 1, and measure from one corner collimation BB to an adjacent horizontal corner BB (not diagonal). Verify that the distance displayed is nominally 10 cm.
2. If this is the first test for this system, record this measurement as the baseline value, which will be used in future test cycles.
3. If this is not the first test for this system, verify that the measurement is within +/- 5% of the baseline value, otherwise corrective action is required.

TEST 7 – DISPLAY JITTER

This test evaluates the vertical or horizontal jitter (non-linearity) of the displayed image. The test does not require an additional exposure. Perform this test semiannually.

1. Load the Initial Image from Test 1 and zoom it to full magnification, or select the 1:1 magnification setting on the DR Modality application display.
2. Visually inspect the short and long axis of the Jitter Bar (the large upsidedown L located at the top of the QC phantom). The horizontal and vertical sides of the jitter bar must appear straight, sharp, well-defined, and not jagged, otherwise corrective action is required

CORRECTIVE ACTION

If any of the QC Test results fall outside of the recommended parameters, contact your dealer for corrective action. Many of these tests, such as exposure linearity and collimator beam alignment, are performed annually by equipment inspectors. These tests help prevent non-compliance findings during these annual inspections.

CIRS/DR QC Report Form – Periodic Tests

Detector ID or Serial #	Equipment Location: X-Ray Room #	Detector Location

Baseline Tests

Date: _____ QC Technologist: _____

Test 1 – Exposure linearity and sensitivity

Test 1 Baseline Data

Data Type	Initial Image	Low-mAs Image	High-mAs Image
mAs			
EXI			

Test 1 Monthly Data, EXI Values

[illegible]

Test 1 Corrective Action Log

[illegible]

Test 2 – High and low contrast reproducibility

Test 2 Baseline Data

Pixel Value Readings	High Contrast Wedge			Low-Contrast Disc	
	Step 2	Step 4	Step 6	Disc 1	Disc 4
Reading 1					
Reading 2					
Reading 3					
Readings Avg					

Test 2 Monthly Data, Pixel Values (part 1)

Pixel Value Readings	Date	High Contrast Wedge			Low-Contrast Disc		QC Tech Initials
		Step 2	Step 4	Step 6	Disc 1	Disc 4	
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							

Test 2 Monthly Data, Pixel Values (part 2)

	Date	High Contrast Wedge			Low-Contrast Disc		QC Tech Initials
		Step 2	Step 4	Step 6	Disc 1	Disc 4	
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							
Reading 1							
Reading 2							
Reading 3							
Average							
% Deviation							

Test 2 Corrective Action Log

Date	Corrective Action Taken

Test 2 Alternative Results – Visual Evaluation

Date	Pass	Fail	Comments	QC Tech

Test 3 – Artifacts, noise, and residual images

Test 3 Results

Date	Pass	Fail	Artifacts Noted	QC Tech

Test 3 Corrective Action Log

Date	Corrective Action Taken

Test 4 – Image resolution

Test 4 Baseline Data

Measured resolution in lp/mm	
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Test 4 Monthly Data, Resolution Values

Date	Resolution, lp/mm	Deviation	Pass	Fail	QC Tech

Test 4 Corrective Action Log

Date	Corrective Action Taken

Test 5 – Collimator beam alignment and display

Test 5 Semiannual Test Results

Date	Vertical	Horiz	Rad/Light Field Deviation, Measured	Is radiation field larger or smaller?	Field Deviation Pass Fail	Numeric Indicators Pass Fail	QC Tech

Test 5 Corrective Action Log

Date	Corrective Action Taken

Test 6 – Linear measurement tool accuracy

Test 6 Baseline Measurement

Measurement, cm	
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Test 6 Semiannual Test Results

Date	Measurement, cm	Is measurement less than or greater than baseline?	Pass	Fail	QC Tech

Test 6 Corrective Action Log

Date	Corrective Action Taken

Test 7 – Display jitter

Test 7 Semiannual Test Results, Jitter Bar edges straight and sharp

Date	Pass	Fail	QC Tech

Test 7 Corrective Action Log

Date	Corrective Action Taken

CARE AND HANDLING

The phantom is manufactured from multiple layers of plastic and metal which require special care. The layers are glued together and can separate if exposed to high temperatures or placed without surface support. It is recommended to store the phantom on a flat surface. Avoid using petroleum distillates or solvents to clean the phantom as they may damage the surface finish.

Technical questions should be referred to CIRS customer service at (800) 617-1177.

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 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 pre-paid.

With RMA number, items may be returned to:

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

PRODUCT	WARRANTY PERIOD
Model 139702 - DR QC Phantom	60 Months

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Computerized Imaging Reference Systems, Inc. has
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