Multi-Purpose & Endoscopic Phantom User Guide

Model ATS 570



Multi-Purpose & Endoscopic Phantom User Guide

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1 Introduction

The Model 570 Multi-Purpose & Endoscopic Phantom is an easy, comprehensive means of evaluating imaging systems over the full range of clinical imaging frequencies (2 MHz to 18 MHz). The phantom is designed with a combination of monofilament line targets for distance measurements and tissue-mimicking target structures of varying sizes and contrasts. Due to the acoustic similarity of the background material and the target structures, artifacts caused by distortion, shadowing, and enhancement have been eliminated. Four grayscale targets ranging in contrast from +6 to -3 dB are provided to evaluate the system's displayed dynamic range and grayscale processing performance.

The Model 570 offers a new and improved scan surface design to easily accommodate linear, sector, endoscopic probes and mechanical sector probes such as used for rectal scanning. All ATS urethane phantoms are guaranteed for the useful life of the phantom, defined as 10 years.

CIRS is certified to ISO 13485:2016 standards. We have an in-house test facility to measure acoustic properties of materials. In addition, ultrasound imaging systems are used to inspect each phantom. Every ultrasound phantom that CIRS distributes has passed thorough testing during manufacture and completion to ensure the highest quality product available. A Certificate of Compliance is issued with each phantom.

Additional guidance on establishing a quality assurance program can be found in the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org.

Key Tests with Model ATS 570

- Uniformity
- Depth of Penetration
- Beam Profile/Focal Zone/Lateral Response Width
- Vertical Distance Measurement
- Horizontal Distance Measurement
- Axial and Lateral Resolution
- Contrast Resolution
- Grayscale Contrast Sensitivity
- Dead Zone Assessment

For more information on these tests, see *Testing Procedures* on page 5.

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2 Setup and Measurements

General Guidelines for Performing Measurements

To evaluate the performance of diagnostic ultrasound imaging systems, the Model ATS 570 has a combination of monofilament line targets and tissuemimicking cylindrical targets of varying sizes and contrasts.

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.
- If a convex probe is used, center the target within the scan plane in order to minimize degradation and distortion introduced on the outer edges of the probe.
- 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 liver preset values for an abdominal probe) 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 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 anywhere 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 AIUM at www.acr.org or www.aium.org for further guidance on establishing a QA program.

3 Testing Procedures

The following sections outline procedures for routine quality control tests with the Model ATS 570. It may be useful to refer to the target map, shown in *Specifications* on page 15, when reviewing these procedures.

Uniformity Testing

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.

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

Depth of Penetration Testing

The ability of an imaging system to detect and display weak echoes from small objects located at specified depths (penetration) is referred to as sensitivity. Clinically, weak reflecting echoes are commonly produced from internal structures of organs. Definition of these structures can be extremely important in the interpretation of the ultrasound findings. Sensitivity can be affected by the pulser/receiver section of the system, the degree of focusing of the transducer, attenuation of the medium, depth and shape (geometry) of the reflecting object, and electromagnetic interference from the local surroundings. A system's maximum depth is limited by output power, TGC, gain, transducer frequency, focal depth, number of scan lines, and electrical noise. Testing is performed as follows:

- **1** Position the transducer over the 8 mm group of anechoic targets.
- 2 Freeze image and obtain a hard copy.
- 3 Examine the image to determine the last or deepest target structure displayed. Using the electronic calipers or the timing markers, measure the depth of this target.

- 4 This test should also be performed with output levels set at the highest and lowest settings. This enables any changes in output to be more easily detected.
- **5** Document the depth measurement on the quality assurance record.

Results

The system's depth of penetration should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Beam Profile, Focal Zone, and Lateral Response Width

The focal zone is the region surrounding the focal point in which the intensity and the lateral resolution is the greatest. Clinically, structures examined within the focal zone will provide the best diagnostic information obtainable. The focal zone can be affected by changes in the pulsing/receiving section of the imaging system or damage to the transducer. Testing is performed as follows:

- Position the transducer over the vertical group of line targets on the phantom, until a clear image is obtained. A line rather than a dot is produced on the display. The length of the line is indicative of the width of the beam. Therefore, targets inside the focal zone form a shorter line than those outside of the focal zone. Adjustments in the gain settings will change the length of the line targets displayed. Freeze the display and obtain a hard copy.
- 2 For a variable focused transducer, scans with several different focal zone settings should be performed. Dynamically focused transducers may not display changes in the width of the line targets. However, a change in the intensity can be observed upon adjustment of the transmitting focus of the transducer.
- 3 Using the hard copy, draw a line connecting the ends of the echoes received from the line targets (both sides). The line should form a smooth curve. This will illustrate the shape of the sound beam. Now locate the narrowest portion, this is the focal zone. Measure the width of the beam and the depth at this point.
- 4 Document the depth of the focal zone and the measurement of the focal width on the quality assurance record.

Results

The system's focal zone should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Vertical Distance Measurements

Vertical distance measurements are obtained along the axis of the sound beam. Accurate representation of the size, depth, and volume of a structure is a critical factor in a proper diagnosis. Most imaging systems use depth markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained using the timing markers and/or electronic calipers. The resulting measurement is then compared to the known distance between the line targets in the phantom. The accuracy of vertical distance measurements depends on the integrity of the timing circuitry of the imaging system. Testing is performed as follows:

- 1 Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.
- 2 Using the electronic calipers or the timing markers, measure the greatest distance that can be clearly imaged between line targets.
- **3** Document the measurement obtained on the quality assurance record.

Results

The system's vertical distance measurements should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Horizontal Distance Measurements

Horizontal distance measurements are obtained perpendicular to the axis of the sound beam. Proper diagnosis depends on the accurate representation of the size and volume of a structure being examined. Most imaging systems use distance markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained. The resulting measurement is then compared to the known distance in the phantom. The accuracy of the horizontal distance measurements depends on the integrity of the transducer scanning assembly, the output intensity, and the resolution of the imaging system. Testing is performed as follows:



Note: The Model 570 General & Small Parts Phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Due to the geometry and variety of sector scan transducers, a separate set of horizontal line targets are provided to evaluate lateral resolution. Please refer to Specifications on page 15 for the location of these groups.

- 1 Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
- **2** Using the electronic calipers or the timing markers, measure the greatest distance that can be clearly imaged between line targets displayed.
- **3** Document all of the measurements on the quality assurance record.



Note: Some sector scanners have distance markers on the outside edges of the sector image with no other indicators available. Handheld calipers must be used for distance measurements within the image on the monitor.

Results

The system's horizontal distance measurements should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Axial And Lateral Resolution Testing

Resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately along the axis of the beam. Whereas, lateral resolution defines the system's ability to image objects separately that lie perpendicular to the axis of the sound beam. If a system has poor resolution capabilities, small structures lying close to each other will appear as one image, causing improper interpretation of the ultrasound findings. Axial Resolution depends on the transducer's center frequency, damping characteristics, and pulse length. Generally, the higher the frequency, the better the system's axial resolution. Lateral Resolution depends on the transducer, number of displayed scan lines, and the system's sensitivity and gain settings.

The locations in the phantom are referenced from the first axial target.

The line targets are spaced at 5.0, 4.0, 3.0, 2.0, 1.0 mm intervals both axially and laterally. The last point of the axial array target group is also the first target point in the lateral array group. Testing is performed as follows:

- 1 Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
- 2 Examine the image to determine if all of the line targets within the group are clearly displayed as separate target points. Record the closest spaced target points which can be imaged (refer to specification drawing). Obtain a hard copy of the display.
- **3** Document all observations made on the quality assurance record.

Results

The system's ability to resolve the array targets at given depths should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Grayscale Contrast Sensitivity

Grayscale or Grayscale processing uses the amplitude of the echoes received to vary the degree of brightness of the displayed image. The adjustment of the echo signal required to go from a just noticeable (lowest grayscale level) echo to the maximum echo brightness is referred to as the displayed dynamic range. Clinically, grayscale processing and displayed dynamic range allow echoes of varying degrees of amplitude to be displayed in the same image.Testing of grayscale contrast is performed as follows:

- 1 Position the transducer over the grayscale target group until a clear image is obtained.
- 2 Freeze image and obtain a hard copy.
- 3 Examine the image. The targets should appear circular in shape, with clear sharp edges and vary in the degree of brightness ranging from low to high levels of contrast. The presence or absence of any shadowing behind the structures should be noted.
- 4 All findings should be documented on the quality assurance record.

Results

This target group varies in echogenicity and provides a good indication of the performance of the grayscale processing and displayed dynamic range. The system's grayscale processing should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Dead Zone Assessment

The dead zone is the distance from the front face of the transducer to the first identifiable echo at the phantom/patient interface. The dead zone occurs because an imaging system cannot send and receive data at the same time. Therefore, no clinical data can be collected in this region. However, if artifacts are noted within the dead zone, they may indicate fluctuations in the input power to the system. The depth of the dead zone depends upon the frequency and performance of the transducer and the pulsing/receiving section of the system.

The depth of the dead zone may be measured as follows:

- 1 Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.
- 2 This group is composed of 9 line targets. The first target is positioned 2 mm below the scan surface. Subsequent targets are spaced 1 mm apart, to a depth of 10 mm.

- 3 Using the electronic calipers, measure the distance between the first target imaged and the echo produced by the scan surface. The resulting value will be the depth of the dead zone.
- **4** Document the depth measurement on the quality assurance record.

Results

The system's dead zone should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

References:

- BOOTE, E., FORSBERG, F., & AMP; GARRA, B. (2008). ROUTINE QUALITY ASSURANCE FOR DIAGNOSTIC ULTRASOUND EQUIPMENT. AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE.
- MICHELL M. GOODSITT, PAUL CARSON; "REAL-TIME B-MODE ULTRASOUND QUALITY CONTROL TEST PROCEDURES, REPORT OF AAPM ULTRASOUND TASK GROUP NO. 1," MEDICAL PHYSICS, 25 (8) AUGUST 1998
- W. N. MCDICKEN, PHD, "DIAGNOSTIC ULTRASONICS, PRINCIPLES AND USE OF INSTRUMENTS," JOHN WILEY & SONS, 1976.
- SANDRA L. HAGEN-ANSERT; "TEXTBOOK OF DIAGNOSTIC ULTRASONOGRAPHY," MOSBY, 1989.

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4 Support and Maintenance

Hardware Maintenance

Inspection

Periodically inspect the phantom and accessories for damage. If damage is visible, if any mechanical or electrical degradation is suspected, or if errors are suspected, discontinue use and contact Sun Nuclear Support. See *Contacting Sun Nuclear Support*.

Repair

The phantom and the parts provided with the phantom cannot be repaired by the user. If there are problems with any of the devices, contact Sun Nuclear Support.

Cleaning

For best results, the phantom should be kept clean at all times and stored at room temperature. In particular, a build-up of dried coupling gel on the scan surface should be avoided. The phantom may be cleaned with warm water using a lint-free cloth. Particularly stubborn stains and dirt may be removed with a mild household cleaner. The use of petroleum solvents should be avoided since they may adversely react with the rubber-based material.

Disposal and Recycling



Do not discard unit as waste. Recycle the components in accordance with local regulations.

Contacting Sun Nuclear Support

You may request support in two ways:

- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
 - U.S.A.: +1 321-259-6862, Option 3
 - Netherlands: +31 20 399 90 41, Option 1
 - Germany: +49 61 02 50 49 500, Option 2

Support Website

- 1 Open an internet browser and navigate to <u>sunnuclear.com/support</u>.
- 2 Enter your email address and password and then click **Login**.
 - To download product information, click **Products and Devices**, select the product, and then select the download type.

• To open a Support request, click **Open New Case**, complete the form, and then click **Create Case**.

5 Specifications

Target Layout

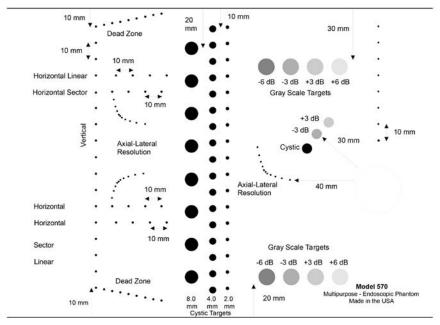


Figure 5-1. Target Map

Phantom

Characteristic	Specification
Housing	PVC
Outer Dimensions	27 x 21.5 x 9.6 cm
Scanning Surface	17.5x7.5 cm, 14.0 x7.5 cm
Scanning Material	Urethane Rubber
Speed of Sound	1450 m/s at 23°

Wire Targets

Characteristic	Specification	
Material	Nylon monofilament	
Diameter	0.12 mm	

Endocavity

Characteristic	Specification
Opening	Ø 26.9 mm x 71 mm deep
Slots	12.7 mm; Ø 0.5" \times 10 mm deep (from bottom of the curve to the flat surface)

Vertical Distance Group

Characteristic	Specification
Number of Targets	B1: 17
	B2: 8
Depth Range	B1: 10–160 mm
	B2: 10–80 mm
Spacing	B1: 10 mm
	B2: 10 mm

Horizontal Distance Group

Characteristic		Specification
Number of Groups	2	
Depths	5 & 5 cm	
Number of Targets	10	
Spacing	2 cm	

Dead Zone Group

Characteristic	Specification
Number of Targets	9
Depth Range	2.0–10.0 mm
Spacing	1 mm

Axial-Lateral Resolution Group

Characteristic	Specification
Number of Targets	11
Lateral Displacement	1 mm
Spacing	5.0, 4.0, 3.0, 2.0, 1.0 mm
Depth	7.0, 11.0, 4.0, 16.0 cm

Contrast Targets (Cysts)

Characteristic	Specification
Туре	Non-echogenic, cylindrical
Column 1	8 mm targets, Qty 8; spaced at 2 cm intervals
Column 2	4 mm targets, Qty 17; spaced at 1 cm intervals
Column 3	2 mm targets, Qty 17; spaced at 1 cm intervals

Grayscale Targets

Characteristic	Specification
Туре	Echogenic, cylindrical
Number of Sets	3
Column 2	4 mm targets, Qty 17; spaced at 1 cm intervals
Column 3	2 mm targets, Qty 17; spaced at 1 cm intervals

Set 1

Characteristic	Specification
Number of Targets	4
Contrast Levels	+6, +3, -3, -6 dB
Diameter	10 mm
Depth from Top Scan Surface	30 mm

Set 2

Characteristic	Specification
Number of Targets	4
Contrast Levels	+6, +3, -3, -6 dB
Diameter	10 mm
Depth from Bottom Scan Surface	20 mm

Set 3

Characteristic		Specification	
Number of Targets	2		
Contrast Levels	+3, -3 dB		
Diameter	6 mm		
Distance from Endocavity Ope	ning 30 mm		



Note:

All dimensions without tolerances are nominal. All measurements made at $22^{\circ}C \pm 1^{\circ}C$.

Appendix A: Quality Assurance Record

MODEL ATS 570 MULTI-PURPOSE & ENDOSCOPIC PHANTOM QUALITY ASSURANCE RECORD

Ultrasound Pe	erformance			cord			Date Routine Tes Baseline	ting		
Technician / Sonographer: _								tial Se		ada
System Identification						Software Upgr New Phantom New Transduc				
System Manufacturer:							Ne	w ira	IISOUC	91
Transducer Type:				\$/N:						
ATS Phantom Model:	S/N:									
General Inspection		Pass	s Fail						Pass	Fail
Power Cord (cracks, plugs, o	discoloration)			Transduce	er (Cable, housi	ng, plug	, transducer face)			
Dust Filters (clean & dust fre	е)			Scanner c	onsole (free of	damage)			
Controls (Clean, broken kno	bs & switches)			Wheels (ro	otate freely, lock	s hold p	properly)			
Display (clean, free scratche contrast controls)	es, Brightness/			Comment	S					
System Settings										_
Power	dB	Gain			dB	Dynami	ic Range			dE
Pre-Processing	F	Post-Pro	cessing	i i		Progra	amed Presets			
Transmit Focus	cm li	mage M	lagnifica	tion		Room 1	Temperature:			
Geometric Accuracy Testi	ng		10.000	antom stance	Baseline Measured	Baseline Distance Measured Measured		Erre	or/Cha	nge
Vertical Distance Measurem	ients									
	Electronic C	alipers		mm		mm	mm			mn
Display Devices	s used for interpr	etation		mm	mm		mm			mn
Horizontal Distance Measur	ements									
	Electronic C	alipers		mm		mm			mn	
Display Devices	s used for interpr	retation		mm		mm	mm			mn
Dead Zone (Ring-down ram	ip)									
	Electronic C			mm		mm	mm			mn
Display Devices	s used for interpr	retation		mm		mm	mm			mn
Spatial Resolution				antom stance	Baseline Measured	Baseline Distance Measured Measured		Error/Change		
Axial Resolution					5					
	Electronic Ca	alipers		mm		mm	mm			mn
Display Devices	used for interpre	etation		mm		mm	mm			mn
Lateral Resolution										
	Electronic Ca	alipers		mm		mm	mm			mn

mm

mm

Display Devices used for interpretation

mm

mm

Focal Zone & Sensitivity					Baseli Dept			Measured Depth		Error/Change	
Focal Zone											
	E	lectronic Cali	pers		mm		mm		mm		m
Displa	ay Devices used	for interpreta	ation	mm		1	mm		mm		m
Sensitivity											
	E	lectronic Cali	pers		mm		mm		mm		m
Display Devices used for interpretation		mn		mm		mm			m		
Functional Range of Depths			Target Shape			Ta	get E	dges	ľ.	Change	
Resolution Target Sizes (mm)	Displa Baseline	Display**	E	Baseline	1	Display**	Baseline	T	Display**	8	Yes/No
1.0	mm	mm			+			+			
2.0	mm	mm						+		1	
30	mm	mm									
4.0	mm	mm			\square						
	mm	mm			\square					\square	
6.0								_			
6.0 8.0	mm	mm						-			
8.0 10.0	mm	mm	nterpr	etation		**Display I			interpretation		
8.0	mm mm	mm ces used for in	nterpr	etation	-		Detected	_ Arti icale		d	Change Yes/No
8.0 10.0 mage Uniformity	mm mm	mm ces used for in d		etation System Sett		_ No Artifact	Detected	_ Arti icale	fact Detecte	d	Change Yes/No
8.0 10.0 mage Uniformity mage Uniformity	mm - Display Devic Artifact Detecte	mm ces used for ir d First gain and fo	Scan antom ocal d	System Set	tings erent ings.	_ No Artifact Gain Settings	Detected	_ Arti icale	fact Detecte	d	
8.0 10.0 mage Uniformity mage Uniformity Repeat Scan a f artifact persists,	mm - Display Devic Artifact Detecte	mm ces used for in d First gain and fo ation and/or o	Scan antom ocal d correc	System Sett and at diffe listance sett tive action is	tings erent ings.	_ No Artifact Gain Settings	Detected Gray S Lev	Arti icale el	fact Detecte	d	Yes/No
8.0 10.0 mage Uniformity mage Uniformity Repeat Scan a f artifact persists,	mm - Display Devic Artifact Detecte at a different reg further investig	mm ces used for ir d First gain and fo ation and/or or d Dynamic F	Scan antom ocal d correc	System Sett and at diffe listance sett tive action is	tings erent ings. s recor	_ No Artifact Gain Settings mmended.	Detected Gray S Lev	Arti cale el	Focal Sett	d	Yes/No nterpretation
8.0 10.0 mage Uniformity mage Uniformity Repeat Scan a f artifact persists,	mm - Display Device Artifact Detecte at a different reg further investig cale - Displaye	mm ces used for ir d First gain and fo ation and/or or d Dynamic F	Scan antom ocal d correc Range	System Set and at diffe listance sett tive action is	tings erent ings. s recor	_ No Artifact Gain Settings mmended.	Detected Gray S Lev	Arti cale el	Focal Sett	d	Yes/No
8.0 10.0 mage Uniformity / Repeat Scan a f artifact persists, Gray S Targets	- Display Devic - Display Devic Artifact Detected at a different reg further investig cale - Displaye Range of Baseline	mm ces used for ir d First gain and fo ation and/or or d Dynamic F Contrast Display**	Scan antom ocal d correc Range	System Seti and at diffe istance sett tive action is Target Shap Baseline	tings erent ings. s recor	_ No Artifact Gain Settings mmended. ircular Display**	Detected Gray S Lev **D Target Ed Baseline	Arti cale el	Focal Sett Focal Sett Devices used Clear/Sharp Display**	d	Yes/No nterpretati Change
8.0 10.0 mage Uniformity / Repeat Scan a i artifact persists, Gray S Targets (dB)	mm - Display Devic Artifact Detecter at a different reg further investig cale - Displaye Range of Baseline Yes/No	mm ces used for ir d First gain and fo ation and/or or d Dynamic F Contrast Display** Yes/No	Scan antom ocal d correc Range	System Seti and at diffe istance sett tive action is Target Shap Baseline	tings erent ings. s recor	_ No Artifact Gain Settings mmended. ircular Display**	Detected Gray S Lev **D Target Ed Baseline	Arti cale el	Focal Sett Focal Sett Devices used Clear/Sharp Display**	d	Yes/No nterpretati Change
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Signature:

Appendix B: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Sun Nuclear Corporation Symbols

The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.



WARNING: This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)



CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)



CAUTION: This symbol indicates a pinch hazard. (EN ISO 7010, W024)



Note: Important or supporting information.



Manufacturer's Identification (name and address). (EN ISO 15223-1, 5.1.1)



Date of Manufacture. (EN ISO 15223-1, 5.1.3)



Temperature limitation. (EN ISO 15223-1, 5.3.7)



Humidity limitation. (EN ISO 15223-1, 5.3.8)



Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)



Serial Number. (EN ISO 15223-1, 5.1.7)



Catalog Number. (EN ISO 15223-1, 5.1.6)



Consult instructions for use. This equipment must be used in accordance with the instructions in this manual. Read all instructions and safety labels before use. (EN ISO 15223-1, 5.4.3)



Do not throw in trash; dispose of in an environmentally friendly way. (EN 50419)

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator is solely responsible for the accurate setup and use of the phantom.

Reporting Health or Safety Related Issues or Concerns

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

Modifications to Equipment

Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.



