Doppler Flow Phantom User Guide

Models ATS 523A & 524

SUN NUCLEAR
A MIRION MEDICAL COMPANY

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1 Introduction

The Doppler Flow phantoms provide a reliable means of evaluating a Doppler Flow Imaging System's ability to detect the location and direction of flow, flow velocity, and sensitivity.

The phantoms are constructed of a rubber-based, tissue-mimicking material. This material extends the useful life of the phantom by avoiding problems due to melting, freezing, dehydration, and breakage from dropping, which are commonly associated with hydrogel (water-based) phantoms. By eliminating these problems, the durability, quality, and reliability of this product are guaranteed for three years.

The acoustic properties of all biologic and nonbiologic materials are affected by temperature variations. Most diagnostic imaging systems and tissue-mimicking phantoms are calibrated at room temperature, commonly referred to as 23°C. To ensure measurement accuracy, ATS incorporates a thermometer strip affixed to the outside surface of the phantom.

The sound velocity of most diagnostic imaging systems is calibrated to 1540 meters per second (mps), the assumed average velocity of sound through human soft tissue. The rubber-based, tissue-mimicking material has a sound velocity of 1450 mps at 0.5 dB/cm/MHz (measured at 3.5 MHz) at room temperature (23°C).

The rate of fluid flow through the phantom when measured by a doppler imaging system is not affected by the differences in sound velocity; therefore, distortion of these measurements will not occur.

Product Description

Model 523A Cardiac Doppler Flow Phantom

The Model ATS 523A tissue-mimicking doppler flow phantom contains four flow channels of varying diameters simulating the deep vasculature, such as the cardiac and abdominal vessels. Two fixed-angled scan surfaces maintain a constant angle between the sound beam and the Doppler Fluid flowing through the phantom.

The scan surfaces are angled at 18° and 56°, permitting continuous scanning at depths ranging from 3 to 17 cm.

Model 524 Peripheral Vascular Doppler Flow Phantom

The Model ATS 524 tissue-mimicking doppler flow phantom contains four flow channels simulating superficial vasculature. The simulated vessels are located 15.0 mm below the scan surface. Built-in scanning wells are provided to permit the use of water or a low viscosity gel as acoustic coupling agents.

The Model 524 contains four flow channels with diameters 2, 4, 6, and 8 mm, without stenosis.

If the user requires depths greater than 15 mm, we recommend the use of our Model 528 scanning wedge. The wedge is constructed of the same tissue-mimicking material as the doppler flow phantoms and provides an additional 50 mm of scanning depth.

Tests Performed

The following tests are performed:

- Flow Velocity
- Sensitivity at varying depths
- Maximum Penetration
- Location of Flow

2 Setup

Equipment and Materials Required

The following are required:

- Doppler Flow Pump Model 769
- Model 769DF Doppler Fluid

Procedure

1. Select a clean, flat, stable working surface.
2. Check to make sure all of the above equipment/materials are available.
3. Set up the Doppler Flow Pump according to the manufacturer's directions.
4. Arrange the system components to provide easy access during a testing procedure. The phantom should be positioned near the pumping system.
5. Use provided coupling hoses to connect pump to the phantom.
6. Gently shake the Doppler Fluid to ensure any material which may have settled to the bottom is combined with the solution.

Note: *In the operation of any flow phantom, it is likely that some air bubbles will enter the fluid stream, either through cavitation in areas of expanded diameters or entrainment of air at a fitting or connector. For these reasons, a large reservoir is required. As the pump begins to circulate the test fluid through the system, entrapped air bubbles will enter the fluid and be pumped into the return side of the reservoir.*

A large reservoir will allow enough time for the entrapped air bubbles to separate from the returning test fluid. The air bubbles may appear as foam and will float on the top of the test fluid on the return side of the reservoir.

Note: *When using with the Model 769 doppler flow pump, the pressure will not exceed 9 psi, even at the maximum flow rate of 750 ml/s. If you notice an obstruction in the flow circuit, immediately turn off the pump.*

The phantom is now ready for performance testing.

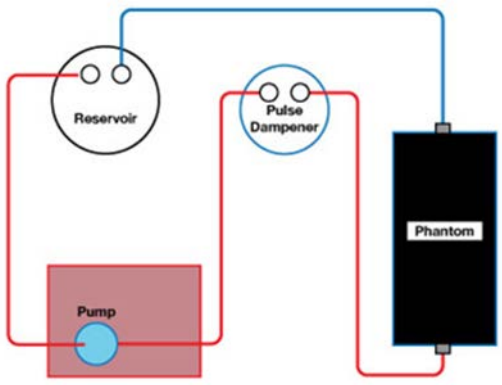

Figure 2-1. Phantom Setup Diagram

3 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 phantoms and the parts provided with the phantoms 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 buildup 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 www.sunnuclear.com/support.
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**.

4 Specifications

Product Specifications

Tissue-Mimicking Material

Table 4-1. Tissue-Mimicking Material Specifications

Characteristic	Specification
Type	Urethane Rubber
Freezing Point	< -40°C
Melting Point	> 100°C
Attenuation Coefficient	0.5 dB/cm/MHz (measured at 3.5 MHz)
Speed of Sound	1450 mps at 23°C

General

Table 4-2. Phantom Specifications

Characteristic	Model 523A	Model 524
Overall Dimensions	32x14x10 cm	22x14x10 cm
Weight	15.2 lbs (6.9 kg)	6.5 lbs (2.9 kg)
Housing Material	PVC	PVC
Scan Surfaces	2	1
Scan Surface Dimensions	25.5x12.0 cm at 18° 9.5x12.0 cm at 56°	17.5x9.8 cm

Flow Channels

Table 4-3. Flow Channel Specifications

Characteristic	Model 523A	Model 524
Type	Circular	Circular
Number of Channels	4	4
Diameters (mm)	2	4
Scan Surface Depths	3.0-11.0 cm at 18° 4.0-17.0 cm at 56°	
Maximum Fluid Pressure – psi (kg/cm)	15 psi (1.05 kg/cm)	15 psi (1.05 kg/cm)
Connector	Quick Disconnect	Quick Disconnect

Appendix A: Regulatory Supplement

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.

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