

Model 527 Pirer onal (sc) ni , tij i Di ople Fl | 1 is toi | E |

Made in USA

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 is guaranteed for three years.

The acoustic properties of all biologic and non-biologic 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 1,540 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 with an attenuation coefficient of 0.5dB/cm/Mhz when measured using a 3.5 MHz transducer at room temperature (23°C).

The differences in the speed of sound if gone uncorrected, will cause distortion of the distance (e.g. depth of penetration) measurements obtained. The measurements are corrected by multiplying the measurements obtained by the correction factor of 0.94.

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

The Model 527 tissue mimicking Doppler flow phantom is designed to test directional discrimination of color Doppler flow imaging systems. This phantom monitors the ability of the system to discriminate the direction of flow in small vessels, of close proximity, at varying depths.

The phantom contains four pairs of 2.0 mm flow channels. Connecting the channels (as shown in Figure 2) creates bi-directional flow within the pair at equal flow rates. The edge-to-edge spacing between the flow channels within the each pair progressively increases from 1.0 mm to 4.0 mm.

A fixed-angled scan surface maintains a constant angle between the sound beam and the test fluid flowing through the phantom at 18° or 56° permitting continuous scanning at depths ranging from 3.0 to 17.0 cm.

TEST PERFORMED

- · Directional Discrimination
- Flow Velocity
- · Sensitivity at varying depths
- Maximum Penetration
- · Location of Flow

SPECIFICATIONS

GENERAL

Overall Dimensions: 32.0 x 13.5 x 16.0cm* Weight: 15.2 lbs - 6.9 Kg*

Housing Material: PVC Wall Thickness: 1.0 cm*

Scan Surfaces: 2

Dimensions: 25.5 x 11.5cm @ 18° 9.5 x 11.5cm @ 56°

TISSUE MIMICKING MATERIAL

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 m/s at 23°C

FLOW CHANNELS:

Type: Circular

Number of Channels: 8 Number of Pairs: 4

Diameters: 2.0 mm

Scan Surface Depths: 3.0 - 11.0 cm @ 18°

3.5 - 15.0 cm @ 56°

Maximum Fluid

Pressure: 8 psi

CONNECTORS:

Type: Luer-Lock

^{*}Nominal dimensions

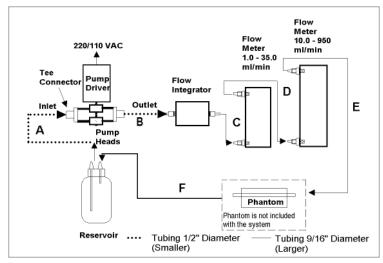


Figure 1

SET-UP PROCEDURE

NOTE: THE SET-UP OF THE MODEL 527 IS UNIQUE PLEASE FOLLOW THE DIRECTIONS GIVEN BELOW CAREFULLY.

The Model 527 is designed to be used in conjunction with ATS Model 707 Doppler Test Fluid and the ATS Model 700 ATS Doppler Flow Controller and Pumping System.

Equipment and Materials Required

The Model 527 is supplied with various parts, please check to make sure you have received the following items:

- 16 Male Luer-lock Plugs
- 4" (Inside Diameter 3/32") Connecting Tubing with Male Luer-Lock connectors on both ends. Used to connect matching channel pairs at one end of the phantom.
- 1 6" (Inside Diameter 3/32") Connecting Tubing with Male Luer-Lock connectors on both ends. Used to connect unmatched pairs at one end of the phantom, requiring a long distance.

Procedure

- 1. Check to make sure the above equipment/materials are available.
- 2. Select a clean, flat, stable working surface. Arrange the system components to provide easy access during a testing procedure. The phantom should be positioned near the pumping system.
- 3. Set-up the Doppler Flow Pumping System according to the manufacturers directions. Follow the steps below when connecting the Model 527.

- 4. Connect the Model 527 phantom to the pumping system as shown on the above diagram.
- 5. All of the flow channels need to be filled with test fluid to avoid an air-phantom interface.
- 6. When you are now ready to prime the pumping system and fill the flow channels, turn the "Speed Dial" on the pump driver to "0". Turn on the pump. Slowly increase the speed of the pump to achieve the desired fluid flow. Allow the pump to run until it is completely primed and no visible air-bubbles are seen in the tubing. When is accomplished, turn the "Speed Dial" back to "0".
- 7. Disconnect the pair #1 flow channel and replace the luer-lock plugs, to prevent the fluid from leaking out of the channels.
- 8. Repeat this procedure for the remaining flow channel pairs.

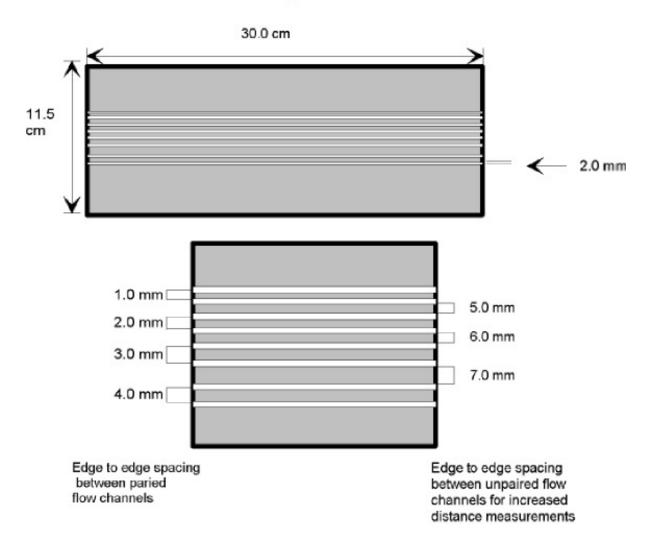
NOTE: In the operation of any flow phantom it is likely some air bubbles will enter the fluid stream; either through cavitation in areas of expanded diameters or entrainment of air at a fitting or connector. For these reasons a large reservoir is required. As the pump begins to circulate the test fluid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

9. Select the desired flow channel pairs for testing. Use the procedure above to connect the flow channels to the pumping system. If greater edge-to-edge distances are required, a combination of two flow channel pairs can be used as illustrated in Figure 2.

NOTE: THE PRESSURE OF THE FLUID DELIVERED TO THE PHANTOM MUST NOT EXCEED 8 psi (POUNDS PER SQUARE INCH). IF FLUID PRESSURES ARE USED IN EXCESS OF 8 psi THE PHANTOM WILL BE PERMANENTLY DAMAGED.

The phantom is now ready for performance testing.

FIGURE 2 MODEL 527



CARE AND HANDLING OF QUALITY ASSURANCE RUBBER-BASED PHANTOMS

For best results the phantom should be kept clean at all times. 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.

When doppler flow testing has been completed, pump an adequate amount of water through the channels to remove the test fluid prior to storing.

NOTE: THE PRESSURE OF THE FLUID DELIVERED TO THE PHANTOM MUST NOT EXCEED 8 psi (POUNDS PER SQUARE INCH). IF FLUID PRESSURES ARE USED IN EXCESS OF 8 psi THE PHANTOM WILL BE PERMANENTLY DAMAGED.

STATEMENT OF WARRANTY

ATS Laboratories, Incorporated warrants that for the duration of the warranty period, its products are free from functional defects in materials and workmanship. If ATS Laboratories, Incorporated, deems the product to be defective, at our sole option, we will repair or replace the product, free of charge in a reasonable amount of time.

Warranty Period:

The warranty period begins on the date the product is delivered to the purchaser.

Rubber-Based Phantoms Lifetime defined as between 10 years

Conditions of Warranty

- 1. The defect must be reported and the Product returned to ATS Laboratories, Incorporated within the warranty period.
- 2. The Product must be packaged properly to avoid damage during shipping.
- 3. All transportation charges will be paid by the purchaser.

Invalidation of Warranty

- 1. If the product has been altered or repaired other than by ATS Laboratories, Incorporated.
- 2. If the product has been subject to abuse, misuse, negligence or accident such as;

Rubber-Based Doppler Flow Phantoms:

- a. If the purchaser has exposed the Phantom to petroleum solvents.
- b. If the phantom has been subjected to fluid pressure above 8 psi (pounds per square inch).

ATS shall not be otherwise liable for any damages, including but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties as stated above.