Model 43A Doppler String Phantom

Instructions for Use

Model 43A

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Model 43 A Instructions for Use

Document 500002, Rev G, 15 September 2022

CIRS
900 Asbury Ave
Norfolk, VA 23513 USA
+1-321-259-6862
www.sunnuclear.com

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Contents

Section 1. Overview. 1
Features of the Model 43A 1
Starting a Quality Assurance Program 1
Section 2. Setup Instructions 2
Parts List 2
Installing the Diffuser Mat. 2
Installing the Target (String or Rubber O-Ring). . . . 2
Setting Up the Transducer Clamp. 4
Filling the Tank 6
Connecting the Controller 7
Section 3. Operating Instructions 8
Front Panel Controls and Indicators 8
Using Constant Speeds. 9
Using Preprogrammed Waveforms 10
Section 4. Remote Operation. 11
Introduction 11
Setting Up the Virtual Com Port 11
Setting Up the Terminal Emulator. 11
Getting Started 12
Help Menu. 13
Selecting Velocities and Waveforms 13
Constant Speeds 13
Test Waveforms 13
Human Waveforms. 14
Flow Reversal 14
Commands Available via Remote Control 14
Section 5. Maintenance Instructions . . . 15
Replacing Targets 15
Rubber O-Ring Targets. 15
String Targets 15
Cleaning the Model 43A 15
Replacing Fuses 15
Calibrating the Model 43A 16
Section 6. Specifications. 17
Appendix A: Graphs of Wave Forms . . . 19
Test Waveforms 19
Sine Wave, 100 cm/sec 19
Sine Wave, 150 cm/sec 20
Sine Wave, 200 cm/sec 20
Triangle Wave, 100 cm/sec 21
Triangle Wave, 150 cm/sec 21
Triangle Wave, 200 cm/sec 22
Stepped Ramp 22
Physiological Waveforms 23
Adult Common Carotid 23
Adult Aortic 23
Adult Femoral 24
Pediatric Umbilical 24
Stenotic Common Carotid 25
Pediatric Renal 25
Pediatric Ductus Arteriosus 26
Pediatric Middle Cerebral 26
Pediatric Descending Thoracic. 27
Appendix B: QA Form 29
Doppler Mode Inspection 29
Sample Volume Registration (to string target) 29
Color Registration (to string target) 29
Directional Discrimination. 29
Doppler Velocity Accuracy 29
Doppler Velocity Accuracy 29
Doppler Mode Inspection 30
Sample Volume Registration (to string target) 30
Color Registration (to string target) 30
Directional Discrimination. 30
Doppler Velocity Accuracy 30
Doppler Velocity Accuracy 30
Date: 30
Appendix C: Regulatory Supplement. . . 31
Symbols 31
Operator Responsibility 32
Reporting Health or Safety Related Issues or Concerns. 32
Modifications to Equipment 33

This page is intentionally left blank.

1 Overview

Features of the Model 43A

The Model 43A Doppler string phantom is an accurate device for testing Doppler ultrasound scanners. It is especially useful for checking sample volume registration, color registration, directional discrimination, and Doppler velocity accuracy.

The Model 43A offers superior accuracy by using a string or O-ring target that never changes (unlike suspended scatterers in fluid flow phantoms), and a high precision motor. The motor speed is adjusted 1000 times per second, allowing realistic reproductions of human blood flow velocity patterns and constant velocities from 1 mm/sec to 4000 mm/sec.

The Model 43A has been designed for ease of use. It can be set up quickly and easily with ordinary tap water or blood-equivalent fluids, it is simple to use, and almost no maintenance is required. A USB interface is also provided for automated use, if desired. Ultrasound technologists, biomedical technicians, researchers, and manufacturers can rely on the Model 43A for hassle-free, reliable testing.

Starting a Quality Assurance Program

Each ultrasound lab will have different Quality Assurance (QA) needs depending on equipment, maintenance agreements, and applicable laws and policies. However, many technicians recommend testing ultrasound scanners regularly at 3-month intervals. In addition, any time you suspect a problem with an ultrasound scanner, you will want to test it immediately.

To ensure that each testing session is consistent and thorough we recommend using a standard form for recording the results of your tests. Recording your findings also provides written documentation of your QA program. A sample QA form is provided in Appendix B of these instructions.

2 Setup Instructions

Parts List

The Model 43A includes:

- Electronic controller
- Rugged plastic tank with motor and pulleys attached
- Clamp assembly with 2 clamp sizes
- USB flash drive (contains USB port drivers for remote operation and PDF copy of this user manual)
- USB Type A to Type B cable
- Set of 5 string loops and 1 rubber O-ring
- Diffuser mat
- String tensioning tool
- Power cord

Installing the Diffuser Mat

Full-power ultrasound can reverberate in the tank, causing interference with ultrasound signal. If desired, you can use the diffuser mat to reduce reverberations in the tank. Place the mat in the bottom of the tank underneath the string with the fabric side facing up. It may also be helpful to reduce the power level on your ultrasound scanner.

Installing the Target (String or Rubber O-Ring)

IMPORTANT: If you are using a an O-ring target, only use part number 43-OR1. Using a different target will invalidate the target speed calibration and certificate.

1. Loosen the adjusting screw on the two pulleys (Adjustable Pulleys) at the end of the tank opposite the motor.
2. Take one of the string loops (or O-ring) out of the bag and lay it over the pulley that is attached directly to the motor (Motor Pulley).

3 Draw the string half-way around the Motor Pulley, behind the two Idler Pulleys below the motor, and around the two Adjustable Pulleys.

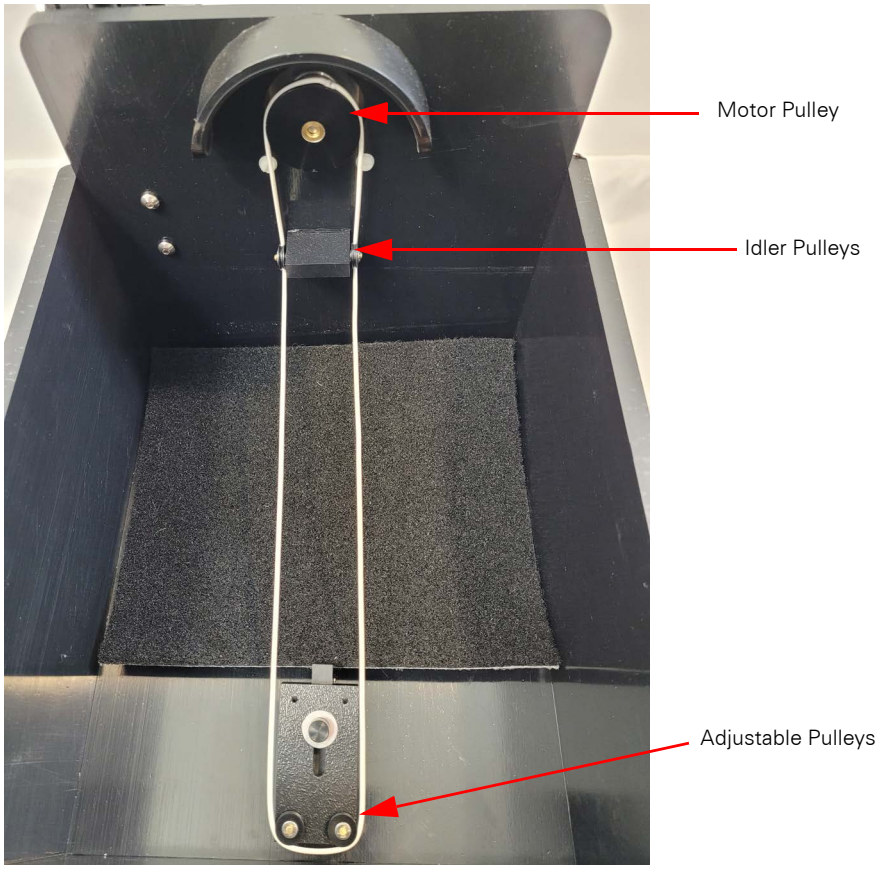


Figure 2-1. String Installed Around Motor, Idler, and Adjustable Pulleys

4 Adjust the string tension by moving the Adjustable Pulleys. Use the String Tensioning Tool (included) to ensure correct tension as follows.

a. Find the String Tensioning Tool and note Surfaces A and B, with the metal rod between them.

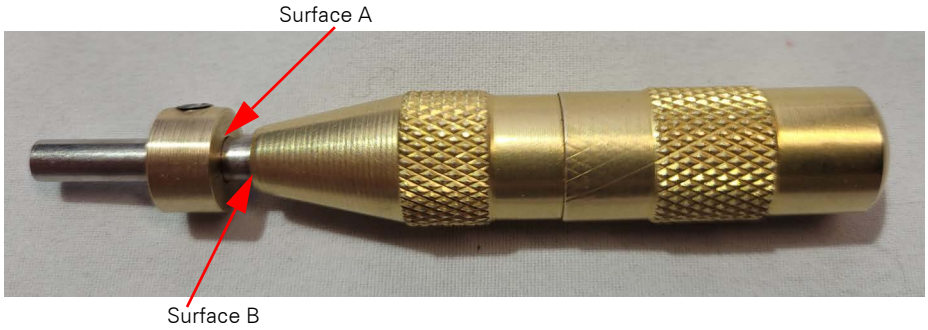


Figure 2-2. String Tensioning Tool

b. Press the String Tensioning Tool against the base plate for the Adjustable Pulleys as shown, until Surface A meets Surface B. Then tighten the thumbscrew on the base plate

to secure the pulleys in place. This procedure ensures 7°N (25°oz) of tension on the string.

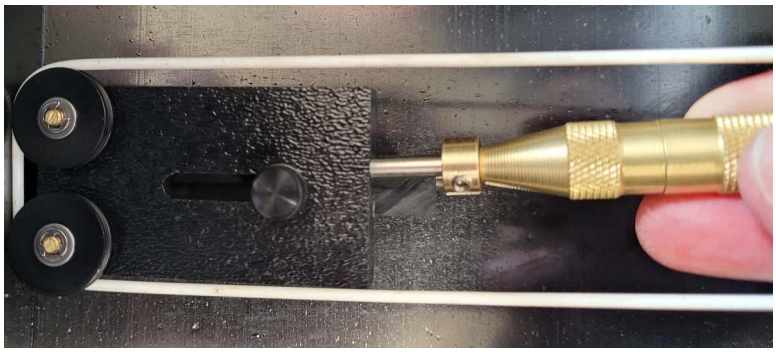


Figure 2-3. Press String Tensioning Tool Against Base Plate on Adjustable Pulley

c. Store the String Tensioning Tool in the holder on the back of the tank for future use.

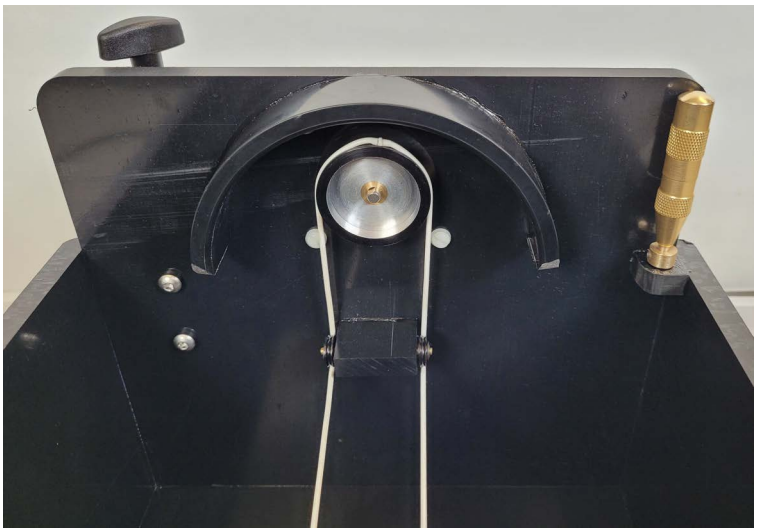


Figure 2-4. Storage Position for String Tensioning Tool

Setting Up the Transducer Clamp

The Model 43A is shipped with a transducer clamp system consisting of an articulated arm, a large clamp, a small clamp, and an arm attachment fixture that is bolted to the tank.

Figure 2-5. Large and Small Clamps

1. The attachment fixture on the tank has two sockets. Insert the end of the arm that has the 3/8-inch (9.5-mm), internally-threaded stud into the upper socket with the flat side of the stud facing up. This end of the arm is labeled "Tank end." Tighten the thumbscrew.

Figure 2-6. Insert the Arm

2. Attach either the large or small clamp to the other end of the arm as shown. This end of the arm is labeled "Transducer Clamp End."

Large clamp

Small clamp

Figure 2-7. Large and Small Clamps Attached to Arm

- To attach the large clamp, insert the stud into the receptacle on the clamp. You may need to press the silver button while inserting the stud. Then tighten the thumbscrew.
- To attach the small clamp, insert the screw on the clamp into the threads at the end of the stud and turn until tight.

3. Turn the clamp adjusting knob to open or close the clamp so that it fits your scanhead.
4. Adjust the clamp and articulated arm so that the transducer end of the scanhead is below the water level. Make sure the scanhead is at the desired angle with respect to the string.

Note: *Although the scanhead clamp can be placed in water temporarily, it should be stored in a dry location to prevent corrosion.*

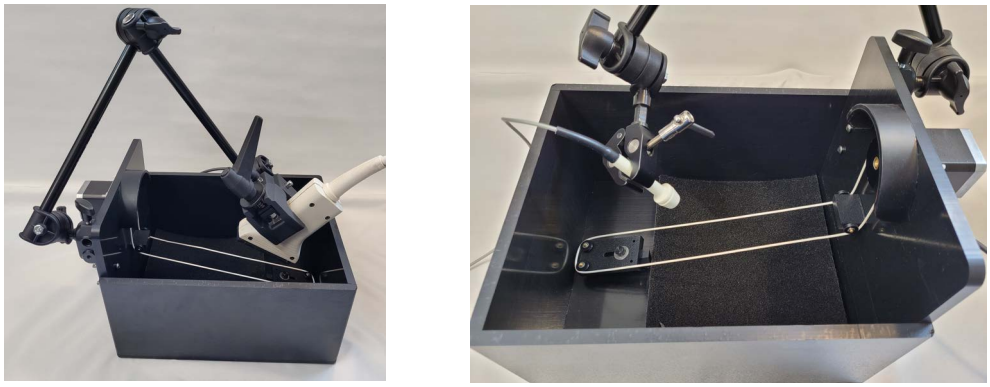


Figure 2-8. Large Clamp and Small Clamp Installed

Filling the Tank

Place the tank on a firm surface and fill it with either tap water or velocity-corrected fluid (see note below). Fill the tank until the two small pulleys beneath the motor are just submerged. This depth works well, but it may be changed to meet your needs. The maximum fluid level is just below the motor.

After filling the tank, there will be dissolved air bubbles in the water. For best results, wait an hour before using the Model 43A so the water can de-gas.

CAUTION: Fill the tank only with water, a water/Glycol mixture, or other suitable, non-corrosive mixture. Using corrosive liquids will invalidate the warranty.

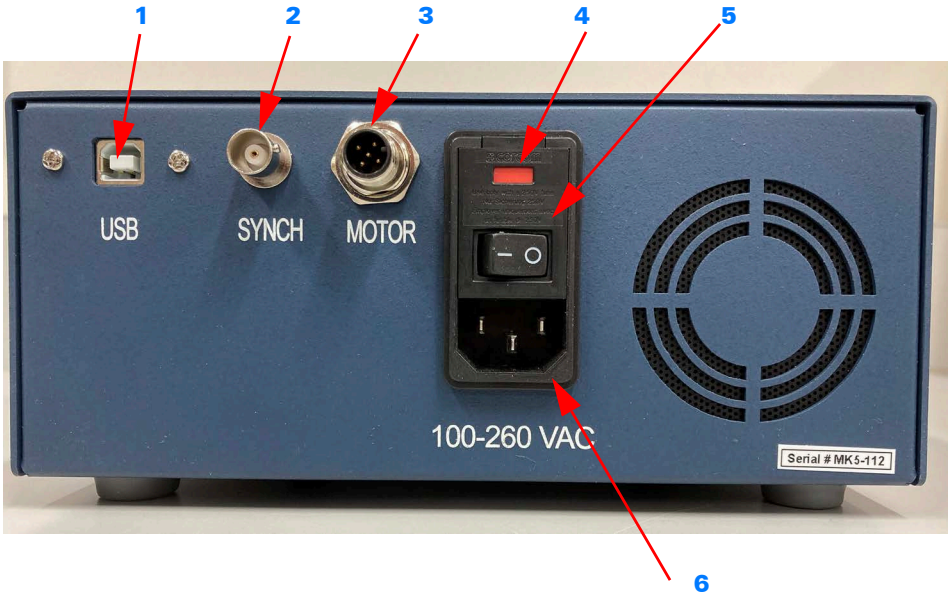
Note: *The speed of sound is 1480 meters per second in water, and 1540 meters per second in the human body. Doppler scanners are calibrated for 1540 meters per second, so you may prefer to use a water/glycol mix that also has a speed of sound of 1540 meters per second. This mix is called velocity-corrected fluid.*

The Model 43A has been designed to work with either plain water or velocity-corrected fluid (H2O/Glycol). When turned on, the Model 43A will prompt you to enter the type of fluid in the tank. When set for use with water, the Model 43A compensates for the different speed of sound by adjusting the speed of the target, and the display indicates the speed your scanner should be detecting. When set for use with velocity-corrected fluid, the Model 43A moves the target at the actual speed indicated on the display.

Connecting the Controller

You are now ready to connect the controller to the motor and the power supply.

1. Before plugging in the controller, make sure the power switch on the back is turned off.
2. Plug the motor cable into the Drive Motor receptacle on the back of the controller.
3. Plug the power cable into the AC Receptacle and into a 120 or 240 volt AC power source.



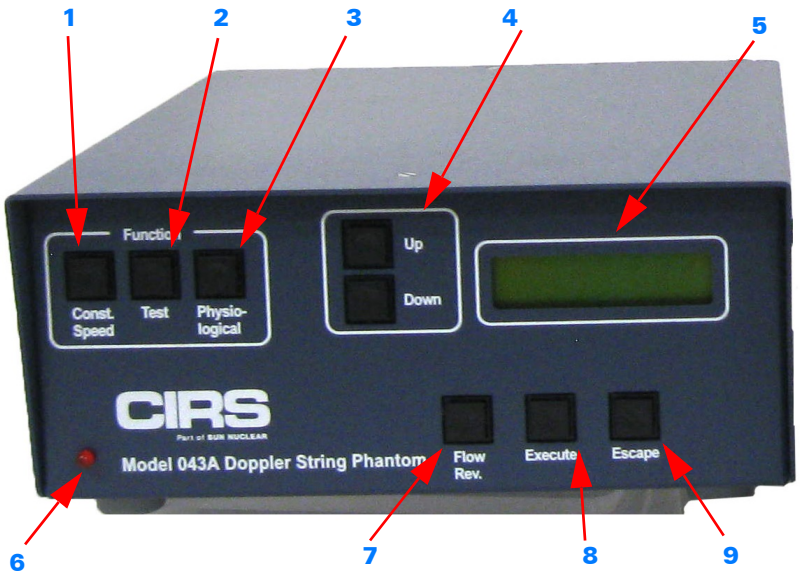
Item	Description
1	USB connector. For remote operation, connect a USB Type A to Type B cable (included) between this connector and your computer. See *Remote Operation* on page 11 for more information. **CAUTION: Only use the USB port to connect the controller to a computer. Do not connect any other USB device to the controller.**
2	Sync port. Sends 5V ECG pulse approximately once per second.
3	Drive Motor receptacle. Connect the motor cable to this port.
4	Fuse access. See Replacing Fuses on page 22.
5	Power switch.
6	AC receptacle.

Figure 2-9. Rear View Connectors and Switches

3 Operating Instructions

CAUTION: To prevent overheating, do not run the motor continuously for longer than 15 minutes. Supplemental cooling, such as a desk fan, may enable longer run times if needed.

Front Panel Controls and Indicators



Item	Description
1	Constant Speed. Selects to operate the motor at constant speed. The speed is set using the Up and Down keys.
2	Test. Selects the Test waveform group.
3	Physiological. Selects the Physiological waveform group.
4	Up and Down scroll buttons. Selects menu items and controls motor speed.
5	Display window. Displays start up, menu, and action prompts.
6	Power indicator. Illuminates when power is ON.
7	Flow Reverse. Reverse the direction of the simulated flow. The current selection is indicated in the Display window's upper left corner.
8	Execute. Starts the motor.
9	Escape. Stops current function so another function can be started.

Figure 3-1. Front View Controls and Displays

Using Constant Speeds

The Model 43A can be set for constant string speeds ranging from 1 to 4000 mm/sec. Constant speeds are useful for a quick check to verify that your scanner is reporting correct image registration and target velocity for the scanning angle you're using. You can also detect false data caused by a broken transducer or a loose connection.

1. After setting up the Model 43A, turn on the power switch (located on the back of the controller).
   The display reads:
   SELECT FLUID
   ∧H2O ∨GLYCOL.
2. If the tank is filled with water, press the UP button. If the tank is filled with velocity-corrected fluid, press the DOWN button.
   The display reads:
   SELECT TARGET
   ∧STRING ∨O-RING.
3. If you are using a string target, press **UP**. If you are using an O-ring, press **DOWN**.
   The display reads:
   SELECT A FUNCTION.
4. Press **CONST. SPEED**; then press **UP** or **DOWN** to select the desired speed in millimeters per second.

Note: *Holding down either the* **UP** *or* **DOWN** *button causes the speed setting to scroll faster.*

5. Press **EXECUTE** to start the motor.

To change the speed, you may press **UP** or **DOWN** at any time while the motor is running.

To reverse the direction of simulated flow, press **FLOW REV** at any time. An arrow in the upper left corner of the display indicates the flow direction.

To change functions (for example, to switch from constant speeds to test waveforms), press **ESCAPE**.

Using Preprogrammed Waveforms

The Model 43A has several preprogrammed waveforms to help you test your ultrasound scanner under realistic conditions, with velocity fluctuations you might expect in a patient. Each waveform has 1000 data points to provide accurate simulations. The waveforms are divided into two groups: test waveforms and physiological waveforms. Graphs of all the waveforms are included in Appendix A of this User's Guide.

The test waveforms are:

- Sine waves with peak speeds of 1000, 1500, and 2000 mm/sec
- Triangle waves with peak speeds of 1000, 1500, and 2000 mm/sec
- Stepped ramp wave with stops at 10, 200, 400, 600, 800, and 1000 mm/sec

The physiological waveforms are:

- Adult common carotid
- Adult aortic
- Adult femoral
- Pediatric umbilical
- Stenotic common carotid
- Pediatric renal
- Pediatric ductus arteriosus
- Pediatric middle cerebral
- Pediatric descending thoracic

1. After setting up the Model 43A, turn on the power switch (located on the back of the controller).

   The display reads:
   SELECT FLUID
   ∧H2O ∨GLYCOL.

2. If the tank is filled with water, press **UP**. If the tank is filled with velocity-corrected fluid, press **DOWN**.

   The display reads:
   SELECT TARGET
   ∧ STRING ∨O-RING.

3. If you are using a string target, press **UP**. If you are using an O-ring, press **DOWN**.

   The display reads:
   SELECT A FUNCTION.

4. Press **TEST** or **PHYSIOLOGICAL** to select a waveform group.

The display shows a waveform.

5. Press **UP** or **DOWN** to select a waveform. (See Appendix A for graphs of waveforms.)
6. Press **EXECUTE** to start the motor.

   To select a different waveform, you may press **UP** or **DOWN** at any time while the motor is running.

   To reverse the direction of simulated flow, press **FLOW REV.** at any time. An arrow in the upper left corner of the display indicates the flow direction.

   To change functions (for example, to switch from physiological waveforms to constant speeds), press **ESCAPE**.

4 Remote Operation

Introduction

The remote control software allows all of the same functions that are available from the front panel. It is primarily a USB communications feature for use with automatic testing equipment, but may be used by anyone wanting to control the phantom for standardized testing. It may be controlled by a laptop, desktop, or a process control computer.

The USB port on the Model 43A is Type B female. To establish the link between the Model 43A controller and your computer, you will need a USB Type A to Type B cable (included).

While the Model 43A is being controlled remotely, the buttons on the front panel are also functional. You can use either the computer or the front panel at any time.

Setting Up the Virtual Com Port

You will need to set up a virtual serial Com Port on your computer, so your computer's USB port functions as a serial port that can communicate with the Model 43A. The USB flash drive included with the Model 43A contains the appropriate Com Port drivers for both Windows and Mac.

1. Insert the flash drive into your computer and install the appropriate driver. (See the Readme file on the flash drive for instructions.)
2. Connect a USB cable from the Model 43A controller to your computer, turn on the controller, and then open 'Device Manager' on your computer. A list of devices and hardware will be displayed. Find 'Ports' (COM and LPT). You may need to expand the list of ports by clicking on the '>' symbol.
3. Find the COM port number that has appeared. This COM port will be the port number that you enter when you start the terminal emulator.

Setting Up the Terminal Emulator

To send commands to the Model 43A, you can use Tera Term or any common terminal emulator such as Pro-Comm Plus, CoolTerm (Mac), or Microsoft Hyperterminal. Use the following settings.

Terminal:

- Terminal ID: VT100
- New-line Receive: CR+LF
- New-line Transmit: CR+LF
- Handle/Allow Backspace and DEL keys

COM Port:

- Port: COM port number from step 3 above
- Speed: 115200
- Data: 8 bit
- Parity: None
- Stop bits: 1 bit
- Flow control: None

To begin using the remote control feature:

1. Ensure the Model 43A controller is powered off (rear panel switch).
2. Plug the power cable into the AC Receptacle and into a 110 or 220 volt AC power source.
3. Plug the motor cable into the Drive Motor receptacle on the back of the controller.
4. Plug the USB cable into the USB receptacle on the back of the controller, and into your computer.
5. Turn on the power on the controller (rear panel switch).
6. Start the communications program and ensure all settings are correct.

   Introductory text will appear on your computer screen, followed by the following prompt:

   SELECT H2O or GLYCOL:

   H20 - TYPE U

   GLYCOL - TYPE D

   Ready>

   If this text does not appear, check all connections and then turn the controller off and back on. When the text appears, the system is ready.

Note: *When entering commands, either upper or lower case may be used. Upper case is used in this manual for easier reading.*

Note: *Between each command, wait until the controller responds that it is ready for the next command.*

7. Similar to using the front panel of the controller, press the **U** key on the keyboard to select H2O, or **D** to select glycol.

Note: **U** corresponds to **Up** on the front panel and **D** corresponds to **Down** on the front panel.

   After you make your selection, the following text will appear:

   SELECT TARGET:

   O-RING - TYPE U

   STRING - TYPE D

   Ready>

8. Press the **U** or **D** key to make your selection.

   After you make your selection, the following text will appear:

   SELECT A FUNCTION:

   SELECT A FUNCTION ON FRONT PANEL

   OR TYPE H FOR HELP MENU

   Ready>

9. You can type **H** to access the Help menu, or go directly to any of the following functions:

   Constant speed: Press **C** on the keyboard

   Test waveforms: Press **T** on the keyboard

   Physiological waveforms: Press **P** on the keyboard

Help Menu

The Help Menu (shown below) can be displayed at any time by entering **H** on the keyboard.

MARK 5 MENU

C - CONSTANT SPEED

S - SET CONSTANT SPEED, mm/S

T - TEST WAVES

P - PHYSIOLOGICAL WAVES

U - UP KEY

D - DOWN KEY

E - EXECUTE KEY (display temperature at function selection screen)

Enter - EXECUTE KEY

R - REVERSE FLOW

Esc - ESCAPE KEY

H - COMMAND MENU

X - Clear Screen

Selecting Velocities and Waveforms

The following examples demonstrate how to generate various target velocities and waveforms.

Constant Speeds

To create a constant flow at 520 mm/sec, follow these steps:

1. Turn the controller on.
2. Enter U or D to select the type of fluid in the tank.
3. Enter U or D to select target (string or O-ring).
4. Enter C to select Constant speeds.
5. Either press Enter again to start the motor immediately at 100 mm/sec, or press S to select a different constant speed.
6. After pressing S, enter the desired speed in mm/sec. For example, type S420 and press Enter to select a speed of 420 mm/sec.
7. The speed is now set to 420 mm/sec. If the motor is running, it will immediately change speeds. If the motor is not running, press Enter to activate the motor.

Note:

- *Only whole numbers are allowed for velocities.*
- *Press* **S** *at any time to select a different constant speed.*
- *Press* **ESC** *to stop the motor.* **ESC** *is not available while the motor is accelerating to a new constant speed. To stop the motor while it is accelerating, turn off the power switch on the back of the controller.*

Test Waveforms

To select a changing velocity profile such as a sine wave that ranges from -1000 mm/sec to +1000 mm/sec, follow these steps:

1. Turn the controller on.
2. Enter **U** or **D** to select the type of fluid in the tank.
3. Enter **U** or **D** to select target (string or O-ring).
4. Enter **T** to select Test waves. The screen displays TEST WAVEFORM MODE SELECTED.

5 Press **Enter** to start the motor with the Sine wave at 1000 mm/sec, or press **U** or **D** to select a different waveform and then press **Enter**.

Note: *You can press* **U** *or* **D** *while the motor is running to select a different waveform.*

Human Waveforms

To select a human Doppler waveform such as the 'Common Carotid' waveform, follow these steps:

1 Turn the controller on.

2 Enter **U** or **D** to select the type of fluid in the tank.

3 Enter **U** or **D** to select target (string or O-ring).

4 Enter **P** to select Physiological waves. The screen displays **PHYSIOLOGICAL WAVEFORM MODE SELECTED**.

5 Press **Enter** to start the motor with the Common Carotid waveform, or press **U** or **D** to select a different waveform and then press **Enter**.

Note: *You can press* **U** *or* **D** *while the motor is running to select a different waveform.*

Flow Reversal

To reverse the flow direction of any constant speed or waveform, first execute the desired speed or waveform, and then enter an **R**. The target string will stop, and then accelerate up to the desired speed or waveform in the opposite direction.

Commands Available via Remote Control

Table 1. Commands Available via Remote Control

Key	Command	Description
C	CONSTANT SPEED	Used to select constant velocity. Velocities must be whole numbers; decimal numbers are not allowed.
S	SET CONSTANT SPEED, MM/S	Used only when controller is already in constant speed mode. Press S followed by a whole number between 1 and 4000, for example, S500° <Enter>. Decimal numbers are not allowed.
T	TEST WAVES	Used to access test waveforms.
P	PHYSIOLOGICAL WAVES	Used to access physiological waveforms.
U	UP KEY	Used to select water type and target type in tank, move up in the menus, and to increase constant speeds.
D	DOWN KEY	Used to select water type and target type in tank, move down in the menus, and to decrease constant speeds.
E	EXECUTE KEY	Used to select options currently displayed.
	<Enter>	Same as EXECUTE key. When display is at the SELECT A FUNCTION prompt, pressing Enter displays the motor temperature.
R	REVERSE FLOW	Used to reverse the direction of the target in all modes.
Esc	ESCAPE KEY	Used to shut down motor and go back to basic mode selection.
H	HELP MENU	Used to display the list of available commands.
X	CLEAR SCREEN	Used to clear the computer screen.

5 Maintenance Instructions

Replacing Targets

Occasionally, targets break and need to be replaced. You can order replacement targets from CIRS.

Rubber O-Ring Targets

For replacement O-ring targets, order part number 43-OR1. Using a different O ring may cause inaccurate target speeds.

String Targets

For a pack of 20 replacement string loops, order part number 43-SL-20. You can also make your own string loops using these instructions. In general, string loops should have a small, unobtrusive knot that will roll smoothly over the pulleys in the tank.

1. Set up two pins 38.5 cm (15 3/16 inches) apart. Push-pins on a wooden measuring stick work well.
2. Form a loop of string around the pins. Woven 3-0 silk suture material is recommended, although other types of braided string will work. Unbraided fishing line is not recommended because it may give an unreliable signal.
3. Tie a knot to secure the loop, and trim the ends to about 6 mm (¼ inch) long. (A surgeon's knot is recommended.)
4. Put a very small drop of super glue on the knot. The glue should **not** soak into the ends of the string and make them stiff.
5. After the super glue has dried, roll the ends of the string between your fingers to separate the threads as much as possible.
6. Apply rubber cement to the knot and string ends, allow it to dry slightly, and then roll the knot between your fingers to form a smooth ball.

Cleaning the Model 43A

The Model 43A is designed to be virtually maintenance-free. The controller and tank may be cleaned with a damp cloth. Do not use solvents, because they could weaken the tank.

Replacing Fuses

The Model 43A requires two fuses, which can be replaced if necessary. The fuse type is 5x20mm slow blow, 3 Amp.

IMPORTANT: Before you change the fuse, disconnect the Model 43A controller from AC mains power.

The fuse compartment is located on the rear panel, above the power switch. To open the compartment, insert a small, flat-blade screwdriver into one of the two recesses at the top of the fuse panel and pry the compartment open. Then use the screwdriver to pry the red fuse carrier out.

Calibrating the Model 43A

The Model 43A is computer-controlled, so you don't need to make any adjustments. However, many customers choose to have their Model 43A calibrated periodically, which is performed by JJ&A Instruments. JJ&A checks the target speed at a variety of settings, using instruments that are certified according to the National Institute of Standards and Technology (NIST). After verifying that the Model 43A is functioning correctly, a calibration certificate and complete test report are provided. JJ&A may be contacted directly to arrange for calibration at the following address:

JJ&A Instruments
P.O. Box 1161
Rathdrum, ID, U.S.A.
425-788-0779
sales@jja-instruments.com

6 Specifications

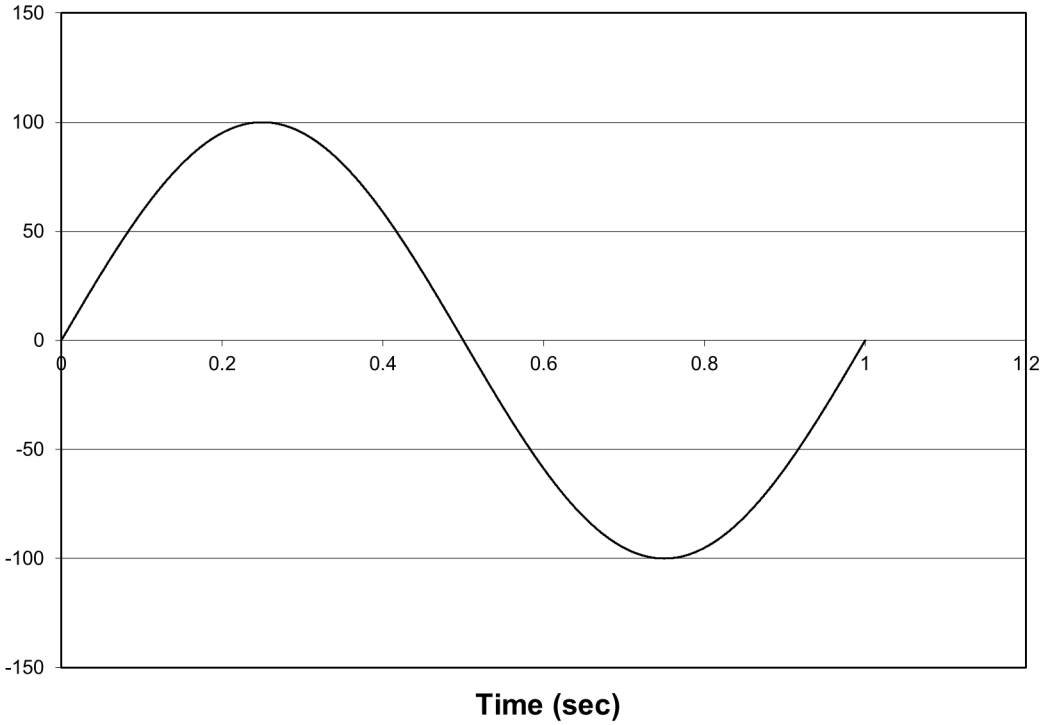
- Flow simulation speeds of 1 to 4000 mm/sec, bidirectional
- Waveform simulations:
  - Sine waves with peak speeds of 1000, 1500, and 2000 mm/sec
  - Triangle waves with peak speeds of 1000, 1500, and 2000 mm/sec
  - Stepped ramp wave with stops at 0, 200, 400, 600, 800, and 1000 mm/sec
  - Physiological waveforms including adult common carotid, adult aortic, adult femoral, pediatric umbilical, stenotic common carotid, pediatric renal, pediatric ductus arteriosis, pediatric middle cerebral, and pediatric descending thoracic
- Speed accuracy certified to ±1% of stated speed
- Power input: 95-260 VAC, 50/60 Hz

This page is intentionally left blank.

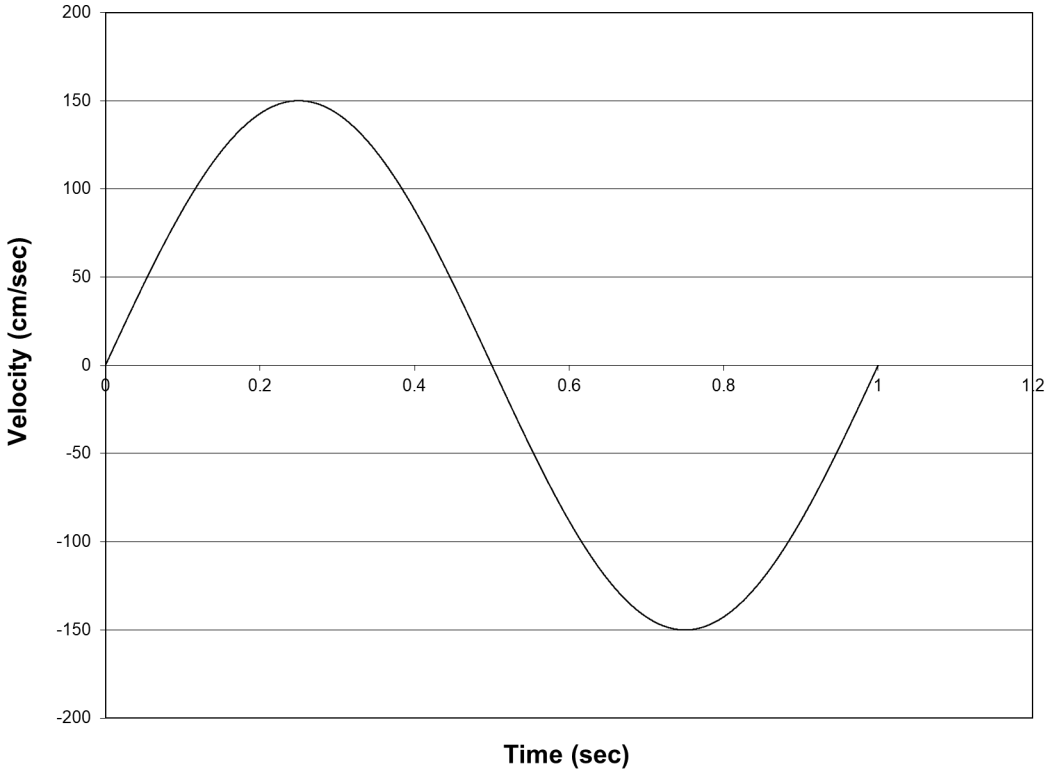
Appendix A: Graphs of Wave Forms

Test Waveforms

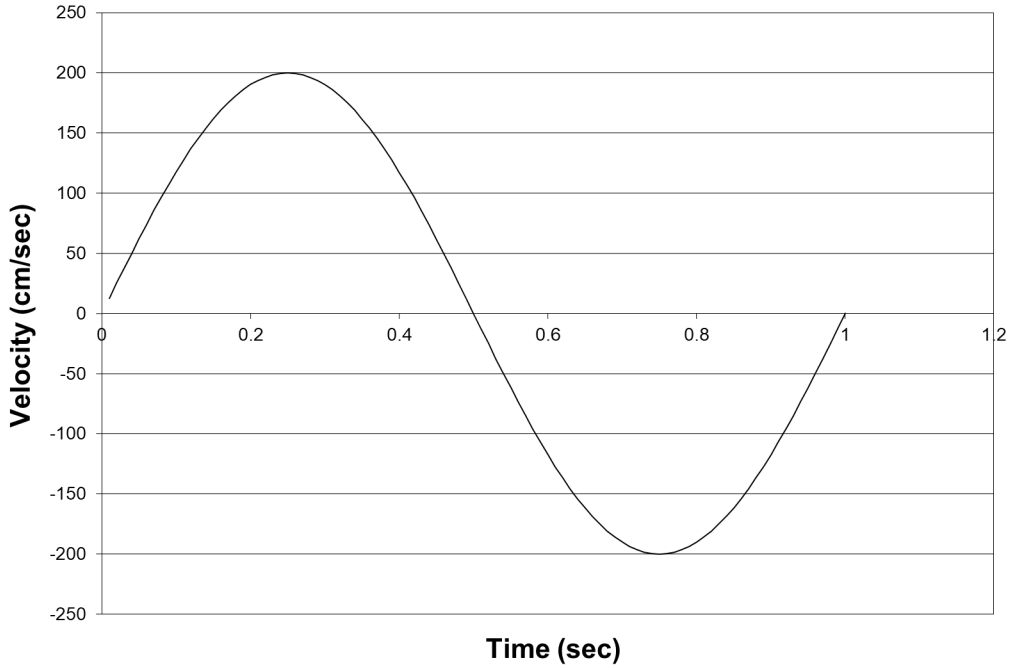
Sine Wave, 100 cm/sec



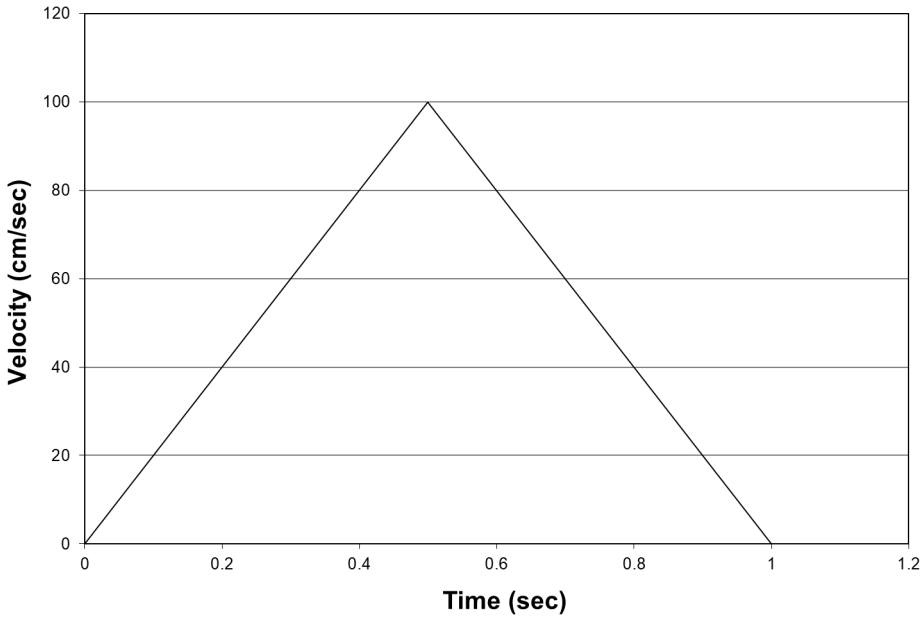
Sine Wave, 150 cm/sec



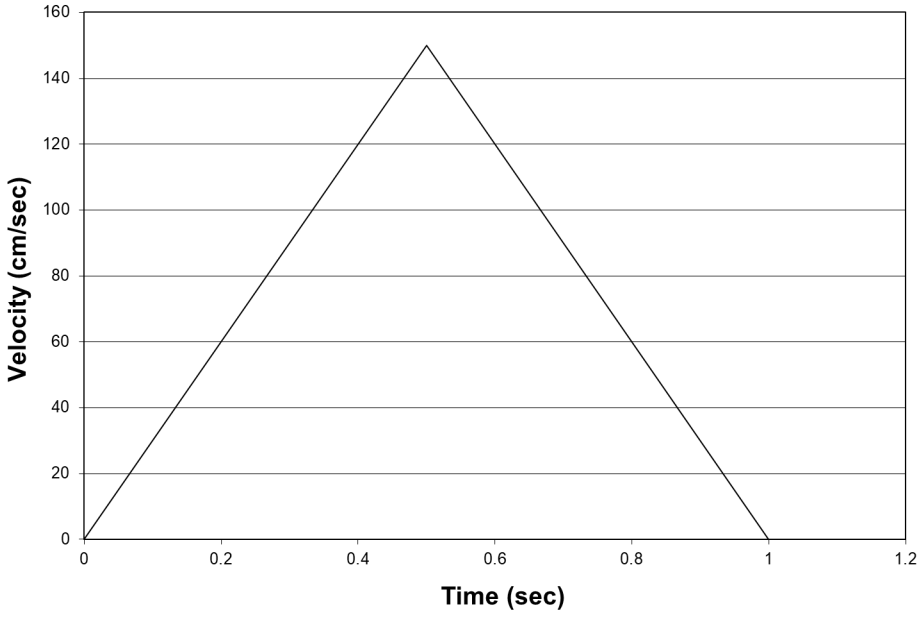
Sine Wave, 200 cm/sec



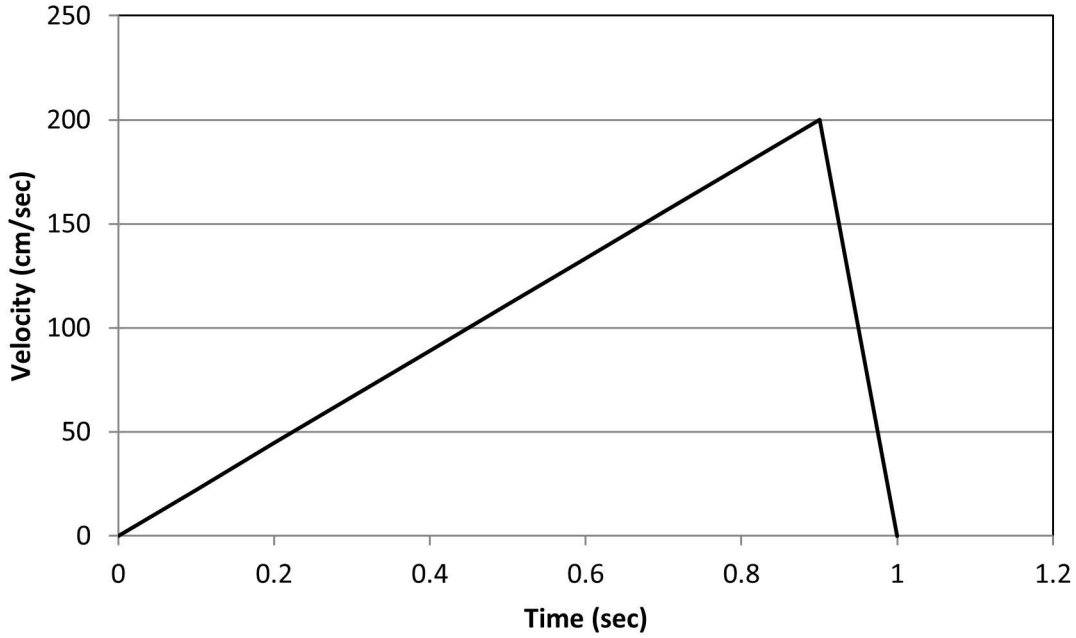
Triangle Wave, 100 cm/sec



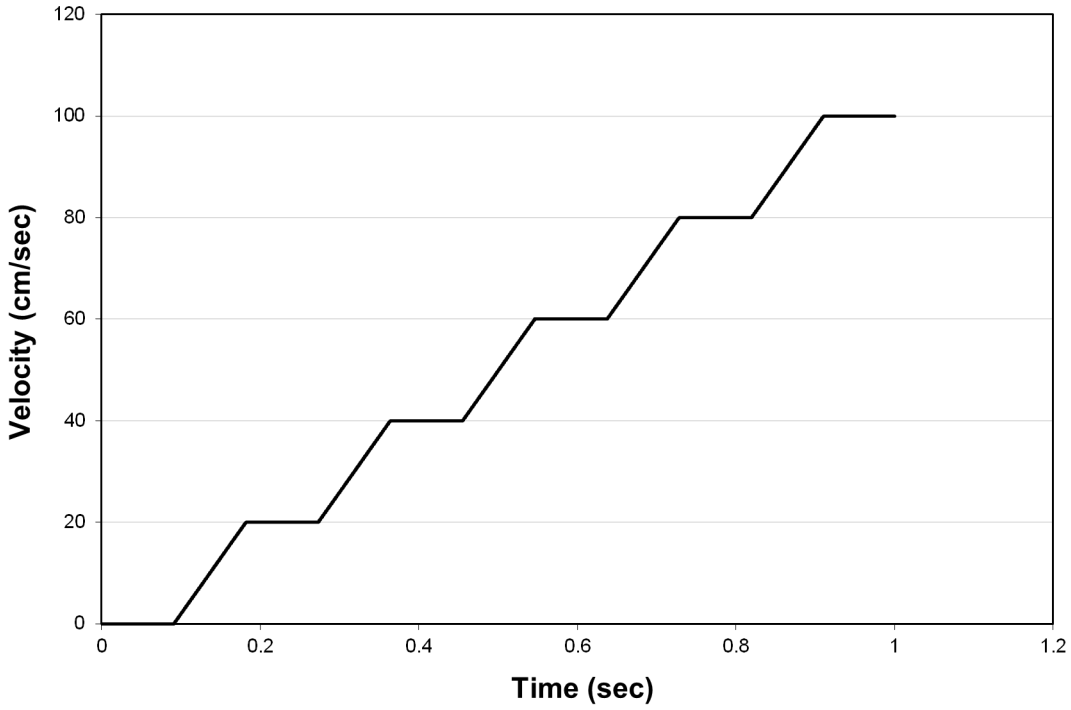
Triangle Wave, 150 cm/sec



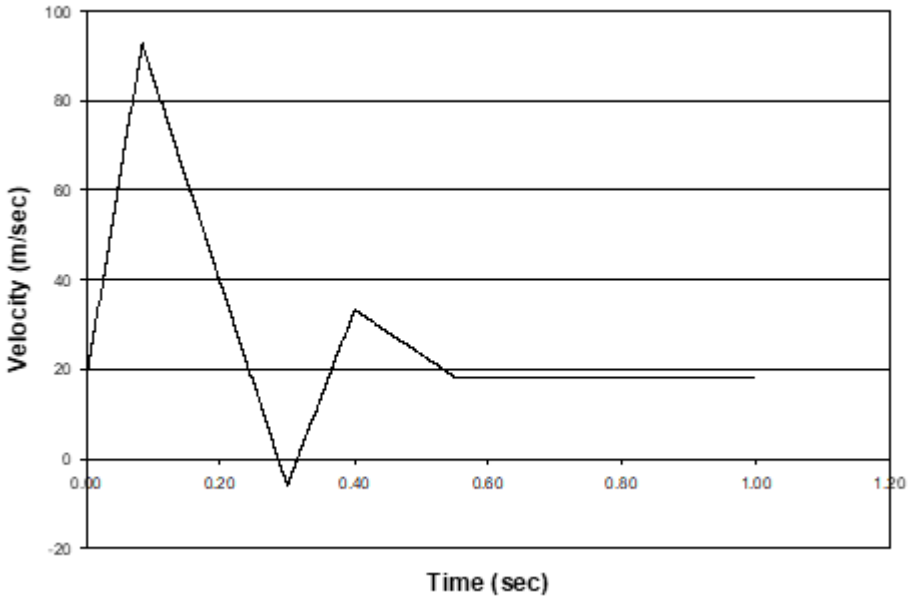
Triangle Wave, 200 cm/sec



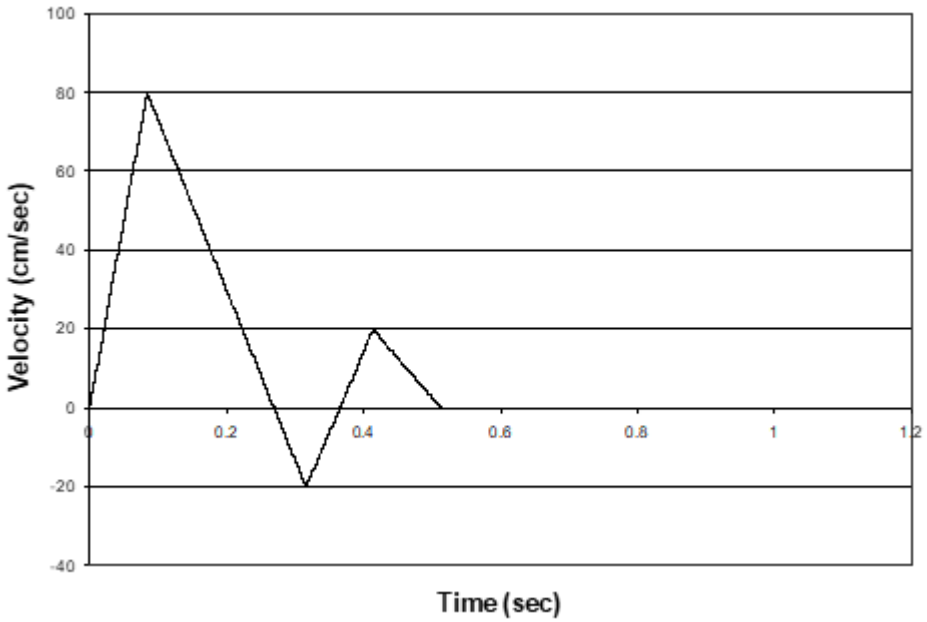
Stepped Ramp



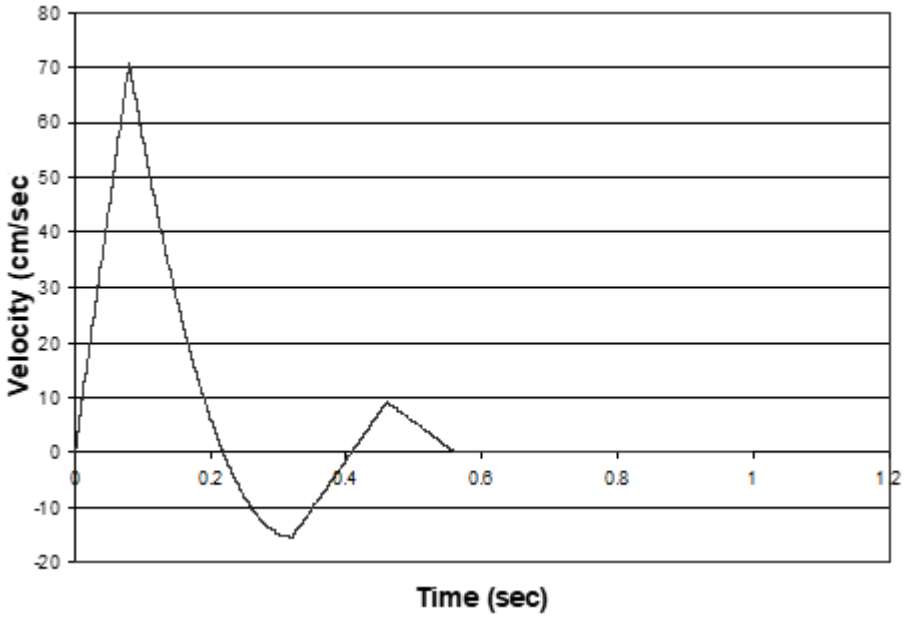
Adult Common Carotid



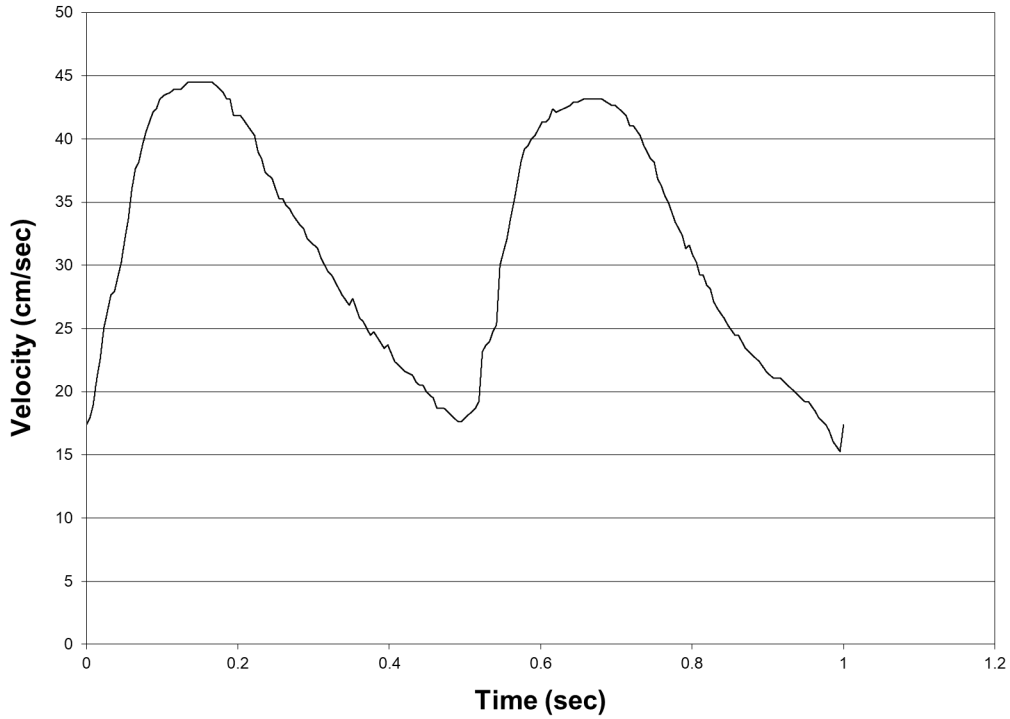
Adult Aortic



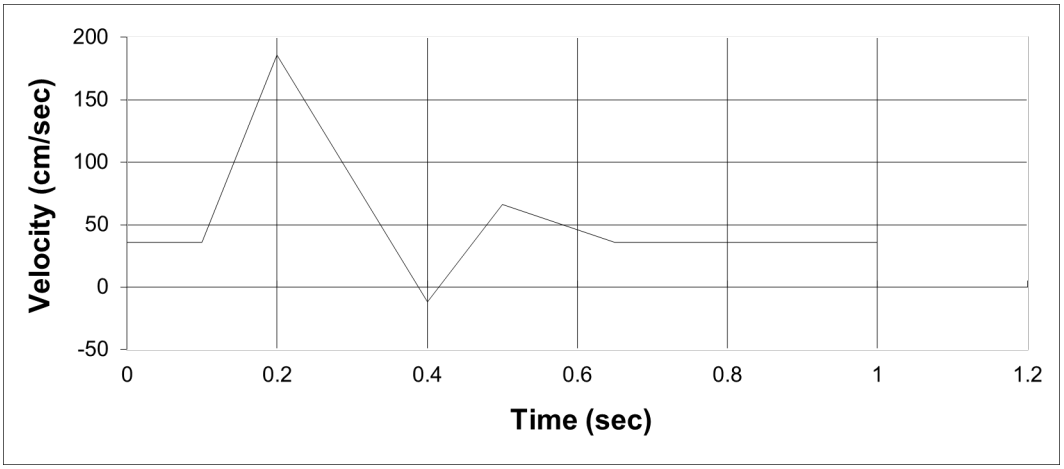
Adult Femoral



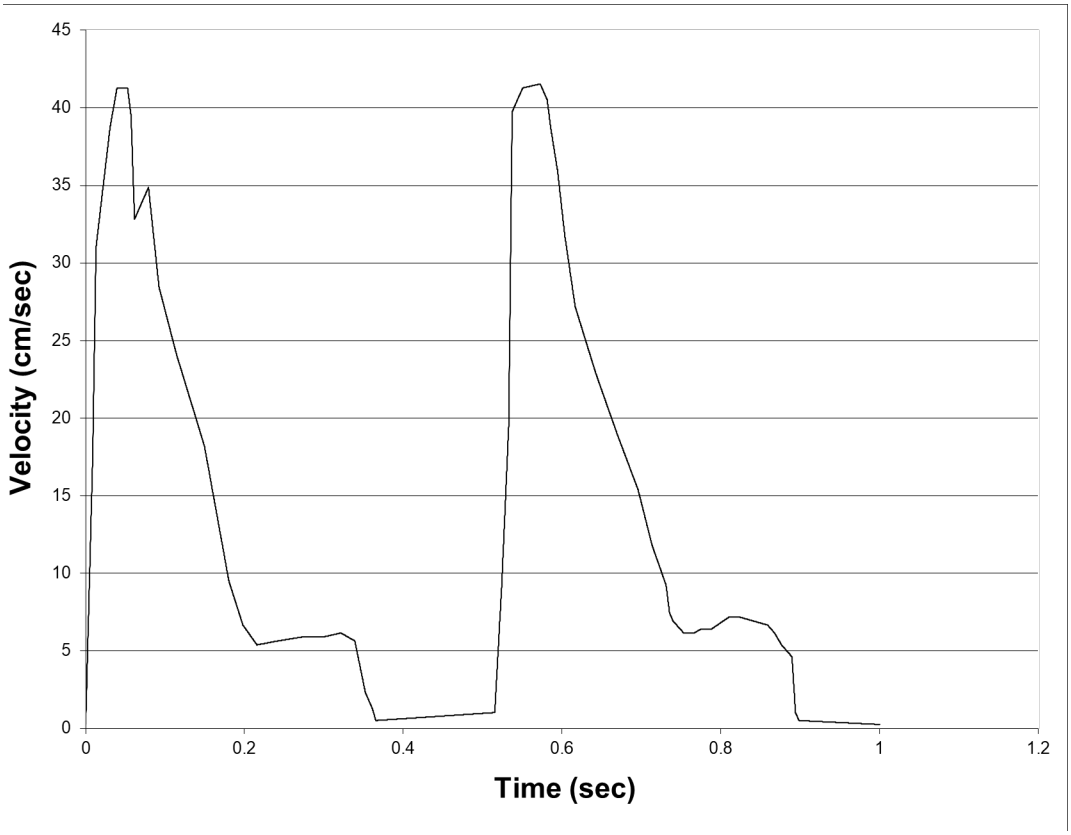
Pediatric Umbilical



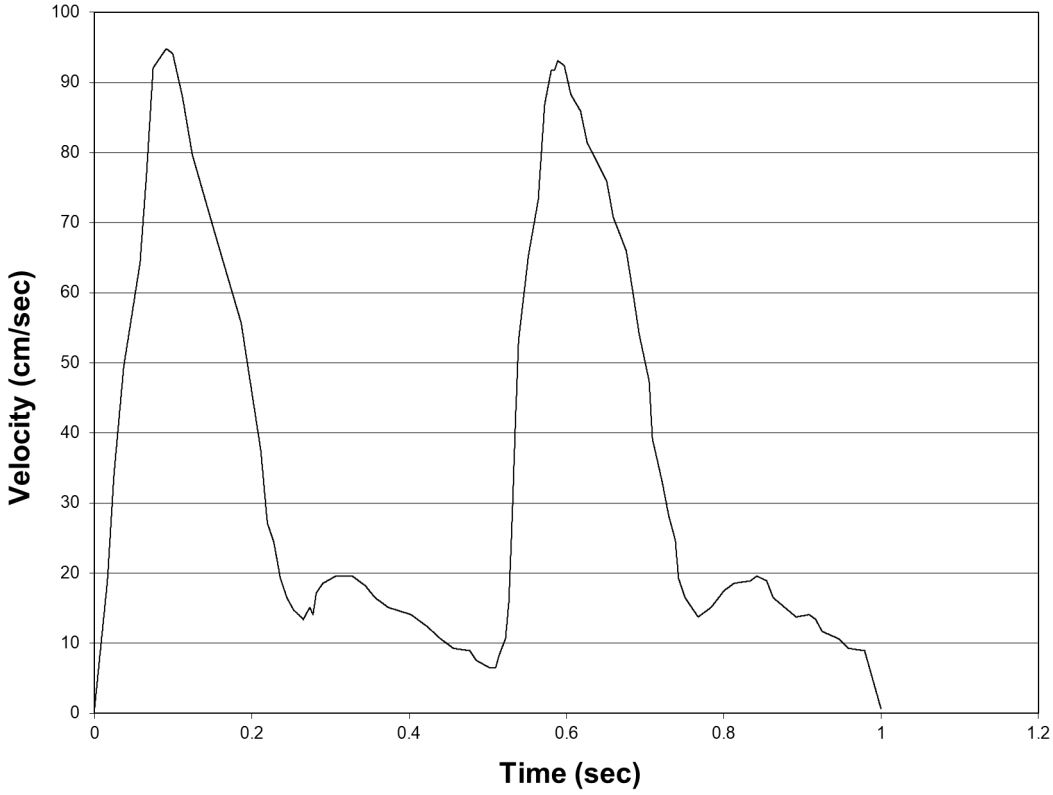
Stenotic Common Carotid



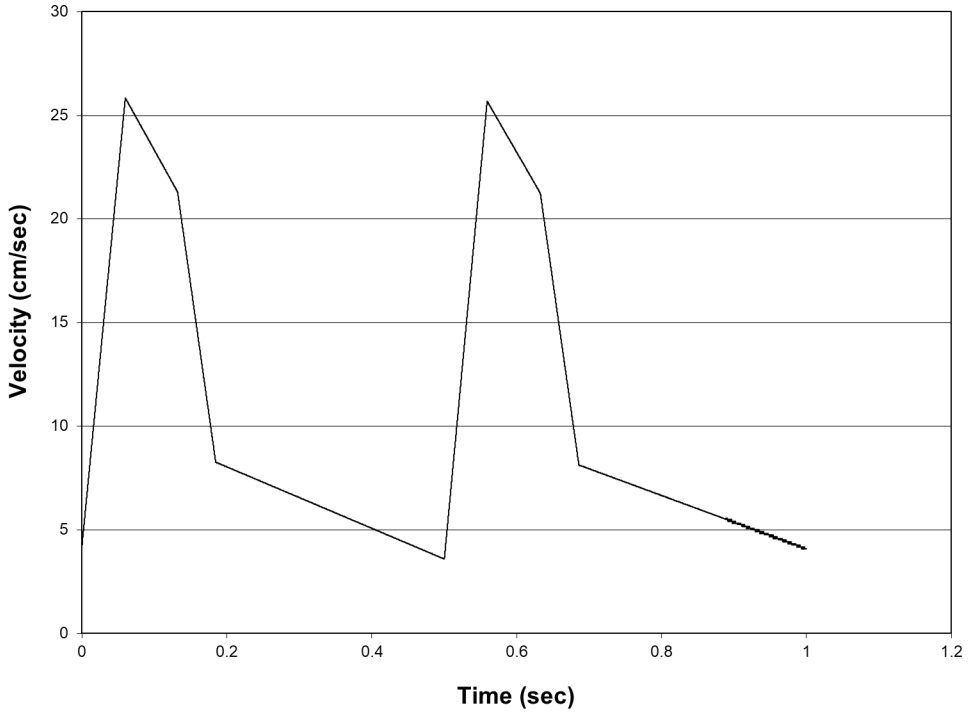
Pediatric Renal



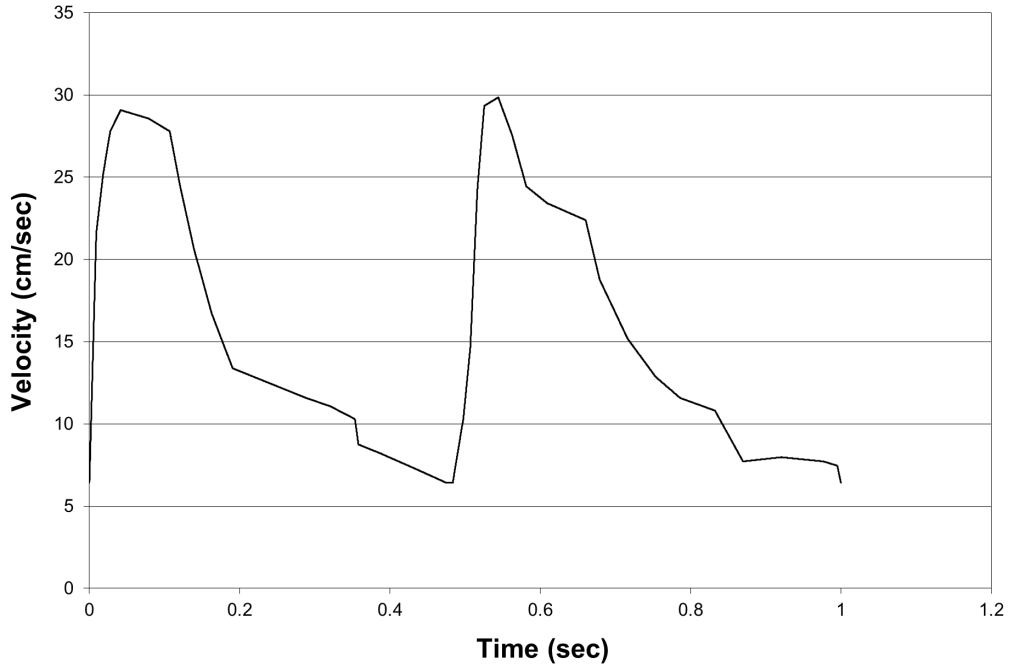
Pediatric Ductus Arteriosus



Pediatric Middle Cerebral



Pediatric Descending Thoracic



This page is intentionally left blank.

Appendix B: QA Form

(Example Page)

Doppler Mode Inspection

System Model _____ Serial #_____Probe Type_____

Sample Volume Registration (to string target)

√ = on target, or enter ± mm

√	√	√	√						

Date: 1/08 4/08 7/08 10/08

Color Registration (to string target)

√ = on target, or enter ± mm

√	√	√	√						

Date: 1/08 4/08 7/08 10/08

Directional Discrimination

Color	√	√	√	√						
Spectral	√	√	√	√						
audio	√	√	√	√						

Date: 1/08 4/08 7/08 10/08

Doppler Velocity Accuracy

(Continuous speed, angle corrected at 60 degrees to string target.)

√ = in spec, or enter velocity observed in cm/sec

200	√	√	√	19						
150	√	√	√	14						
100	√	√	√	√						
60	√	√	√	58						
30	√	√	√	√						

Date: 1/08 4/08 7/08 10/08

Doppler Velocity Accuracy

(Continuous speed, angle corrected at 45 degrees to string target.)

√ = in spec, or enter velocity observed in cm/sec

200	√	√	√	20						
150	√	√	√	15						
100	√	√	√	√						
60	√	√	√	62						
30	√	√	√	√						

Date: 1/08 4/08 7/08 10/08

Note: *This page may be reproduced for customer use.*

Doppler Mode Inspection

System Model _____ Serial #_____Probe Type_____

Sample Volume Registration (to string target)

√ = on target, or enter ± mm

Date: 1/08 4/08 7/08 10/08

Color Registration (to string target)

√ = on target, or enter ± mm

Date:

Directional Discrimination

Color										
Spectral										
audio										

Doppler Velocity Accuracy

(Continuous speed, angle corrected at 60 degrees to string target.)

√ = in spec, or enter velocity observed in cm/sec

200										
150										
100										
60										
30										

Doppler Velocity Accuracy

(Continuous speed, angle corrected at 45 degrees to string target.)

√ = in spec, or enter velocity observed in cm/sec

200										
150										
100										
60										
30										

Date:

Appendix C: Regulatory Supplement

Note: *Velocities on the device are precisely calibrated, but 1-second periods are approximate.*

Symbols

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

WARNING: This symbol indicates a risk of electric shock. (EN ISO 7010, W012)

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

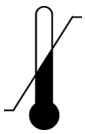
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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)

This symbol indicates a general mandatory action. (EN ISO 7010, M001)

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator of the device bears the full responsibility for validating measurement results.

Reporting Health or Safety Related Issues or Concerns

Should the need arise to report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

CIRS
900 Asbury Ave
Norfolk, VA 23513 USA
+1-321-259-6862

European customers, contact Sun Nuclear's Authorized European Representative.

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Swiss customers, contact Sun Nuclear's Authorized Swiss Representative.

MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau
Switzerland

Australian customers, contact Sun Nuclear's Australian Sponsor:

alphaXRT Pty. Ltd.
Suite 1.15, Level 1, 90-96 Bourke Road
Alexandria NSW 2015
Australia

Brazilian customers, contact Sun Nuclear's Brazilian Sponsor:

Vera Rosas
VR Medical Importadora e Distribuidora de Produtos Medicos Ltda
Rua Batataes, 376 - Jardim Paulista
Sao Paulo - SP
01423-010, Brasil

Modifications to Equipment

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

+1 321 259 6862 // **sunnuclear.com**
Sun Nuclear Corporation, 3275 Suntree Boulevard, Melbourne, FL 32940 USA

SUN NUCLEAR
A MIRION MEDICAL COMPANY