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The Nickel ™
Ultrasound Probe and System Testing Device

Operator's Manual

Table of Contents

User Responsibilities

Users are assumed to have at least a basic technical and operational knowledge of ultrasonic systems, probes and the fundamentals of electronics in addition to the knowledge of the proper use and precautions associated with battery-operated devices. Users will be responsible for reading and following the instructions provided within this manual. Users will also be responsible for exercising all safety precautions recommended in the Nickel Operator's Manual and the product labeling included therein.

If you have any questions, please call 303-682-5871, toll-free in the United States and Canada at 1-888-476-6672, or send e-mail to the Test Instruments Division at tid@4sonora.com.

General Warnings

1. Do not operate the Nickel if the unit has been submerged in water or any other liquid. Call Sonora Medical Systems to arrange for servicing.

2. Shock Hazard –There is no shock hazard associated with this device.

3. Service - Do not attempt to service the Nickel beyond replacing batteries. There are no serviceable parts inside. Opening the body of the Nickel will void the warranty.

4. Only AAA batteries may be used. Batteries are replaceable by the Operator. Use of rechargeable batteries (NiCad or NiMh) is not recommended. The lower voltage out from these batteries is insufficient to adequately power the Nickel. Dispose of batteries properly per local regulations.

5. Potential contamination – Do not use the Nickel to test transducers that have not been properly cleaned and/or disinfected prior to use. Follow the transducer manufacturer's recommendations for cleaning the transducer.

6. The safety and/or functionality of the Nickel may be impaired if used in a manner not specified herein.

Safety & Regulatory Standards

The Nickel is marketed on a worldwide basis and complies with applicable safety and electromagnetic compatibility (EMC) standards imposed by the USA and EC (EU) including:

- General product safety, Directive 2001/95/EC of the European Parliament and of the Council
- EMC, Directive89/336/EEC amended by Directives 91/263, 92/31/EEC and 93/68/EEC
- EN 61326:1997 –– EMC requirements -Electrical equipment for measurement, control and laboratory use - EMC requirements

Note: The Nickel is not a "medical device" as defined by the United States Food and Drug Administration (FDA). Therefore, no 510(k) is required to market this product in the United States.

Notice: Multiple U.S. and International Patents are pending on this device

Product Description

The Nickel is an easy to use ultrasound acoustic performance-testing tool for transducers as well as for various modalities and functions within the systems. The Nickel provides assurance to the operator with instant feedback from the LED (light emitting diode) housed within the on/off switch of the device that, in fact, all of the elements within the array of a probe are transmitting an acceptable acoustic pulse. If a sufficiently strong transmitted acoustic pulse is present, the Nickel receives that pulse from an element thereby turning the LED to a non-red color. The color is frame rate dependent; with a low frame rate it will blink slowly and may appear as an orange or amber color, with a high frame rate the LED may be steady-state green. The Nickel then processes the pulse, inputting a simulated echo into that same element. This multi-frequency simulated echo is then processed by the ultrasound system and displayed on the monitor within the image field as shown by example in **Photo 1** or in the Doppler trace as shown by example in **Photo 2**. This displayed input signal provides the user with the assurance that all signals received by the transducer are being processed and displayed. The absence of a detected or displayed signal indicates the need for further testing and possible repairs to either the probe or the system. If the LED is red when it should be turning a non-red color, it may indicate a dead or weak element within the array. It may also be due to a broken wire in the probe cable, a broken or bent pin in the probe connector, or an electronic component problem within the probe connector. The absence of a signal may also indicate the lack of a transmit signal from the ultrasound system itself, due to a defective transmit channel or the failure of other front-end electronic components.

The Nickel is not designed to be a calibration tool. It is an indicator of the overall functional health of both the probe and the various major electronic segments of the ultrasound system that define the performance of the various modes of operation (e.g., B-Mode, Doppler, Color Flow and M-Mode). The simulated echo signal that is inputted into the transducer from the Nickel also allows the testing of some special functions within any given ultrasound system, for example algorithms used for spatial compounding, second harmonic imaging, various pseudo-color displays and dynamic focusing.

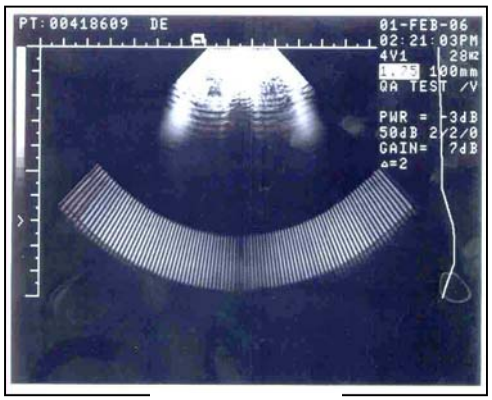


Photo 1

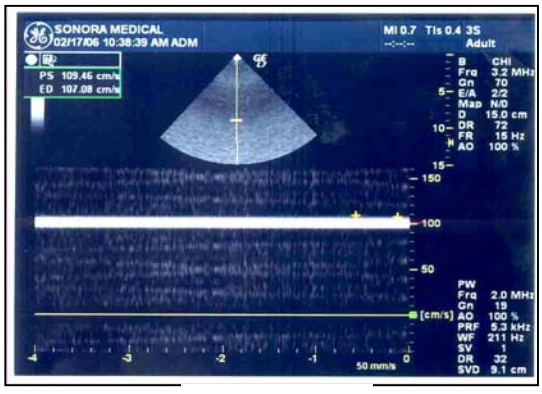


Photo 2

Getting Started

Open and read the “Read Me First” file that is on the USB flash drive (memory stick) supplied with the Nickel. This file contains miscellaneous important information relative to the operation and care of the Nickel. In addition to the Operator’s Manual, you may want to access the Nickel website (www.sonora-nickel.com) for video instructions showing the proper basic operation of the Nickel and how to set-up the ultrasound system to prepare for testing.

The Nickel shipping box contains the USB flash drive, 2 AAA batteries and the Nickel device itself. If you purchased the optional Keepsake Box, the two AAA batteries included with the Nickel are stored underneath the foam tray in the shipping box. To remove the batteries, first remove the Nickel from the tray then lift the pull-tab shown in **Figure 1**.

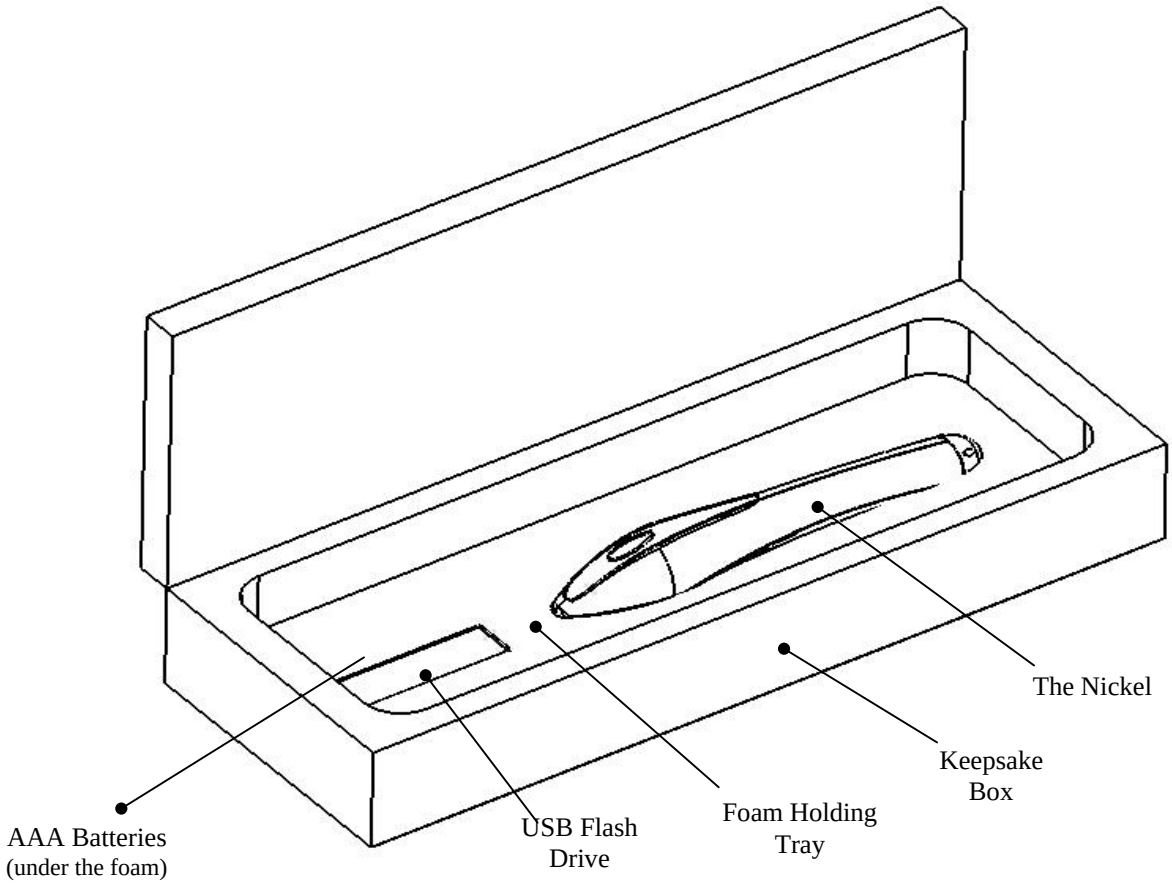


Figure 1

Inserting and Removing the Batteries

Two AAA size batteries are used to power the Nickel. To insert the batteries unscrew the battery compartment cover (see **Figure 2** below). Place the first battery into the battery compartment positive end (+) first followed by the second battery, also positive end (+) first. Screw the battery compartment cover back into place. Press the On/Off switch and hold it down. A green light should emit from the LED briefly, followed by a steady state red light. If no light is emitted, unscrew the cover and check the polarity placement of the batteries. If there is still no light, try new batteries. If there is still no light, contact the Nickel Help Desk at Sonora Medical Systems; 303-682-5871 or toll free at 1-888-476-6672.

- Note: Remember re-chargeable batteries are not recommended for use -

If the LED responds as noted above, then you are ready to run the Nickel.

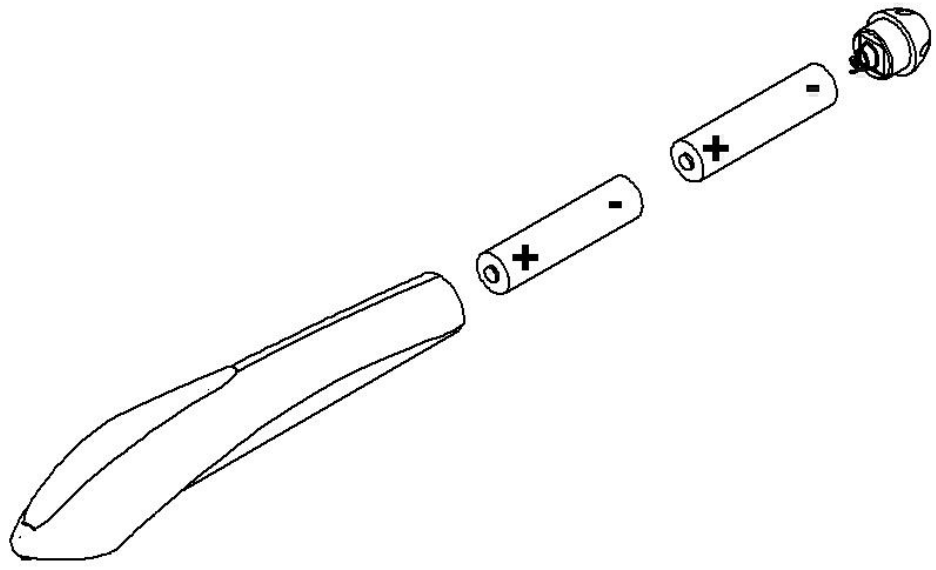


Figure 2

Components of The Nickel:

As shown in **Figure 3** below there are four main components to the Nickel device:

(1) The PVDF transducer
(2) The LED
(3) The On/Off switch
(4) The AAA battery compartment

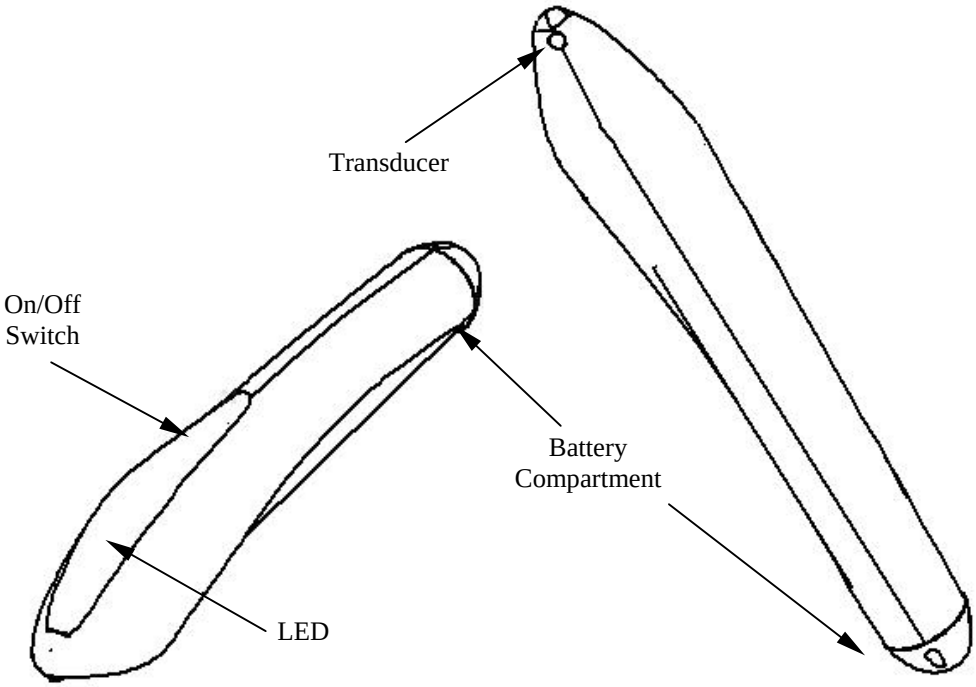


Figure 3

Using the Nickel to Check a Probe

Please read the following and/or go to the Nickel website (www.sonora-nickel.com) for video instructions on how to use the Nickel. When using the Nickel to test the performance of a transducer (also referred to as a probe or scanhead), please observe the following:

- When you first press down the On/Off switch the LED will turn green, then quickly flash to a steady-state red. This is the Nickel self-test. If the green light doesn't flash, refer to the Nickel Troubleshooting and FAQ section of this manual.
- **Do not use any acoustic coupling gels or any other liquids or materials between the transducer lens and the Nickel transducer. No coupling media are required for proper use of the Nickel.**
- When scanning the Nickel across the aperture of the transducer (probe) under test make sure you keep the On/Off switch depressed and apply light pressure to ensure good contact between the Nickel transducer and the probe under test. Move the Nickel very slowly across the array; depending on the array type, finding an individual non-transmitting element can require patience. Always start the test in the middle of the array and move to one side. Then put the Nickel back to the middle of the array and then move to the other side. **Caution: Applying a great deal of force on the Nickel may damage the lens – use a light touch, just enough to cause the LED to go from red to a non-red color and to see a signal on the system monitor.**
- Proper alignment of the Nickel transducer to the transducer under test is vitally important for a good test. The Nickel transducer should be parallel with the elements within the array under test and angled in such a manner as to be in full contact with the face of the array. **SEE FIGURE 4**
- As the Nickel receives an adequate signal from an element within the array under test the LED will go from red to a non-red color (e.g., with low frame rates the LED may appear to be a pulsating amber or orange color, with high frame rates it may be a steady green color). If no signal or a weak signal is received from an element, the LED will remain steady-state red.

- Make sure the probe is attached to the ultrasound system and that the transducer is active. Make sure that the system freeze button is not engaged, as the system does not transmit a signal to the probe when the freeze button is depressed. Make sure that you are only in B-mode (no multiple modes at this point).
- Start with the Nickel in the middle of the array under test. Scan the probe from the middle of the array to one side to ensure the elements in that half of the array are working. Do not worry about looking at the system monitor during probe testing but focus on the Nickel LED. Next move back to the middle of the array and scan slowly to the other side of the probe under test. **Remember to move the Nickel very slowly across the array, be patient and maintain proper alignment between the Nickel transducer and the probe under test**. **The key to successfully using the Nickel is practice.**
- After ensuring the elements within the array are functional, scan back across the array and observe the ultrasound system monitor for display of the input signal from the Nickel. The procedure for doing this is outlined on the next page, as well as being demonstrated on the instructional video on our website.

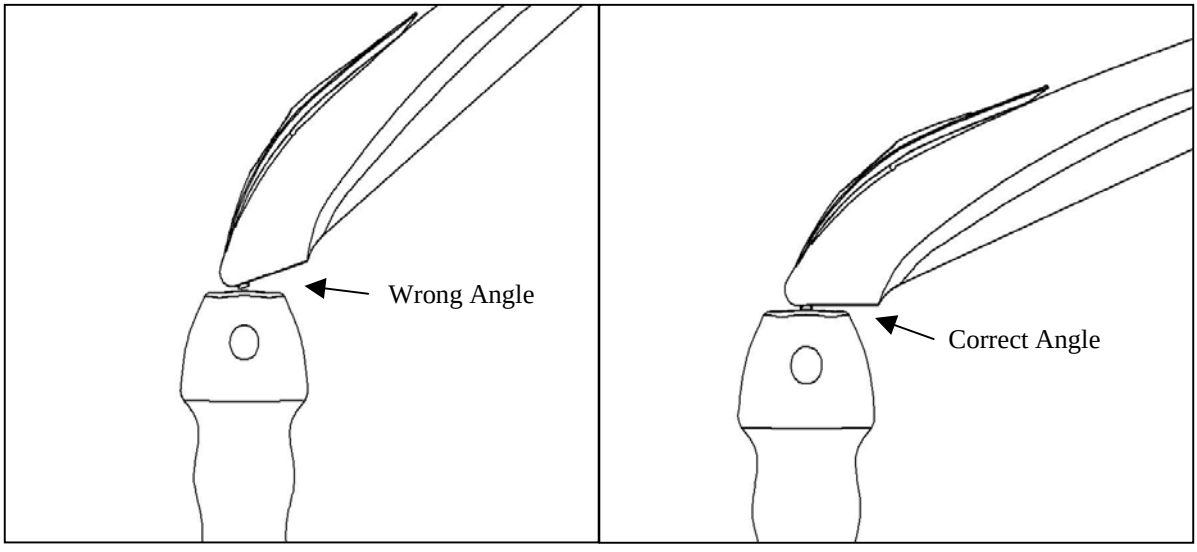


Figure 4

Using the Nickel to Check the Ultrasound System: B-Mode

Please read the following on how to use the Nickel for checking B-mode ultrasound system performance, and/or refer to www.sonora-nickel.com for a demonstration. When using the Nickel to test the performance of the B-mode of the system, please observe the following:

- Set the overall B-mode depth to at least 7cm, to 12cm with lower frequency probes.
- Select a single focal zone (do not use multiple focal zones as it may introduce electronic switching artifact in the image). Set the focal zone caret at roughly 6cm depth.
- Ensure all special image-processing functions such as 2nd harmonic imaging and spatial compounding (e.g., SonoCT™ by Philips) are disabled.
- Set the overall system B-mode gain to mid-range.
- Set all TGC slide pots to maximum.
- Set the Acoustic Output Power to maximum (maximum MI on the system monitor).
- Make sure the system freeze button is not depressed.
- Select the probe to test and activate that probe from the system.
- Place the Nickel on the center of the aperture of the active probe under test (as shown in Figure 4), obtain a good signal and then slowly scan across the face of the transducer while keeping the On/Off switch on the Nickel depressed and maintaining light and consistent pressure.
- Observe the signal being displayed on the monitor as you move the Nickel across the array. A phased array probe will show the Nickel signal across most of the sector display (all elements are fired with a phased array), while a linear or curved array will only display the Nickel signal within the active aperture.
- Image dropout may indicate a failure in the front-end electronics of the ultrasound system. Make sure that you first test the probe as outlined on Page 8 to ensure its proper operation. If image dropout is observed, focus your efforts on that area of the array where the signal is dropping-out to confirm the Nickel input signal is good (LED is Green). If the Nickel input signal is good and there is a dropout in the display, this points to probable faults in the front-end (scanner) electronics such as receivers.

➢ **Remember the three P's: patience, practice and proper pressure**

Using the Nickel to Check the Ultrasound System: Doppler

Please read the following on how to use the Nickel for checking PW Doppler mode ultrasound system performance, and/or refer to www.sonora-nickel.com for a demonstration. Also, see the Appendix for system specific set-up instructions. When using the Nickel to test the performance of the PW Doppler mode of the ultrasound system, please observe the following:

- Reduce the PW Doppler sample cell size to minimum (usually 1mm on most systems).
- Place the PW Doppler radial line cursor in the middle of the sector or linear display.
- Place the sample cell within the Nickel signal band as shown in the B-mode.
- Place the PW Doppler zero velocity line (also referred to as the baseline in some systems) so that the majority of the velocity scale is shown in the positive direction yet still showing one major increment of negative scale (see **Photo 3**).
- Set the PW Doppler Pulse Repetition Frequency (PRF) from ~ 5.3kHz to 6.5kHz depending on the system you are using.
- Set the Doppler wall filter to ~ 200Hz (again system dependent).
- Set the PW Doppler gain just to the point where you can see speckle noise in the display.
- Set the audio level to mid-range.
- Make sure the B-mode refresh function is not active (i.e., the B-mode image is frozen).
- Place the Nickel in the middle of the aperture and acquire a transmit signal.
- The Nickel Doppler signal should appear in the 30cm/sec to 1.2m/sec range depending on probe frequency (Doppler frequency), and be audible.

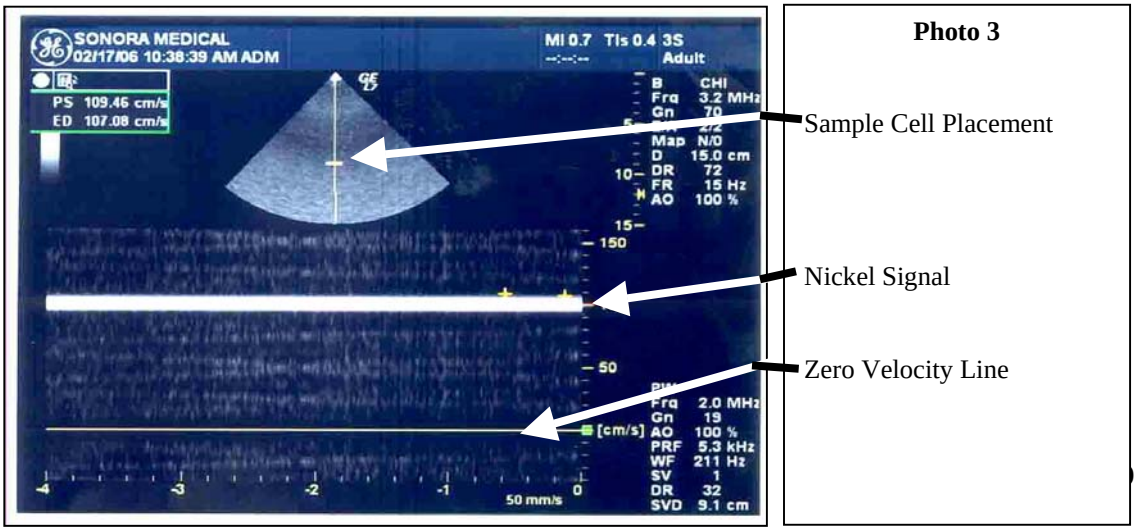


Photo 3

Check the Ultrasound System: Color Flow

Please read the following on how to use the Nickel for checking Color Doppler mode ultrasound system performance, and/or refer to www.sonora-nickel.com for a demonstration. When using the Nickel to test the performance of the Color Flow mode of the system, please observe the following:

- Place the color flow ROI (region of interest) within the middle of the Nickel B-mode image band (see **Photo 4**).
- Select any of the normal color flow display algorithms and use a relatively high PRF setting.
- Set the color flow gain just to the point where color flow noise speckle is seen with the ROI.
- Make sure the acoustic power output (transmit power) is at maximum.
- Place the Nickel in the center of the probe aperture and acquire signal.
- Observe the color flow signal being illuminated within the ROI.

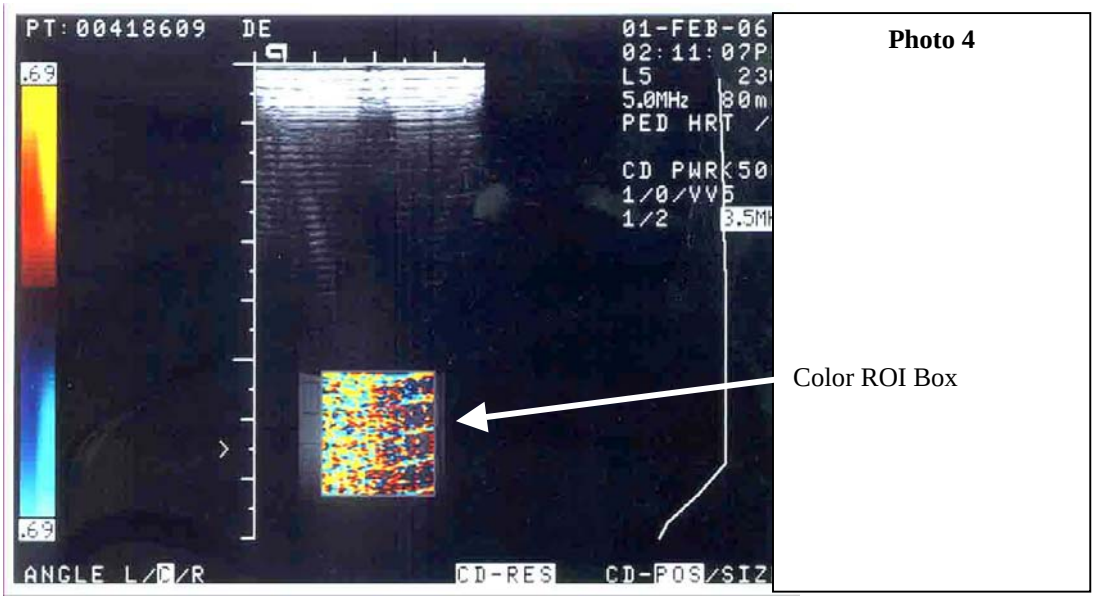


Photo 4

Nickel Specifications

- Tests all brands of electronic array transducers
- Broadband PVDF transducer
- Transmit and Receive function
- Light Emitting Diode (LED) indicator displaying red, various red-green combination colors and steady state or pulsating green
- Single push button operation
- Battery operated using two AAA batteries (**non-rechargeable type**)
- Operational battery life more than 10 hours of continuous operation
- Rugged housing
- Self-test indicator
- 12-month warranty (excludes failure to operate properly or physical abuse)

FAQ and Nickel Troubleshooting

Problem: While attempting to use the Nickel, the LED does not illuminate.

Replace the AAA batteries. If properly installed new AAA batteries do not correct the problem, contact the Nickel Help Desk.

Problem: When initially starting the Nickel the green LED no longer comes on.

Contact the Nickel Help Desk.

Problem: During the probe test, the LED stays red even though I know some of the elements must be good.

Replace the batteries. If this does not correct the problem, contact the Nickel Help Desk.

Question: Can rechargeable batteries be used in the Nickel?

No. Do not use rechargeable batteries as they produce insufficient voltage required by the Nickel for proper operation.

Question: Do I use acoustic coupling gel when using the Nickel?

Do not use any coupling media when using the Nickel

Question: Can I use the Nickel on any manufacturer's system and probe combination?

The Nickel will respond to the acoustic pulse from any probe provided that the probe has sufficient output. Most diagnostic ultrasound systems sold provide this level of output.

Question: Can I test the CW (continuous wave) Doppler function on my ultrasound system?

The Nickel's simulated echo input does not allow for testing CW Doppler.

Nickel Maintenance and Calibration

Cleaning

The outside case of the Nickel may be wiped with a damp (not wet) cloth to remove dust and dirt. Polish with a dry cloth. Do not use polishing agents, as they may penetrate the device and cause component failures.

Calibration

Your Nickel does not require calibration.

Battery Life

You can expect at least 10 hours of continuous operation from good quality AAA batteries such as supplied with the device.

Proper Storage

The Nickel should not be exposed to extreme cold (less than 32° F/ 0° C) or heat (more than 120° / 50° C). If exposed to a large and sudden change in temperature, such as being brought in from a freezing automobile into a heated building, it should not be used until the Nickel has reached the ambient temperature. It is recommended that the Nickel be stored in a protective case when it is not in use.

Service and Technical Support

For service and technical support contact the Nickel Service Support Help Desk in the Test Instruments Division of Sonora Medical Systems.
Phone: 303-682-5871 or 888-476-6672, and ask for Nickel Service Support
Fax: 303-682-5915, and mark to attention of Nickel Service Support
E-mail: tid@4sonora.com

Nickel Part Numbers

Part #	Description
10616	Nickel Unit
10597	Keepsake Storage Box (Optional)
10637	USB Flash Drive with User Manual
10596	AAA Battery

Accessories

	Coming Soon

To order Nickel parts, please call 1-888-476-6672 or 303-682-5871 for information.

You may also fax your request to 303-682-5915 or email sales@4sonora.com.

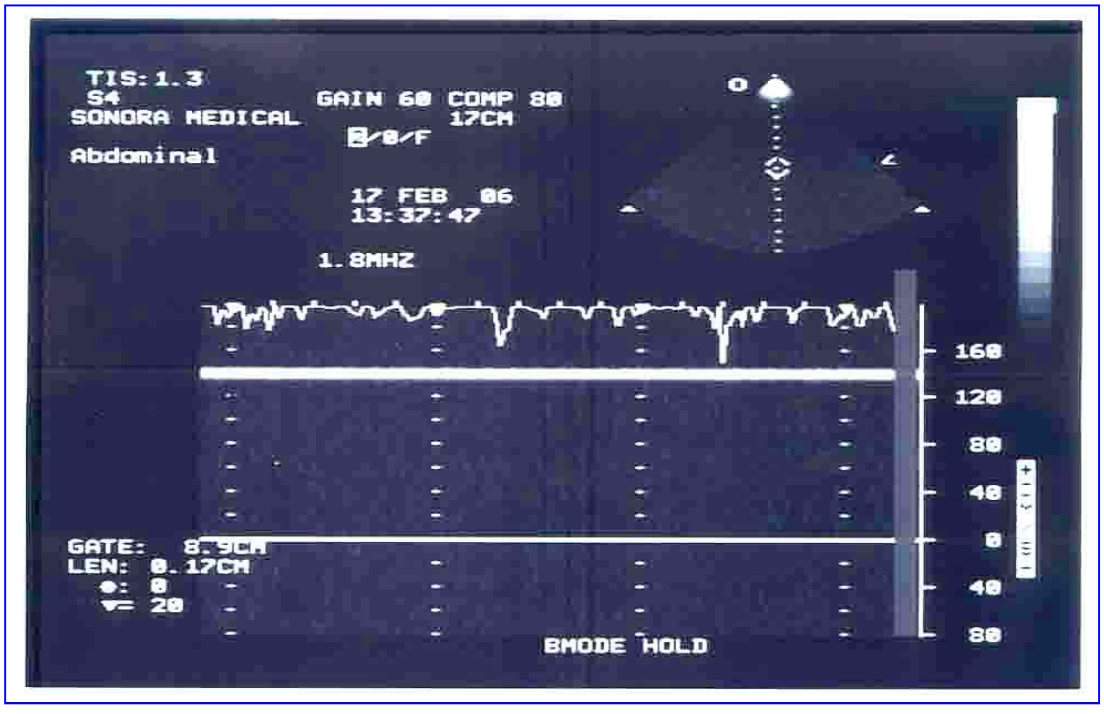
Appendix – Getting Started with Pulsed Doppler

Basic Operational Set-up Sheet
System(s): Philips Sonos 4500, 5500 & 7500
Pulsed Wave (PW) Doppler

Probe: s3 (21311A) or s4 (21330A) Phased Array

System Set-up:

- Cardiac Application
- AO @ 100% (acoustic output)
- Gain @ 75%
- PRF – Not displayed on Sonos Systems
- Doppler Frequency @ 1.8MHz
- SV size at 1.7mm (sample volume)
- SV depth @ ~ 9.0cm
- B-mode image must be in Fundamental frequency (Fusion 1)
- WF @ 200Hz (wall filter)
- B-mode depth @ 17cm and B-mode image not being refreshed (BMODE HOLD)
- Baseline (zero velocity line) set so that –80cm/sec shows below baseline and 160cm/sec shows above baseline as shown below

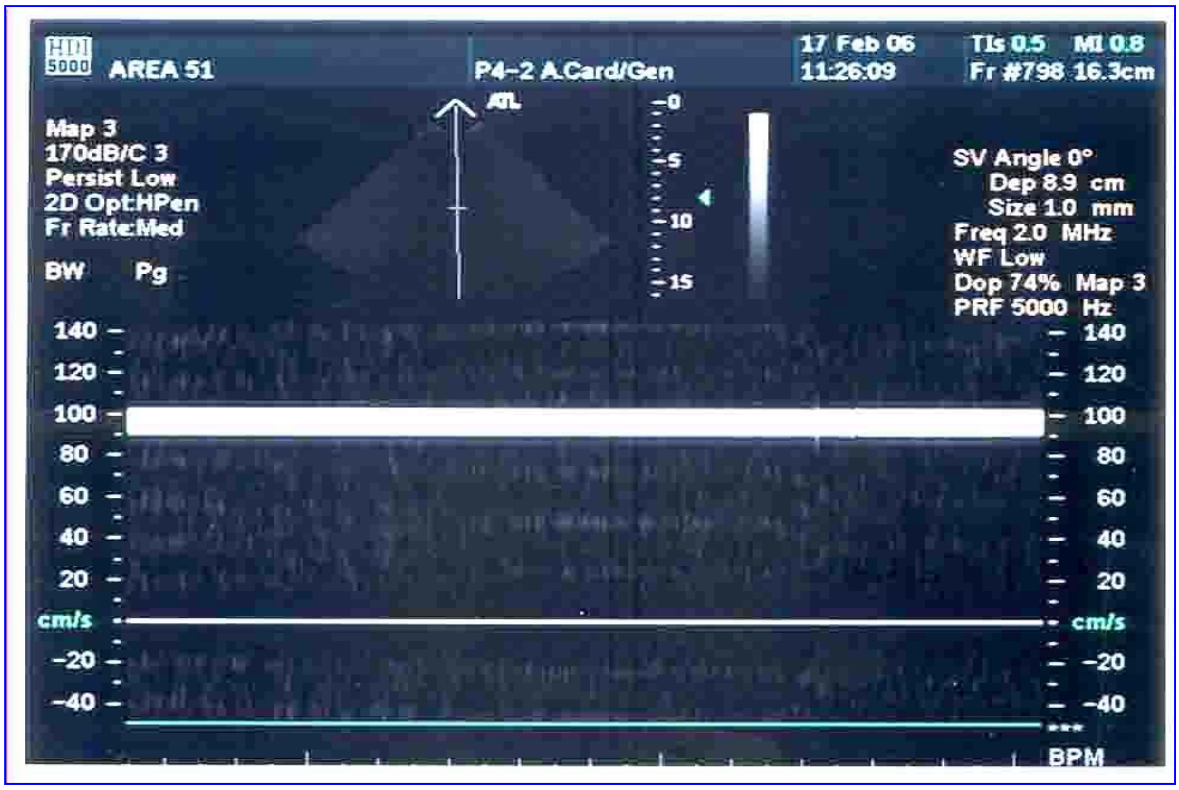


Basic Operational Set-up Sheet
System(s): Philips HDI 5000
Pulsed Wave (PW) Doppler

Probe: P4-2 Phased Array

System Set-up:

- General Adult Cardiac Application
- AO @ 100% (acoustic output)
- Gain @ 74%
- PRF @ 5kHz
- Doppler Frequency @ 2.0MHz
- SV size at 1.0mm (sample volume)
- SV depth @ ~ 9.0cm
- B-mode image must be in Fundamental (non-Harmonic) frequency
- WF @ Low (wall filter)
- B-mode depth @ 16cm and B-mode image not being refreshed (frozen)
- Baseline (zero velocity line) set so that –40cm/sec shows below baseline and 140cm/sec shows above baseline as shown below

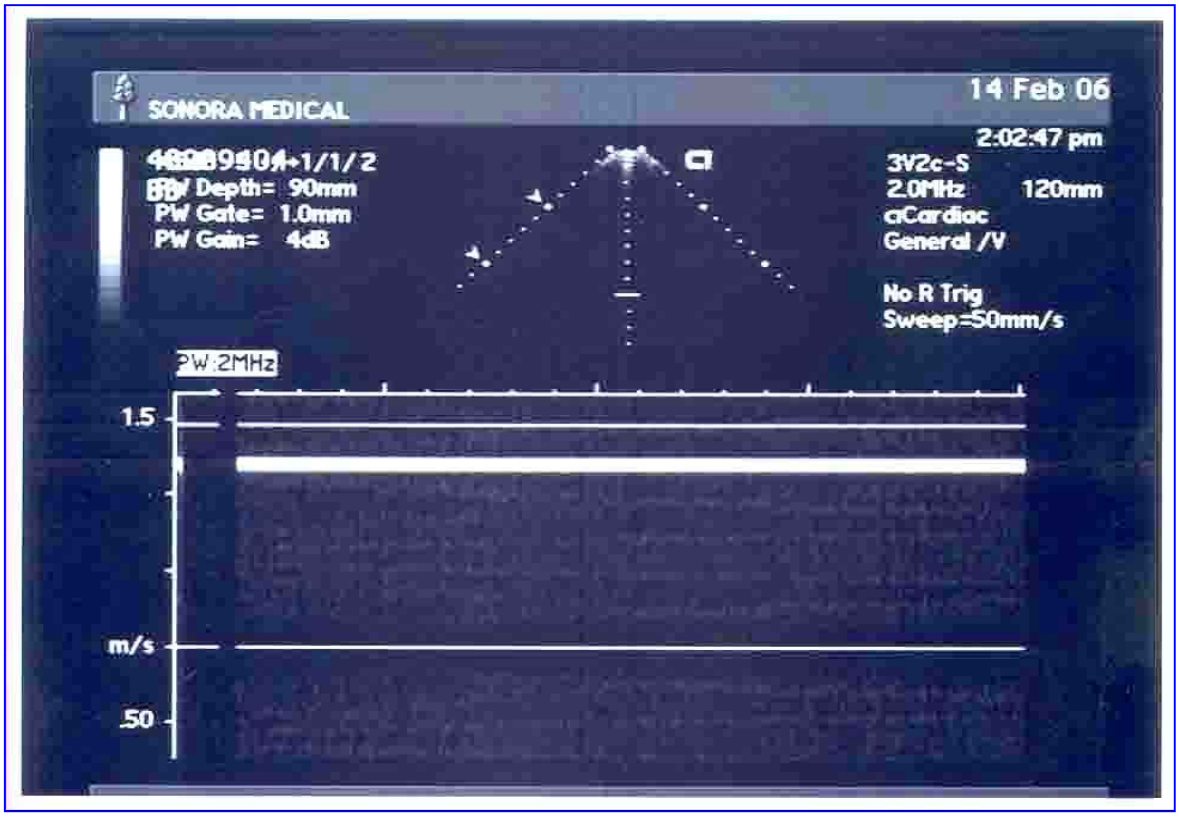


Basic Operational Set-up Sheet
System(s): Siemens/Acuson Sequoia
Pulsed Wave (PW) Doppler

Probe: 3V2c Phased Array

System Set-up:

- General Adult Cardiac Application
- AO @ 100% (acoustic output)
- Gain @ 4dB
- PRF - not displayed on Sequoia
- Doppler Frequency @ 2.0MHz
- SV size at 1.0mm (sample volume)
- SV depth @ ~ 9.0cm
- B-mode image must be in Fundamental (non-Harmonic) frequency
- WF @ Low (wall filter)
- B-mode depth @ 12cm and B-mode image not being refreshed (frozen)
- Baseline (zero velocity line) set so that –50cm/sec (.50) shows below baseline and 150cm/sec (1.5) shows above baseline as shown below

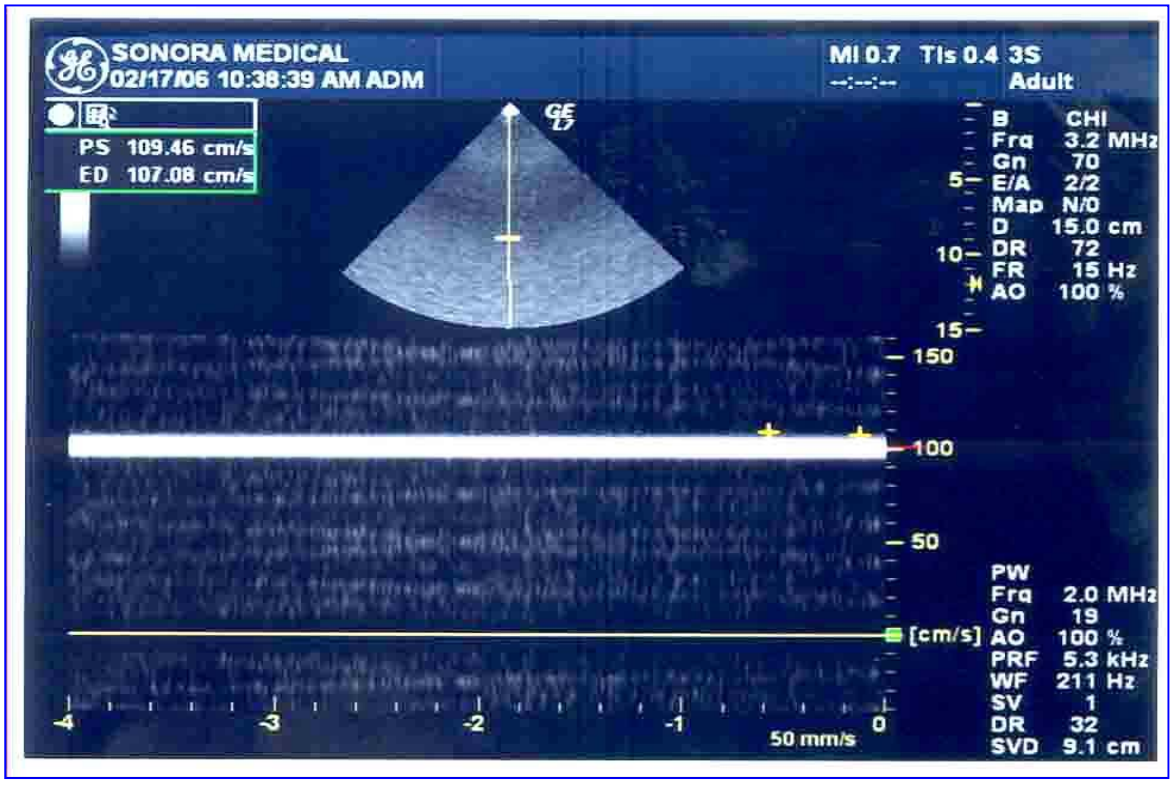


Basic Operational Set-up Sheet
System(s): GE Logiq 7 & 9
Pulsed Wave (PW) Doppler

Probe: 3S Phased Array

System Set-up:

- Cardiac Application
- AO @ 100% (acoustic output)
- GN @ 16 (gain)
- PRF @ 5.3kHz (pulse repetition freq)
- Doppler Frequency @ 2.0MHz
- SV size at 1.0mm (sample volume)
- SV depth @ 9.0cm
- DR @ 32 (dynamic range)
- WF @ 211Hz (wall filter)
- B-mode depth @ 15cm
- Baseline (zero velocity line) set so that –40cm/sec shows below baseline and 160cm/sec shows above baseline



Basic Operational Set-up Sheet
System(s): Philips iE33
Pulsed Wave (PW) Doppler

Probe: S5-1 Phased Array

System Set-up:

- General Adult Cardiac Application
- AO @ 100% (acoustic output)
- Gain @ 20%
- PRF – not shown on iE33
- Doppler Frequency @ 1.6MHz
- SV size at 1.0mm (sample volume)
- SV depth @ ~ 9.0cm
- B-mode image must be in Fundamental (non-Harmonic) frequency
- WF @ 150Hz (wall filter)
- B-mode depth @ 11cm and B-mode image not being refreshed (frozen)
- Baseline (zero velocity line) set so that –40cm/sec shows below baseline and 160cm/sec shows above baseline as shown below