DUAL-MODE AUSCULTATION USING THE A SCOPE[®] (NOISE-IMMUNE STETHOSCOPE)

USER MANUAL

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INDICATED USE

The Active Signal Technologies (Active Signal) A SCOPE[®], a dual-mode noiseimmune stethoscope, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of acoustic signals generated by physiologic activity in the body. In the presence of relatively mild ambient noise it is used in Acoustic Mode and functions as a passive electronic stethoscope to receive sounds produced by the heart, lungs, bowel and other internal organs. To retain audibility at higher background noise levels it can be switched to Doppler Mode where an audible tone corresponding to heart and lung activity is produced by the ultrasound frequency-shift caused by physiologic motion.

A SCOPE[®] can be used on any person undergoing a physical assessment. It is not intended to be used for diagnosis and treatment by unlicensed, untrained, or unqualified medical persons.

READ THIS FIRST

Users of A SCOPE[®] should familiarize themselves with all WARNINGS, CAUTIONS and NOTES before starting operation of this device.

"**Warning**" is the term for the words and graphics that alert the user to possible injury, death or other serious adverse reactions associated with the use or misuse of this device.

"**Caution**" is the term for the words and graphics that alert the user to possibility of a problem with the device associated with its use or misuse.

"Note" provides information to supplement the text.

The following Warnings, Cautions and Notes are in this User Manual:



CAUTION

The user must be aware that the patient's voice can be very loud when received through the A $SCOPE^{$ [®]} in Acoustic Mode.

WARNING

For use in high-noise environments, in-ear speakers [ear buds, such as military communications earplugs (CEPs)] are recommended in combination with good quality circum-aural hearing protectors or noise canceling headphones.

WARNING

Rapid gel application to the front face of the device can create a loud signal in the headset. Accordingly, when applying the gel turn down the volume temporarily or apply the gel slowly and cautiously.

NOTE

While the A SCOPE[®] is water resistant for brief periods,

it should not be immersed in fluids.

NOTE

When the volume is set too high in Doppler Mode you will notice that the low frequency sounds will overload the headset (ear buds) and start to cut out, producing sharp discontinuities in the sounds you hear. If this happens, decrease the volume until the sound becomes continuous again.

CAUTION

If the Doppler gel has bubbles in it or appears frothy from movement through hair, wipe it off and apply fresh gel because the air pockets impede the ultrasound signal.



CAUTION

Do not store for periods longer than a week, or ship the device, with batteries in the battery compartment.

NOTE

The theory and application of Doppler ultrasound is beyond the scope of this manual. However, the instructions included in this manual should enable the user to detect and recognize heart and lung returns in Doppler Mode.

NOTE

Although the A SCOPE[®] is designed to be robust and reliable, it is an advanced medical instrument and should be handled with care.

NOTE

The A SCOPE[®] should be used only by personnel trained in its use.

NOTE

Do not autoclave the A SCOPE[®].

CONTRAINDICATIONS

The Doppler Mode of the A SCOPE[®] is not intended for fetal use.

The audible signals produced in Doppler Mode do not contain the same diagnostic information as the sounds heard through a conventional acoustic stethoscope. The Doppler Mode of the A SCOPE[®] is only intended for detection of tissue motion in the heart and lungs.



SAFETY OF ULTRASOUND

The American Institute of Ultrasound in Medicine has addressed concerns relating to the safety of ultrasound and has issued the following statements quoted from their website (<u>www.aium.org</u>) as of February 2011:

Prudent Use and Clinical Safety

Approved March 19, 2007

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

No independently confirmed adverse effects caused by exposure from present diagnostic ultrasound instruments have been reported in human patients in the absence of contrast agents. Biological effects (such as localized pulmonary bleeding) have been reported in mammalian systems at diagnostically relevant exposures but the clinical significance of such effects is not yet known.

Ultrasound should be used by qualified health professionals to provide medical benefit to the patient.

As Low As Reasonably Achievable (ALARA) Principle

Approved March 16, 2008

The potential benefits and risks of each examination should be considered. The ALARA (As Low As Reasonably Achievable) Principle should be observed when adjusting controls that affect the acoustical output and by considering transducer dwell times. Further details on ALARA may be found in the AIUM publication "Medical Ultrasound Safety."

Active Signal has strived to use as low an ultrasound power as practical for the intended application(s). The level of ultrasound power in the A SCOPE[®] is not adjustable and so prudent use by the operator would include minimizing the length of time that the patient is exposed to the ultrasound output.



Statistical Maximum Values of Acoustic Output

Ultrasound output power was measured on 3 randomly-selected units by an independent laboratory. All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 [1] and UD-3 [2] using a calibrated hydrophone, and the reporting requirements of the September 9, 2008 FDA Guide [3] for Track 1 and Track 3 devices. The following table summarizes the acoustic output values calculated from the 3 samples to be the maximum likely for 90% of all units with 90% confidence.

System:	A SC OPE®	Operating Mode:	CW Doppler
Transducer	1109-120000A	Application:	Tissue
Model:			Motion
Center	2 MHz		
Frequency:			

Acoustic Output Parameter:	МІ	I _{SPTA.3} (mW/cm ²)
Global Maximum Value:	0.0373	65.4
Preamendments output exposure levels	1.9	94

Where: $I_{SPTA.3}$ (mW/cm²) is the Derated Spatial-Peak Temporal-Average Intensity

MI is the Mechanical Index

Derated acoustic output exposure quantities were obtained from exposure quantities measured in water by multiplying by the derating factor ϕ , which is based on the measured center frequency of the acoustic signal (f_c , MHz) and the distance from the transducer under test to the hydrophone (z, cm) using: .

$$\phi = e^{-0.069 f_c z}$$



Measurement Uncertainties

The total uncertainty reported by the independent laboratory was \pm 28.2 percent for the intensity value, and \pm 14.1 percent for the Mechanical Index. The uncertainties comprise the stated uncertainty in the NPL hydrophone calibration, the digitizer, and spatial averaging, and a \pm 1°C variation in water bath temperature. The center frequency uncertainty is \pm 2 percent arising from the digitizer. No non-linear distortion was observed.

System Features Affecting Acoustic Output

The acoustic output is set by the manufacturer and no manual or software interactive adjustments are provided on the A SCOPE[®]. The ultrasound transducer is turned on by pressing a button and may be turned off by pressing another. The A SCOPE[®] will automatically power down after 10 minutes of inactivity. Users are advised to minimize ultrasound exposure time by switching to passive Acoustic Mode whenever possible.

- "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3," NEMA Standard Publication UD-2, National Electrical Manufacturers Association, 2004.
- "Standard for the Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2" NEMA Standard Publication UD-3, National Electrical Manufacturers Association, 2004.
- "510(k) Guide for Measuring and Reporting the Acoustic Output of Diagnostic Ultrasound Medical Devices," Center for Devices and Radiological Health, FDA, 1985, and revised in 1989, 1990, 1991, 1993, 1994, 1997, 2008.



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Unpacking the A SCOPE®

A SCOPE[®] Kit



KEY to illustration

on next page

- 1. A SCOPE[®]
- 2. Headphones, with Amphenol[™] SMB
- 3. Cable, Extension CEP with Amphenol[™] SMB
- 4. Cable, Adapter CEP to 1/8 phono (DVD)
- 5. Kit, Earplugs CEP
- 6. Canal Tips (2 sets)
- 7. Gel, Ultrasound 60-g tube
- 8. Battery, AA Alkaline (4)
- 9. Case with closed-cell foam insert and Quick Start Guide (see photo at left)
- 10. User Manual, CD
- 11. User Training Guide, DVD
- 12. Rubber Overmold, battery cap (anti-roll)



Contents of the A SCOPE[®] Kit



KEY on previous page



Getting Started: The User Training Guide DVD

Important

For successful auscultation with the A SCOPE[®] it is helpful to have some understanding of its technology. It is also important to spend time practicing with it on healthy volunteers to develop the skills needed to use it effectively on patients.

A training DVD (Part Number: 090-112-0100) is included in the A SCOPE[®] kit to help you get up to speed rapidly on how to locate the instrument and become familiar with typical Doppler sounds from the heart and lungs.

Note

Because the sounds produced by the stethoscope are in a very low frequency range they do not reproduce well in most DVD players and cannot be heard easily through ordinary speakers and headsets. Accordingly, the sounds have been enhanced for training purposes on the DVD and can only be appreciated fully using the special low-frequency over-ear headset included in the A SCOPE[®] kit.

A short **adapter cable can be found in the A SCOPE[®] kit** allowing the over-ear headset to plug into the 1/8" phono socket found on most DVD players.





Understanding Your New Stethoscope

The purpose of this instruction manual is to familiarize you with operation of the A SCOPE[®] dual-mode stethoscope.

The A SCOPE[®] is a dual-mode noise-immune stethoscope that provides highfidelity reproduction of physiologic sounds in moderate background noise, and audible Doppler returns from the heart and lungs when auscultation has to be performed in higher ambient noise. Acoustic Mode (also labeled 'Std' or standard) uses solid-state acoustic sensing to enable very sensitive, broad-band auscultation in moderate noise. Doppler Mode (also labeled 'Dop'), used in loud conditions, reveals the presence of heart and lung function using continuous wave (CW) ultrasound frequency shifts to detect physiologic movement within the body.

> **NOTE** The ultrasound power transmitted to the patient's body is below typical levels used in fetal heart monitors for home use.

Two Independent Modes of Operation

Acoustic Mode

In this mode the device operates in a very similar manner to other electronic stethoscopes and delivers familiar physiologic sounds amplified to suit the user. In many common applications where the background noise is loud enough to make auscultation difficult with a conventional or electronic stethoscope (for example, in emergency rooms, trauma centers, accident scenes, ambulances, etc.), the Acoustic Mode of the A SCOPE[®] still can generate clearly audible, high-fidelity sounds, particularly if used with CEP type ear buds and hearing protection.



Doppler Mode

This mode is used at background noise levels where vital sounds are no longer audible in Acoustic Mode. The Doppler Mode provides audible returns corresponding to physiologic activity, or motion, in the heart and lungs. As such, these audible returns are not the physiologic 'sounds' recognizable by a conventional stethoscope user. Hence, a few minutes are needed to become accustomed to the 'Doppler Shift' sounds associated with 'heart activity' and 'lung activity'. Because this mode employs active ultrasound, the signals are transmitted to and received from internal body organs in a high frequency band that is unaffected by commonly encountered background noise (for example, the low frequency audio noise produced by ground vehicles, generators and aircraft). Thus, if the user's ears are properly isolated from environmental noise (using CEPs with circum-aural hearing protection or noise-canceling headsets) the Doppler returns can be heard clearly even when the external noise is very loud.



Operation of the A SCOPE[®]

Figure 1. Major components of the A SCOPE®.



Set up

Connect the headphones using the connector on the side of the stethoscope. If using military communications earplugs (CEPs), use the extension cable supplied to provide enough length for you to work on the patient.



Figure 2. Connecting the headset cable.

Powering Up

Turn the device on by pressing either Mode Button. "Std" for Acoustic Mode or "Dop" for Doppler Mode.



Power On Acoustic Mode

Power On Doppler Mode

Figure 3. 4-button control panel.

NOTE

To prolong battery life, the unit will automatically power-off ten minutes after the last time a mode button was pressed. The unit has no Off Switch.



Gripping the A SCOPE®

Grasp the central stalk of the stethoscope between the index and middle fingers and rest your thumb over the control buttons. The wire from the stethoscope to the headset should run conveniently under your wrist.





Figure 4. Holding the A SCOPE[®] for a patient exam.

Using Thumb Controls

To turn the device on in Acoustic Mode momentarily press and release the button marked 'Std'. To turn the device on in Doppler Mode momentarily press and release the button marked 'Dop'. To adjust the volume up, momentarily press and release the button marked with the up arrow. To adjust the volume down, momentarily press and release the button marked with the down arrow. To slowly slide the volume up or down press and hold the appropriate volume button and release when the desired volume is obtained.



HINT: The top and bottom buttons select the mode, i.e. **D**own for **D**oppler (button closest to the patient's skin) and **u**p for aco**u**stic (button away from the patient). The farthest button from your wrist increases the volume and the button nearest your wrist reduces the volume.

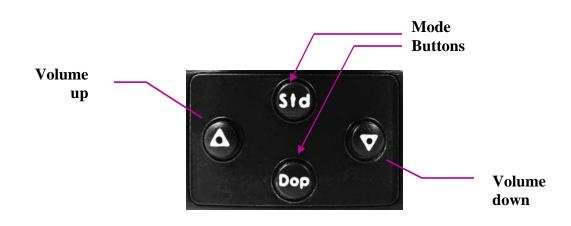


Figure 5. Position of the volume controls and mode buttons.

Note that the volume controls for the Doppler and Acoustic modes operate independently. Volume adjustments made in one mode will not affect the other. The stethoscope will retain its last used Acoustic and Doppler mode volume settings when stored with batteries. Whenever replacing batteries, press and hold the volume-down button for about 10 seconds in each mode, release, and then adjust the volume up by pressing the volume up button 4 or 5 times. This is to achieve a comfortable starting point for volume adjustment.

Volume Adjustment

Continuous volume adjustment can be accomplished by holding down the up or down button. After 1 second, the volume gradually ramps in the desired direction until the button is released. Alternatively, by momentarily pressing and releasing



the up or down button the volume can be moved step-by-step over its full range of 32 steps. To move the volume control all the way up to the maximum press and hold the volume up button for 10 seconds. To move the volume control all the way down to the minimum press and hold the volume down button for 10 seconds.

The audio output amplifier in the A SCOPE[®] is designed to drive a wide variety of devices such as headphones, communications earplugs (CEPs), or other similar devices. To do this it needs to be capable of driving these diverse devices with sufficient power to effectively and accurately reproduce the physiologic sounds. This means that the amplifier is also capable of overloading some of these devices if the volume is set high enough. Care must be taken by the user to avoid overload conditions. Overloading does not cause any damage, but it can cause the audio output to appear to be limited or attenuated. The user might erroneously respond to this attenuation of the signal by increasing the volume, driving the output device further into overload.

Shut Down

When you have completed the exam remove the headset and unplug from the stethoscope. Wipe off any remaining gel from the front face or sides of the stethoscope. Wipe down the entire stethoscope with a germicidal wipe approved for hospital use just as you would with a conventional stethoscope. If wipes are not available, the device can be wiped down with a soft cloth or tissue dipped in rubbing alcohol.

Switching Off the A SCOPE[®]

The unit has no power button. Instead it will time out (power off) approximately ten minutes from the last time a mode button was pressed. However, the volume settings will be preserved from the moment it powered down.



Rubber Overmold, battery cap (anti-roll)

The "Rubber Overmold, battery cap" (item 12, page 10, "Contents of the A SCOPE[®] Kit") is a pliable silicone rubber molded cover that is intended to be slipped on over the battery compartment section of A SCOPE[®] to prevent the stethoscope from rolling away if placed or dropped on a tilting or slanting surface. The overmold must be removed to change the batteries and must be only put into place after the battery cap has been returned to its closed and locked position. When cleaning the stethoscope this rubber cover must be removed and cleaned separately. When replacing A SCOPE[®] in its carrying case the rubber overmold must be removed and stored in the right-side rectangular compartment, otherwise the case will not close and attempting to force it closed might damage it and the stethoscope.

Storage

When the A SCOPE[®] is not in use, return it to its protective case and stow properly. If the unit will be stored for more than a week, remove the batteries and keep them separately in the storage case.

Performing a Medical Exam

Acoustic Mode

In mild noise and quiet settings, the over-the-ear headset provided with your A SCOPE[®] is recommended. Connect the headset to the stethoscope by pushing the small metal female SMB connector firmly onto the recessed male connector in the housing (Figure 2). Place headphones over the ears, then momentarily depress and release the 'Std' button on the control panel to power up the device. Grasp the stethoscope by inserting your index and middle fingers on either side



of the central stalk (Figure 4) and rotate the device until your thumb rests comfortably over the four button control panel. The wire to the headset will run under your wrist and should not interfere with your patient exam. In the Acoustic Mode, the physiologic sounds you hear with the A SCOPE[®] should sound much the same as your conventional or electronic stethoscope. Your auscultation locations and procedures in this Mode will be unchanged from well established medical practice. Listen in a few representative locations and adjust the volume to a comfortable level. You might find that you can increase the volume more than you can with other electronic stethoscopes and retain clarity because there is less noise and distortion in the signal.

CAUTION

Be aware that the patient's voice can be very loud when received through the A SCOPE[®] in Acoustic Mode

If it is uncomfortable when the patient talks, request silence or remove the stethoscope from the skin until the conversation is over. The volume will hold at whatever level you set until you adjust it, even after the device switches itself off. While in Acoustic Mode you will find that the device will allow you to hear clearly in moderately noisy environments that might otherwise make auscultation difficult. Under these conditions, some clinicians find that the acoustic signal can be improved by pressing the front face more firmly into the skin. Beyond this, you should not notice anything different compared to your old familiar stethoscope.

Doppler Mode

When auscultation in Acoustic Mode becomes too difficult because of intrusion by external noise, you will need to switch to Doppler Mode. Typically this becomes necessary at ambient noise levels between 80 and 95-dB depending on the user's hearing, the type of headset, and the strength of signals sensed on the patient.

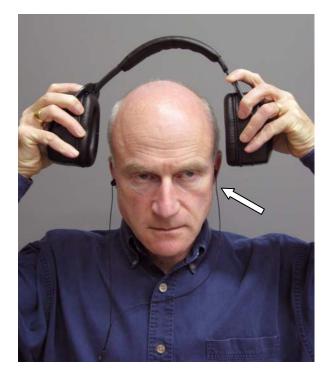


WARNING

Under these conditions, in-ear speakers [ear buds, such as military communications earplugs (CEPs)] are recommended in combination with good quality circum-aural hearing protectors or noise-canceling headphones.



Figure 6. Doppler returns are best heard using in-ear ear buds or CEPs combined with a circumaural hearing protector or a helmet with integrated hearing protection.



Connect the headset to the stethoscope by pushing the small metal female SMB connector firmly onto the recessed male connector in the housing (Figure 2). Insert ear-buds into ears in accordance with manufacturer's instructions. Place hearing protectors over the ears and ear buds (Figure 6), and push the 'Dop' button on the control panel (closest from the patient's body) to power up the device (Figure 3). Apply a generous amount of ultrasound gel to the front face of the A SCOPE[®]. A dollop that covers the area of a quarter on the center of the face is sufficient (Figure 7).





Figure 7. Ultrasound gel on front face of the A SCOPE®.

WARNING Rapid gel application can create a loud signal in the headset. Accordingly, when applying the gel turn down the volume temporarily or apply the gel slowly and cautiously.

The Doppler 'frequency shift' sounds you hear with the A SCOPE[®] will not sound like the physiologic sounds picked up in Acoustic Mode (or the sounds from a conventional or electronic stethoscope). You will therefore need to familiarize yourself with the frequency shift sounds produced by lung motion and heart motion. Practicing on yourself or on a volunteer is recommended before working on a patient. Some of the frequency shift sounds might sound faint, muffled, or seem to be in a frequency range that is lower than you are accustomed to, particularly when examining the lungs. Practice adjusting the volume to bring the sounds out more clearly from other artifacts in the signal.

NOTE

When the volume is set too high you will notice that the low-frequency sounds will overload the headset (ear buds) and start to cut out, producing sharp discontinuities in the sounds you hear. If this happens, reduce the volume until the sound becomes continuous again.



Guidelines for Obtaining the Best Physiological Signals in Doppler Mode

A SCOPE[®] Positioning and Manipulation

As with any Doppler ultrasound device, positioning is critical and requires a little self-teaching before working on a patient. The following hints apply to both heart and lung auscultation of the chest in Doppler Mode.

The device will not pick up any signal from internal organs if it is located over bone because the bone reflects most of the transmitted ultrasound back into the device. Accordingly, for thoracic exam the center of the front face of the A SCOPE[®] needs to be located over the mid point of the intercostal space in the region being examined. In addition, the prominently marked diameter line on the battery cover must be aligned parallel to the length direction of the intercostal space. This line separates the Doppler transmitting and receiving elements both of which must 'see' the intercostal space. In some cases a good signal can also be obtained perpendicular to this direction, but generally not in any intermediate orientations.

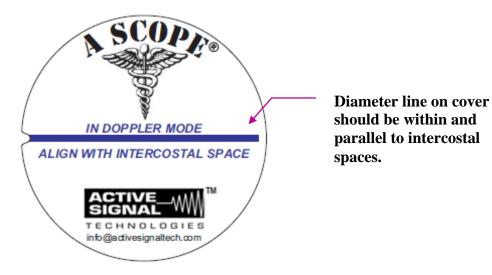


Figure 8. Decal and alignment mark on battery cover.



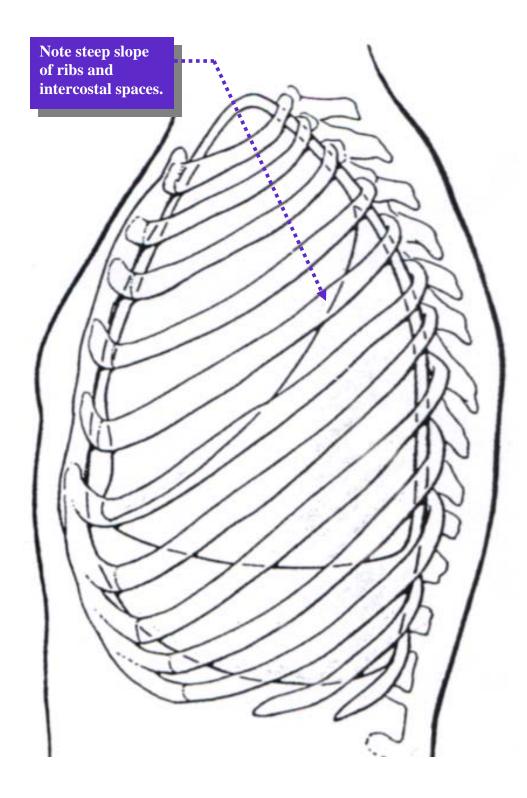


Figure 9. Lateral view of thorax showing rib orientation.



Locating a good listening point might require a few adjustments, included in the list below, which will become rapid and instinctive with practice.

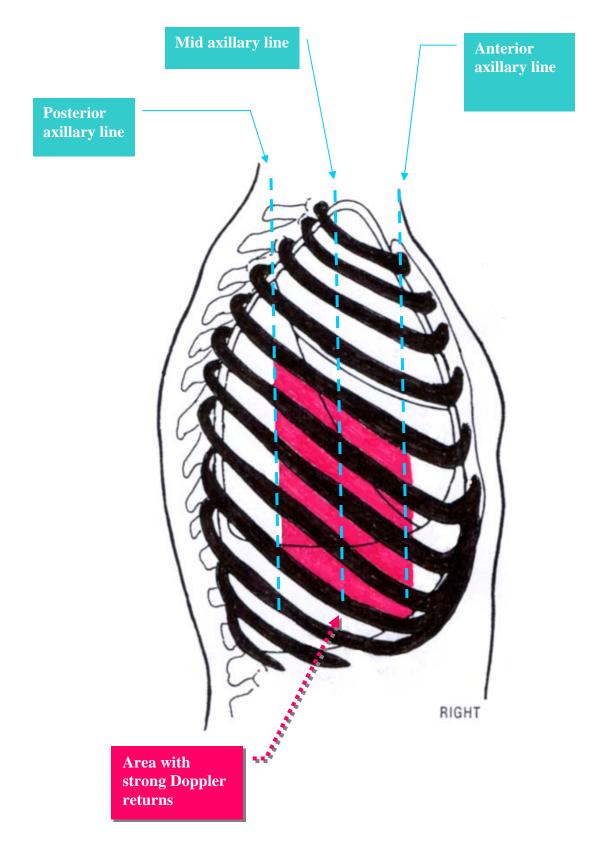
- 1. Try more than one intercostal space in the region of interest.
- 2. Reposition the head by sliding the A SCOPE[®] along the length of the intercostal space.
- Make small adjustments to the angle of the front face to the body by rocking the device - pushing slightly harder on one side or the other of the diameter line on the battery cover.
- Recheck the precise orientation of the ribs (and intercostal space) with your fingers. Rotate the A SCOPE[®] until the line on the battery cover is precisely parallel to the ribs.
- Even when you have located a good spot for listening this can shift with time because the gel-covered face might move slightly out of position. Be prepared to optimize the location and orientation again.

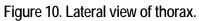
Anatomic Locations for Doppler Auscultation

Lung Function

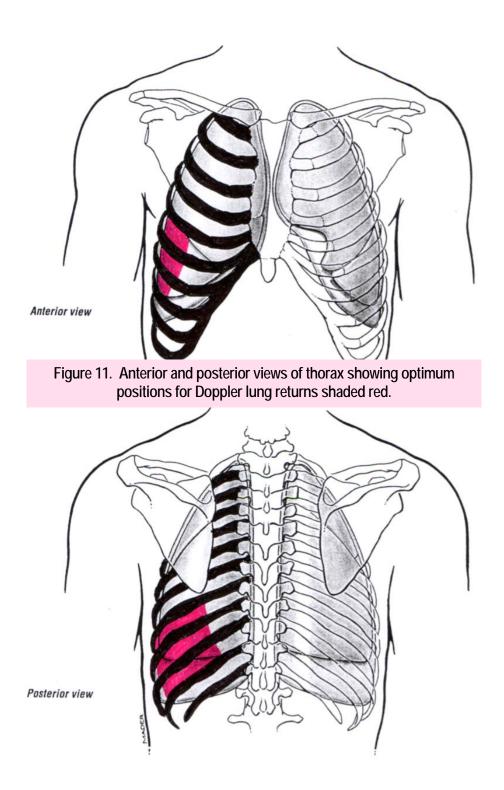
With a conventional stethoscope, lung sounds are associated with air movement through different size tubes and cavity resonances, and present well in particular locations. These are not necessarily the same places where gross lung motion due to breathing can be detected. However, as with conventional acoustic auscultation of the chest the patient has to take deep breaths to provide a satisfactory signal. Some good starting points for the exam are shown in Figure 10 and Figure 11.













Lung Function (continued)

The region below the armpit between the posterior axillary line and the anterior axillary line (Figure 10) can often be accessed on an injured patient and yields Doppler returns in the area shaded in red. Note that the ribs are typically sloping steeply downwards in this area with respect to the mid axillary line. Be sure that the marker line on the battery cover is parallel to the slope. Alternative areas of the lung for detecting Doppler returns are shown in Figure 11 -- lower portion of the lung approached from the front of the patient, and lower portion of the lung approached from the battery. Doppler returns from the latter two areas might not be as strong as along the mid axillary line. As discussed above, breathing / lung Doppler returns might not seem very distinct and can be fairly deep in tone. They are best heard with in-ear speakers (ear buds or CEPs) with complete isolation from ambient noise (hearing protectors), even when used in a relatively quiet room. The typical Doppler return from the lung has been described as similar to a 'cardiac rub' heard with a conventional stethoscope.

Heart Function

With a conventional stethoscope, cardiac sounds are generated by periodic filling and discharge of the chambers of the heart, ejection of boluses of blood into the primary arteries and movement of the physical structures of the valves. Some of the gross motions associated with these physiologic processes can also be detected in Doppler Mode. The strongest Doppler returns generally can be obtained near the apex of the heart (the area used for mitral valve auscultation with a conventional stethoscope). However, Doppler returns can also be detected sometimes over the aortic, pulmonic, and tricuspid valves (Figure 12).

It should be noted that the best locations for picking up Doppler returns might not be exactly the same as used for acoustic heart auscultation with a conventional stethoscope. For example, when listening for a Doppler return from the apex of the heart, the mitral valve position is a good starting point but only a starting point. Further searching along the intercostal space is almost always needed.



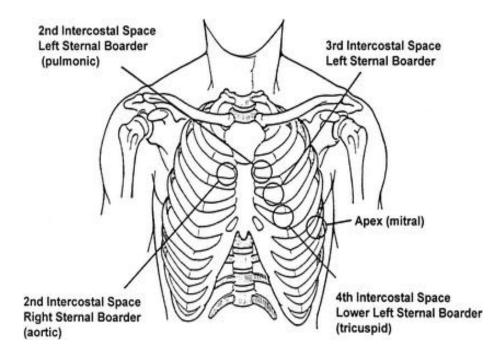


Figure 12. Conventional locations for acoustic auscultation of the heart.

General Tips for Doppler Auscultation

- Be patient finding a good location and correctly orienting the stethoscope.
- Check the front face often to be sure it remains well coated with Doppler gel.
- Avoid air bubbles.

CAUTION

If the Doppler gel has bubbles in it or appears frothy from movement through hair, wipe it off and apply fresh gel because the air pockets impede the ultrasound signal.

 Starting at a low volume setting (3 to 5 steps from the lowest setting) can make it easier to home-in on the physiologic Doppler return with less distraction from artifact and noise. It is better to increase the volume after a good location has been found.



Care and Maintenance

Cleaning

The A SCOPE[®], cable(s), and Rubber Overmold, should be cleaned externally with alcohol as needed and returned to the case. Alternatively, cleaning can be performed with germicidal wipes approved for hospital use.

Maintenance

The A SCOPE[®] has been designed to operate for many years without adjustment or maintenance. Because the device is custom assembled, tuned, and calibrated in the lab, no field maintenance or adjustments should be attempted by the user. If the device fails to operate as expected at any time, please return to Active Signal Technologies for repair. Instructions for return are provided in the Service section of this manual.

Batteries

The unit uses two standard AA alkaline batteries.

In continuous use with a typical mix of Acoustic and Doppler examination the batteries should last for ~60 hours. There is no battery life indicator and no warning about low batteries. When the batteries are drained the unit will go silent and will not respond when any of the buttons on the control panel are pushed.

STORAGE AND SHIPPING

Do not store for periods longer than a week or ship the device with batteries in the battery compartment.



Changing the Batteries

If at any time the stethoscope ceases to work, the first thing to try is replacing the batteries. To do this, turn the cap counter-clockwise to access the battery compartment (Figure 13).



Figure 13. Accessing and replacing the batteries.

.....



Figure 14. Battery cover unlocked



battery cover locked.



With the cap removed, inspect the O ring between the housing and the cap. If it is damaged, replace it. Remove both batteries (never mix new and used batteries) and replace with fresh batteries taking care to observe the correct polarity. Replace the cap by aligning the white line on the side of the battery cover with the white dot on the housing. Push into place and rotate clockwise to engage the keep. You should hear a faint click when the keep engages. Replacement of the batteries resets the volume to default settings (50%) and power to off. Accordingly, after replacing batteries, press the volume-down button for about 10 seconds in both modes (thus lowering volume to 0), and then adjust the volume up to 5 steps in both modes. This provides a good starting point for adjusting volume the next time the stethoscope is used.

Precautions

- The instructions included in this manual should enable the user to detect and recognize heart and lung returns in Doppler Mode. However, the theory and application of Doppler ultrasound is beyond the scope of this manual.
- Although the A SCOPE[®] is designed to be robust and reliable, it is an advanced medical instrument and should be handled with care.
- The A SCOPE[®] should only be used by personnel trained in its use.
- While the A SCOPE[®] is water resistant, it should not be immersed in fluids.
- Do not autoclave the A SCOPE[®].



Service

Service Information and assistance is available from:

Active Signal Technologies Inc. Hammonds South, Unit Q 611 North Hammonds Ferry Road Linthicum Heights, MD 21090-1322

PHONE: 410 636-9350 EMAIL: <u>info@activesignaltech.com</u>

It you need to send the A SCOPE[®] back for repair, please call the above number to get a return authorization number (RA#). Please have the following available:

- 1. Serial number (label located next to battery holder)
- 2. Name, phone number, e-mail address of the person using the A SCOPE[®] when it failed
- 3. Name, phone number, e-mail address of the person responsible for setting up this RA
- 4. Addressee and return address for shipping the repaired A SCOPE[®]
- 5. Information about the nature of the problem including circumstances of failure and symptoms

Ship the A SCOPE[®] with well cushioned and protective packaging (in its original container if possible) to the above address.

Ship it insured via any major national carrier and provide tracking information.

In your return package please include the assigned RA number, the contact information in items 2, 3, and 4 above, and a written description with as much detail as possible about the nature of the problem with the device including circumstances of the failure and symptoms observed.

For service outside of the United States, please contact the local representative from whom you purchased the A SCOPE[®].



Specifications

Mechanical and Electrical

Modes	1. Passive Acoustic	
	2. Continuous Wave Doppler Ultrasound	
Doppler frequency:	2.1 MHz +/-10%	
Maximum ultrasound po	<90 mW/cm ³	
Physical dimensions	Weight:	340 grams (0.74 lb)*
(* including batteries)	Height:	3.2 inches
	Diameter:	2.6 inches (largest dimension)
Batteries	Туре:	User replaceable Alkaline
	Voltage:	1.5 volt
	Size:	AA
Typical continuous	Power off :	~9000 hours (~1 year)
operation battery life (** minimal audio output)	Acoustic mode:	120 hours (~5 days)**
	Doppler mode:	45 hours (~2 days)**
Audio power amplifier	Power :	1.4 Watts into 8 ohm load
	THD:	0.19% (typical @ 0.5W)
	Efficiency:	84% @ 400 mW
	Frequency response:	5 Hz – 20 KHz



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Environmental Limits

Temperature

Operating temperature range with batteries: _____-20°C to +55°C.

Storage temperature range with batteries: _____--20°C to +35°C.

Storage temperature range without batteries: ____ -65°C to +150°C.

Humidity

Operating humidity range:______5% to 95% noncondensing (operating the device in humidity above 95% and in condensing environments is allowed but exposure time should be limited).

Storage humidity range:______5% to 95% noncondensing.

Altitude

Operating altitude range:_____0 to 40,000 feet.

Storage altitude range:_____0 to 60,000 feet.

This device might be damaged by sudden decompression at high altitude.

