



MESA Exam 6

Arterial Pulse Wave

Manual of Operations

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INTRODUCTION

The Northwestern University Echocardiography Core Laboratory (NUECL), in collaboration with the laboratory of Dr. Julio Chirinos (University of Pennsylvania) will serve as the arterial pulse wave core laboratory for the Multi-Ethnic Study of Atherosclerosis (MESA) Exam 6. The NUECL and the laboratory of Dr. Chirinos will help ensure the quality and reproducibility of arterial stiffness recordings performed during MESA Exam 6. The arterial pulse wave data will be acquired with the VaSera VS-2000 device (Fukuda Denshi USA, Redmond, WA; Shipping address: 17725-C NE 65th Street, Redmond, WA 98052).

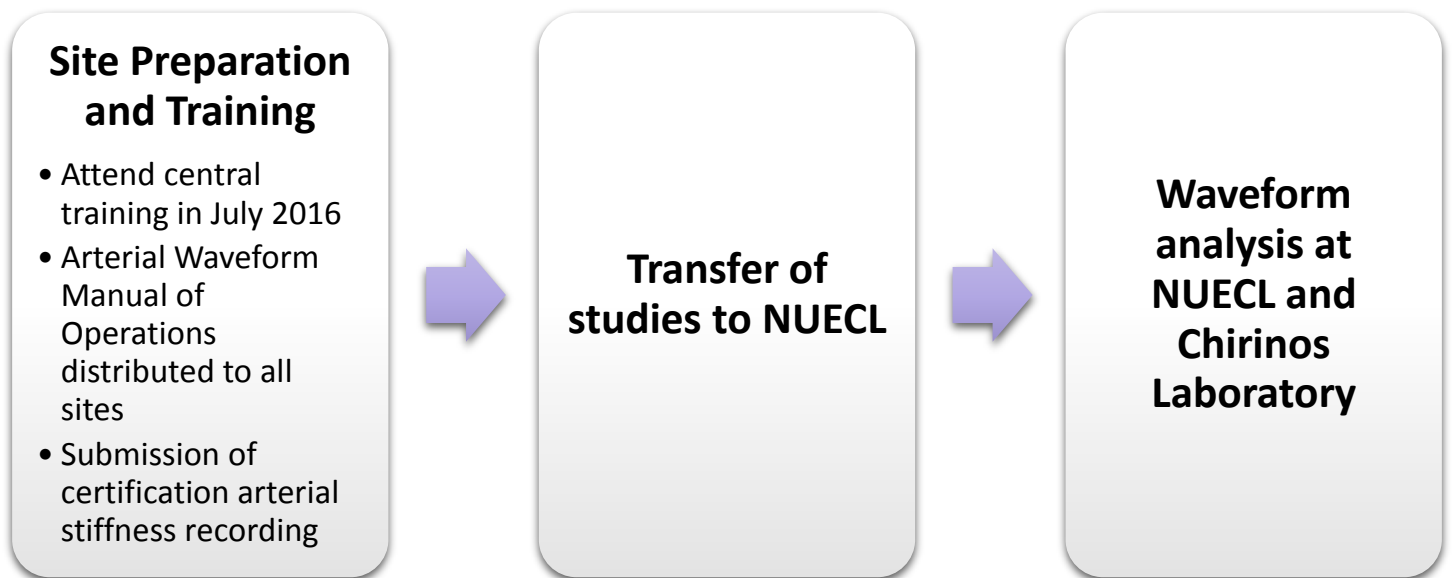
The VaSera VS-2000 device obtains blood pressure measurements and arterial pulse waveforms with oscillometric blood pressure modules that enable sequential measurements of brachial and ankle blood pressures, as well as heart-to-ankle arterial stiffness, and heart-to-thigh arterial stiffness. This manual contains all key information study sites will need to perform high quality arterial pulse wave recordings and analysis.

ARTERIAL PULSE WAVE MEASUREMENT OBJECTIVE:

The objective of the arterial pulse wave measurement in MESA Exam 6 is to (1) ascertain arterial stiffness measures; and (2) provide a central aortic wave form that will be coupled with echocardiography for time-varying myocardial-pressure stress relationships.

Roles and Responsibilities	
Study Sites	<ul style="list-style-type: none">• Send representative (sonographer) to attend central training in July 2016• Ensure that each site sonographer performs a 'certification' arterial stiffness recording prior to performing an arterial stiffness recording on a study subject• Perform complete, high-quality arterial stiffness recordings per the protocol contained in this document• Submit arterial waveform data to the NUECL in proper format, in a timely fashion• Keep the NUECL informed of changes in study staff at the site
NUECL and Chirinos Laboratory	<ul style="list-style-type: none">• Train and certify each site sonographer• Receive, review, and analyze study arterial stiffness recordings• Serve as a resource for sites regarding all arterial stiffness recording-related questions

STUDY-WIDE PROCESS OVERVIEW



SONOGRAPHER CERTIFICATION

All sites must be certified by the NUECL to ensure the performance of the highest quality arterial stiffness recordings and to maintain consistency in how these recordings are performed study-wide. Any sonographer who will be performing arterial stiffness recordings must submit one certification study performed using the protocol contained in this manual and transferred electronically to the NUECL for review and certification. Studies will be evaluated for adherence to protocol and image quality. Feedback and suggestions from the NUECL technical director will be provided for each certification study submitted. If the certification study is deemed inadequate, sonographers will have the opportunity to re-submit a new study. Upon submission of an adequate sample study, the sonographer will be officially certified.

A general outline of the process is outlined below:

1. Participate in central training
2. Read and review the Arterial Pulse Wave Manual of Operations, and contact the NUECL with any questions before performing the certification arterial stiffness recording
3. Perform the certification recording on a non-study subject, making sure to include all required information
4. Copy the study directly from VaSera device to the Northwestern Box MESA Exam 6 folder (each site will receive a site-specific link).
5. Wait for confirmation of certification from the NUECL before submitting any arterial stiffness recordings performed on study subjects

BACKGROUND INFORMATION

The VaSera VS-2000 device uses sensitive brachial cuffs, ankle cuffs, and thigh cuffs to obtain oscillometric blood pressure measurements and arterial pulse waveforms and a phonocardiograph on the chest to record heart sounds (Figure 1). Five waveforms are generated during the test: a phonocardiograph recording, and 4 arterial pulse wave recordings (Figure 2). Two test runs per subject will be performed; one using ankle cuffs, and one using thigh cuffs.



Figure 1: Appropriate set up of the VaSera device

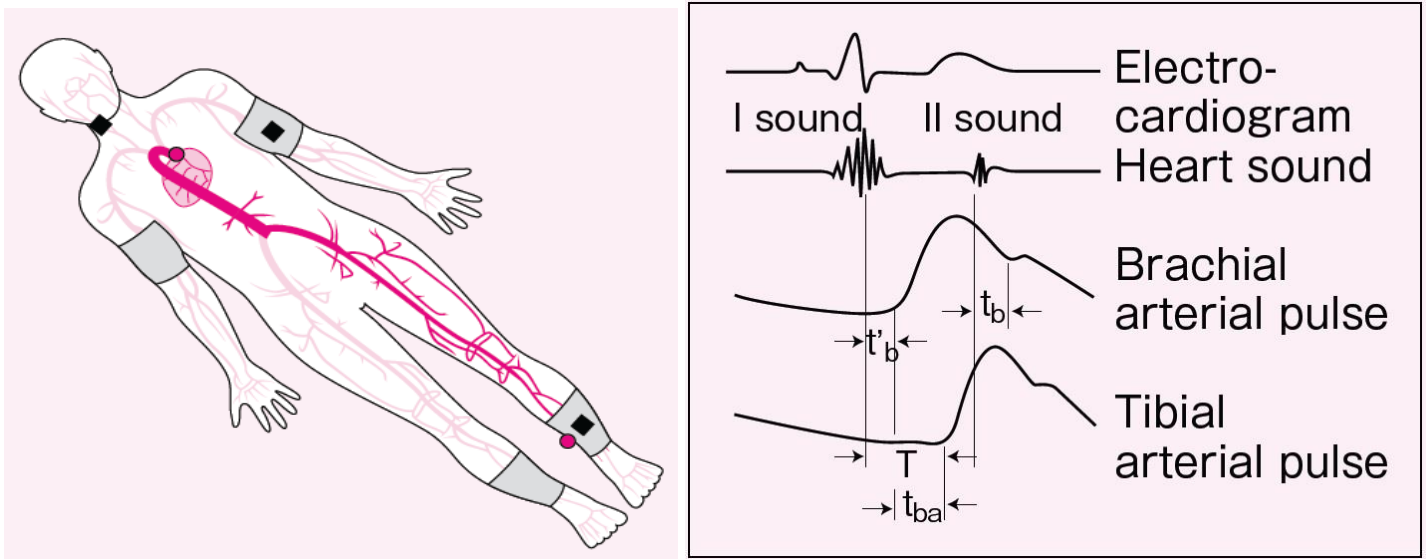


Figure 2: Proper placement of brachial and arterial cuffs (left) and the four distinct waveforms acquired by the VaSera device (right)

The arterial waveforms and phonocardiogram obtained by the VaSera device form the basis for estimation of arterial stiffness and blood pressure measurements.

CONDITIONS BEFORE MEASUREMENT

Before beginning the arterial stiffness measurement, ensure the following:

- Room temperature: The temperature of the testing room should not be too cold; above 72 degrees is ideal.
- Bed/exam table size: Subjects should be put to lie horizontal (head pillow allowed) on a bed/exam table that is wide enough to allow for arms resting comfortably supported at sides, without effort, and long enough that heels are supported by the bed surface.
- Subject's clothing: light, loose fitting clothing is optimal; cuffs should be wrapped against bare skin, but if clothing needs to be pushed or rolled up, avoid situations where this affects blood flow (no constriction). Shoes and socks should be removed.
- Rest before measurements: Pre-measurement rest is critical to test accuracy. Subjects should be comfortably supine for five minutes prior to beginning the measurement.
- Motionless & silent: Ensure that the subject does not move or speak during the measurement.
- No sleep: Do not allow subjects to fall asleep during the measurement period.
- Reduction of weight of legs and arms against bed surface: Rolled towels or the grey VaSera limb cushions can be used to raise the ankles and arms from the bed to prevent extra compression of the cuffs during measurements.

SELECTING THE APPROPRIATE CUFF SIZE

It is **critical** that the cuffs used for the examination fit the arms and ankles of the subject appropriately. If the cuffs are the right size, the INDEX mark falls within the RANGE zone when the cuffs are wrapped over the arm or ankle (refer to the table below for detailed information on cuff sizes). If the cuff used is too small, blood pressure measurement will be artificially elevated and the arterial stiffness value cannot be measured accurately.

<i>Cuff Type</i>	<i>Range of Limb Circumference</i>
Brachial – Small	17-22 cm
Brachial – Medium	22-30 cm
Brachial – Large	30-39 cm
Ankle – Medium	20-30 cm
Ankle – Large	30-42 cm
Thigh – 150LL	120 cm (maximum)
Thigh – 150M	80 cm (maximum)

WRAPPING CUFFS PROPERLY

Wrapping the Brachial (Arm) Cuffs

- Ensure that the air hose outlet of the cuff is lined up with the center of the brachial artery on the inside of the upper arm.
- The bottom part of the cuff should be immediately above the elbow, but not over the elbow joint.
- Wrap the cuff firmly, but make sure that it is not so tight that it constricts the brachial artery.

Wrapping the Ankle Cuffs

- Ensure that the air outlet hose extends upward from the medial ankle bone – if the cuff is wrapped correctly, the arrow on the label points to the apex (peak) of the ankle bone (malleolus).
- The lower edge of the cuff should be approximately 1 cm above the ankle bone.
- The ankle cuffs may be easier to wrap if the subject bends his/her knees
- Wrap the cuff firmly, so there are no gaps at the cuff's upper and lower edges, and ensure that it does not constrict the ankle.
 - If the circumference of the ankle is smaller than the calf, wrap the cuff in a slightly spiral shape so that uniform pressure is applied to the top and bottom of the cuff and no gaps are present between the cuff and the ankle.

Wrapping the Thigh Cuffs

- Wrap the cuff firmly around the upper thigh, with its upper edge as high to the femoral pulsation point as possible.
- For obese subjects, use the extra-large size thigh cuff.

ATTACHMENT OF THE HEART SOUND MICROPHONE (PHONOCARDIOGRAM)

The heart sound microphone transmits the heart sound to the sensor via bone conduction. Firmly attach the heart sound microphone using double-sided tape over the sternum, between the second ribs.

Key points:

- Attach the microphone directly over the bone, avoiding areas of thick hair and/or body fat (both of which can interfere with sound detection)
 - For subjects who are obese, position the microphone over the sternum at a slightly higher location
 - For subjects who have thick body hair, use surgical tape or a beanbag to keep the microphone close to the body
- Make sure that the cord of the heart sound microphone does not have any tension and is clear from snagging.
- The heart sound microphone is highly sensitive to ambient sound, so keep the room quiet during testing.

CAUTION! Be careful not to drop the heart microphone (phonocardiograph); it can break internally with shock, and under this situation, will no longer measure clear heart sounds.

PERFORMING THE EXAMINATION

Enter the subject ID number (format used is standardized for the study), gender, height, and date of birth into the system. Explain the examination to the subject in detail to avoid unnecessary stress. Ensure that the room is quiet, that the cuffs are correctly wrapped and positioned, and that the subject is silent, still, and relaxed. During the examination itself, avoid doing anything that may interrupt the subject's state of relaxation, stillness, and silence.

The test takes approximately 8 minutes per run. One run will be performed using the ankle cuffs. One run will be performed using the thigh cuffs (see "Thigh Cuff Instruction Sheet For VaSera VS-2000"). A two-minute rest period between runs, per subject, is required.

During the measurement of arterial stiffness, a weak cuff inflation pressure (50 mmHg) is applied to cuffs on all four limbs (whether measuring heart-to-ankle or heart-to-thigh arterial stiffness), and the ankle and brachial blood pressures are measured bilaterally. Thigh blood pressures are not measured. Brachial blood pressure accuracy is important, since it is applied to the calculation of arterial stiffness.

Immediately after pressing the start button, check the waveforms. Confirm that each type of waveform is being accurately recorded on the screen. The key point is to confirm that the heart sound, brachial notch, and rise of the pulse wave are detected without any problems:

- **NOTE: The samples shown in this document include ECG signals. These ECG signals are not produced by the current VaSera model (VS-2000), but were produced by a prior model (VS-1500AU)**
- Heart sound waveform: Check that there is a primary radical wave in the second heart sound
- Brachial pulse wave: Check that the pulse wave rises smoothly and that there is a notch on the downward slope
- Ankle pulse wave: Check that the pulse wave rises smoothly and that there is a clearly defined starting point to each pulse (there should be no notch on the ankle wave form).

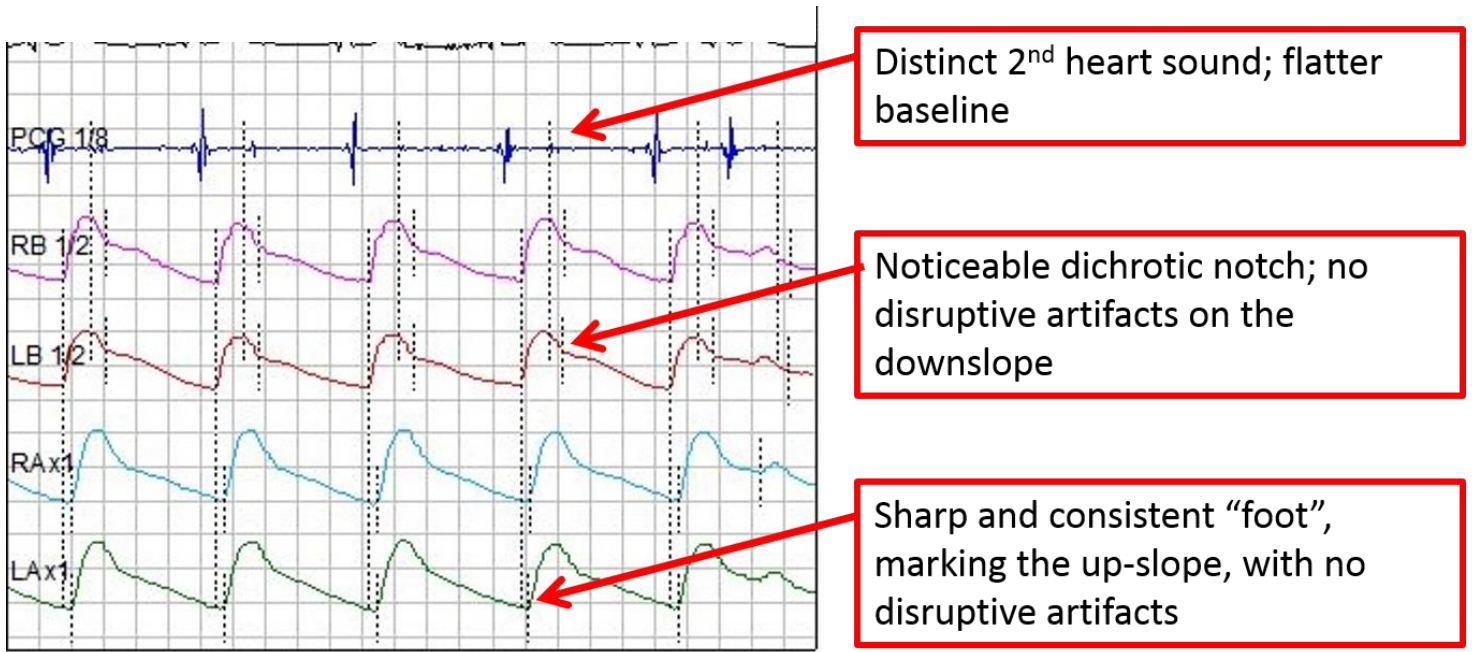


Figure 3: The four types of waveforms recorded during the examination and the appropriate appearance of each.

Always check the phonocardiograph signal; if you can't distinguish the second heart sound, the VaSera device probably can't either.

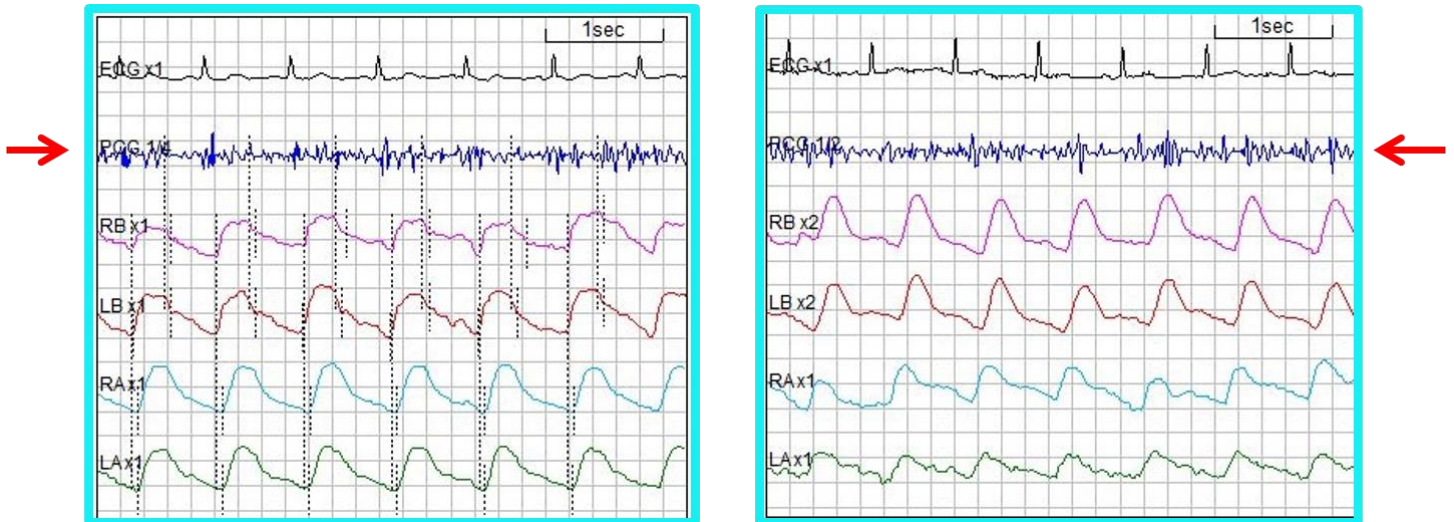


Figure 4: Example demonstrating noise in the phonocardiograph signal (red arrows)

Check the brachial waveforms: is the dicrotic notch clearly visible and easily distinguishable?

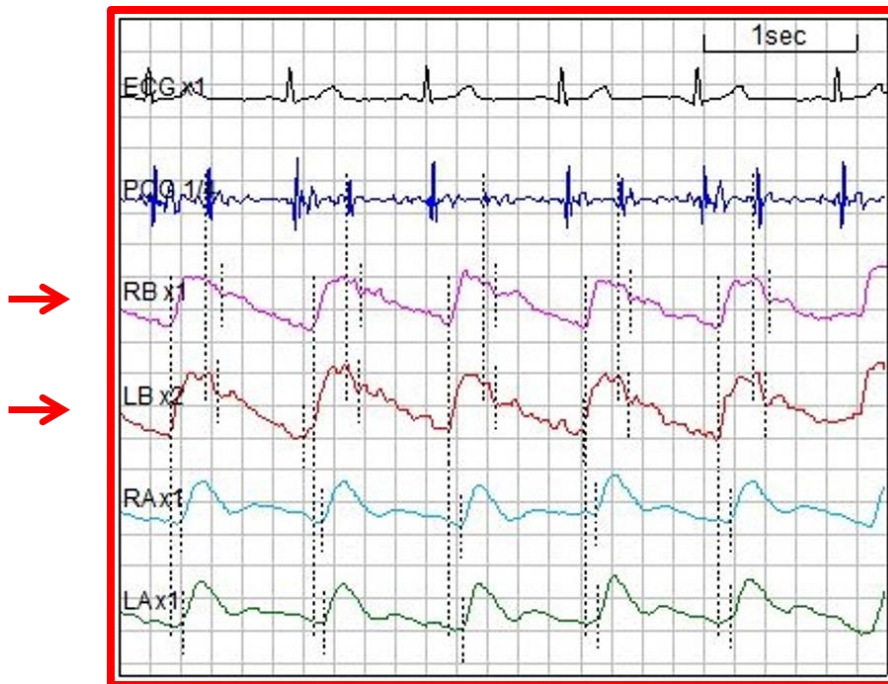


Figure 5: Example demonstrating the right and left brachial waveforms, with a dicrotic notch visible bilaterally

Check the ankle signal. Are the troughs or “feet” of the ankle waveforms at the ends of consistent and regular up-slopes? NOTE: there is no dicrotic notch expected on the arterial waveform measured at the ankle.

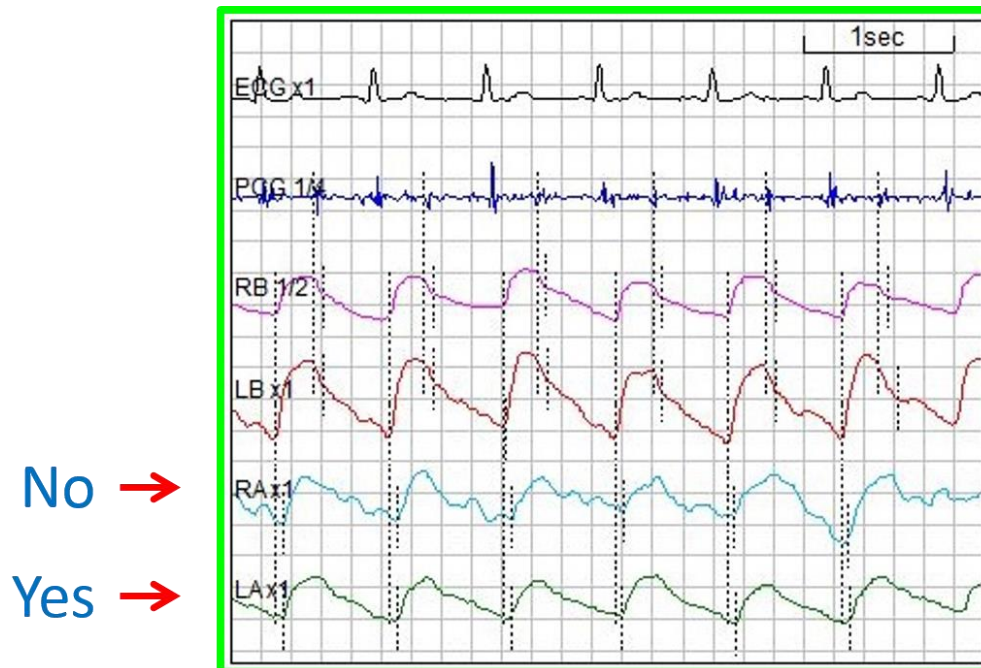


Figure 6: Figure demonstrating the right and left ankle waveforms. The right ankle waveform is noisy, while the left ankle waveform is clear, with well-defined “feet” and regular up-slopes

Ensure that the waveforms are free of artifact. Any movement from the subject, beyond relaxed breaths, can disrupt the signals.



Figure 7: Figure demonstrating artifact in the phonocardiograph signal

Once you are satisfied with the quality of all three waveforms, confirm that the check condition is ++ or +. If the check condition is – or --, confirm that cuffs and heart sound microphone are attached correctly, and repeat the measurement. If there is a - or -- sign resulting for either measurement side, the test result is not valid and should not be submitted to the NUECL.

INSTRUCTIONS FOR ELECTRONIC TRANSFER OF ARTERIAL STIFFNESS WAVEFORMS TO THE LOCAL PC AND TO THE NUECL

1. All data is automatically stored to the data storage USB media attached to the VaSera device. At the end of the examination, remove the USB media from the VaSera device; then, insert it into the PC (non-Macintosh computer) that has had the “VaSera Data Management” software installed on it.
2. Open the data management software, and click FILE → IMPORT → IC CARD
3. Data can be imported from the “ECGDATA” folder location on the USB media, which can be browsed to.
4. Follow the appropriate steps for importing data from a specified date-range, using a start date of 8/15/2016 or earlier; “unregistered files” refers to files that have not yet been imported to the computer.
5. Click on the SEARCH icon (magnifying glass icon) just below the top menu, in order to gain access to the imported files. Using a start date of 8/15/2016 or earlier, set a date range of data to “search” and click SEARCH; A list of available test records will appear on the left side of the window. You may view the data for test records listed by clicking on them, one by one. That selection’s graphical and numerical data will appear on the right side of the window, in the format that has been selected from the report format menu at the top-right section of the window. The recommended format to use is “Overview1”.

6. To export the selected test record's data, click on FILE → EXPORT → [select the desired type of file to export]; **"Inspection Data"** is a flat spreadsheet file containing all numerical data for the searched files, exported as a CSV-file, that can be opened in an MS-Excel spreadsheet; **"Graphic File"** is a graphic of the waveforms (a report) in JPEG- or PDF-file format; **"Wave Data"** is the waveform data file (one per subject-test). For each subject, please export all 3 types of files.
7. When saving data that is being exported, make sure to rename each file to reflect the format provided for study name ("M") + site number (1-6) + a hyphen (-) + subject ID (seven digits) + test type ("A" for ankle-cuff; "T" for thigh cuff) + iteration number for the test type (1-3). Therefore, for the second recording of a thigh-cuff test done for subject number 0012345 at site number 6, the file name would be: M6-0012345T2.
8. Upload the 3 exported files for each subject to the Northwestern Box folder (a link will be provided to each site for uploads).
9. Create a folder on your local PC called "VaSera Raw Data Files"; this will be your main folder for raw data storage.
10. Within the "VaSera Raw Data Files" folder create a sub-folder with the folder named according to the current date and institution initials in the following format: yyyyymmdd-InstitutionInitials.
11. Copy all folders on the VaSera USB media to the sub-folder within the "VaSera Raw Data Files" folder with the current date.
12. Zip the sub-folder mentioned above, and upload it to the Northwestern Box folder.
13. Repeat all steps above, according to an agreed upon schedule for data transfer.

In addition to the electronic transmission of arterial waveform data via Northwestern Box, the site sonographer is responsible for filling out an Echo and Arterial Waveform Transmittal Form to accompany each arterial waveform study sent to the NUECL (Appendix A). This form is used to record basic physiologic information about each subject and also gives the site sonographer the opportunity to comment on any problems with waveform acquisition. Because arterial waveforms will be acquired at the same time as the study echocardiogram, a combined form will be used. A copy of this form should be filled out and emailed to the technical director of the NUECL (lauren.nelson@northwestern.edu) each time an arterial waveform recording is submitted.

QUALITY ASSESSMENT

Upon receipt of each arterial stiffness recording, all waveforms will be evaluated for quality and adherence to protocol. Feedback will be provided to the site sonographer via the combined Echo and Arterial Stiffness Feedback Form (Appendix B). The feedback process is intended to improve future image quality and ensure protocol compliance. Comments and technical tips will be provided when necessary.

REFERENCES

- Fukuda Denshi Co., LTD. A guideline for using VaSera more effectively: what to do and check when taking measurements. Japan: ME Times, 2

CONTACT INFORMATION

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**Exam 6
Echocardiogram
Transmittal Form**

Participant ID #:
 Acrostic:
 Technician ID:
 Date: / /
Month Day Year

Transcribe from participant visit records:

Age: Height: . cm Weight: . kg Male Female

Rhythm: Normal sinus rhythm Heart Rate: bpm Blood Pressure: Systolic .
 Atrial fibrillation Diastolic .
 Other

1. Were all required echo views obtained?

Yes
 No → **If NO, please explain:**

2. Are there any referral or alert findings?

No
 Yes →

2a. What are the findings? (CHECK ALL THAT APPLY)

<input type="checkbox"/> Suspected tamponade	<input type="checkbox"/> Mild or moderate stenosis of any valve
<input type="checkbox"/> Aortic aneurysm or dissection	<input type="checkbox"/> Moderate mitral or aortic regurgitation
<input type="checkbox"/> Abscess or obvious vegetation	<input type="checkbox"/> Moderate or greater dynamic LVOT obstruction
<input type="checkbox"/> Intracardiac thrombus or mass	<input type="checkbox"/> Intra-cardiac shunt
<input type="checkbox"/> Pseudoaneurysm	<input type="checkbox"/> Moderate to severe pulmonary hypertension
<input type="checkbox"/> Significant arrhythmia	<input type="checkbox"/> RV pressure or volume overload
<input type="checkbox"/> Severe left or right ventricular enlargement	<input type="checkbox"/> Low ejection fraction or WMA
<input type="checkbox"/> Severe regurgitation or stenosis of any valve	<input type="checkbox"/> Other, please specify: <input type="text"/>
<input type="checkbox"/> Moderate or greater pericardial effusion - no evidence of tamponade	



Exam 6
Echocardiogram
Transmittal Form

3. Comments for the echo reading center, including any problems encountered with the participant, image acquisition, or machine failure:

RESULTS OF THE ARTERIAL PULSE WAVE EXAM:

Complete



Quality of Wave Form: Good Fair Poor

Were multiple recordings performed? Yes No

Incomplete



Reason exam incomplete or not done:

- Poor arterial waveform
- Undetectable arterial waveform
- Equipment malfunction
- Time/staff/room constraints
- Examinee refused or uncooperative
- Examinee physically unable
- Other

Comments:

MESA ECHO AND ARTERIAL WAVEFORM FEEDBACK FORM

Study ID: _____

Echo date: _____

Date received by NUECL: _____

Reviewed by: _____

<i>Echocardiography</i>			
Imaging Window	Score	Indication	Comments
Parasternal Long Axis View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Parasternal Short Axis View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Apical 4 Chamber View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Apical 5 Chamber View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Apical 2 Chamber View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Apical 3 Chamber View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Subcostal/Suprasternal View	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Legs Elevated with Wedge	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Endocardial Definition	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
Image Settings	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> B <input type="checkbox"/> S <input type="checkbox"/> N/A	
<i>Arterial Waveform Recording</i>			
Right side: Issues affecting waveform quality?	<input type="checkbox"/> Yes/ <input type="checkbox"/> No		<input type="checkbox"/> PCG / <input type="checkbox"/> brachial / <input type="checkbox"/> ankle / <input type="checkbox"/> thigh
Left side: Issues affecting waveform quality?	<input type="checkbox"/> Yes / <input type="checkbox"/> No		<input type="checkbox"/> PCG / <input type="checkbox"/> brachial / <input type="checkbox"/> ankle / <input type="checkbox"/> thigh
Additional Comments:			
Total score: /40 %			

1= Poor 2= Limited 3=Satisfactory 4=Excellent B=Body Habitus S=Sonographer error

Reviewing sonographer signature: _____ Date _____