Uscom instructions

Equipment

Ensure that the Uscom, transducers, and screen pens are kept together. These are **for RSA-PACE trial use only** (which includes training). They should not be used for patient care or other research studies.

The Uscom unit should be running at least software version 2.0.

The Uscom can be used on battery power. This will last up to 2 hrs from full charge. Battery status is shown in the top right of screens.

Setting up the device & logging in

Patient records are linked to the USER login account (not the LOCATION), so **a single USER login must be used by all researchers at a single site for the trial data**. However, each researcher needs their own USER account for training purposes (see Training Requirements).

Keep a note of the USER NAME and PASSWORD (but not attached to the device). The PASSWORD can be saved onto the device so that only the USER NAME needs to be remembered (click REMEMBER PASSWORD at the bottom of the USER LOGIN screen.). A new user account is created by clicking LOGIN and then NEW USER. **Passwords cannot be recovered**. Some settings are reset for each NEW USER, so ensure the setup is correct for each login.

To create a new USER, click LOG IN from the WELCOME screen then NEW USER.

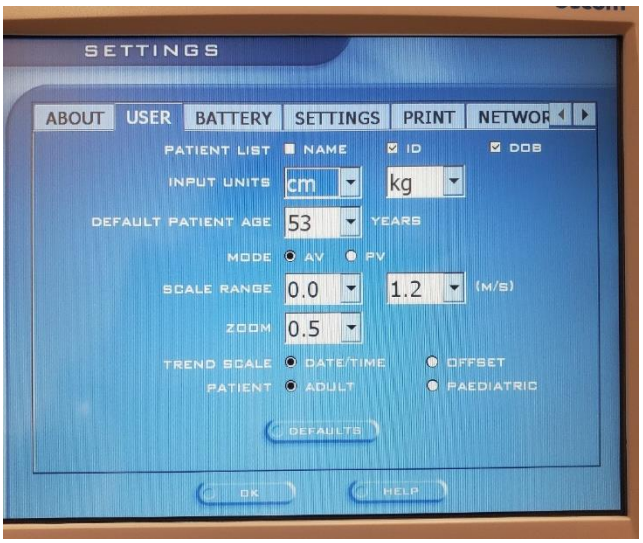
When logging in ensure the LOCATION is set to the local site code.

If you need to reset the region or date/time, the SETTINGS tab is only available after you have logged in:

1. Click on USCOM on the WELCOME screen
2. Go to the SETTINGS tab
3. Ensure the DATE, TIME, and TIME ZONE are appropriate. (If you change them, shut down and restart the USCOM device to save the new values.)

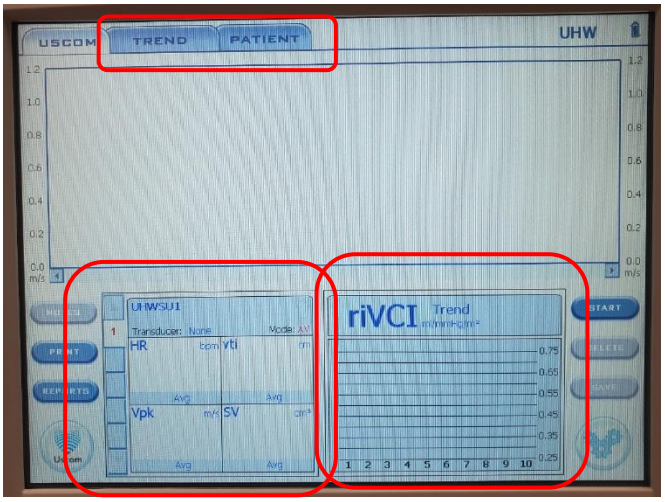
The default USER settings have been changed. You may need to reset these for new USER accounts. After you have created the account:

1. Click on USCOM on the WELCOME screen
2. Go to the USER tab
3. Ensure ID and DOB are ticked and NAME is not. Note that this only affects what data is displayed. Patient NAME or ADDRESS must not be entered in the PATIENT DETAILS screen.
4. Select ZOOM value to 0.5. (This is the horizontal scale and allows the maximum number of beats to be visible. This is 14 seconds.)
5. Click OK



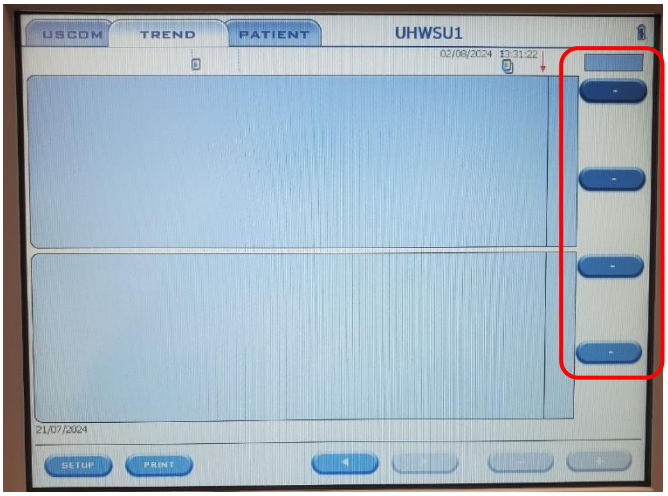
Each patient record includes multiple Examinations, which are identified by a date and time. Each Examination can have multiple Measure Cards. Each Measure Card is a measurement/recording and also has its own timestamp. It is possible to open up the last Examination and add a new Measure Card.

Check that the Measure Card has been set up to show 4 variables on the screen – VTI, HR, Vpk and SV. From the Welcome screen click NEW. In the Examination screen the Measure Card is the bottom left hand box. Tap on the top of the Measure Card. Select the bottom right screen type (4 variables). Click on the required variable in the list (VTI, HR, SV, or Vpk) then click on the line in the top 4 where you want to put it. Alternatively click on one of the 4 variables in the Measure Card that you want to change and select it from the list.



Ensure that riVCI is the variable shown in the Trend window on the bottom right of the screen. This is done by tapping in the top of this window and selecting riVCI from the list of variables[1].

Go into the TREND tab at the top of the Examination Screen and ensure that the 4 traces are all off. On the right hand side are 4 darker blue ovals. There should be a '-' displayed in each one. If there are parameter names instead, click on the name and select OFF. This is to prevent researchers from seeing changes in the patient's cardiac outcomes while the patient is being treated.



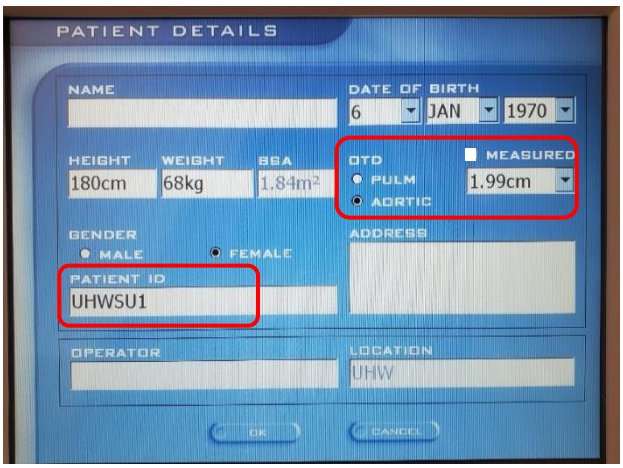
There is no reason for a researcher to review any previously recorded Examinations or Measure Cards or to look at Trend data and it may introduce bias into the trial if you know how the patient is responding over time.

How to add a new patient

1. On the WELCOME screen click NEW PATIENT

[1] Or some other parameter from the list that is not very informative. This is just to prevent users from seeing trends in value that are significant to the trial outcomes.

2. Enter the participant ID (including site code) and DOB. **Do not enter NAME or ADDRESS**.
3. Input patient data: height (cm), weight (kg), gender. The device will calculate the patient's body surface area (BSA) and outflow tract diameter (OTD). Click between 'aortic' and 'pulmonary' to get the values for both valves. Leave it set to 'aortic'.
4. Enter OPERATOR initials if you are about to start an examination.



All measurements for this patient will be linked to this record.

New patients can also be added by clicking OPEN on the WELCOME screen, and then NEW.

To select an existing patient

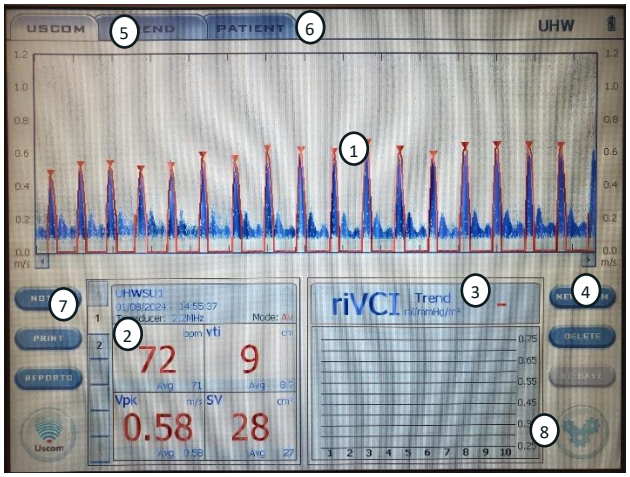
1. On the WELCOME screen click OPEN.
2. SELECT PATIENT using their ID and DOB, and click OK. This will show a list of all their past Examinations.
3. Select NEW – this will bring up the PATIENT DETAILS screen.
4. Enter OPERATOR initials.
5. Click OK to get to the Examination screen.

To conduct a patient measurement

To get to the Examination screen

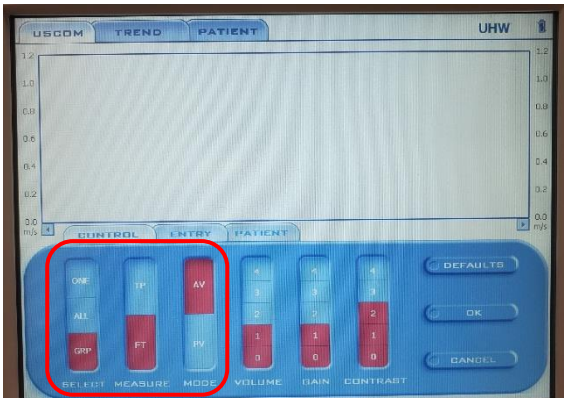
1. If you have just set up new patient details, click on OK.
2. From the WELCOME screen,
    a. Click OPEN to go to the SELECT PATIENT screen.
    b. Choose the correct participant and click OK to go to the OPEN EXAMINATION screen.

c. Either click NEW (enter OPERATOR initials) and then OK, or click on a recording and then click NEW EXAM.



The Examination Screen

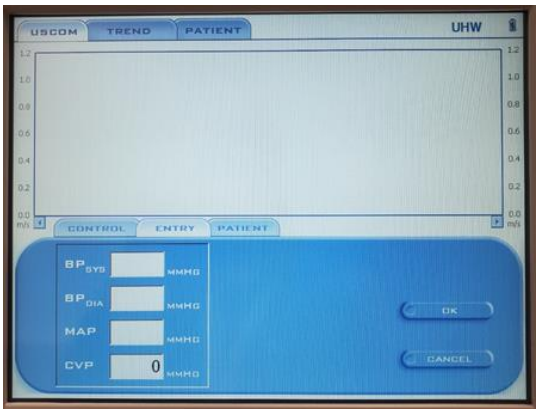
1. The flow trace
2. There are 2 Measurement Cards in this Examination
3. Trend – should be showing riVCI
4. START measurement
5. TREND tab – should be blank
6. PATIENT tab – check the Exam time and add NOTES.
7. NOTEs – say whether the current Exam is paced or unpaced.
8. Controls key



Press the controls key (bottom right hand corner – 3 cogs, see Figure 1) and ensure the following are selected:

- SELECT = GRP
- MEASURE = FT
- MODE = AV (unless using the pulmonary artery)

VOLUME, GAIN and CONTRAST can be altered to the users' preference.



To enter the participant's blood pressure, go to the ENTRY tab on the same screen and enter the systolic and diastolic pressures. The BP value will become invalid after 10 minutes. It must also be re-entered for each new Examination.

Press START to begin recording. FREEZE to stop.

Patient position and signal quality

Do not take measurements with a data stick connected to the Uscom.

The patient should lie supine with head and neck in a neutral position; a pillow may, or may not, be needed. If you are having trouble getting a good signal, try positioning the patient in a slightly left lateral position.

Apply gel to the transducer and press the transducer in the suprasternal notch, aiming caudally towards the ascending aorta/aortic valve. Move the direction of the ultrasound beam around until you get the strongest signal with the largest velocities. The highest velocities are at the valve orifice and when the beam is parallel to flow through the valve. A good signal is obtained when a continuous, well-defined triangular waveform is obtained. This should be well-defined, sharp and 'pointy' and extend for the full duration of systole. If the valve is only partly insonated there will be shadows on the right hand side of the triangle waveform. The supraclavicular fossa can also be used.

See also pages 20-30 of the Uscom "the Basics" guide and the quick check cards that come with the Uscom.

You may have to press quite hard, but this should only be mildly uncomfortable, not painful for the patient. It can be more difficult to get a good signal quality on older people.

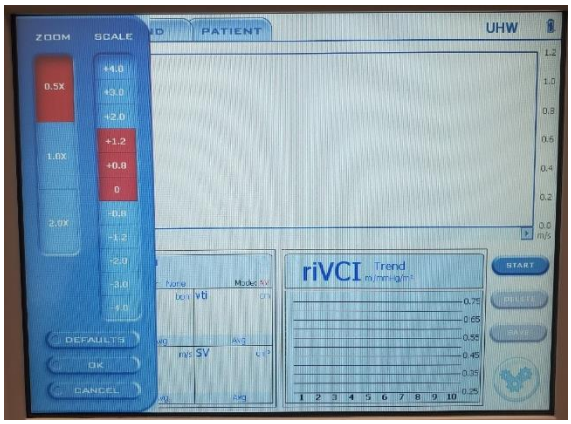
If you are measuring at the aortic valve the flow triangle will point up, if at the pulmonary valve it will point down.

To take a measurement

Do the measurement with the **FlowTrace (red outline) turned off**. After pressing START, click the TRACE button on the left hand side to turn this on and off. The trace will automatically be applied after you FREEZE the recording.

If you need to change the GAIN or VOLUME (or change to the pulmonary valve), go to the controls in the bottom right corner (the cogs symbol). Ensure SELECT is set to GRP. GRP calculates the average value for all beats displayed. If anything else is set there will only be 1 beat of data in each Measure Card.

If you need to change the vertical or horizontal scale, tap on one of the vertical axes. SCALE changes the vertical scale. ZOOM changes the horizontal (number of beats shown). You can change the ZOOM to 1.0 or 2.0 to help see the signal quality, but ensure this is set back to 0.5 before saving the data.



You must obtain a high quality signal for a minimum of 14s, not just a couple of beats. The device stores the last 20s of data when you press FREEZE. However, the device will SAVE what is shown on the screen. The screen shows the maximum

of 14 s of data only when the ZOOM is set to 0.5. You can START and FREEZE as many times as you need to get a good quality series of heartbeats.

When you have a good recording, you can scroll back through the last 20s to find the 14s with the best, most complete beats. If any individual beats look poor quality these should be removed from the dataset by tapping on them – the red FlowTrace outline should disappear from only that beat. The bottom left of the screen shows the parameter averages for all the beats displayed.

Each time you press SAVE you create a new Measure Card for the patient. Different Measure Cards in the same Examination are shown as the numbered vertical tabs on the left of this.

If you realise you have saved a recording with the wrong settings you can delete this immediately and rerecord a measurement. However, do not go into the EDIT screen or try to DELETE a recording at a later time as there is a risk of deleting the wrong recording or the whole patient data. In this case, add a NOTE to the recording to explain what the problem was. Also make a note in the CRF 'Comments' for that Study Visit. Then re-record the measurement if possible. The data can be examined later.

During Study Visits

Study Visits will have 1 or 2 Examinations. Each Examination will have 3 Measure Cards. A separate Examination is to be used for the paced and the unpaced recordings in the same visit.

1. Enter the new patient details or select the current patient details.
2. Start a new Examination.
3. Enter the most recent blood pressure values.
4. Do 3 recordings.
    a. Ensure good quality signals
    b. Capture 14s of good quality data
        i. ZOOM is set to 0.5
        ii. All the high quality beats on the screen have a red outline
        iii. GRP is selected (not ALL or ONE)
    c. Save each recording
    d. Enter the HR for each of the 3 recordings on the CRF, if required.
5. Click on the PATIENT tab at the top, note the Exam Time of the last/current Exam in the top right hand box. Write this on the CRF.
6. Click on NOTES on the left hand side. Click ADD at the bottom. Write whether these are paced or unpaced measurements.

7. Exit the Examination screen by pressing the USCOM in the bottom left corner.
8. If the participant is having paced and unpaced measurements during this visit, start a new Examination and make another set of 3 recordings. Make sure you click NEW Examination and do not add more Measure Cards to the Examination you have just saved. You must re-enter the BP values.
9. A report must be created for each measurement performed, and then saved onto REDCap. See the section below for instructions on how to do this.

If you have mistakenly saved a Measure Card that is incorrect or poorly done you can DELETE it immediately by clicking on the number of the Measure Card and selecting DELETE from the righthand side. Then re-record the measurement. Do not try to delete a Measurement Card later on.

Important points to remember

1. Data is linked to the USER account and passwords cannot be recovered. You must use the same USER account for trial data and make a note of the password or the data will not be recoverable.
2. Do not enter PATIENT NAME or ADDRESS in the Uscom. Only use participant ID and DOB.
3. Enter BP for each Examination.
4. Each Examination is 3 Measure Cards, and is for *either* paced *or* unpaced recordings. Don't record both in the same Examination.
5. Ensure you follow good practice to get the best signal possible for each measurement.
6. You must ensure that you have a full screen of good quality signal and that the FlowTracer outline only includes good beats before you SAVE. **This cannot be corrected later.**
7. When you SAVE participant recordings you must have ZOOM set to 0.5 and SELECT set to GRP or you will not be recording the correct data.
8. Add a NOTE to say whether the Examination is paced or unpaced.
9. Do not attempt to review the patient trends.

Saving data onto REDCap

Data downloads from the Uscom device have to be uploaded the REDCap. From here it will be downloaded by the trial management team for processing and analysis.

Each time a recording is performed on the Uscom device, the data are saved to the device. At the end of the measurements (3 or 6 recordings) save a PDF Report from each recording onto a USB memory stick. At the end of all the Uscom recordings (either after the Post Pacing Visit or when the participant is withdrawn) a CSV data file for the participant must be downloaded onto a USB memory stick. PDFs and the data file must be uploaded to the REDCap database.

Plug a USB stick into the back of the Uscom device after completing all recordings for that patient's study visit. (Do not insert it before or during recording.)

Download from the Uscom to the datastick

Download the PDF snapshot of each measurement

- Navigate to the correct patient and recording on the Uscom screen.
- Press the 'REPORTS' button in the bottom left corner of the Uscom screen.
- Select 'Uscom Report Card with Trace – All' and press 'PREVIEW'.
- Press the 'SAVE' button in the bottom left corner to save the PDF to the USB stick. The file name will contain the patient's initials, not their trial ID.
- Repeat this for each of the 3 (or 6) saved measurements during that study visit.

Download the CSV Data File of the participant's results

- Go to the main Uscom screen (Welcome), press the 'Uscom' menu button at the bottom of the list. This brings you to the Settings page.
- Along the tabs at the top, navigate to the 'EXPORT' tab using the arrow buttons.
- Select the patient to be exported.
- Press the 'SAVE' button in the bottom right corner. This will export the file to the USB stick.
- Remove the USB stick.

Upload the files to REDCap

- Insert the USB stick into a computer.
- Open the USB stick folder (usually found under 'Devices and drives').
- PDFs
    - Locate the 'Reports' folder within the USB stick.
    - Rename the files using the following format:
      [Trial_ID]-[Study visit name]-[Paced/Unpaced]-[Recording number]
      E.g. CAV001-PD1-Paced-1
- CSV parameters
    - Locate the 'Exports' folder within the USB stick.
    - Rename the file using the following format:

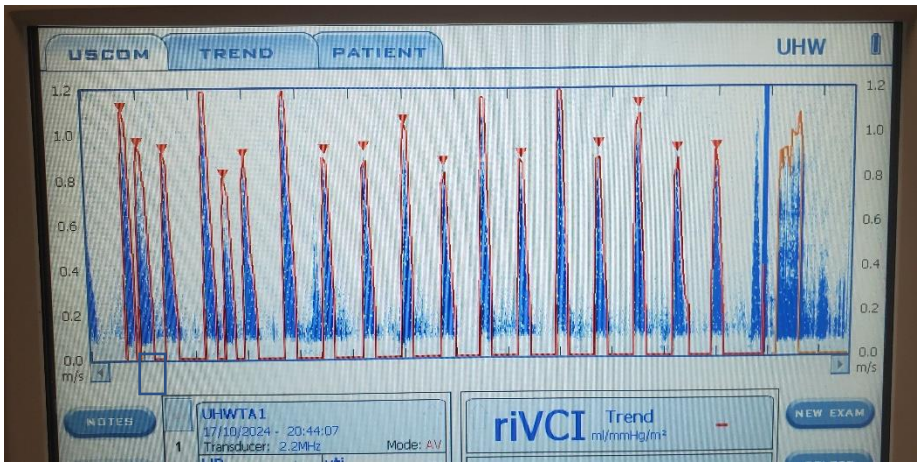
[Trial_ID]-[Uscom Data]
E.g. CAV001-Uscom Data

REDCap Upload

- Log in to REDCap and navigate to the correct patient entry.
- From the Record Home Page, open the appropriate form:
    - PDF Snapshot: Each visit where Uscom is performed has separate forms for paced and unpaced recordings. Upload all three recordings for each visit.
    - CSV Data File: A single form is available at the end of the Record Home Page.
- Click 'Upload file' to open the upload box.
- Click the 'Choose File' button to open File Explorer.
- Locate the file (either on the USB stick or saved on the PC) and click 'Open'.
- In the upload box, click the blue 'Upload file' button. The file will now be uploaded to REDCap.

Appendix – Examples of incorrect recordings

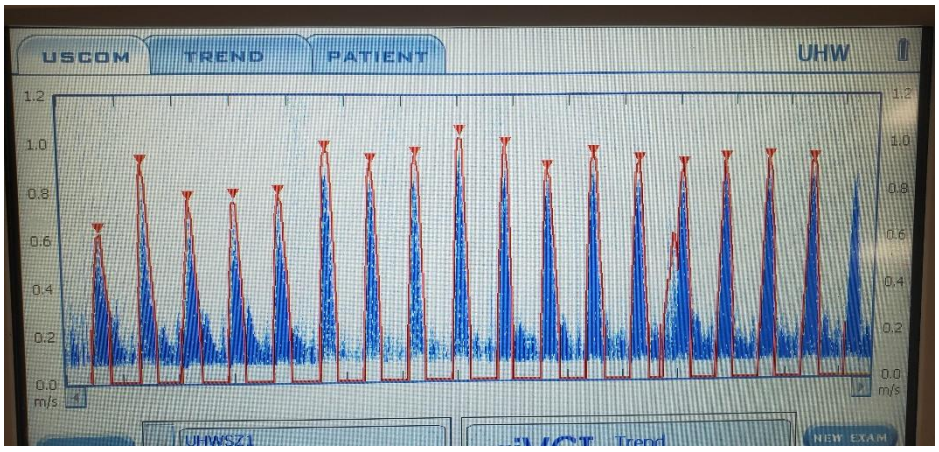
Care and time must be taken to ensure that the Uscom data is collected at the aortic valve, and that only correctly measured beats during sinus rhythm are included in the FlowTracer measurements. The following images show recording errors made during training. At the end of these is advice from Uscom personnel about how to ensure correct measurement technique.



(A) This patient has unusual beats and the quality of the signal varies, as shown by the different shapes of the beats and change in shading. Try to get a full screen of normal sinus rhythm. Freeze the display and move the selected window back and forth until you have a screen full of good quality regular beats before you apply the FlowTracer (red outline).

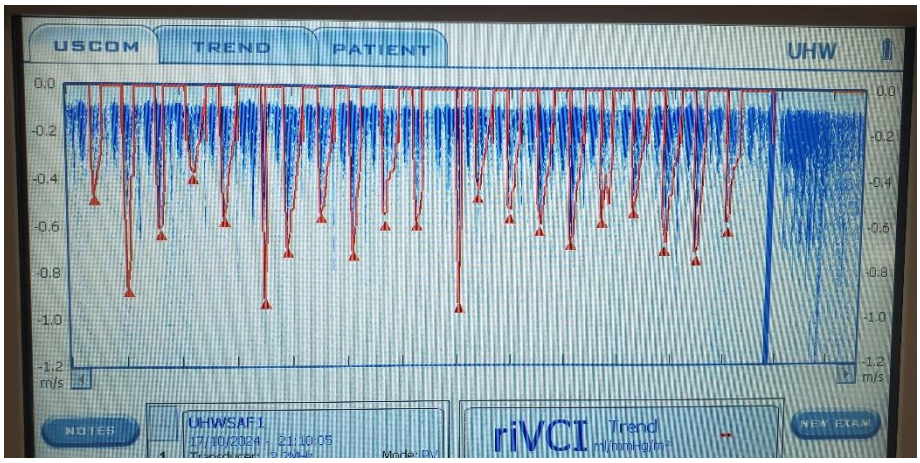
Always adjust the vertical scale to get the whole outline of the beat in.

The partly-traced last beat in red should have been removed. It is important to check the spacing from the end of one beat to the beginning of the next as, if traced incorrectly, this affects the HR which will give incorrect readings. As all the beats from 7th from the left look regularly spaced, the patient does not appear to be in AF. Beats 2 and 5 from the left look unusual and beats 1 and 2 are very close; these may be ectopics. Removing beat 2 and 5, as well as the last one would have given a correct HR.

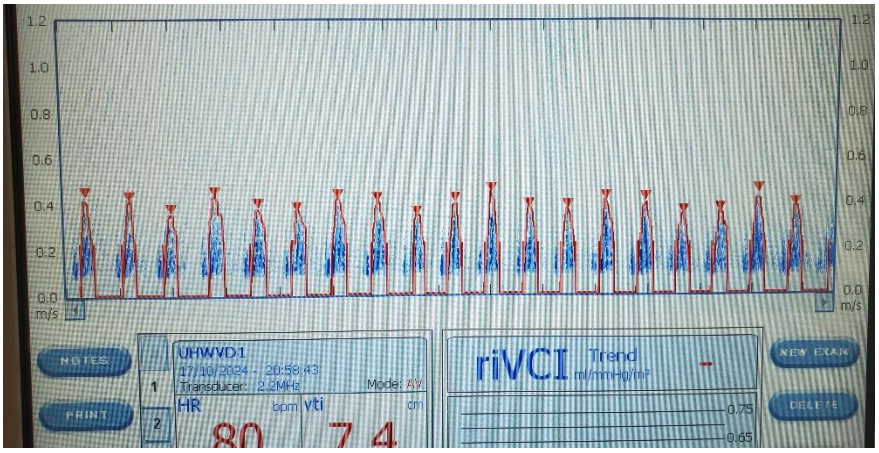


(B) The signal quality varies across the recording. The flow profiles on the right look good and Vpk is higher than those on the left. This is the correct probe position.

Measurement should have continued for several seconds to get a full screen of beats that looked like this. The 4th beat from the right has not been outlined correctly. Beats like this should be removed from the FlowTracer (red outline) by tapping on them.

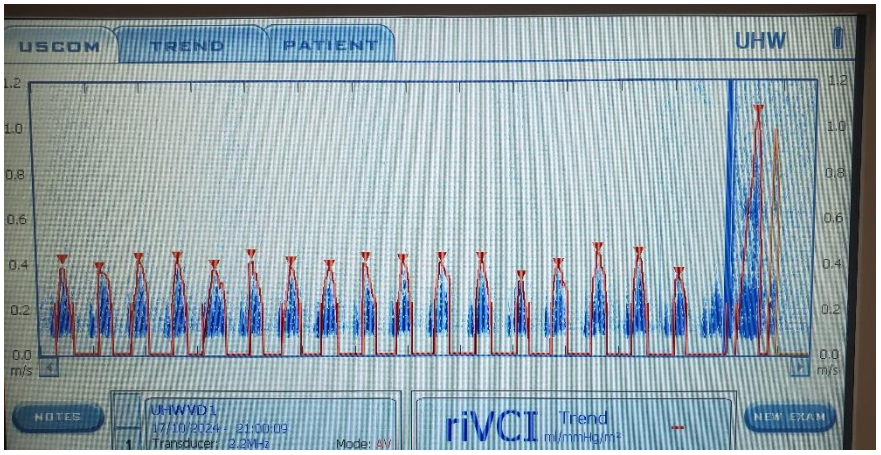


(C) We decided not to use the pulmonary valve. This signal quality is very poor and the calculated VTI is highly variable.

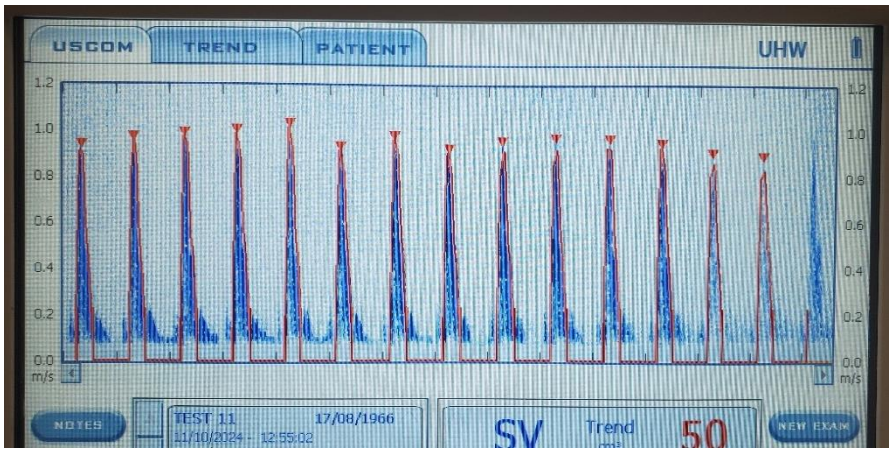


(D) This is not targeting the aortic valve. More manipulation is required; probably more pressure and more gel.

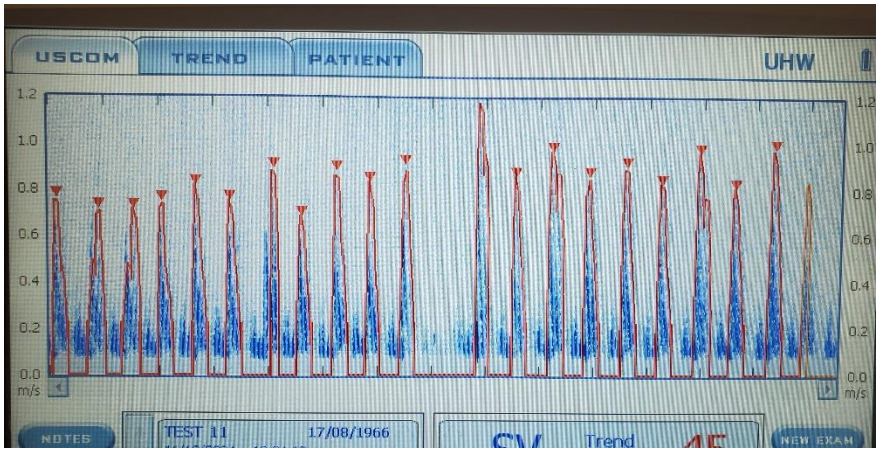
Keep trying until you get the strongest signal and the highest velocities consistent with the aortic valve signature.



(E) Again, this is not measuring at the aortic valve. The FlowTracer outline should have been removed from the shapes at the right hand and of the screen. These have been calculated as normal beats.

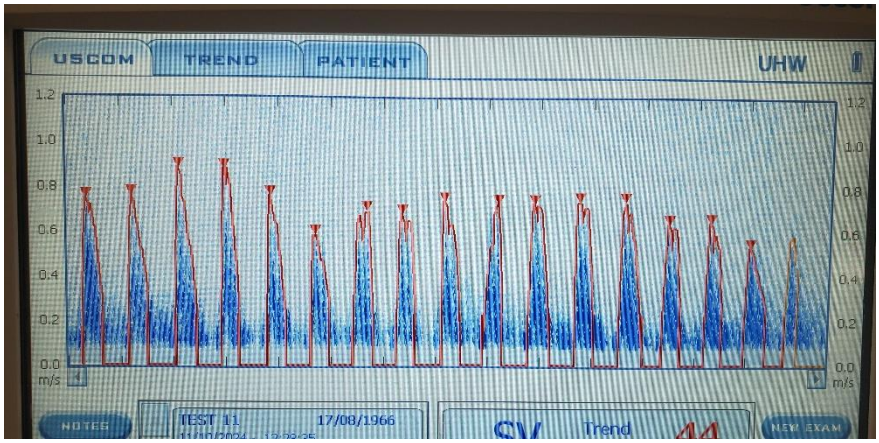


Lower peak velocities and paler profiles on the right side at the end may be due to insufficient pressure applied or movement of the transducer. The operator has identified good profiles at the beginning. This needs to be continued until a full screen is recorded. Poor quality beats should always be removed from the FlowTracer outline.

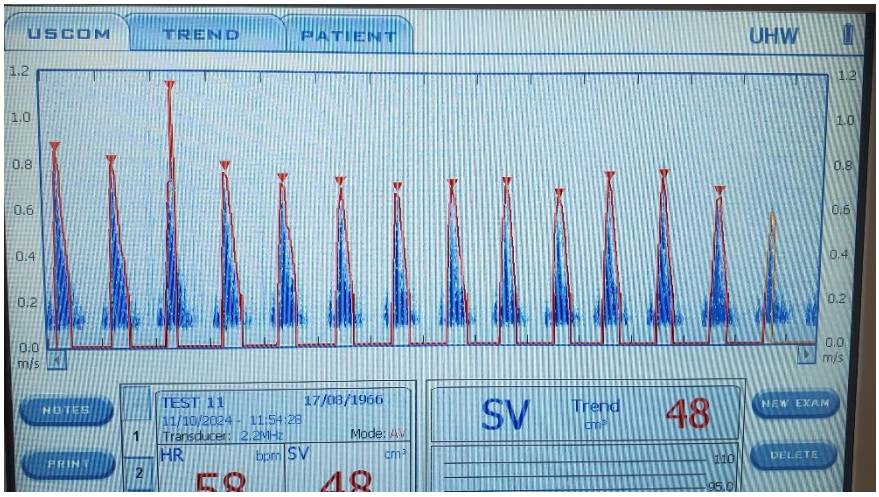


(F) Beats are varying in shape and outline. This is not measuring in the aortic valve. There is a lot of pale shading and some peaks are not visible. Possibly more gel required.

The large 'beat' in the middle is erroneous and should have been removed from the FlowTracer outline.

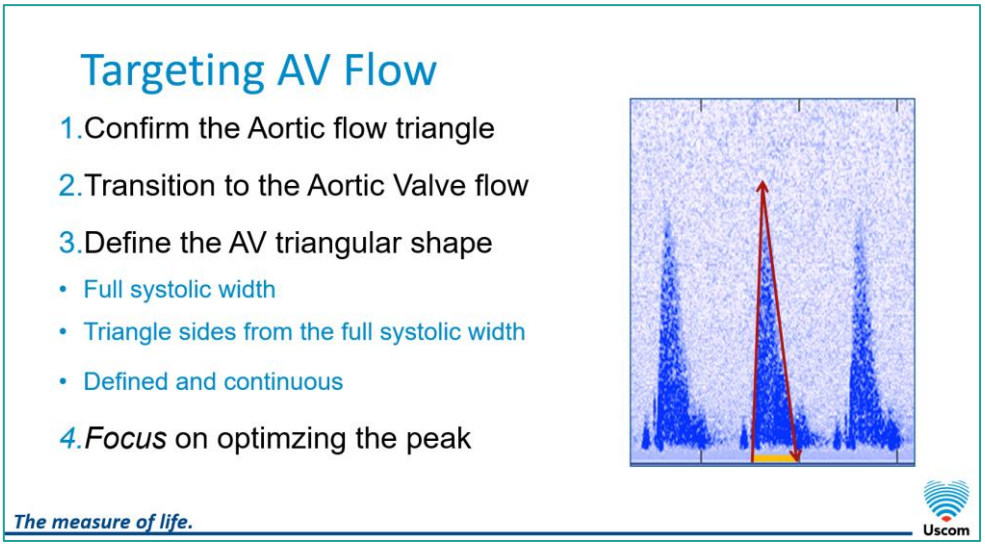


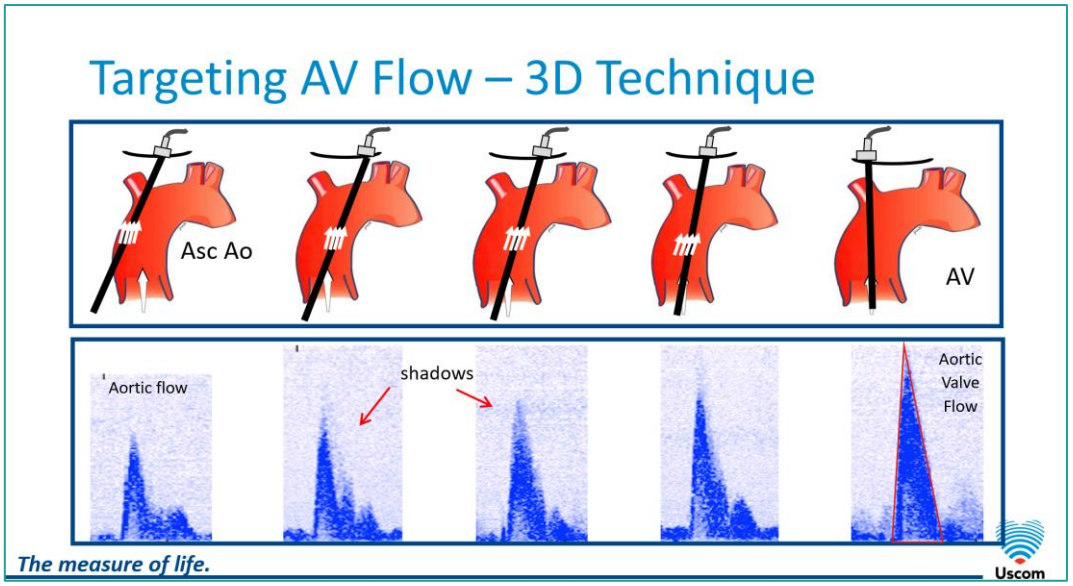
(G) The double peak means the trace is flat at the top with no peak identified. Earlier beats show higher peak velocities, so there is more flow than is being measured.



(H) The signal quality is varying as the FlowTracer outline is decreasing over time. The last few beats have pale shading and no clear peak. Maybe the pressure was lost, or the probe moved. The 3rd beat is erroneous and should be removed from the recording.

Advice for targeting the aortic valve





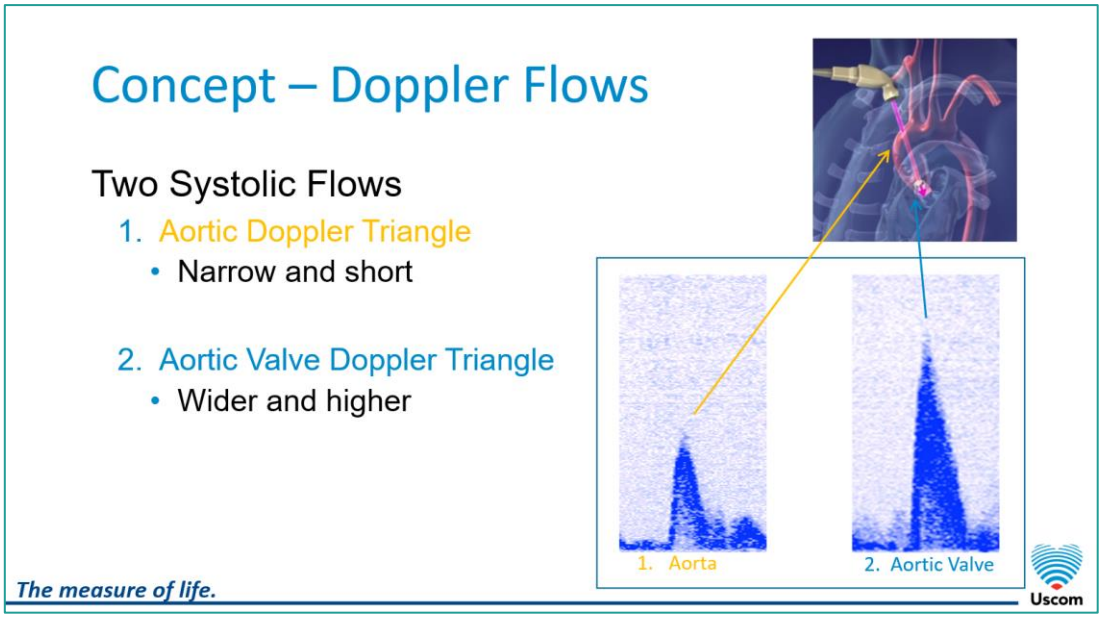
Targeting AV Flow – 3D Technique

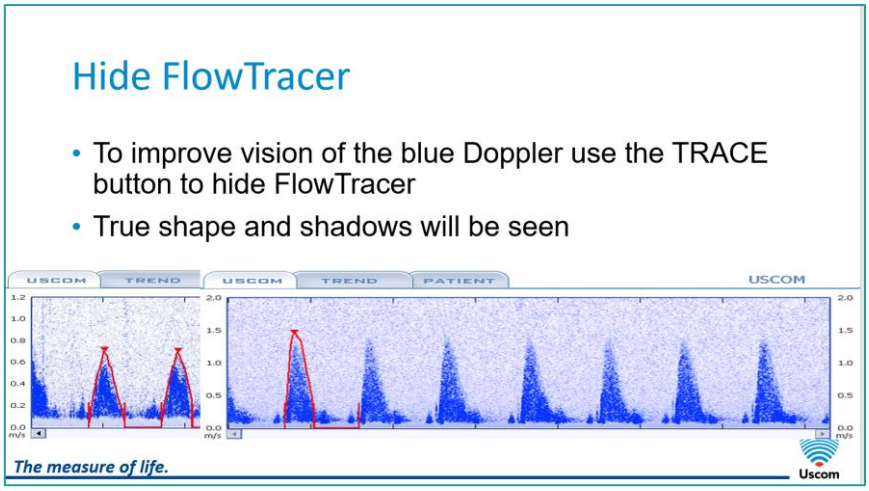
This diagram shows how the Doppler profile changes with transducer position and angulation as we aim to target the AV flow.

Our aim is to obtain the best alignment to flow for the highest velocity.

On placement of the transducer into the SSN, the first systolic Doppler profile you see may differ from patient to patient. It could look like the 1st, 2nd, 3rd or even the 4th stage image.

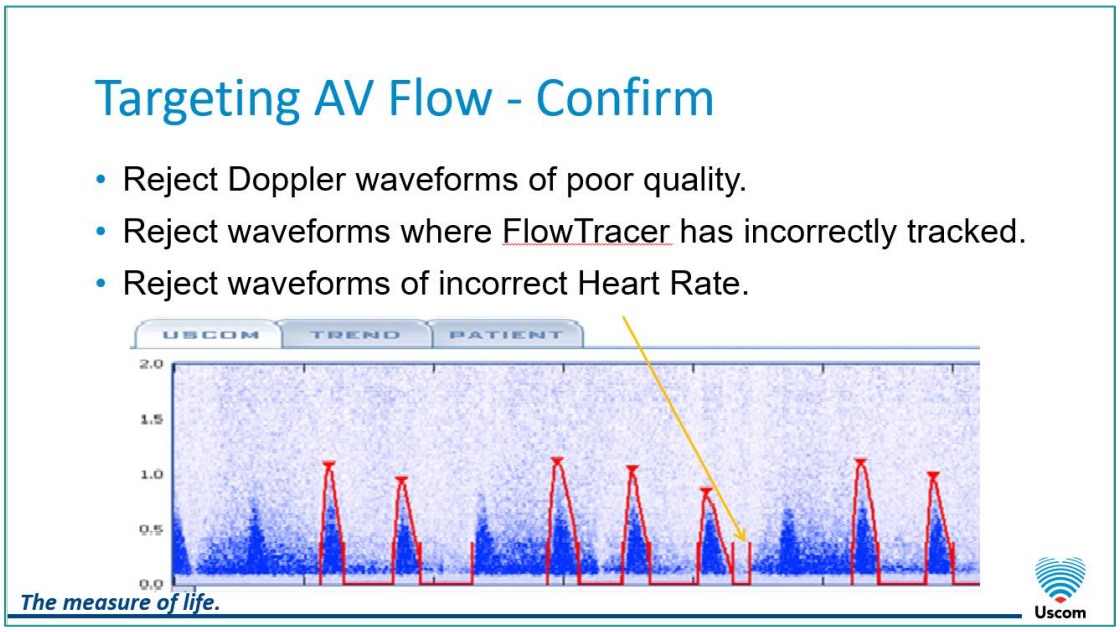
As the Doppler beam moves from Ascending Aorta to Aortic valve, the Doppler profile transitions between the Aorta and the Aortic valve flows. Soft shadows at the top and right side of the Doppler profile are feedback that more transducer manipulation is needed as these edges are not well defined.





Tip – Hide FlowTracer during acquisition

Shadows and peaks are more easily seen when FlowTracer is off. Focus on the triangle's blue Doppler peak and shape, not FlowTracer's red line.



Targeting AV Flow – Confirm

Obtain a screen full of good aortic valve Doppler and freeze. The red FlowTracer will appear showing the tracking of the Doppler.

Visually inspect the FlowTracer's tracking of the Doppler.

- Run your eye over the peaks and then across the base of the triangle to check the FlowTracer has tracked well.
- Reject waveforms where FlowTracer has incorrectly tracked.

- Reject waveforms of incorrect Heart Rate.

It is part of the quality control of the targeting process, ie. to inspect and reject those waveforms that have traced incorrectly or which are of poor quality.

Questions to ask:

- Have I got the complete Doppler profile?
- Has FlowTracer correctly traced the profile?
- Is the heart rate correctly calculated?

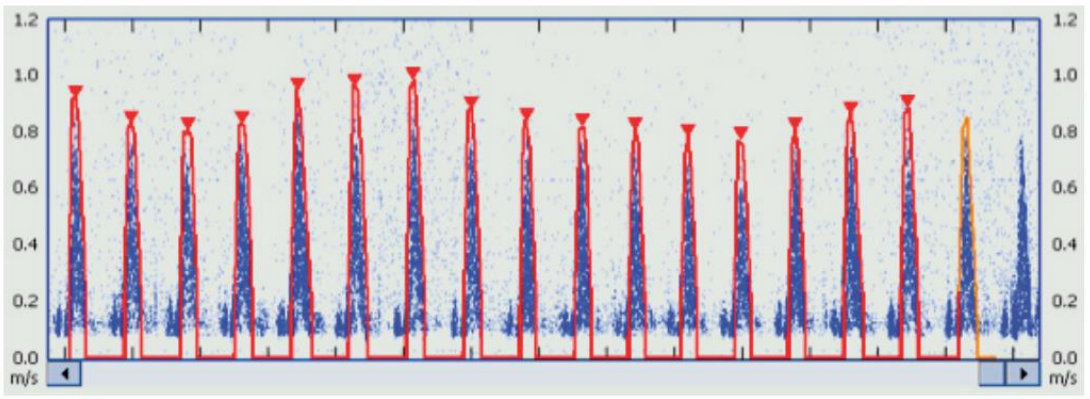
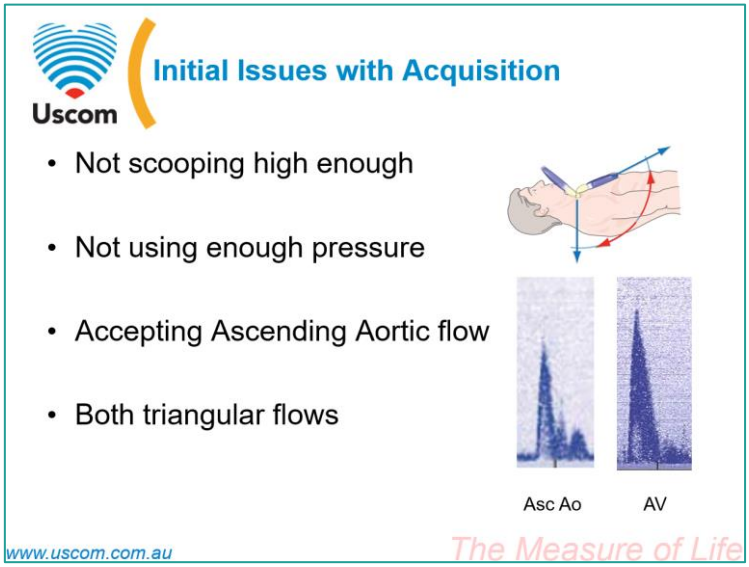


Figure 7: Transaortic Doppler flow profile demonstrating normal respiratory SV variability.

Citation: Robert A PHILLIPS, Stéphane G CARLIER, Alessandro SCALIA, Philippe DELMOTTE, Giles N CATTERMOLE, Joe BRIERLEY. Global Hypertension Guidelines: Are Central Haemodynamics Critical and Neglected. Anesthesia and Critical Care 5 (2023): 87-97.



Accepting the Ascending Aorta instead of the Aortic valve may be due to:

- Not scooping high enough in the Sagittal plane. Head to Toe. The majority of the profile will be found in this plane.
- Not using enough pressure to line up with the valve.
- Not distinguishing the 2 profiles from each other.

Training requirements

The learning curve for the Uscom is about 20-30 studies. About 85% of people are easy to get a signal from, another 10% take a bit more time, and about 5% are impossible to get a good signal from.

You must conduct a minimum of 20 examinations before using the Uscom to measure RSA-PACE participants. Each examination should include at least 3 saved measurements. The first 5-10 examinations can be on healthy volunteers., e.g. colleagues. The last 10 examinations should be on people with HFrEF or having cardiac surgery. For these, record the SV or VTI values and try to ensure that the difference between them is no more than 10%. However, it may not be possible to get good signals from the pulmonary valve.

It is recommended that these are not all conducted on the same day. Do not use the USER account for the RSA-PACE trial data. Each researcher should have their own USER account. It may be useful for all researchers to measure the same subject in the same session, as one may get better signals than the others and they can compare techniques.

Follow the instructions for collecting study data when conducting your training recordings. Your recordings will be checked for correct technique before you are allowed to start collecting study data. If you don't have BP data, just make it up.

Each researcher must record each training Examination on their personal Training Record (see end of document). This must be signed off by the Principal Investigator to state that they are competent to conduct trial measurements. When completed, this Training Record should be filed in the Investigator Site File alongside the Study Delegation Log.

Training Record

Site: _____ Researcher name: _____

No	Date and time of examination	Participant Initials	Volunteer or patient?	Notes (e.g. 'easy', 'impossible', 'many poor quality beats', etc)
1.				
2.				
3.				
4.				
5.				
6.				
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17.				
18.				
19.				
20.				

Signed (researcher): _____ Date: _____

Signed (PI): _____ Date: _____