

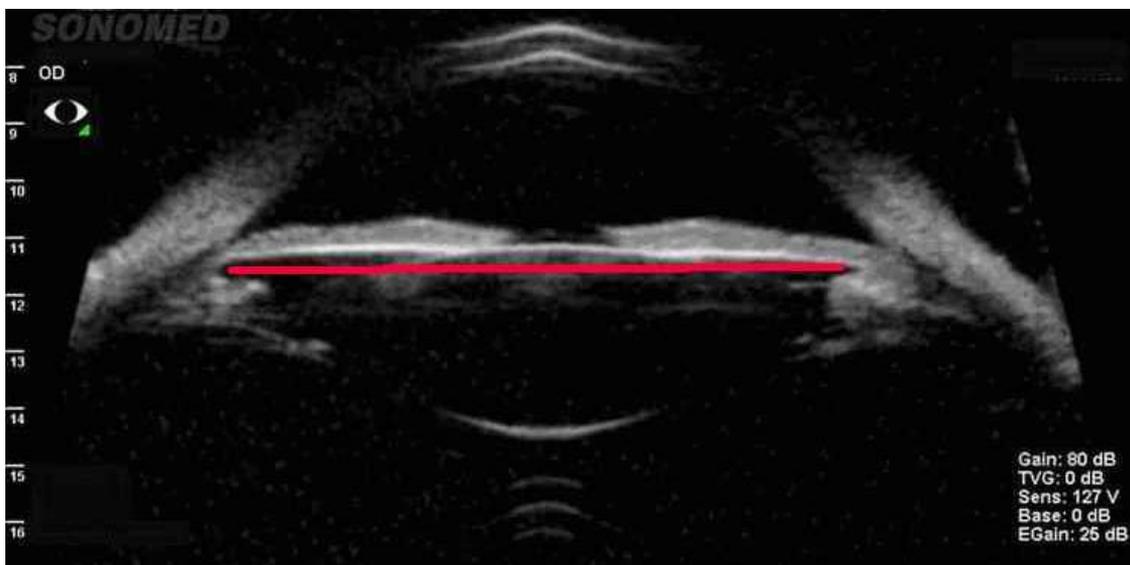


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Procedure to measure the sulcus to sulcus distance by the Sonomed VuMAX II in patients to be implanted with the Staar ICL

Sulcus to sulcus sizing is considered important in the selection of the ICL to be implanted.

A properly sized ICL will prevent the alteration of the anterior segment structures which may generate postoperative complications in the eye.



Image, sulcus to sulcus measurement

The objective of this document is to define the correct procedure to collect images, the correct selection of the images to be measured and the proper technique to do the measurement.

It is important to scan the eye at the horizontal and vertical axis. Even it is unusual; sometimes we can find a larger vertical than horizontal sulcus to sulcus. This is a circumstance that the Clinician needs to consider.

Preop-ICL implant patients will be imaged and measured using the Sonomed VuMAX II. The data to collect from every patient must include clear images of the anterior segment.

The quality of the images must permit the identification of "the sulcus to sulcus distance" and the ability to draw a straight line providing the correct measurements.

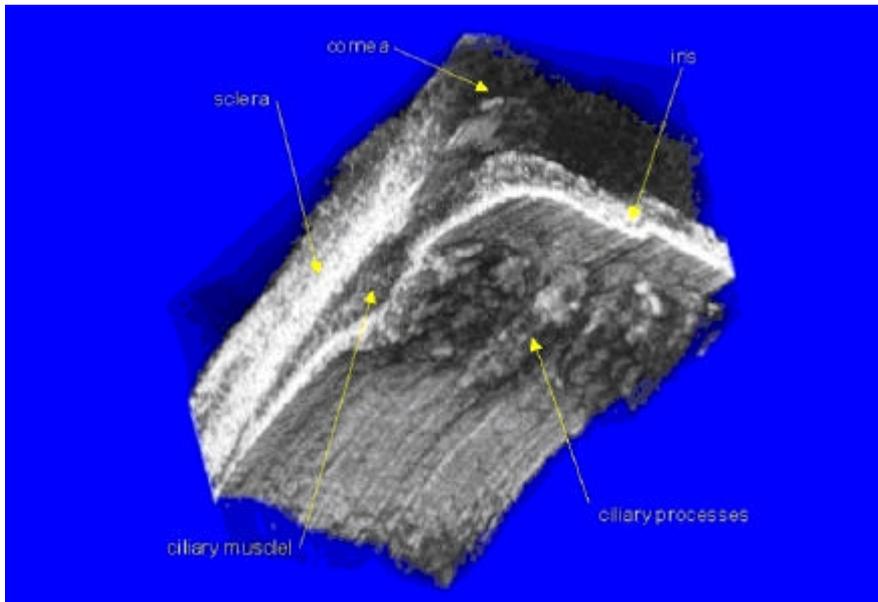
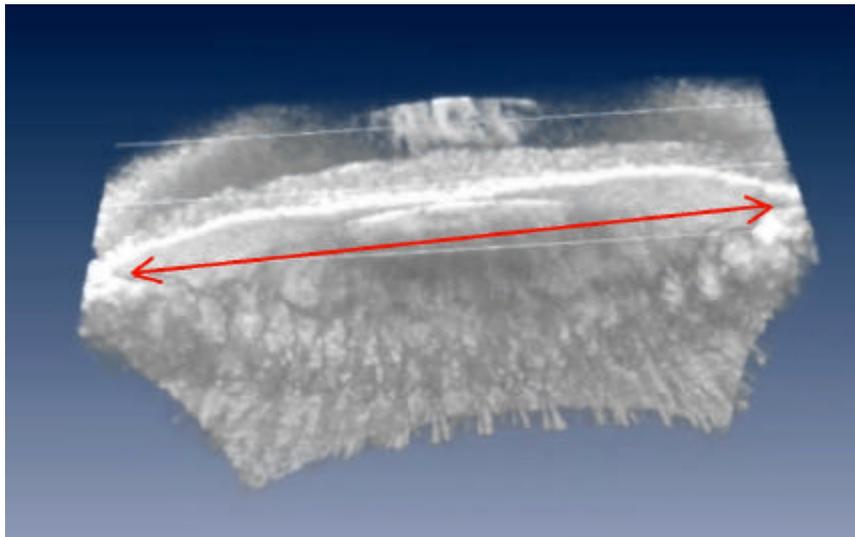


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Note that because of the irregularity of the ciliary body, sometimes the Scan sector falls in 2 "valleys" and may affect the correct estimation of the sulcus. It may show important differences in consecutive pictures of the same area. This is because the scan falls on "hills" and or "valleys" depending on where the cross section "slice" was made.



3D Images of the sulcus and ciliary body



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Examination:

To run an examination is necessary to have a quiet room with a bed, the patient needs to be on supine position. The room lights may need to be dimmed to almost darkness when scanning. This will make the pupil to be naturally dilated and will improve the conditions to collect images.

A bed is ideal, but if not present a 45 degree recline chair can also be used. Ask the patient to recline until his face is completely horizontal. If a reclining chair is used, make sure that the head of the patient is horizontally placed.



Image of the eyecup inserted

It is important to remark that the patient needs to feel comfortable; any forced position will revert on movements during scanning.

The examination usually takes 2 minutes by eye, but in certain patients may go as long as 5 minutes.

Enter a "new patient" and select the eye to be examined. It is also important to define the settings now. The next step will be to insert the eyecup and at this time the control of the unit needs to be done by the footswitch.

Suggested setting values to start can be,

Preset: "High Resolution" (if the eye is too large sometimes won't fit the sulcus to sulcus in one picture, in this case switch to "Sulcus to Sulcus")

Gain: 90 db

E-Gain: 60 db

Leave all the other settings with the default values until you feel familiar with the unit.





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All the settings can be changed by the footswitch during the scanning time, but it is better to have them selected in advance.

Apply anesthetic drops and await 10 or 15 seconds before proceed to insert the eyecup. Start inserting the eyecup asking the patient to "look down", hold the upper lid by your finger and insert one of the sides of the eyecup. At this time ask the patient to "look at you" and gently move down the inferior lid to make the necessary room to insert the eyecup completely.

At this time is convenient to tell the patient that the BSS solution is cold and sometimes produces discomfort (a BSS solution at 37 degree will ease this feeling). Make sure that the eyecup is almost full filled of solution; the focus of the transducer is 12 mm. which will "force" you to scan from far away. This is a big advantage because such a distance from the transducer to the cornea will prevent any accidental contact.

Gently hold the eyecup to prevent leaking during the whole examination, make sure you are not pressing to much to avoid patient discomfort.

Hit the central pedal of the footswitch and the probe will start moving, immerse the probe and control the probe position now by looking at the monitor.



Image immersing the probe

You will immediately see the eye image at the screen, when the cornea is at the top part of the screen you are still 8 mm. away. Then, there is enough space to comfortable move the probe until you find the best position.

Note that both your hands are occupied and the control of the unit is by footswitch.

It is now time to "align" the probe to the best axial position to the eye; have a target at the ceiling to "look at" by the other eye to make the patient to look straight.



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Ask the patient to have both eyes open during the exam. Try different positions until you see the image at the screen is acceptable. The use of the water bath brings you more options to follows the eye position.

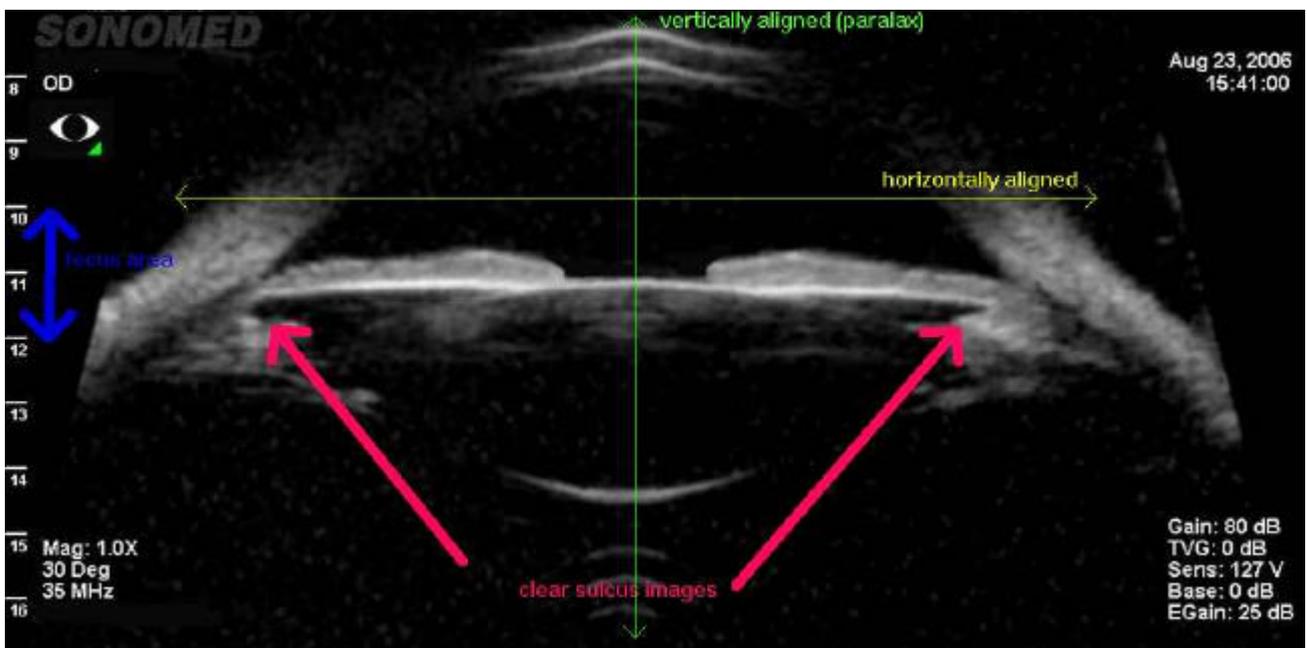
Based on the image buffering function it is advisable to save many clips when the alignment position is reached. Hitting the left pedal at the footswitch will save the last 50 frames captured on a clip and stored on a buffer at the top of the display.

Once you finished the exam, click on the Save icon to stored them, other wise this images will be discarded.

If the 6 available spaces for clips are full, the unit will ask you to hit right pedal to save them automatically and continue with a new session with the same patient. Using this way you don't need to release the probe and or eyecup to continue the exam.

Not having an "alignment" indicator, the following "landmarks" needs to be present on the image captured to be validated for measuring.

- a. The image must be balanced, in other words symmetrically aligned with a theoretical central horizontal line.



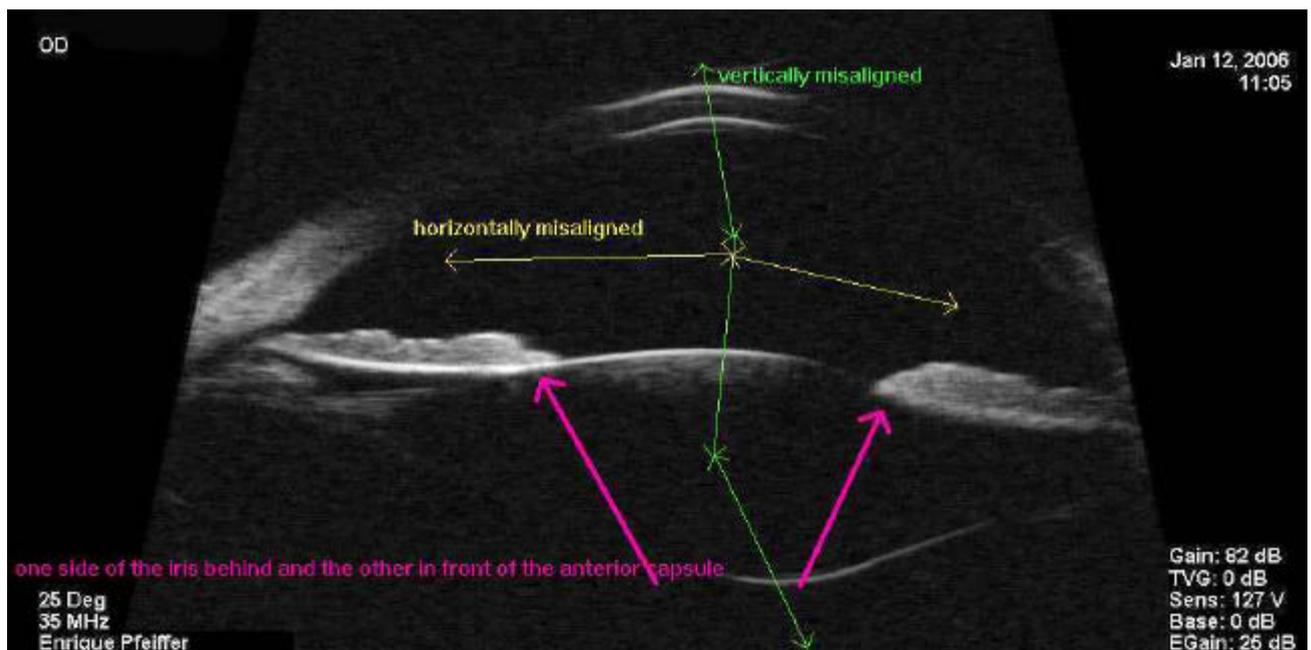
Correct image to be measured





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- b. The vertical alignment is important because the best definition is at 12 mm. (+ - 1 mm.). If the sulcus area falls above or below these values, the image of the sulcus won't be clear.
- c. It is also important to have a corneal and Lens posterior capsule references, they together with the Lens anterior capsule must be balanced a theoretical vertical central line.
- d. It is obvious that a clear sulcus must be present on both sides to make the posterior measurement easier.
- e. An important reference is the "position" of each of the "sides" of the iris over the anterior capsule. Proper alignment of this reference is to have symmetry on how each of them lean on the lens. There is a usual misplacement of the probe which brings the image of one side falling in front of the lens and the other falling behind.



Wrong image to be measured

- f. The pupil size during consecutive scans will bring another good reference of alignment. The largest pupil size will indicate the "center" position on a given scan.

All the above suggested landmarks need to be present on a given image in order to validate the measurements.





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After reviewing the various clips, at least 4 images must to be selected among those clips to be measured.

The correct understanding of the anatomy at the sulcus area will help on to determine the exact area where to place the cursors.

A usual finding is the so called virtual sulcus, where the ciliary body is in contact with the root of the iris, even not showing a space, the sulcus goes all the way through until the end of the pigment epithelial layer line.



It is advisable to collect various clips meanwhile in alignment to be able later on to select the some "validated pictures to be measured.

If all the landmarks above mentioned are present the differences between measurements done in different images will be irrelevant or clearly explained by the anatomy variations.

Following is a sequence of consecutive scan of the same patient, note how the sulcus area varies from one to another. The correct one is clearly remarked in red color; note the variations at the sulcus because of the anatomy since all those images shows almost all the landmarks suggested for "alignment".





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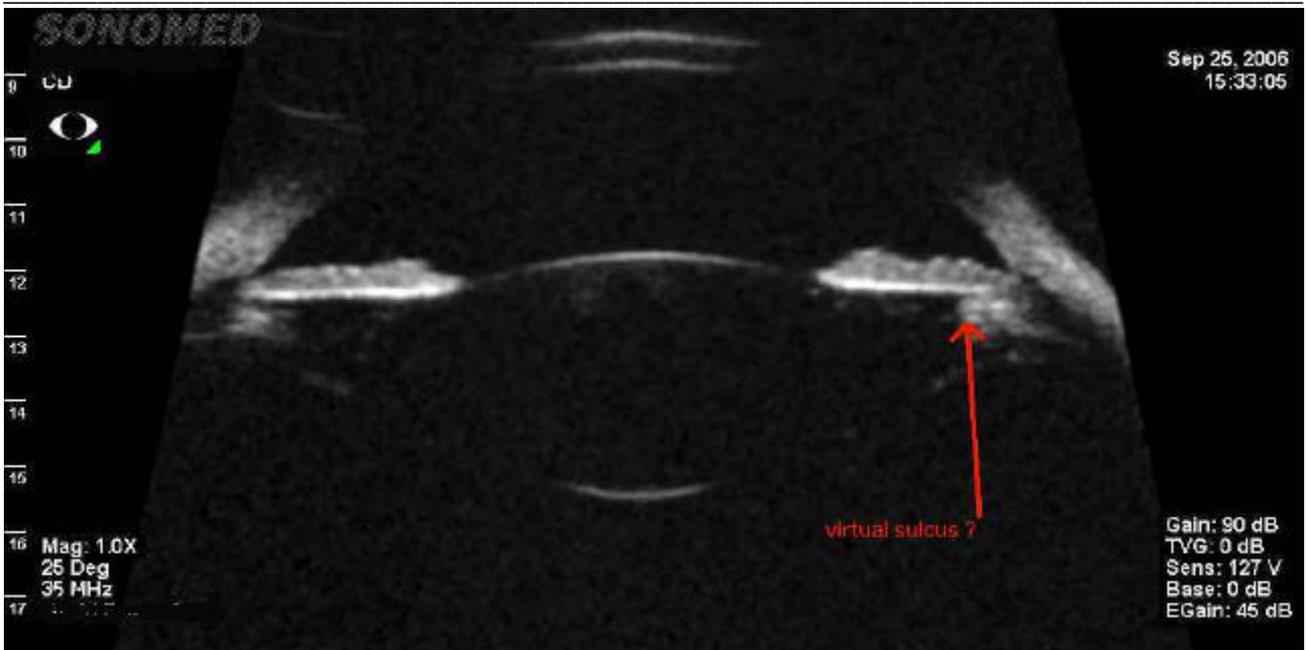


Image 1, at the right side the sulcus looks shorter



Image 2, now the left side looks shorter



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Image 3, again at the right side looks shorter

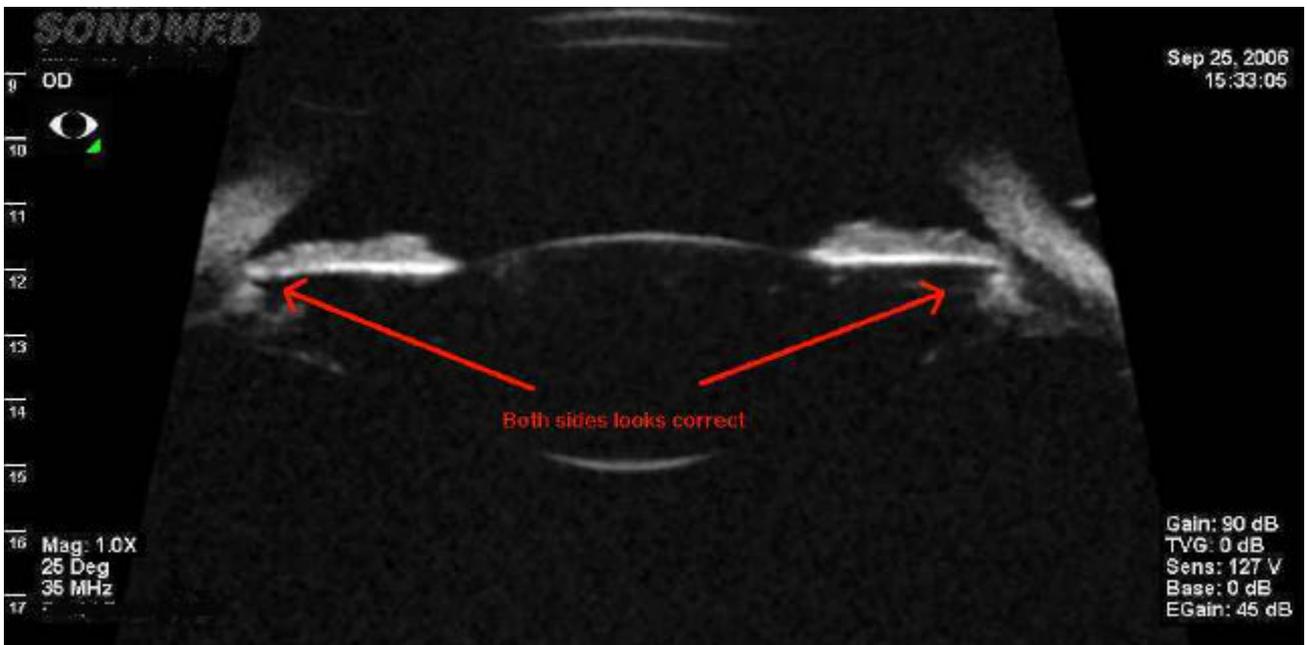


Image 4, this is the correct one at both sides



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Image 5, the left side looks shorter



Image 6, again left looks shorter



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Image 7, the left "opens" a little bit



Image 8, still pretty good



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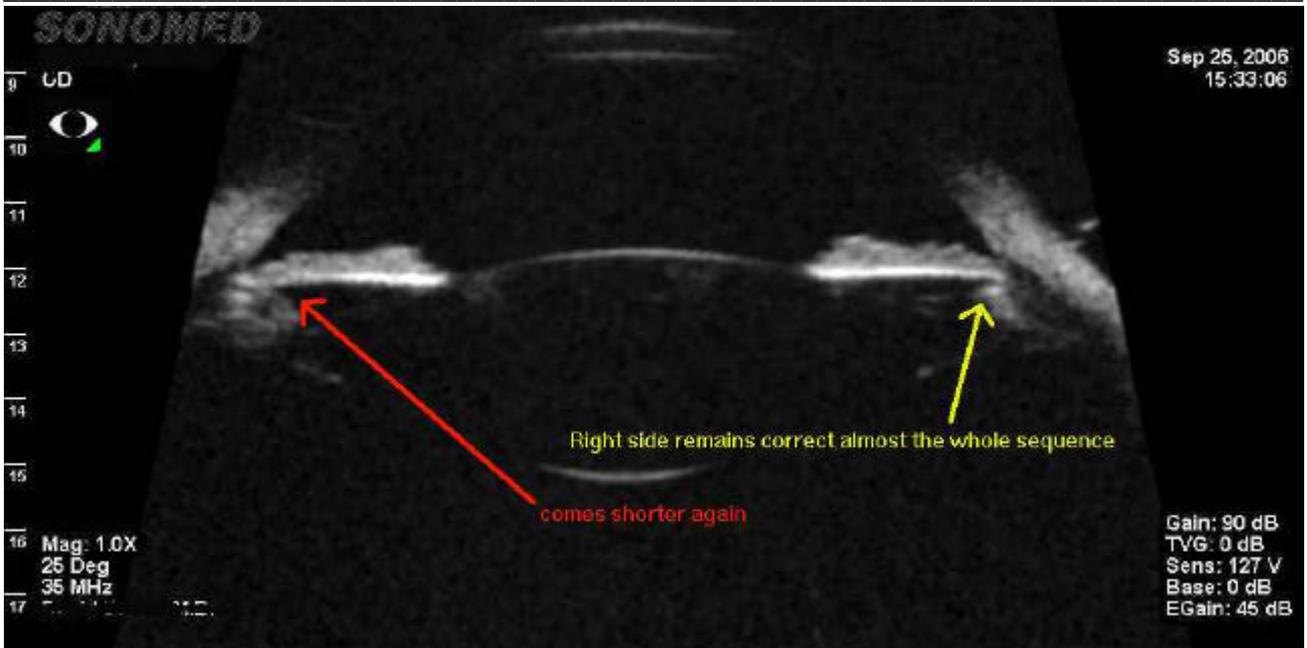


Image 9, again the left side looks shorter, the right side remains unchanged

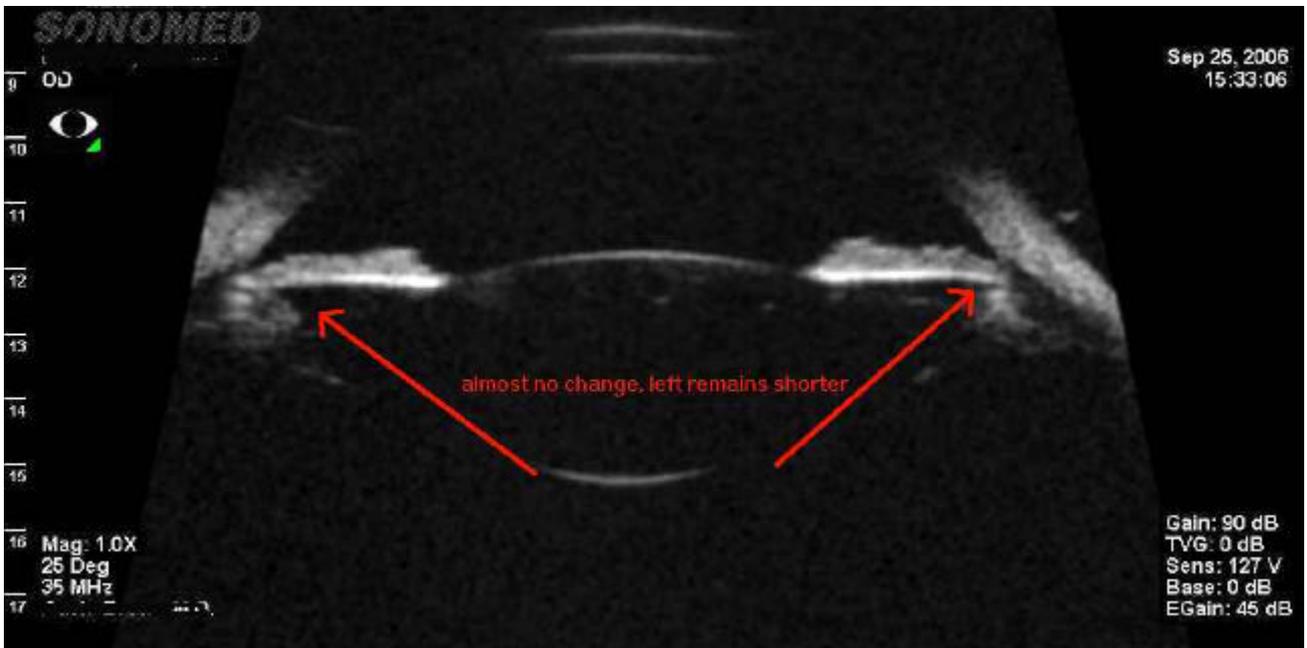


Image 10, left side remains shorter



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During the 10 sequential images taken from a clip, it is clear that the anatomy at this area varies from "slice" to "slice". It is important to understand these variations to determine the correct sulcus to sulcus distance.

The VuMAX provides 2 different ways to measure a distance. There is an **Arbitrary A Scan** tool which allows the user to define a line where an A Scan vector will help on to determine a change on the display. Usually is being used to precisely know distances to a micron level. The Caliper is a simple measurement ruler which will ease the process of many measurements to be made. Each of them will work fine on the sulcus to sulcus measurements.

It is important to keep records of the measured images. Once made, it can be stored on the frame collector at the right side of the display, simply drag and drop with the right mouse key and they will remain saved with the rest of the images belonging to this patient.

Additionally, either video clips or images with overlaid measurements can be exported to selectable paths, using the "image export" or "video clip export" routines. Simply click on them and the selected clip or image will be saved on the desired folder at the computer.

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