SonomedEscalon™

VuMAX™ HD

Simply the Best

OPERATORS MANUAL

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United States Federal law and European regulations restrict the use of this medical device to, or on the order of, a physician. The VuMAX ophthalmic ultrasound device is for use by trained professionals in optometry and ophthalmology in a clinical setting. This group includes ophthalmologists, optometrists and ophthalmic technicians. The device is not intended for use by lay persons in any capacity.

A-scan biometry, also referred to as A-scan, utilizes an ultrasound device for diagnostic testing and is used as co-management tool in examinations of the structural integrity and pathology of the eye. The A-scan can determine the length of the eye and can be useful in diagnosing common sight disorders and is beneficial in cataract surgeries, as it can determine the power of the intraocular lens (IOL) needed for the artificial implant. In addition to axial length, ultrasound biometry can measure anterior chamber depth and lens thickness. Pachymetry is for measuring and mapping corneal thickness of the eye. The B-Scan mode produces a live, two-dimensional image to facilitate the identification and measurement of ocular pathologies in the posterior chamber of the eye, particularly when view of the chamber is obscured, such as is the case with cataracts. A UBM (ultrasound bio-microscope) is a B-scan which utilizes higher frequency transducers than used in a normal B-scan. Using higher frequencies provides much higher image resolution but limits the depth penetration of the signal and is therefore used primarily to visualize the internal components of the anterior segment of the eye only (iris, lens, etc.).

There are no restrictions to the patient population with regards to gender, age or physical limitations. The device is not for use on patients with questionable ocular integrity.

Before examining a patient, the user should become acquainted with the operating procedures, warnings and precautions set forth in the operator's manual. The user should consult additional resources as necessary for further information regarding the proper application of ultrasound technology. This instrument should be used in strict accordance with the instructions outlined in this operator's manual. The safety of the operator and the performance of the instrument cannot be guaranteed if used in a manner not specified by Sonomed Escalon.

Do not use the device together with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.

If difficulty is experienced when operating the unit after carefully reviewing this operator's manual, contact your local Sonomed Escalon distributor for assistance.

There are no user-serviceable parts within the VuMAX system.

To receive a translated copy of this manual, contact your in-country distributor, or call Sonomed directly at 516-354-0900 or 800-227-1285. For technical service and support please contact Sonomed Escalon or your local distributor.

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OVERVIEW

DESCRIPTION

The VuMAX HD is a high-resolution ophthalmic ultrasound system capable of utilizing a range of transducer frequencies for optimized imaging and measurements of various ophthalmic structures. The device is a multi-purpose, personal computer-based system intended for use in ophthalmic applications. The device is designed to capture images of the interior of the eye and make accurate measurements of the structures. The VuMAX HD is a stand-alone system that runs on a Windows 10 Pro platform and may be networked (by the user) for interface with electronic medical records systems, printing, and other purposes. The system consists of the VuMAX HD console with controls and inputs, monitor, ultrasound probe(s) and transducer(s), foot pedal, power supply, and wireless keyboard and mouse. The wireless keyboard and mouse use a min receiver that operates on a 2.4 GHz connection. The ultrasound device is used by coupling the probe/transducer to the eye either through direct contact or immersion methods. Available modes are biometric A-scan, B-scan, and UBM (high-frequency B-scan).

Biometric A-Scan

A-Scan is ultrasound technology that is used to produce length measurements along the visual axis of the eye for calculation of intraocular lens power. This method enables precise measurement of the anterior chamber depth (ACD), lens (L), and vitreous to produce the axial length of the eye. When a cataract is removed, the lens is replaced with an artificial lens implant. By measuring both the axial length of the eye (A-scan) and the power of the cornea (keratometry), a user selected formula can be used to calculate the power of the intraocular lens needed.

Diagnostic A-Scan

Diagnostic A-Scan is ultrasound technology that is used for diagnostic evaluation of detected eye pathologies found with B-Scan screening. This method enables imaging of structural amplitudes for analytical determination of the patient's eye disorder.

B-Scan

B-Scan is ultrasound technology that produces a cross-section, two-dimensional grayscale images for diagnosing pathologies of the posterior segment of the eye. This method enables imaging when the light-conducting media of the eye are opaque. Common conditions such as cataract, vitreous degeneration, retinal detachment, ocular trauma, choroidal melanoma, and retinoblastoma can be accurately evaluated with this modality.

B Scan Biometry

B-Scan biometry allows an A-Scan measurement to be obtained from a B-Scan image by using a captured frame from a B-Scan video. Once the desired frame is selected and saved, the biometry scan is adjusted and the axial reading is displayed. Once the A-Scan is positioned correctly on the B-Scan image, the B-Scan Biometry is used to switch to the A-Scan mode which will visualize the same spikes and then the operation is standard A-Scan from that point on.

UBM / Ultrasound Bio-Microscopy (UBM-Mode)

UBM is ultrasound technology that produces high resolution, cross-section, two dimensional grayscale images of the anterior segment of the eye. This method enables imaging of structural details such as Bowman's membrane, stroma, cornea, anterior chamber, lens, iris, ciliary body, and scleral spur. Other parameters such as iris area and volume, angle opening distance, angle recess area, sclera thickness, and trabecular meshwork-ciliary process can be evaluated and measured. Common conditions such as glaucoma, iris cyst, neoplasms, trauma and foreign bodies can be accurately identified.

INDICATION FOR USE

The VuMAX HD system is intended to be used to visualize and measure distances within the eye and orbit using A-Scan, B-Scan, UBM ultrasound. The device is designed to capture images of the interior of the eye and make accurate measurements of the structures.

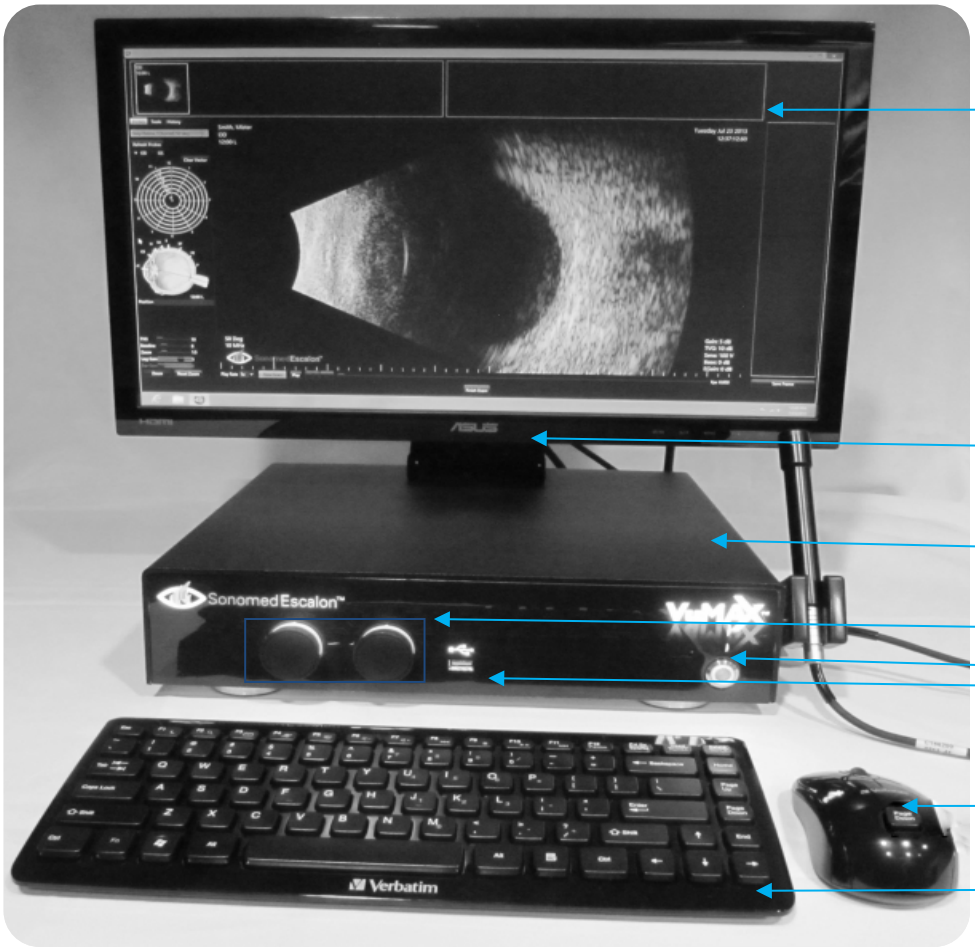
CONTRAINDICATIONS

The VuMAX HD system is not intended for fetal use.

GETTING STARTED

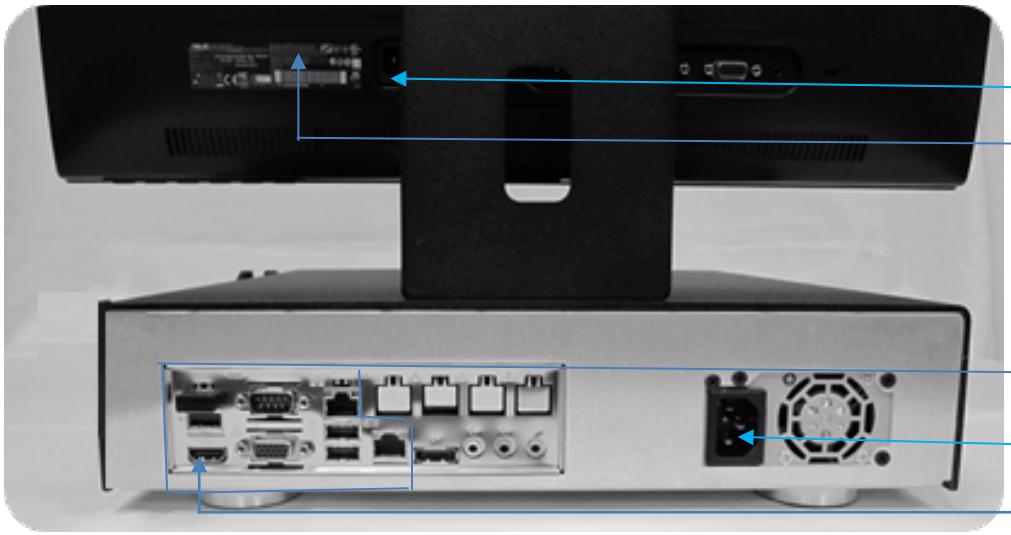
SYSTEM AND COMPONENTS

SYSTEM



CONSOLE SIDE PANEL

CONSOLE REAR PANEL



A-Probe 10 MHz

B-Probe
(12 or 20 MHz Probes)

Water Path Probe
(35 or 50 MHz Transducers)

Diagnostic A-Probe 8 MHz

Foot Pedal

UNPACKING

① Unpack contents from packaging. Be sure to unpack monitor arm located on side foam insert.

② Examine the unit and components to ensure the contents are intact. Visually examine the probes for any signs of cracks, scratches or damage. Do not use probes if damage is apparent.

③ Connect the monitor arm to console using the 4 screws located on top cover. Connect monitor to arm swivel using screws on rear of monitor. Connect power cords to console, monitor, and wall outlets.
CAUTION: Position such that console is well ventilated with easy access to disconnect power cords, as may be necessary.

④ Connect HDMI cable between monitor and unit.

⑤ Connect probe cable to unit and place probe(s) into probe holders.
NOTE: The same cable is used for all B-scan and UBM probes.

⑥ Power on console and monitor. System will boot up into a Windows 10 home screen and the VuMAX- HD icon can be selected to launch the program.
NOTE: Console and monitor may be powered off by pushing their respective power buttons.

CONSIDERATION WHEN JOINING TO NETWORK DOMAIN

The VuMAX HD uses Windows 10 and may be joined to (or removed from) a network domain. However, when doing so, it is required that the local user account is set up as a local administrator on the ultrasound system.

One potential issue to keep in mind is that when an ultrasound system is joined to a domain, the domain rules are typically pushed down, which can prevent a local user account from having full permissions (this would result in the ultrasound system not functioning properly). Please ensure that the local user account is set up as an administrator on the ultrasound system via your domain rules (i.e. the local user must remain as the local administrator).

Administrative operations, i.e., username and password protection, can be configured at the Windows level as needed to prevent unauthorized access.

For questions, please contact technical service at 516-354-0900 or 800-227-1285 or email ultrasound-support@esaclonmed.com.

CONFIGURING THE SYSTEM

① The home screen is the patient database which shows a history of patients and their respective exams. From this screen, select the <***Configure***> button (*Figure 1*).

② Select "**New MD / Examiner**" tab and enter the requested information using the keyboard and clicking the <**Apply**> button. Each MD/Examiner can be designated as an examiner, attending physician, and/or referring physician.

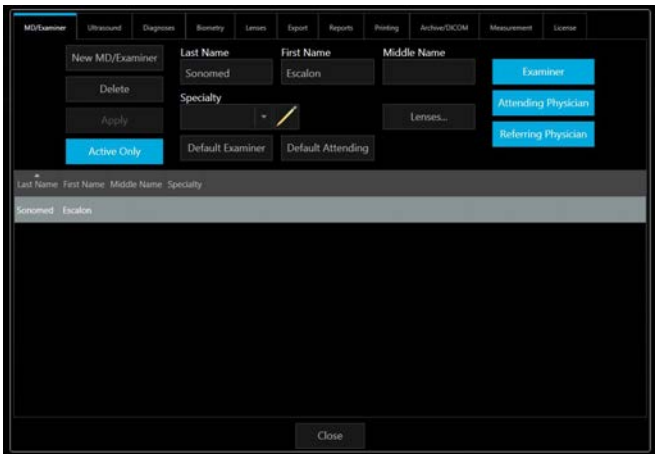


Figure 1 Configure Screen

③ For systems with biometric A-scan option, preferred lenses (IOL's) can be selected by selecting the <**Lenses…**> button. Pressing the <**Add…>** will display a window showing lens manufacturers on the left and lenses produced by that manufacturer in the center of the display. Once a lens is selected, the <**Add…**> button will become active and selecting this button will add the desired lens to the user preferred list. Likewise, a selected lens may be removed by highlighting the lens and pressing the <**Remove**> button. When all lenses have been added, press <**OK**> button. Pressing "**CLOSE**" will return the user to the MD/Examiner screen (*Figures 2 and 3*).

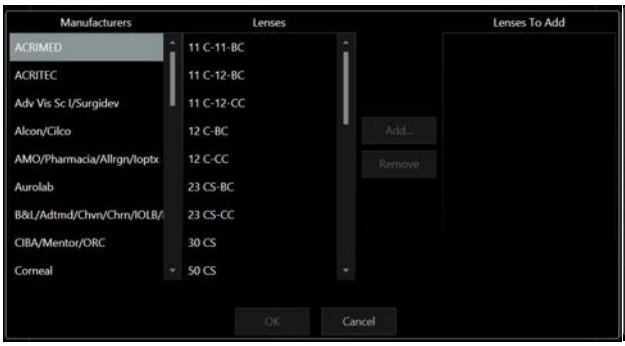


Figure 2: Lens selection screen

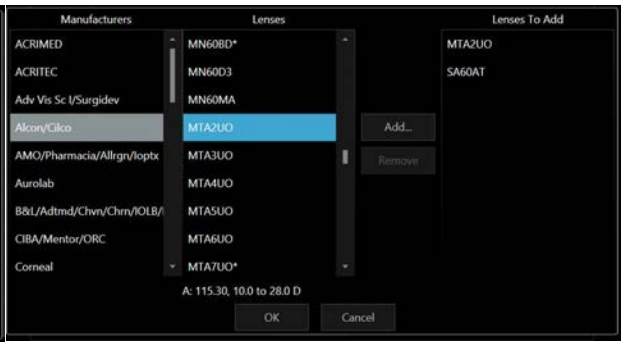


Figure 3: Lenses added

④ The above procedure can be used to enter any number of additional users so that each individual user can select their preferred lenses, etc.

PATIENT DATABASE

Upon opening the VuMAX™ HD program, the home screen shown is the patient database, which shows a history of patients and their respective exams. From this screen, several functions can be performed (*Figures 4-5*):

① **SEARCH** for patients by entering the known information and selecting the <search> button. A list of patients matching the criteria will be shown. Select the <clear> button to return to a list of all patients.

② **ENTER NEW PATIENT** by selecting the <**new patient**> button, entering appropriate information, and selecting the <**Apply**> button. The new patient information will be displayed in the Patient Database Screen (*Figure 5*).

③ **DELETE PATIENT** by selecting the <**Delete**> button in the patient section.
NOTE: Deleting a patient record will also delete all associated exam records. A prompt will appear to confirm intent is to actually delete a patient record.

④ **SELECT PATIENT** by highlighting the patient's name from the patient list – a history of any saved exams for that patient will appear in the exam list to the right under "EXAMS".

⑤ **SELECT EXISTING EXAM** by double-clicking on an exam record for a particular patient. This function opens the exam and displays associated images (see EXAM RECORD section of this user manual).

⑥ **CREATE NEW EXAM** by selecting the <New Exam> button.
NOTE: Patient information must be entered first.

⑦ **DELETE EXAM RECORD** by selecting the <Delete> button in the exam section.
NOTE: Deleting an exam record will delete all associated images and data. A prompt will appear to confirm intent to actually delete an exam record.

⑧ **IMPORT EXAM RECORDS** by selecting the <**Import**> button and following the on-screen instructions.

⑨ **EXPORT EXAM RECORDS** by selecting the <**Export**> button and following the on-screen instructions.
NOTE: This function may be useful when connecting to EMR system, referrals, or creating presentations.

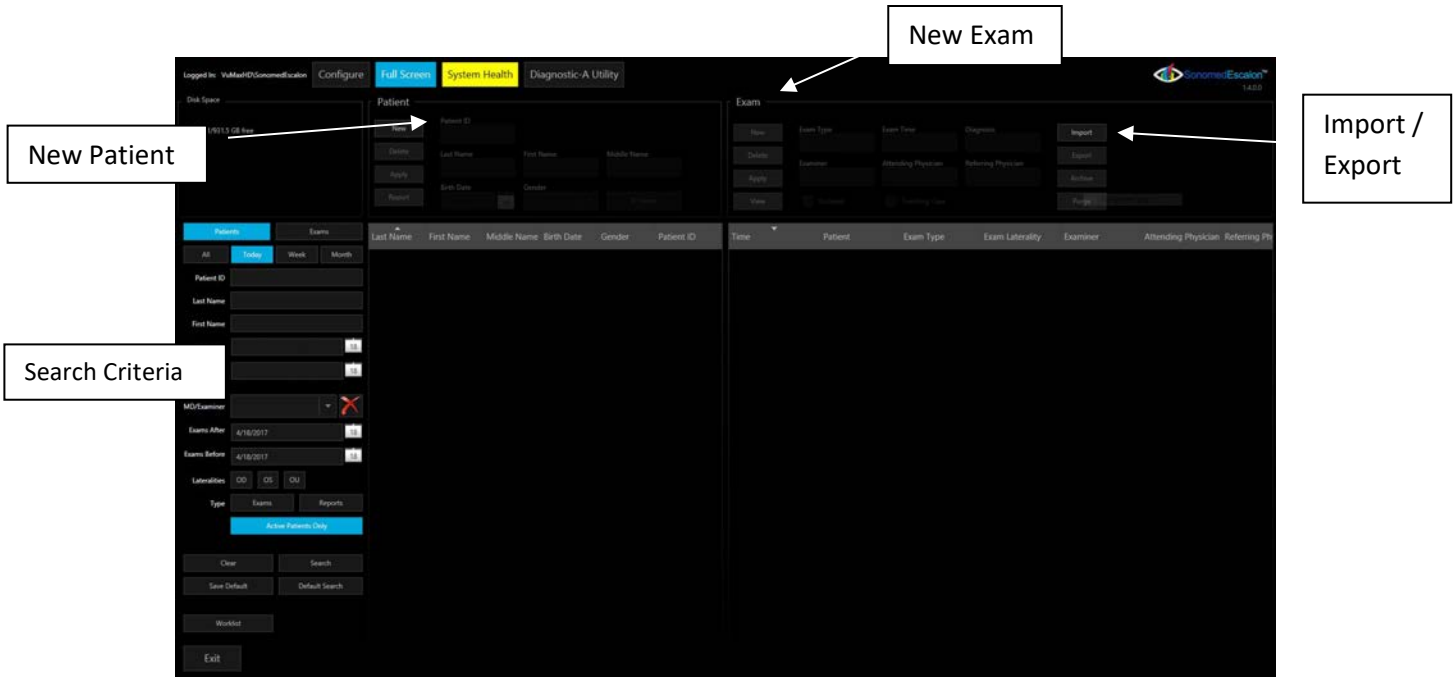


Figure 4: Patient Data Screens

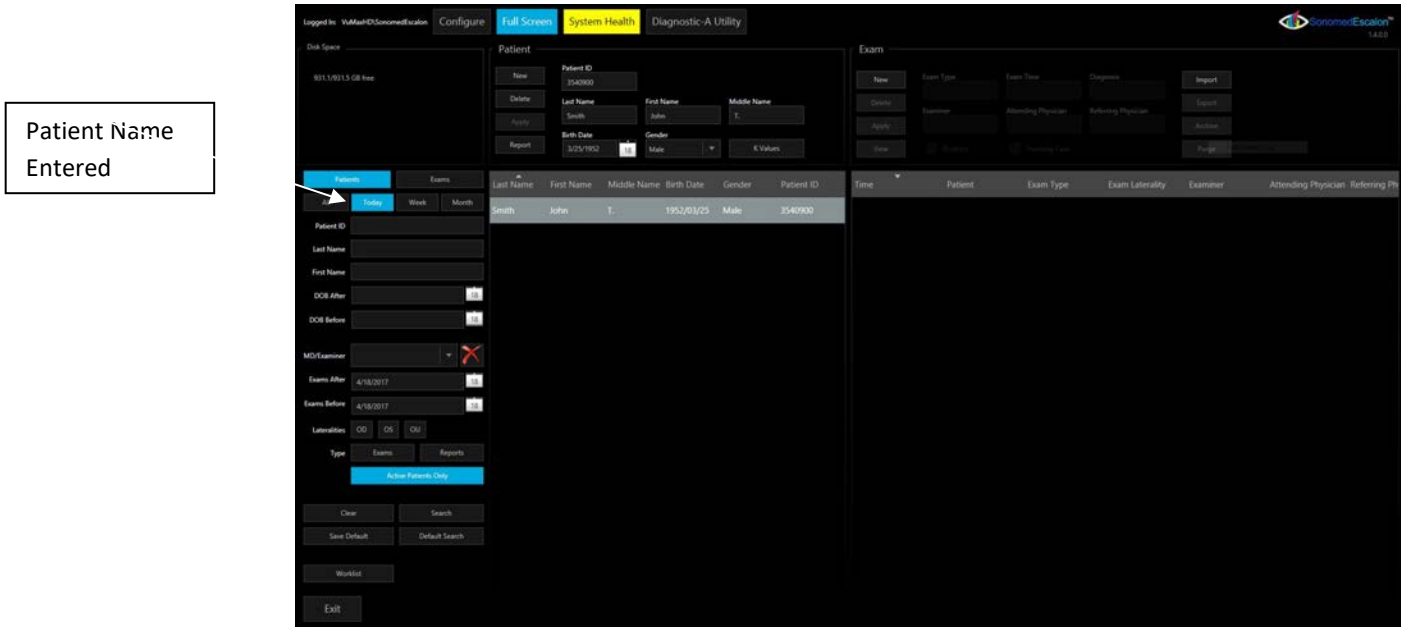


Figure 5: Patient Name Entered

B/UBM EXAM MODES

After Entering a "New Patient" (above) select the <**New Exam**> button from the Patient Database screen (*Figure 6*) and enter the exam information as shown:

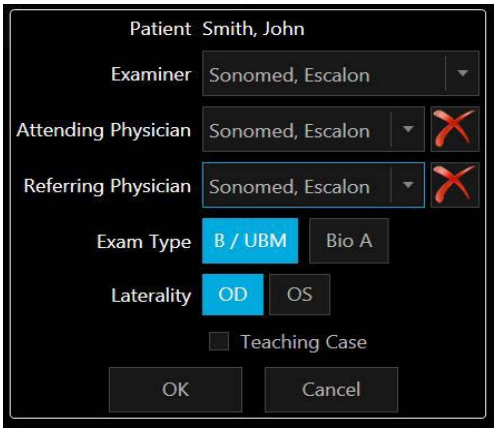


Figure 6: Patient Scan Information

Enter Examiner, Attending and Referring Physicians, Exam type (B-scan, UBM or Biometry A-scan) and Laterality (OD/OS).

If Teaching case, place a check mark in the appropriate box.

Press "OK" when done to open the Exam Window….

① **SELECT THE PROBE FREQUENCY** to be used from the drop-down menu on the left of the display.
UBM Mode: 35 MHz or 50 MHz transducer may be used in conjunction with a water path probe.

② **SELECT APPROPRIATE PRESET SCAN MODE** and/or adjust image controls for optimizing image quality for the desired area of interest (ex. Anterior, Orbit, Angle, etc.). Available image controls and preset scan modes are shown in *Figure 7*.
NOTE*: Image controls may also be adjusted during or after a scan.*

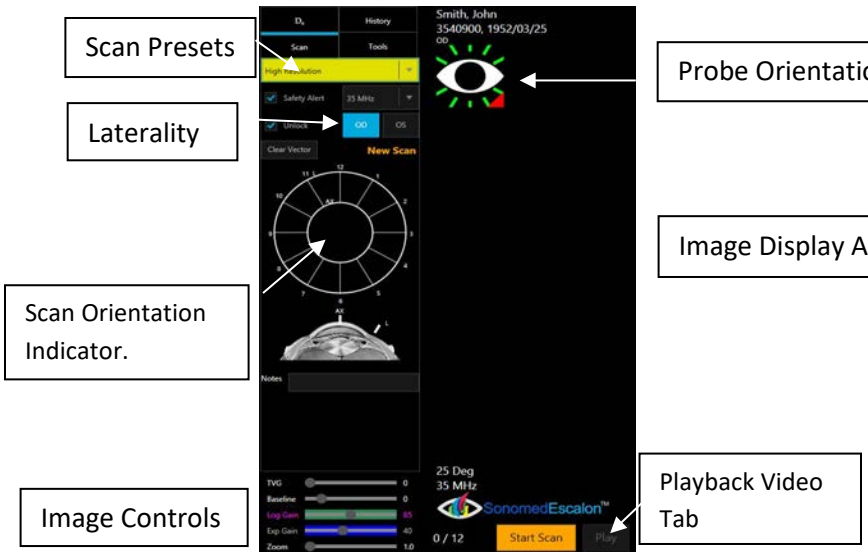
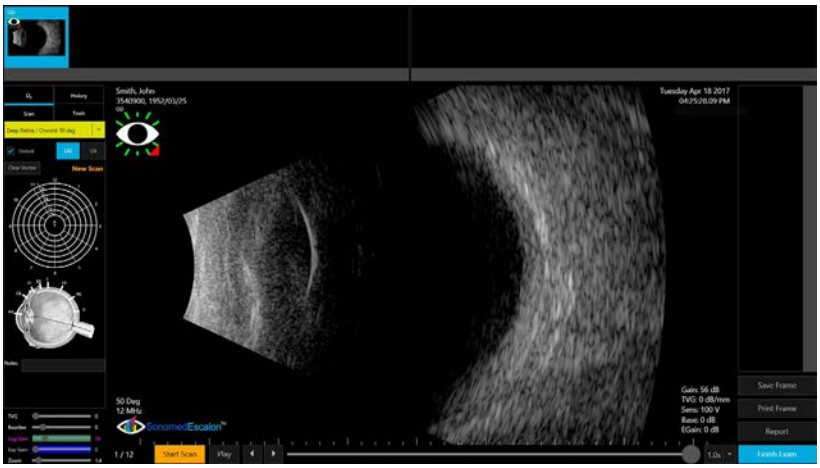


Figure7:Presets/Controls

③ **PLACE PROBE INTO POSITION AND START SCANNING** by either depressing the footswitch or selecting the <**Start Scan**> button. When the footswitch is pressed a second time, or <**Stop Scan**> button selected, a video clip of the prior 50 frames is captured and saved and displayed in the upper part of the display. The clip can be played back by

pressing the <Play> key located below the display window. Up to twelve (12) clips per exam. By “Right Clicking” the mouse over the stored clip, the user will be able to either Delete or Export the clip. [*See Figure 8*]



Note: *See “Tips and Techniques Section of this manual for more information on proper probe positioning, including use of immersion cups for UBM imaging.*

Figure 8: Scan Mode Screen

DANGER! WHEN USING THE WATER PATH PROBE IN UBM MODE (35 OR 50 MHZ), THE USER MUST TAKE EVERY PRECAUTION TO PREVENT THE TRANSDUCER FROM TOUCHING THE EYE. CONTACT BETWEEN A MOVING TRANSDUCER AND THE EYE CAN CAUSE SEVERE INJURY.

④ Pressing the <Start Scan> button again, will begin a new scan. A single FRAME can be “**Saved**” or “**Printed**” from any video clip by stopping the playback at the desired frame and pressing the <**Save Frame**> or <**Print Frame**> keys located at the bottom right side of the display. [*See Figure 9*].

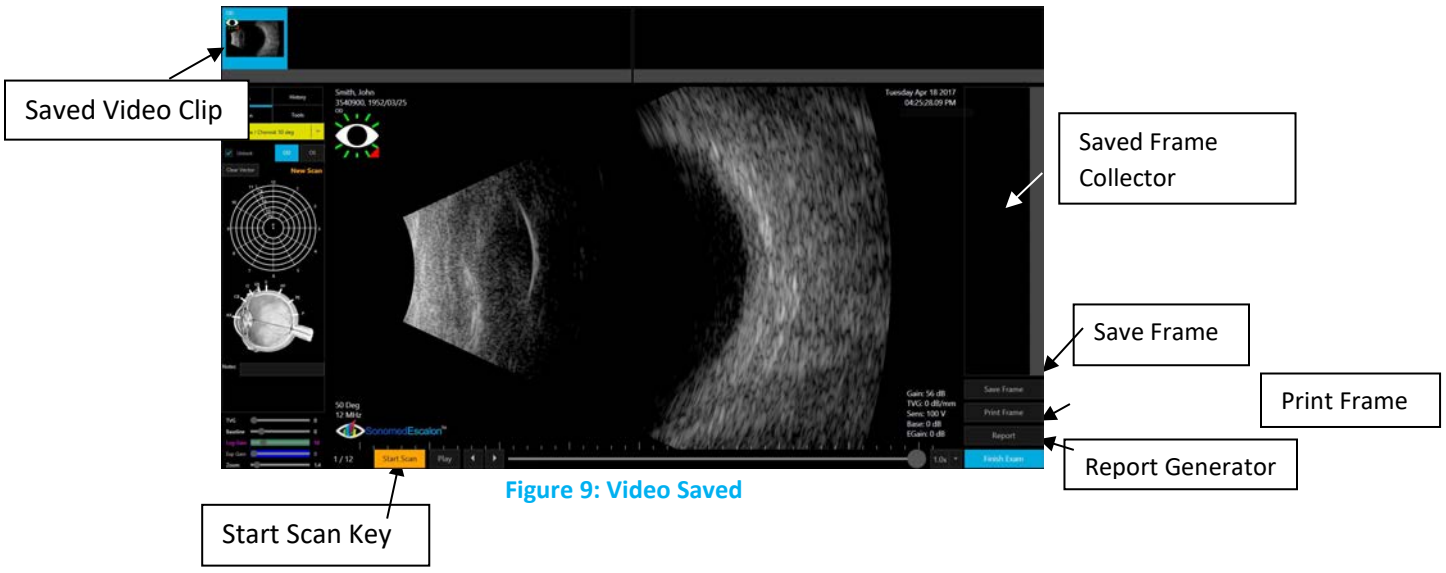


Figure 9: Video Saved

CONTROLS/PRESETS/SCAN MODES

IMAGE CONTROLS

TVG	Time Variable Gain (TVG) attenuates near field portion of scan sector.
Baseline	Raise/Lower the low-level signal threshold to help reduce noise.
Zoom	Adjusts area of scan sector display on monitor. [From x1 – x8]
Log Gain	Adjusts overall amplification of received signal.
Exponential Gain	Adjusts overall signal amplitude in image with minimal effect on low-level noise (otherwise known as “E-Gain”).
NOTE:	Controls may be adjusted by use of the on-screen slider. Gain and E-Gain controls may also be adjusted by use of the rotary knobs on the console front panel which correspond to the color of the highlighted control.

B-SCAN PRESET SCAN MODES

Orbit	Optimized to image the orbit of eye with 50° scan angle.
Vitreous Body	Optimized to visualize detail within vitreous body with 50° scan angle.
Retina Surface	Optimized to visualize detail at retina surface and its interaction with other structures. [
Deep Retina / Choroid	Optimized to visualize detail behind retina and into the choroid with a 50° scan angle. (Zoom @ 1.2x / 40-degree).

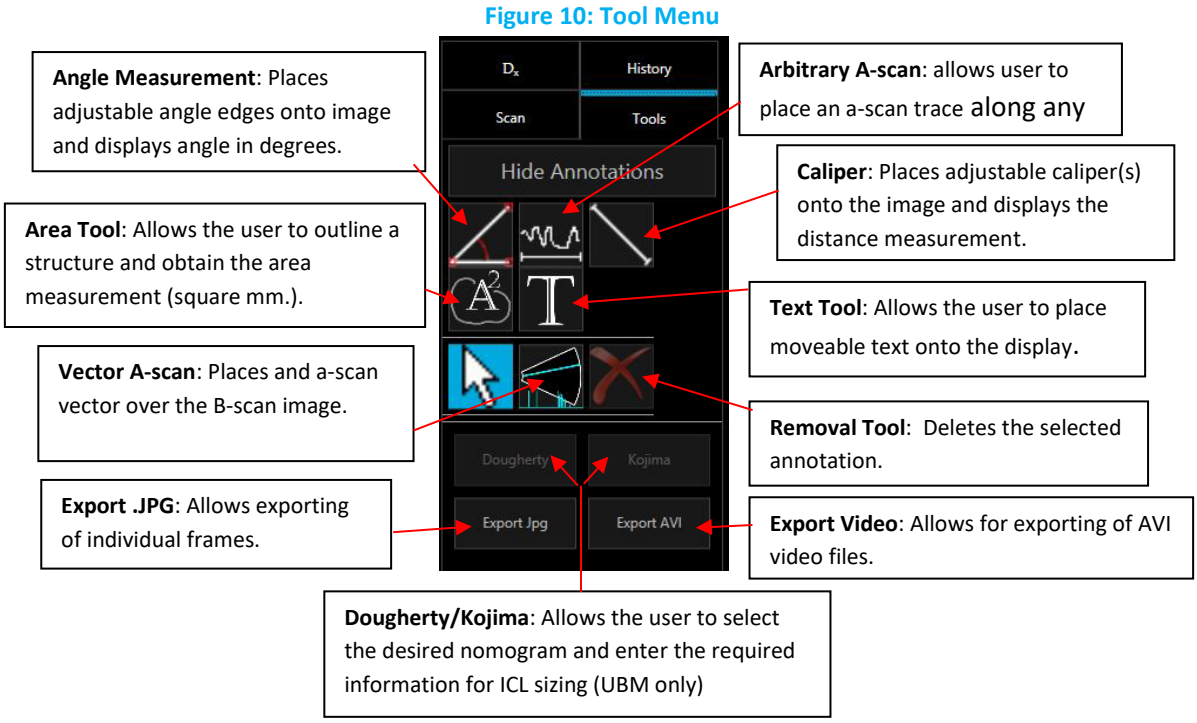
UBM PRESET SCAN MODES

High Resolution	25° scan angle with best possible wide area resolution, ideal to evaluate lenses (IOLs, ICLs, etc.) and lens interactions with rest of eye.
Sulcus-to-Sulcus	Optimized to measure sulcus-to-sulcus for lens sizing with wide 30° scan angle. Note: When measuring sulcus-to-sulcus, ensure iris plane is saturated, with anterior and posterior lens echoes visible. It is advisable to perform multiple scans with measurements to ensure most accurate results.
Angle Detail	With scan angle of 15° and mid-range settings for gain and scan frequency, optimized to provide excellent detail of angle structures, tumors, traumas, and fine details.
Motion Picture	Optimized to display movement within eye, allowing visualization of accommodation dynamics and iris movement during miosis and mydriasis.

⑤ **REVIEW SCAN** by selecting the Play button and selecting the playback rate to the right of the slider (or scroll through video clip one frame at a time using the ‹ / › arrows). Image controls may be adjusted to see the effect on the displayed image, including use of the zoom feature. Individual frames may be saved by selecting the <Save Frame> button.

⑥ **ANNOTATE SCAN** by selecting <**Tools>** tab and selecting the desired function. Annotations are saved with the associated video clip or image. (*Figure 10*)
NOTE: *A frame is automatically saved when an image is annotated.*

Figure 10: Tool Menu



⑦ **EXIT EXAM MODE** by selecting <**Finish Exam**> button located in the bottom right of the display.

TIPS AND TECHNIQUES

DENOTING PROBE ORIENTATION

To denote the probe orientation (*Figure 11)* (scan vector) used during a particular UBM or B-scan, select scan clock position and probe angle (note eye model for confirmation of selection). **NOTE**:P/PE/EP/E/EA/O/CB/AX B-scan standardized labeling based on the Acoustic Section Labeling Diagram from "Ultrasound of the Eye and Orbit", 2nd Edition, by Sandra Frazier and Ronald L. Green, MD).

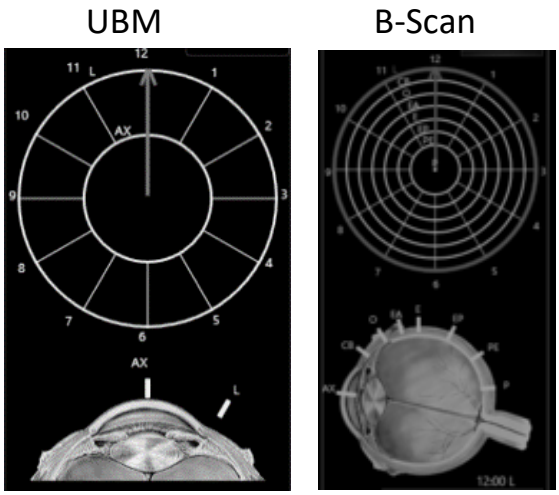


Figure 11: Probe Orientation

UBM PROBE POSITIONING

The UBM water path probe may be used with various sized eye cups, with a nosepiece stand-off, or with a Clear Scan® ultrasound probe cover. All of these accessories are separately available from Sonomed Escalon.

DANGER! THE WATER PATH PROBE IS A TYPE B APPLIED PART AND PROVIDES A BASIC DEGREE OF PROTETION AGAINST ELECTRIC SHOCK AND HAS DIRECT EARTH CONNECTION. WHEN USING THE WATER PATH PROBE IN UBM MODE (35 OR 50 MHZ), THE USER MUST TAKE EVERY PRECAUTION TO PREVENT THE TRANSDUCER FROM TOUCHING THE EYE. CONTACT BETWEEN A MOVING TRANSDUCER AND THE EYE CAN CAUSE SEVERE INJURY.

SULCUS-TO-SULCUS MEASUREMENTS

In order to obtain a reliable sulcus-to-sulcus measurement (*Figure 12*), a few simple steps should be followed:

① Set scan mode to Sulcus-to-Sulcus.

② Ensure 3 key landmarks are present as shown in the image at right.

③ It is advisable to take a few measurements in slightly different scan planes to ensure an accurate result.

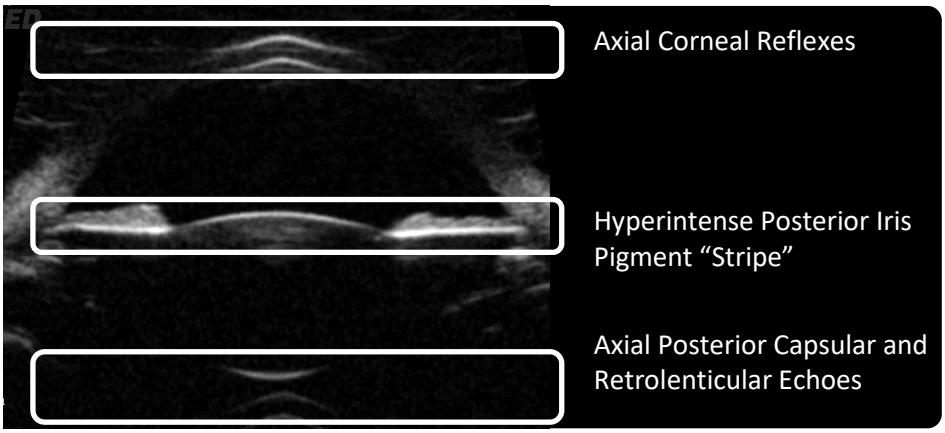
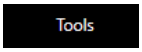


Figure 12: Sulcus to Sulcus

SULCUS-TO-SULCUS MEASUREMENTS USING EYE TRACKING SOFTWARE

1. Patient looking straight ahead.
2. Probe's marker is nasal
3. If test is done on Vumax HD. Under the tools 

click on Eye Tracking software icon  (*Figure 13*)
4. Image will appear on the screen with measurements
5. Make sure that vertical lines for
6. Cornea, ACD and Lens are making
7. one straight line.
8. One video recorded, review all scans
9. Edit calipers for Sulcus-to-Sulcus line if needed.

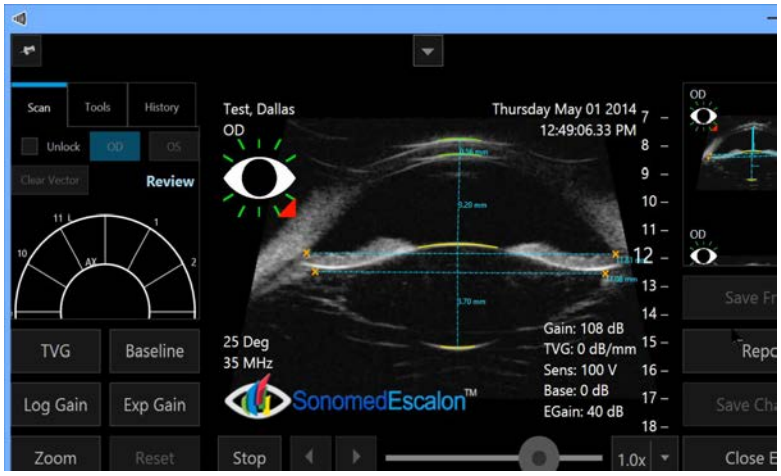


Figure 13: Eye Tracking Software

MEASURING ANGLE AND ANGLE ANALYSES SOFTWARE

1. With Marker Nasal ask patient to look left or right
2. With Marker Up ask patient to look up or down
3. When scans are complete chose an angle image and click on Angle Analyses icon 
4. On the right side of the screen grab "Blue Cross" and position it at the scleral spur
5. Software will display following parameters:
6. AOD (Angle Opening Distance), TIA (Trabecular Iris Angle), ARA (Angle Recess Area), TISA (Trabecular Iris Space Area)

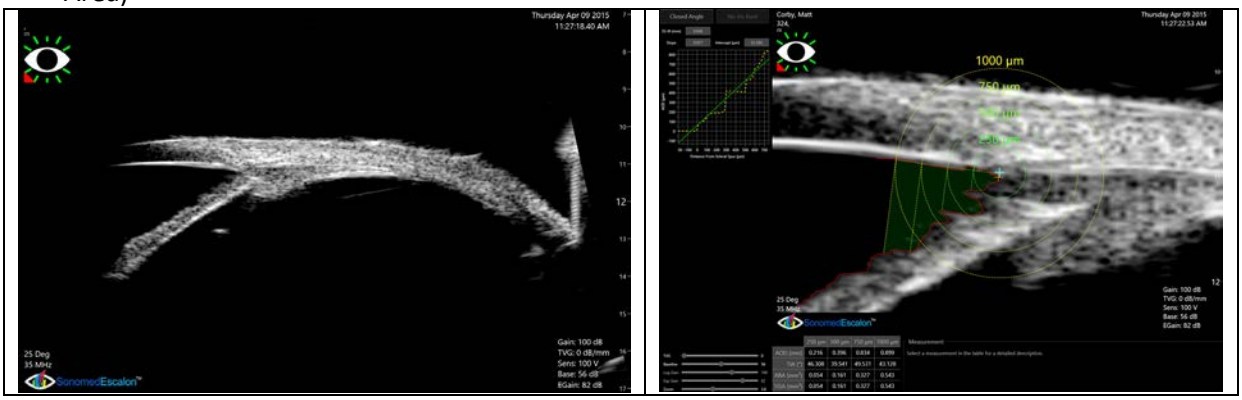


Figure 14: Measuring Angle

BIOMETRIC B-SCAN

The B-Scan biometry is an additional feature that allows users to obtain an A-Scan measurement from a B-Scan image.

The image below in Figure 15 shows the B-Scan biometry icon in the Tools menu, and the B-Scan Biometry button in the video collector section.

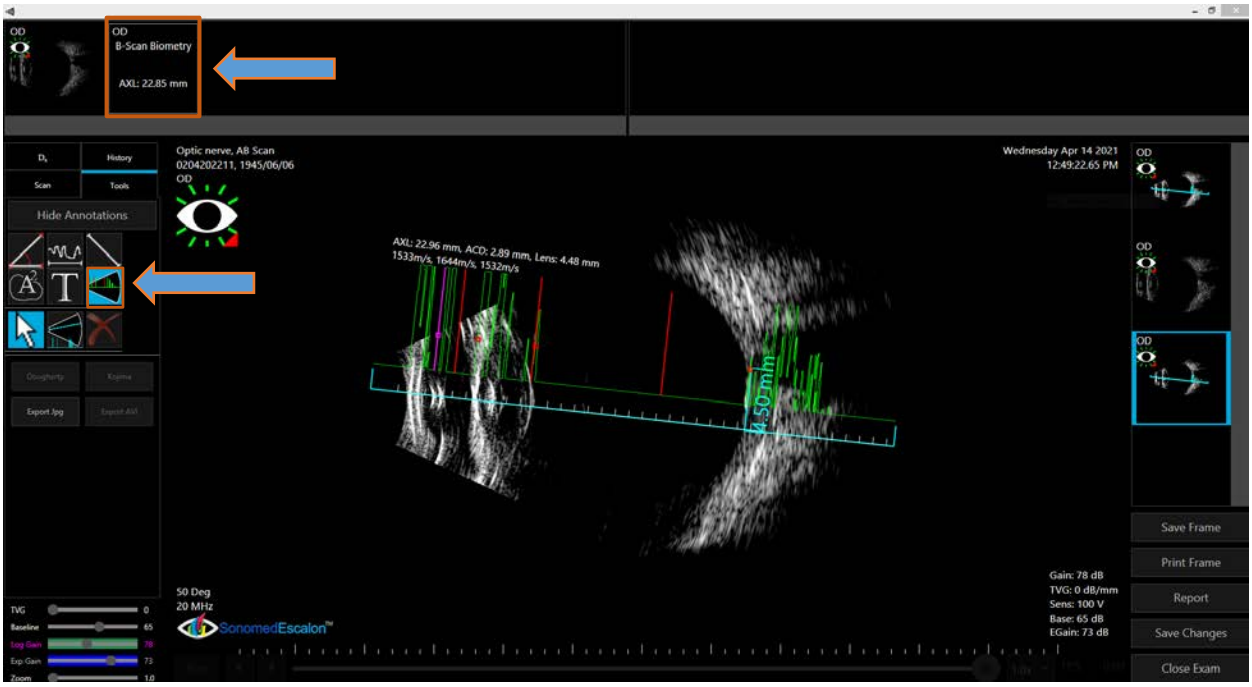


Figure 15: B-Scan Biometry

① Once a B-Scan video has been captured, select a frame that best shows the axial arrangement of the eye, including the anterior and posterior part of the lens. A sample is shown in Figure 16.

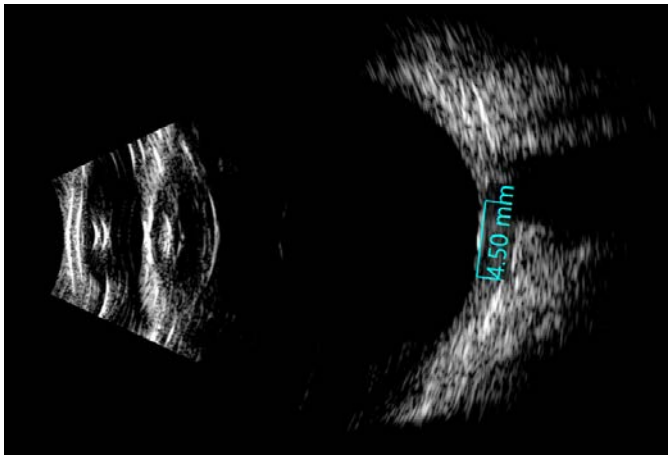


Figure 16: Axial Arrangement of the Eye

② Select the [Save Frame] button and the frame will appear in the frame collector on the righthand side of the screen.

③ Select the [Tool] tab and then the [Caliper] tool to measure 4.50 mm from the eye's optic nerve to the Macula.

④ Select the B-Scan Biometry icon from the [Tool] menu located below the Caliper icon. Refer to Figure 17.

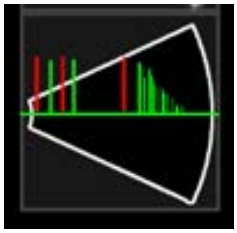


Figure 17: B-Scan Biometry Icon

⑤ The biometry scan will appear on top of the B-Scan as shown in figure 18. The four gates positioned along the axial can be adjusted independently. The entire biometry scan can be moved by dragging it from the scale area on the bottom. It can also be adjusted by dragging on the red boxes on each end of the scale. As the gates are adjusted, the axial reading will be displayed on top. The gain can be adjusted as needed to increase or decrease the spike's height.

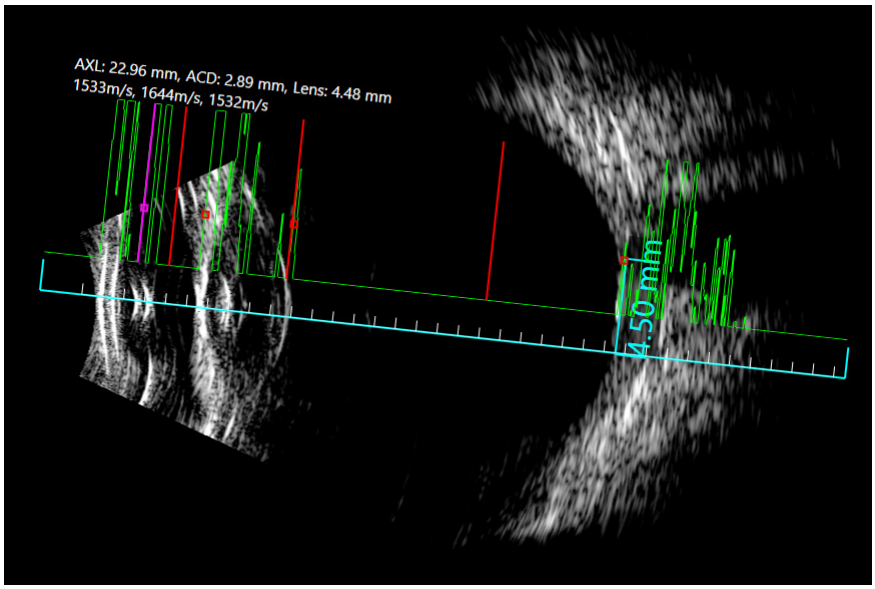


Figure 18: Biometry scan on top of B-Scan

⑥ Once the A-Scan is positioned correctly on the B-Scan image, select the [B-Scan Biometry] tab from the video collector on top to switch to the A-Scan mode as shown in Figure 19.

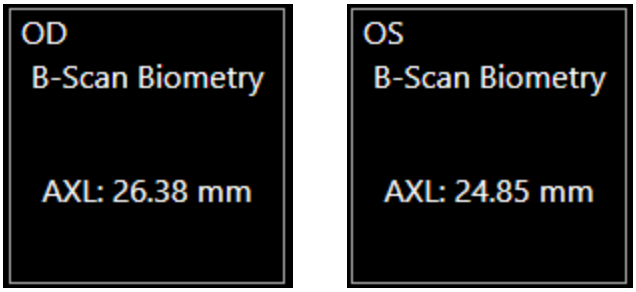


Figure 19: B-Scan Biometry Tab

⑦ The A-Scan will show the same spikes shown in the previous screen, Figure 20. The operation is standard A-Scan from this pint forward.

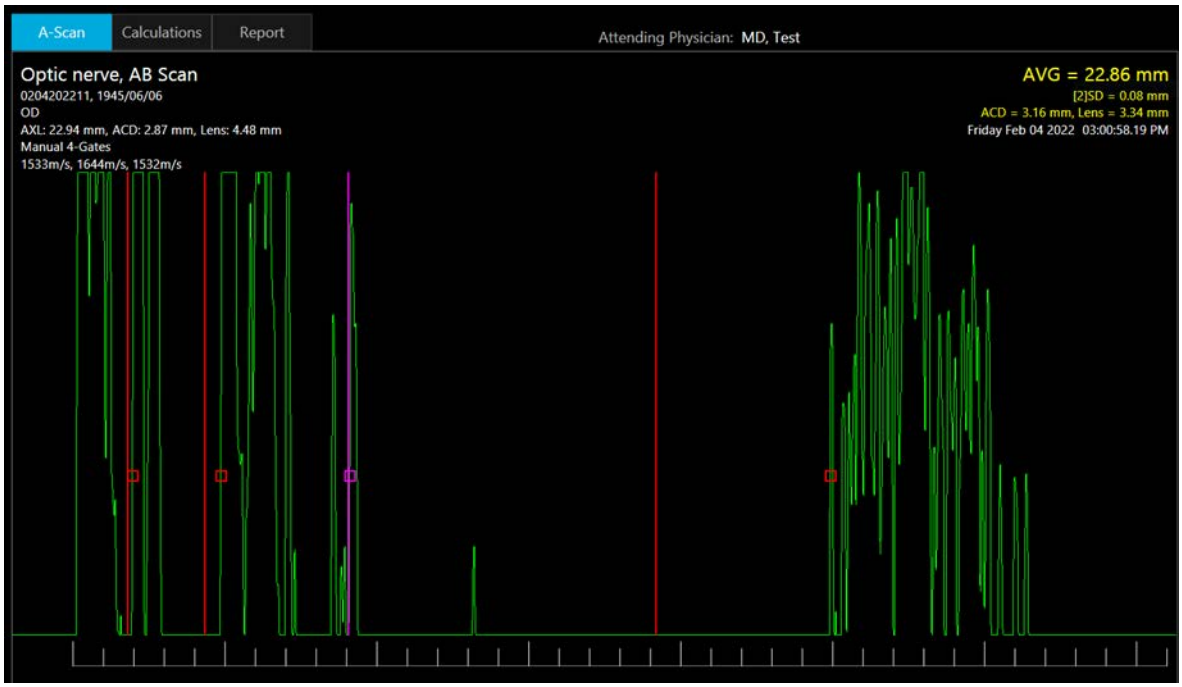


Figure 20: Standard A-Scan Spikes

⑧ Select the [Calculation] tab to switch to Calculation mode as shown in Figure 21.

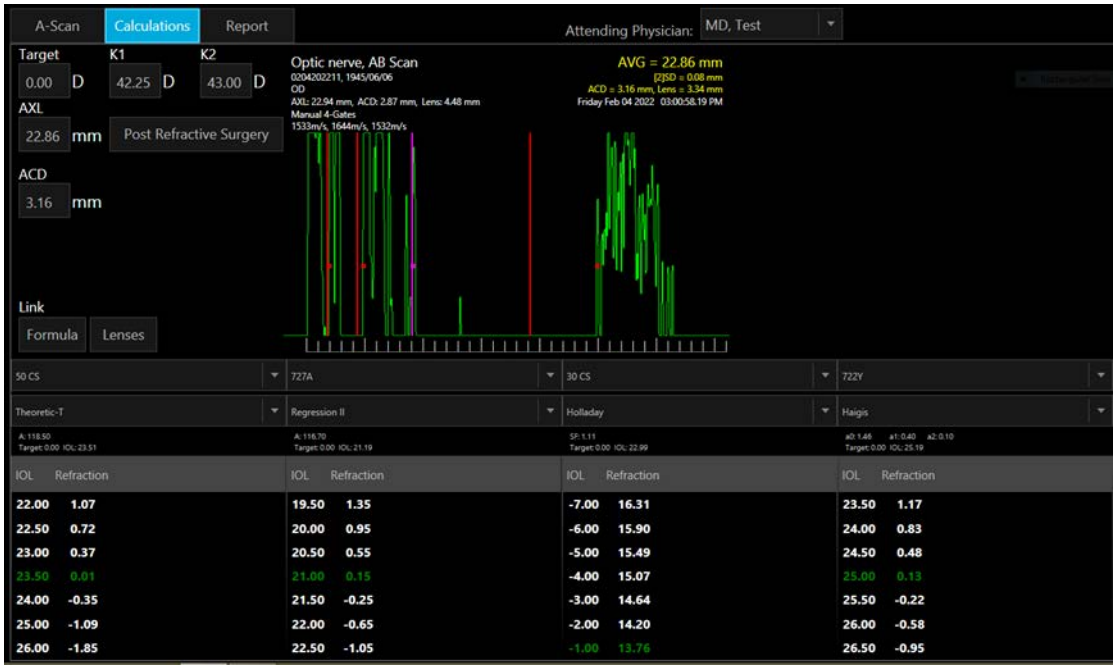


Figure 21: Calculation Tab

⑨ Select the [Add Report] tab to add the calculations to the report page as shown in Figure 22.

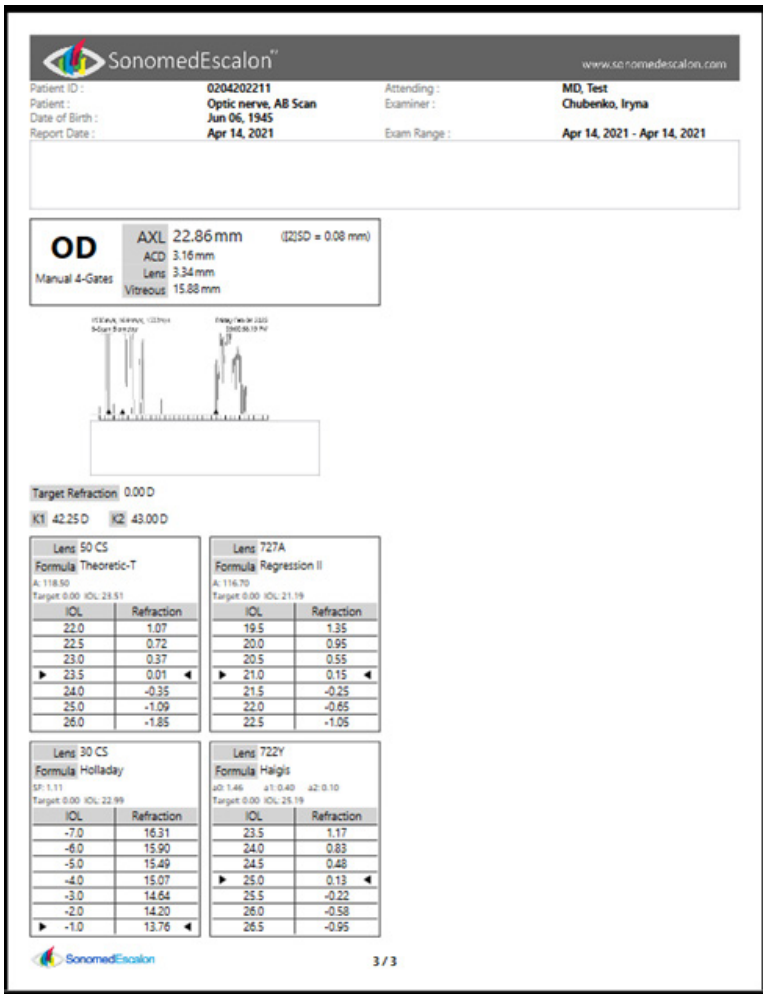


Figure 22: Report

BIOMETRIC A EXAM MODE

① From the Patient Database Screen (*see Fig. 4*) select the "**NEW**" tab located at the top left side of the display under PATIENT.
Note: *for previously entered patient, scroll through the patient list by sliding the scroll indicator just to the right of patient list until the desired patient name is displayed and select*.

② Enter the new patient information into the appropriate fields (*Figure 23*) and press <**Apply**>.
Note: *K-readings can be entered here or later if performing an a-scan biometry measurement. If entered here, press **"OK"** to return to the Patient data screen.*

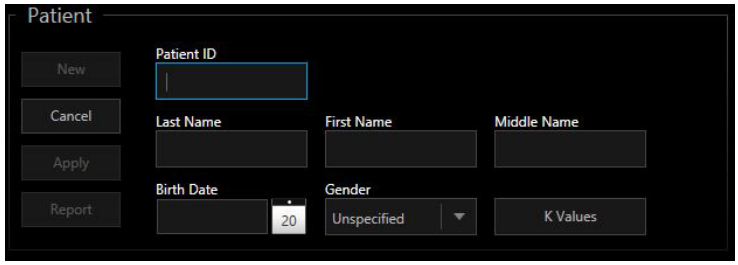


Figure 23: New Patient Window

③ Once the patient information is entered, Select the "NEW" tab located at the top right side of the database display screen under EXAM. Verify (or enter) that **Examiner** [Required], **Attending Physician** [Required] and **Referring Physician** [Optional] are entered. (*Figure 24*)

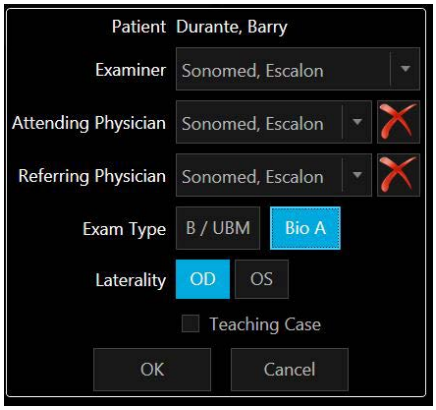


Figure 24: Bio A Selected

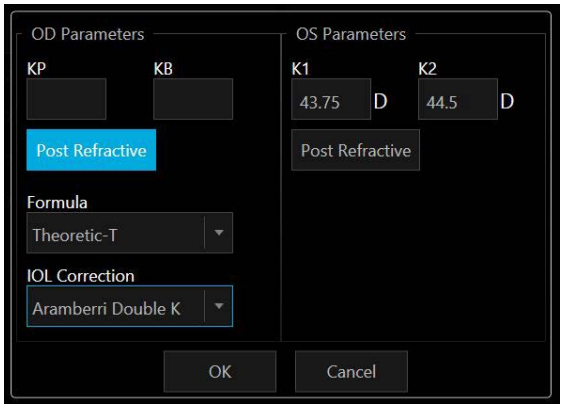


Figure 25: K-Readings

④ Enter the **Exam Type** [Bio A] and **Laterality** [OD/OS]. If the exam is to be used as a "**Teaching Case**" place a checkmark in the box and select "**OK**".

⑤ Parameters: K-Readings can be entered for either/both eyes. If the patient has had previous refractive surgery, selecting the "**Post Refractive**" tab will allow the user to select the formula and IOL correction [Aramberri Double-K, or Latkany Myopic/Hyperopic formulas] to apply to the lens power calculation. Select "**OK**" after all data is entered. (*Figure 25*)

VERIFY CALIBRATION

⑥ The “Verify Calibration” window should automatically be displayed if the “Bio A” tab had been previously selected. (*Figure 26*)
Select “**YES**” to perform the calibration verification using the supplied cylinder located in the probe holder. The VuMax-HD will start emitting an audio “beeping” sound. Place a drop of water onto the cylinder (or tip of probe) for coupling of the probe and cylinder. Place the tip of the probe onto the cylinder and hold; once the correct pattern is accepted, the beeping will stop and the message “Calibration Verified” will appear.

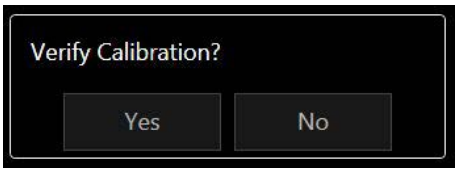


Figure 26: Calibration Window

Note*: It may be necessary to increase the GAIN control in order to achieve the necessary pattern*.
Although it is recommended to verify calibration prior to measuring a patient, the user can Select “**NO**” to bypass the calibration verification procedure if desired.

A-SCAN EXAMINATION MODE

① Verify that the correct laterality (OD/OS) is highlighted at the top of the display. If not correct, the user can change by selecting either OD (top left) or OS (top right) then proceed as follows.
(*Figure 27)*.

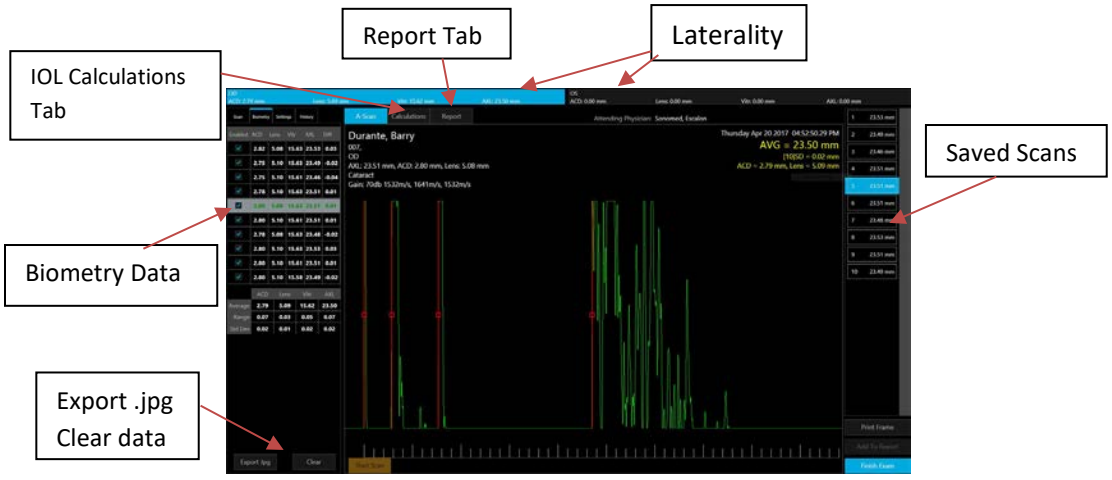


Figure 27: Exam Mode Display

< Scan>.. Used to select the desired scan mode (Cataract, Dense Cataract, Aphakic, Pseudophakic, Manual, Calibration). Here the user can also select “**Immersion**” mode if using an immersion shell for biometry; adjust **gate placement** or adjust the **Gain** control.

<Biometry>.. Will display all of the collected data as scans are performed including *ACD*, *Lens* Thickness, *Vitreous* Length, Axial Length (*AXL*) and the difference from the average measurement (*DIFF*). The user can also “**Export**” the image (.jpg) or “**Clear**” the data.

<Settings>.. Displays the user adjustable velocities used for the various structures (ACD, Lens, Vitreous). Adjustments when needed can be made by using the **^ / ˅** symbols. The **“Continuous Capture”** tab, if selected, will allow the user to set the desired number of scans that the VuMax-HD will obtain with a single press of the footswitch. If “**Immersion**” mode has been selected (above), TWO (x2) footswitch presses would be required to begin obtaining scans – once to activate the transducer for alignment and once to activate the algorithm for scan acceptance.

<History>.. This tab will display a record of all previous exams [Date / Time / Exam Type] for the selected patient.

IOL CALCULATIONS

Once the user has reviewed the scans/data and is satisfied with the results, the **<CALCULATION>** tab, located at the top of the exam mode display screen should be selected (*Figure 28*). In order for calculations to appear, ALL USER DATA MUST ALREADY BE ENTERED VIA THE CONFIGURE MENU. If this was not done previously all lens and preferred IOL formula selection should be made before proceeding to IOL calculations. [See Configuring System on page 5].

① Enter the "Target" refraction and K-readings (if not already entered).

② Average AXL and ACD should populate based on previous screen's biometry a-scan.

③ **<LINK>** tab will enable user to display the same IOL Formula or the same LENS selection for all 4 of the calculation tables.

④ **LENS** and **FORMULAS** can be selected from the drop-down menus which will include all lens models and formulas previously added to the user profile.

⑤ IOL table will display with the "*Target*" refraction entered previously at the center. (The user can edit the center value by changing the value of the "*Target*" refraction field (step ① above).

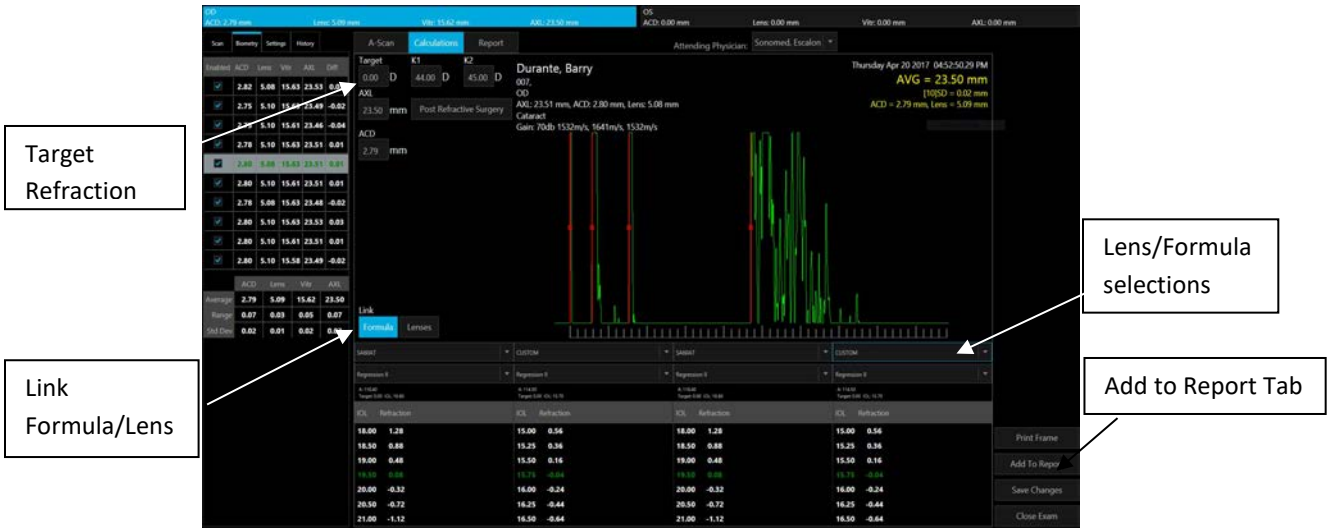


Figure 28: IOL Calculations

⑥ Once all values are approved and accepted, the user should select the **<ADD TO REPORT>** tab located at the bottom right of the display. (*Figure 28*)

⑦ If the fellow eye is also to be measured and included onto the report, the user should select either the OD or OS tab at the top of the display and repeat the measurement/calculation steps as described above.

⑧ Once the eye(s) is measured, calculations performed and "ADDED TO REPORT" the **<REPORT>** tab located at the top of the display should be selected.

REPORTS

Once the <REPORT> tab is selected, the display will show the report template which includes the A-scan(s) and IOL Calculations for each eye for which the measurements/calculations were performed. If required, the user can return to the Calculation table and edit the lens and/or formula data and select the <ADD TO REPORT> tab again. This will generate a second page to the report which will now display pages 2 of 2, 3 of 3, etc…… (*Figure 29*).

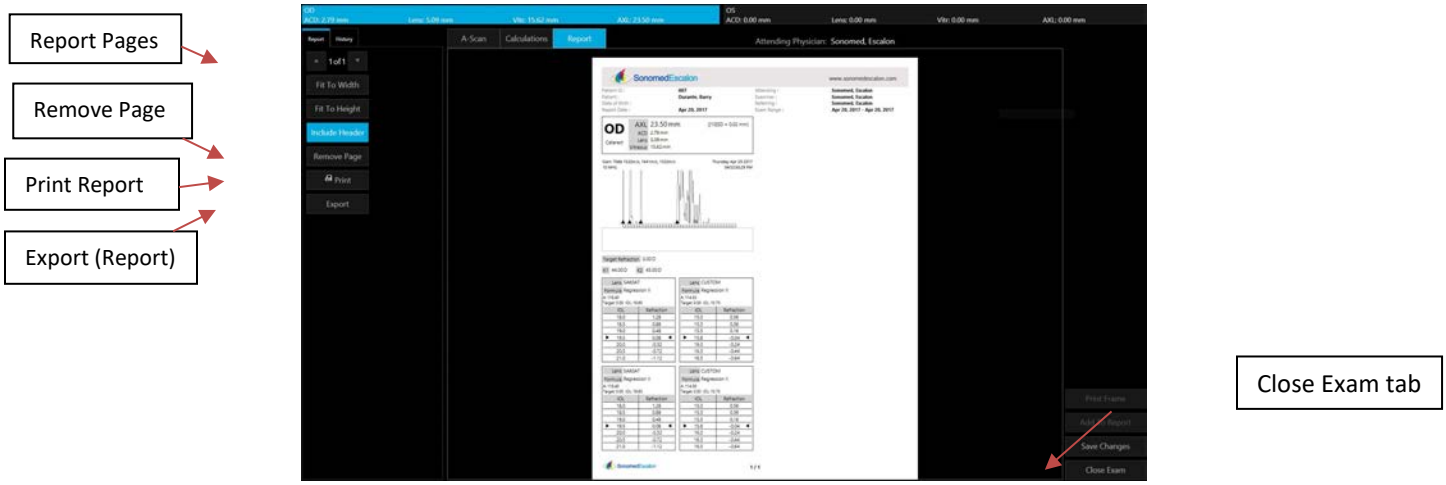


Figure 29: Reports

INCLUDE HEADER: If this tab is highlighted, the default header [SonomedEscalon] will be displayed. Deselecting this tab will cause the Header to be removed from the report.

REMOVE PAGE: Highlighting this tab will remove the currently displayed page from the report.

PRINT: Selecting this tab will display the Windows print window to appear from which the user can select any of the installed printers.

EXPORT: Selecting this tab will display the Export pop-up window to appear for selection of export format by the user.

Press **<CLOSE EXAM>** when finished with the current exam to return to the Patient Database screen.

DIAGNOSTIC A SCAN MODE

① **Power 'On' System:** By pressing the front panel power switch located on the bottom right side of the unit's front panel.

② **Starting Application:** From Windows desktop, double click on the 'Start' icon (*Figure 30*).

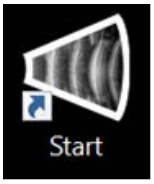


Figure 30: Start Icon

③ **Patient Database Screen:** Upon launching the application the 'Patient Database' screen (*Figure 31)* will display. Here you can add a new patient or find previously performed exams.

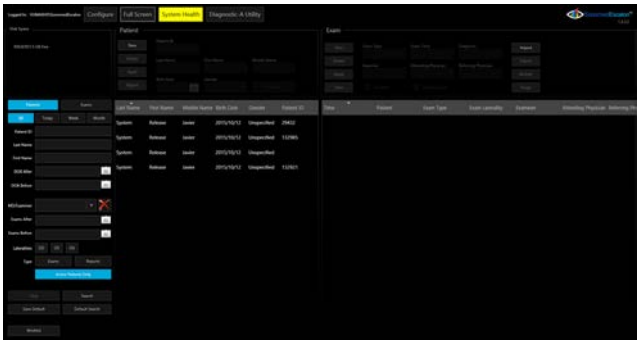


Figure 31: Patient Database Screen

④ **Diagnostic A-Utility:** To start the Diagnostic A-Scan application, select the 'Diagnostic A-Utility' button (*Figure 32*).

Figure 32: 'Diagnostic-A Utility' Button

⑤ **Application Window:** Upon selecting the 'Diagnostic-A Utility' button the VuMAX HD patient database will momentarily close and the Diagnostic A-Scan Utility screen will open (*Figure 33*).

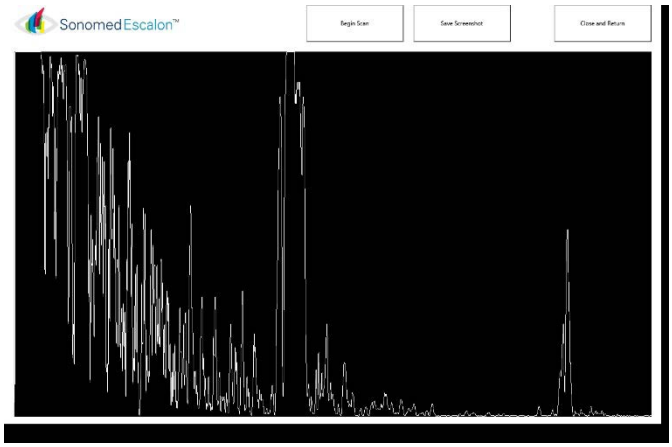


Figure 33: Diagnostic-A Utility Screen

⑥ **Begin Scan, Stop Scan and Save:** To commence a live scan, select the 'Begin Scan' button. Upon selection an A-Scan trace will appear on the main window. To stop scan, click on the correspondent icon as well as for save a screenshot (*Figure 34*)

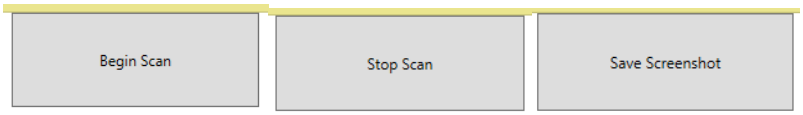


Figure 34: 'Begin Scan' 'Stop Scan' and 'Save" Buttons

⑦ **Save As:** Upon selecting the 'Save Screenshot' button, a Windows 'Save As' screen (*Figure 35*) will be displayed. Navigate through the folders to select a destination folder for saving the patient's saved A-Scan. Note that a 'File Name' is required for saving the document.

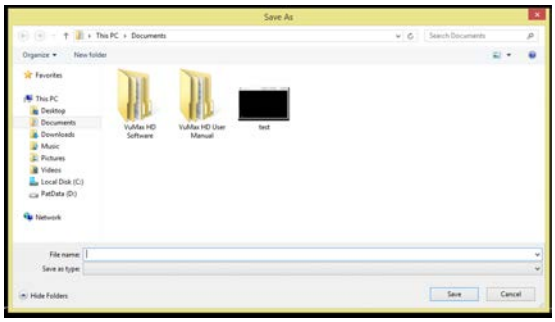


Figure 35: 'Save As' Window

⑧ **Close and Return:** Upon completing examination and saving a record of the test, select the 'Close and Return' button to return to the VuMax HD Patient Database screen.

⑨ **Calibration:** Clicking on the Sonomed Escalon logo while having the control key pressed, it will pop up the S curve calibration as in *Figure 36*.

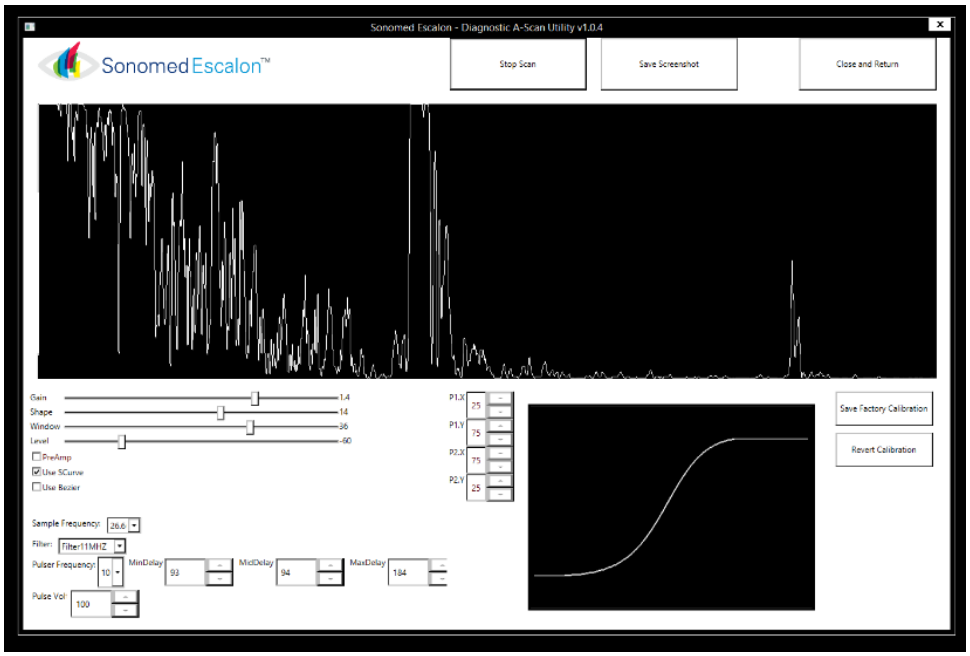


Figure 36: Calibration Screen Window

DATA MANAGEMENT

All patient and exam history is stored on the system hard drive until removed. Two options are provided within the VuMAX HD software to manage and further protect data: archiving and purging. Additionally, connection to an EMR or image management system is possible using DICOM.

ARCHIVING

Archiving saves a copy of data to another drive location as specified by the user. The drive could be a portable, network, or cloud hard drive, depending upon availability and user preference. To archive a single exam, select and highlight exam from list and select <**Archive**> button. To auto archive all data (patient exam records, physicians and user data, lenses, etc.), perform following steps:

① From home screen, select <**Configure**> button and then select <**Archive/DICOM**> tab.

② Set location of an archive by clicking the <**Add**> button, selecting "File System" from the drop-down menu, and then selecting <**OK**>. On next screen, type reference name of archive, location path relative to the VuMAX HD system (e.g. n:/clinic/imaging/ultrasound), and enter credentials if required to access specified location. The <**Test**> button can be selected to ensure the VuMAX HD has access to the specified archive location. Multiple archives may be set up, as desired.

③ Select <**Configure Service**> button and then select <**Auto Archive**> tab*, Figure 37.*

④ Ensure "Archive Exams on Save" option is ***not*** selected and that "Enable Background Archive" option is selected. Make changes, if required, and select <**OK**> (or <**Cancel**> if no changes are required).

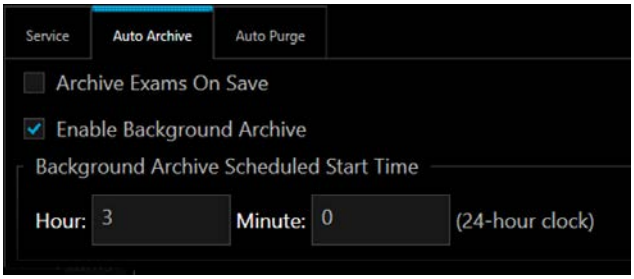


Figure 37 – Auto Archive Settings

⑤ Select <**Run Auto Archive**> button. This will initiate a background archive of all patient exam. The <**Close**> button may be selected and other functions performed while background auto archive is being performed. The status of an archive may be viewed at any time by selecting the <**System Health**> button on the home screen.

PURGING

Purging removes archived exam(s) from the hard drive of the system. It is important to note that an exam may be purged only if it has previously been archived (so as to prevent unintended data loss). Once an exam is archived and purged, it will still show in the list of exams and will be automatically recalled from the archived drive location and displayed on the VuMAX HD if selected and viewed (provided connection is maintained to the archived location).

To purge a single exam, select and highlight exam from list and select <**Purge**> button. To set up auto purge based on how much of the system hard drive is being used, perform following steps:

① From home screen, select <**Configure**> button and then select <**Archive/DICOM**> tab.

② Select <**Configure Service**> button and then select <**Auto Purge**> tab , *Figure 38.*

③ Ensure “Enable Background Purging”, *Figure 38*, option is selected. Denote at what percentage of disk usage purging should start and for which exams are to be purged based on the number of days since exam was performed. Make changes, if required, and select <**OK**> (or <**Cancel**> if no changes are required)

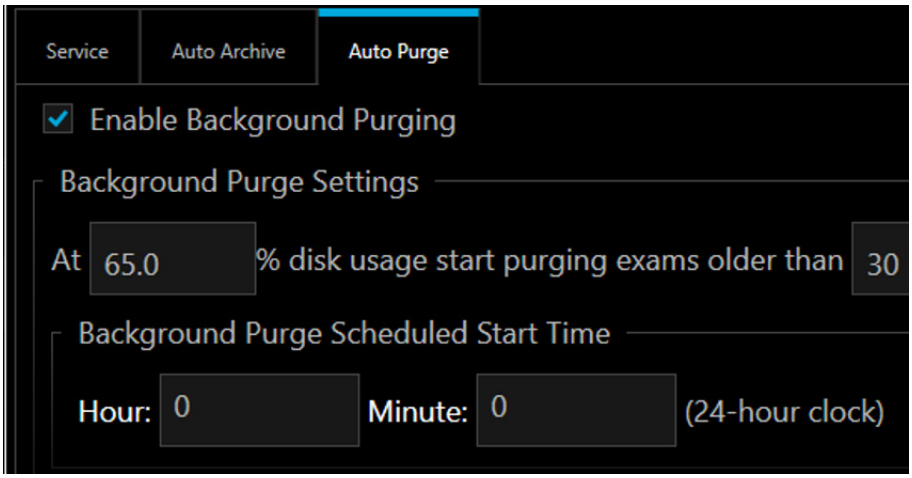


Figure 38 – Auto Purge Settings

④ Select <**Run Auto Purge**> button. This will initiate a background purge of all appropriate patient exam records. The <**Close**> button may be selected and other functions performed while background auto purge is being performed. The status of a purge may be viewed at any time by selecting the <**System Health**> button on the home screen.

DICOM

The VuMAX HD may be connected to an EMR and/or image management system via DICOM if this option has been provided with the system. Please contact Sonomed Escalon for the DICOM Conformance Statement and more information regarding DICOM set-up.

MAINTENANCE *No preventive maintenance required.*

Always inspect probe tips prior to use to ensure no scratches or damage are present. Do not use probes if damage is visible.

SYSTEM CLEANING

Clean the VuMAX™ probes with a damp cloth to remove gel and other debris. Use appropriate products to clean the cables and foot pedals as necessary.
WARNING: Disconnect the AC POWER before cleaning the system.

PROBE CLEANING AND DISINFECTION

The probe must be cleaned and disinfected between patients to prevent patient-to-patient transmission of infection. Prior to any cleaning or disinfecting, unplug the probe from its cable. Cleaning is intended to remove dirt and debris form the probe, and to reduce the presence of microorganisms. Disinfection is performed after cleaning to address microorganisms.

PROBE CLEANING

a) A few drops of common concentrated dishwashing detergent or enzymatic product diluted in warm tap water may be used. Scrub the probe in a soapy solution that facilitates the suspension and washing away of the unwanted contaminants. The probes may be vigorously scrubbed, as needed, to remove contaminants. A soft bristle brush may be used to scrub the narrow gap where the probe window joins the probe cover.
b) Rinse the probe thoroughly with distilled or deionized water and allow to air dry or blot dry with a clean, soft, lint-free cloth that does not leave lint or debris
c) If a water path probe is used, the transducer may be washed with light pressure. Do not scrub the face of the transducer harshly or use any abrasive cleaners or cloths. Careful cleaning will lengthen the useful life of the transducer. *Special care should be taken not to rub the gold surface of the transducer*.

PROBE DISINFECTION

a) For low-to-moderate disinfection: After cleaning, immerse the probe in 70% isopropyl alcohol (70% IPA) for 5-10 minutes. Rinse the probe thoroughly with distilled or deionized water and allow to air dry or blot with a clean, soft, lint-free cloth that does not leave lint or debris. If not used immediately, the probe may be placed in a clean bag for storage.
b) For a higher level of disinfection: After cleaning, immerse the probe in 2-3% W/W hydrogen peroxide for 8-10 minutes. Rinse the probe thoroughly with distilled or deionized water and allow to air dry or blot with a soft, lint-free cloth or gauze. If not used immediately, the probe may be placed in a clean bag for storage.
c) Probes are hermetically sealed and, if necessary, the entire probe (up to the connector) may be immersed in disinfecting solution. However, this should be reserved for rare cases where it is judged by the clinician that the entire probe has been contaminated. When this is not the case, then it is only necessary to immerse the portion of the probe that has been in contact with the patient, plus approximately 2 cm. of the probe cover.

CAUTIONS: NEVER IMMERSE THE CONNECTOR AT THE END OF THE PROBE!
NEVER AUTOCLAVE ANY PROBES OR TRANSDUCERS OR EXPOSE TO HIGH HEAT; EXCESSIVE TEMPERATURE WILL CAUSE DAMAGE

PROBE CLEANING & DISINFECTION RECOMMENDATIONS

- Do not allow probes to come in contact with any solutions for longer than 10 minutes at a time. A longer contact time is at the discretion of the user.
- Thorough rinsing with distilled or deionized water is recommended after contact with any cleaning or disinfectant agent to remove traces of the solution.
- Air drying is acceptable following water rinse.
- If a cloth is desired for drying, blot dry with a clean, soft, lint-free material that does not leave visible debris or lint on the probe.
- Diluted sodium hypochlorite solution (1:10 bleach solution) may be used as a high-level disinfectant on probes that do not have an external transducer. Always rinse very thoroughly and do not use for longer than 10 minutes.
- Do not use bleach on UBM transducers. The gold plated surfaces of the UBM transducers should not come in contact with bleach.
- FDA cleared disinfectants for low-level or high-level disinfection may be used on the probes according to the facility and/or manufacturer's instructions, but not longer than 10 minutes. A longer contact time is at the discretion of the user.
- Thorough and continuous rinsing with copious amounts of the disinfectant solution for several minutes is an effective means of disinfecting between patients.
- Avoid use of abrasives on all probes.

<u>CAUTIONS WHEN CLEANING WATER-PATH PROBES</u>

- If necessary, the transducer may be detached from the water path probe and the two disinfected separately. If detached for cleaning, take care that the surface mount connector (SMC) of the probe and transducer are thoroughly dried before remounting the transducer to the probe. The internal surfaces of the transducer connections must be free of moisture prior to re-assembly. *Special care should be taken not to rub the gold surface of the transducer*.
- The hard, plastic parts of the probe may be scrubbed, as needed to remove contaminants. A soft bristle brush may be used to scrub crevices. Take care to thoroughly, but only lightly, scrub the soft rubber part surrounding the transducer connector.
- The gold surface of the transducer may be washed with very light pressure. Take care NOT to scrub the face of the transducer harshly or to use any abrasive cleaners or cloths. Careful cleaning will lengthen the useful life of the transducer.
- *Sodium Hypochlorite* (i.e. Bleach): Diluted (0.6% concentrations) and undiluted bleach solutions attack the gold plated surfaces of the transducer, and once a breach has been made, the sensitivity of the transducer may be diminished (proportional to the loss of gold plating). Therefore, methods employing 0.6% concentrations, or more, of sodium hypochlorite should be avoided whenever possible.
- *Tap water*: Contaminants in common tap water may contribute to corrosion of the metal surfaces of the probe and transducer after extended use. The use of tap water, rather than deionized water or distilled water is, therefore, contraindicated. If tap water is used, rinse thoroughly with distilled or deionized water and lightly wipe the surface clean of any residues.
- *Abrasives*: The gold plating on the transducer surface is very thin and cannot be thickened without negatively affecting the transducer frequency and performance. Therefore, extreme care must be taken to avoid scratching or otherwise damaging the gold surface of the film. Never use any kind of abrasive cloth or tissue when wiping the transducer surface. Camera lens cleaning paper or soft gauze may be used. Apply no more force than is needed when wiping the transducer surface. Minor scratches to the gold surface will not damage performance. Contact the manufacturer if the gold plating is breached and a silver color is seen in place of the gold.

Scan Type	Probe Type	Use	Patient Contact	Device Classification	Disinfection Level	Recommended	Method
A Scan / Pachymetry	A Probe / Pachymeter Probe	Direct Contact	Mucous Membrane	Semi-Critical	High Level	2-3% Hydrogen Peroxide	Clean probe as needed. Soak for 8-10 minutes. Rinse thoroughly with distilled or DI water.
A Scan	A Probe	Immersion	None	* Semi-Critical	High Level	2-3% Hydrogen Peroxide	
B Scan	B probe	Over the Eyelid	Intact Skin	Non-Critical	Low Level	70% Isopropyl Alcohol	Clean probe as needed. Soak for 5-10 minutes. Rinse thoroughly with distilled or DI water.
B Scan	B probe	Direct Contact	Mucous Membrane	Semi-Critical	High Level	2-3% Hydrogen Peroxide	Clean probe as needed. Soak for 8-10 minutes. Rinse thoroughly with distilled or DI water.
UBM	Water Path Probe with External Transducer	Clear Scan Cover	None	NA	NA	Cleaning or low level disinfection if necessary	Clean probe as needed. 70% Isopropyl alcohol wiped on the probe. Rinse thoroughly with distilled or DI water.
UBM	Water Path Probe with External Transducer	Immersion	None	* Semi-Critical	High Level	2-3% Hydrogen Peroxide	Clean probe as needed. Soak for 8-10 minutes. Rinse thoroughly with distilled or DI water.

* The immersion technique does not involve patient contact, however, the mucous membrane is exposed to the immersion solution and the probe is used in the immersion solution. Therefore, worst case conditions are considered in assigning the device classification as semi-critical.
DI Water = Deionized Water

EYE CUP AND PRAGER SHELL CLEANING AND DISINFECTION

- Eye cups are manufactured using acrylic and silicone. The eye cups may be cleaned using the same procedure as the probes using water with detergents or enzymatic products. Cleaning is performed as needed to remove foreign material (e.g., soil, and organic material).
- The use of facility disinfectants may be used to disinfect eye cups according to label instruction and/or facility procedures followed by thorough distilled or DI water rinse and air dry. Sonomed does not prescribe specific instruction for disinfection of eye cups, however, the eye cups should not be subjected to autoclaving or extreme heat.
- Follow the instructions provided by ESI, Inc. included with the Prager Shell. The Prager tray may be used for cleaning and disinfecting. Place the shell into the tray with the Luer fitting and setscrew facing the notched area of the tray. If used as a cleaning tray for disinfection, fill tray approximately 2/3 with an antiseptic solution (ESI references 7.5 % H_2O_2). After removing the shell from the tray, thoroughly rinse and let air dry.

DISPOSAL

When disposal is required, the equipment and associated cleaning and disinfecting chemicals should be disposed of in accordance with local, state, and federal laws.
In the European Union, follow Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU Annex I, 4.07.2018

TECHNICAL SERVICE AND SUPPORT

There are no user-serviceable parts within the system. Please contact Sonomed Escalon or your local distributor to request technical service and support. Technical support 800-227-1285 or 516-354-0900.
Email: ultrasound-support@escalonmed.com

EVENT REPORTING

In the event a serious injury or incident occurs in relation to the use of the ophthalmic ultrasound, the event should be reported to Sonomed Escalon and the applicable regulatory authorities.

SPECIFICATIONS / PERFORMANCE CHARACTERISTICS

VuMAX General Specifications	
Operating System	Windows 10 Pro
Processor	Intel Core i5, 3.0 GHz
Memory / Data Storage	8GB / 2 x 1 TB RAID SATA HDD
Connectivity	3 x USB 3.0, 2 x USB 2.0, Ethernet, HDMI, Bluetooth 4.1, WiFi (optional)
Console Dimensions	13.5” W x 13.5” D x 3” H (34.4cm x 34.4 cm x 7.6 cm)
Console Weight	13 lbs (5.9 kg)
Power Supply	100-240 VAC 50/60Hz (180W)
Display Screen	21.5” Full HD LCD Monitor
Monitor Weight	7.5 lbs (3.4 kg)
Display Resolution	1920 x 1080 FHD
Display Mounting	Proprietary Monitor Mounting Arm
Printer	Any Windows 10 compatible printer, plus Sony/Mitsubishi Video Printer
Operating Conditions	Operating Temperature: 32 to 98°F (0 to 37°C) Storage Temperature: -40 to 158°F (-40 to 70°C) Operating Humidity: 0 to 90% non-condensing Storage Humidity: 0 to 90% non-condensing Atmospheric Pressure: 70 to 101kPa

A-SCAN SPECIFICATIONS	
Transducer Frequency	10 MHz
Active Diameter	3.5 mm
Examination Modes	Cataract, Dense Cataract, Phakic, Aphakic, Pseudophakic, Manual Mode
Gate Adjustment	Automatic and manual 4-gate positions with auto-detection of scleral spike
Adjustable GAIN Range	40 – 80 dB
Electronic Resolution	± .023 mm
Clinical Resolution	± 0.10 mm
Axial Resolution	0.019 mm
Scan Depth	45 mm

A-SCAN SPECIFICATIONS (cont'd)	
Focal Length	25 mm
Measurement Range	18 – 40 mm
Auto-Calibration	YES
Method	Contact and Immersion
Capture Mode	Automatic, Manual
Tissue Velocity	Adjustable velocity for each tissue segment
Biometry Measurement Parameters	Anterior Depth (ACD) Lens Thickness (LT) Vitreous (VD) Axial Length (AXL) Automatic calculation of average axial length and standard deviation based on 10 measurements
IOL Formulas	Theoretic – T (SRK-T), Regression II (SRK-II), Hoffer-Q, Binkhorst, Holladay, Haigis
Post-Op Refractive Formulas	Latkany Myopic Regression, Latkany Hyperopic, Aramberri Double-K
Diagnostic A-scan	Optional Diagnostic A-scan module with 8 MHz diagnostic A-scan probe

B-SCAN SPECIFICATIONS	
Transducer Frequency	12 MHz (*optional 20 MHz*)
Scan Angle	50 degrees (*40 degrees*)
Scan Depth	60 mm
Focal Zone	13 – 35 mm
Focal Point	24 mm (*22 mm*)
Axial Resolution	0.013 mm (*0.0095 mm*)
Lateral Resolution	0.068 mm (*0.060 mm*)
Frame Rate	20 fps
Grey Levels	256
Time Variable Gain	0 – 7 dB
Adjustable GAIN Range	40 – 130 dB
Exponential Gain (EGain)	Enhanced gain adjustment of 0 – 100 dB
Examination Presets	Deep Retina/Choroid, Vitreous Body, Retina Surface, Orbit and Silicon Oil
Measurements & Annotations	Caliper, Arbitrary A-scan, Angle, Area, Text Box, Marker

UBM SPECIFICATIONS	
Transducer Frequency	35 MHz (*optional 50 MHz*)
Scanning Angle	30 degrees (max)
Frame Rate	20 fps (max)
Max Scan Depth	22 mm
Focal Depth	12 mm
Focal Zone	9 – 13 mm
Axial Resolution	.007 mm (*.004 mm*)
Lateral Resolution	.039 mm (*.035 mm*)
Adjustable GAIN Range	40 – 130 dB
Exponential Gain (EGain)	Enhanced gain adjustment of 0 – 100 dB
Time Variable Gain	0 – 7 dB
Examination Presets	Sulcus-to-Sulcus, High Resolution, Angle Analysis, Motion Picture

DATA AND IMAGING PROCESSING	
Number Saved Images (Frames)	Unlimited
Video Clip Length	12 video clips per exam (50 frames per video clip)
Video Clip Replay	Real-time, scalable slow-motion, frame-by-frame
Number Saved Video Clips per Eye	6 per exam (unlimited exams)
Default Annotation (Frame)	Patient name, ID, user ID, exam date, DOB, Position scan indicator, Gain, E Gain, baseline, Eye tracking overlay, Probe frequency, Scan angle
Additional User Annotation (Frame)	Caliper and angle dimensions, user defined free-form text, arbitrary A-scan
Export File Format	.jpg (images) and .avi (video clips)
Report Template	User customizable report template
Export Report Format	.pdf and DICOM
Connectivity	DICOM compatible (optional license)
Image Brightness / Contrast	Adjustable: TVG, Log, Baseline and Gain
Zoom Magnification	Continuous Interpolative Zoom (0.5x – 4.0x)
Measurement Calipers	Unlimited: Line/Distance, Angle, Area and Arbitrary A-scan Caliper
Eye Tracking Algorithm	Automatic alignment tracking with measurements of CCT, ACD, LT, ATA, STS
Quantitative Angle Analysis Software	Complete and fully automatic angle analysis for AOD, TIA, ARA, TISA

ALARA SECTION AND EMMISSIONS

("As Low As Reasonably Achievable")

STATISTICAL ANALYSIS OF MEASURED DATA

A statistical analysis was performed on the data to examine the upper output limits based on a one-sided tolerance limit approach. The mean and standard deviation of the Spatial-Peak, Time-Average Intensity and Mechanical Index were found, and the upper output limits were calculated from the following formula:

$$X = x + K*Sx$$

Where X is the upper output parameter limit, x is the average of the measured output parameter, and Sx is the standard deviation of the measured output parameter. A value of K was chosen which corresponds to a 90% probability that 90% of all probes would fall below the calculated limits of X.

RESULTS

Statistical analysis showed that the probes tested produced MI and Ispta.3 values below FDA limit values.

ACCURACY

The accuracy of the emissions figures is approximately 26.6% for all intensity values reported, 13.3% for all pressure values reported and 13.3% for the Mechanical Index.

CAUTION

When using this device, the ALARA (As Low As Reasonably Achievable) principle should be followed. This principle is used to reduce unnecessary, potentially hazardous exposure to individuals by keeping dose and test repetition as low as reasonably achievable to achieve the required diagnostic information. Therefore, care should be taken by user to minimize exposure of patient to ultrasound energy by keeping examinations as short as possible.

Probe	**35 MHz Transducer**		**50 MHz Transducer**	
Mode	B-Mode (UBM)		B-Mode (UBM)	
Material	Gold-plated polymer membrane		Gold-plated polymer membrane	
Nominal Center Frequency	35 MHz		50 MHz	
Pule Repetition Frequency	2560 Hz		2560 Hz	
Type	B-Scan (energy emitted during active scan)		B-Scan (energy emitted during active scan)	
Measure	MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	MI [no units]	$I_{SPTA.3}$ [mW/cm^2]
Sample Size	3.0	3.0	3.0	3.0
K	4.258	4.258	4.258	4.258
Mean	0.086	0.025	0.023	0.002
Standard Deviation	0.0070	0.0030	0.0040	0.0004
Limit	0.115	0.037	0.038	0.003

Probe	12 MHz Transducer		20 MHz Transducer	
Mode	B-Mode		B-Mode	
Material	TPX Polymer		TPX Polymer	
Nominal Center Frequency	12 MHz		20 MHz	
Pule Repetition Frequency	2560 Hz		2560 Hz	
Type	B-Scan (energy emitted during active scan)		B-Scan (energy emitted during active scan)	
Measure	MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	MI [no units]	$I_{SPTA.3}$ [mW/cm^2]
Sample Size	3.0	3.0	3.0	3.0
K	4.258	4.258	4.258	4.258
Mean	0.149	0.105	0.135	0.240
Standard Deviation	0.0154	0.0260	0.0117	0.0504
Limit	0.215	0.216	0.184	0.455

Probe	10 MHz (A-Scan) Transducer	
Mode	A-Mode	
Material	Lead Metaniobate	
Nominal Center Frequency	10 MHz	
Pule Repetition Frequency	5880 Hz	
Type	A-Scan (energy emitted during active scan)	
Measure	MI [no units]	$I_{SPTA.3}$ [mW/cm^2]
Sample Size	3.0	3.0
K	4.258	4.258
Mean	0.186	7.82
Standard Deviation	.00458	0.570
Limit	0.206	10.3

Note: The energy will always be attenuated by the tissue between the transducer and the focus when used as recommended. The values presented here are the values at the focal point, the point of maximum intensity.

ACOUSTIC OUTPUT REPORTING TABLES FOR TRACK 1: AUTO SCANNING MODE

Note: Track 1 Reporting Tables show the worst-case indices for each probe type and operating conditions that must be reported.

Transducer Model			**Sonomed Escalon 10 MHz Probe**		**(s/n D09A655)**
Operating Mode			A-Mode		
Application			Ophthalmic		
Acoustic Output			MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Global Maximum Value			0.190	8.42	8.52
Associated Acoustic Parameters	Pr.3 [Mpa]		0.531		
	W_0 [mW]			0.538	0.538
	f_c [MHz]		7.80	7.80	7.80
	Z_{sp} [cm]		1.90	1.90	1.90
	Beam Dimensions	x_{-6} [cm]		0.177	0.177
		y_{-6} [cm]		0.162	0.162
	PD [µS]		0.168		0.168
	PRF [Hz]		5880		5880
	EDS	Az [cm]		0.47	
		Ele. [cm]		0.47	

Transducer Model			**Sonomed Escalon 12 MHz Probe**		**(s/n 22064)**
Operating Mode			B-Mode		
Application			Ophthalmic		
Acoustic Output			MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Global Maximum Value			0.167	0.135	12.9
Associated Acoustic Parameters	Pr.3 [Mpa]				
	W_0 [mW]			0.0832	0.0832
	f_c [MHz]		12.2	12.2	12.2
	Z_{sp} [cm]		1.60		1.60
	Beam Dimensions	x_{-6} [cm]			0.0689
		y_{-6} [cm]			0.0824
	PD [µS]		0.131		0.131
	PRF [Hz]		2560		2560
	EDS	Az [cm]		0.600	
		Ele. [cm]		0.600	
Operating Control Conditions			Scan angle 60°	256 lines per frame	Scan rate 10 Hz

Transducer Model			**Sonomed Escalon 20 MHz Probe**		**(s/n 22160)**
Operating Mode			B-Mode		
Application			Ophthalmic		
Acoustic Output			MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Global Maximum Value			0.122	0.184	11.5
Associated Acoustic Parameters	Pr.3 [Mpa]		0.456		
	W_0 [mW]			0.0296	0.003
	f_c [MHz]		14.0	14.0	14.0
	Z_{sp} [cm]		1.70		1.70
	Beam Dimensions	x_{-6} [cm]			0.0601
		y_{-6} [cm]			0.0605
	PD [µS]		0.0650		0.0650
	PRF [Hz]		2560		2560
	EDS	Az [cm]		0.7	
		Ele. [cm]		0.7	
Operating Control Conditions			Scan angle 60°	256 lines per frame	Scan rate 10 Hz

Transducer Model			**Sonomed Escalon 35 MHz Transducer**		**(s/n 35-00219)**
Operating Mode			B-Mode		
Application			Ophthalmic		
Acoustic Output			MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Global Maximum Value			0.094	0.028	4.780
Associated Acoustic Parameters	Pr.3 [Mpa]		0.460		
	W_0 [mW]			0.003	0.003
	f_c [MHz]		24.095	24.095	24.095
	Z_{sp} [cm]		1.000		1.000
	Beam Dimensions	x_{-6} [cm]			0.039
		y_{-6} [cm]			0.038
	PD [µS]		0.043		0.043
	PRF [Hz]		2560		2560
	EDS	Az [cm]		0.7	
		Ele. [cm]		0.7	
Operating Control Conditions			Scan angle 15°	256 lines per frame	Scan rate 10 MHz

Transducer Model			**Sonomed Escalon 50 MHz Transducer**		**(s/n 50-00376)**
Operating Mode			B-Mode		
Application			Ophthalmic		
Acoustic Output			MI [no units]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Global Maximum Value			0.019	0.001	0.190
Associated Acoustic Parameters	Pr.3 [Mpa]		0.112		
	W_0 [mW]			0.0003	0.0003
	f_c [MHz]		34.168	34.168	34.168
	Z_{sp} [cm]		1.000		1.000
	Beam Dimensions	x_{-6} [cm]			0.035
		y_{-6} [cm]			0.041
	PD [µS]		0.056		0.056
	PRF [Hz]		2560		2560
	EDS	Az [cm]		0.7	
		Ele. [cm]		0.7	
Operating Control Conditions			Scan angle 15°	256 lines per frame	Scan rate 10 MHz

IMMUNITY TEST LEVELS

Electrostatic Discharge

Air Discharge Voltage: 2.0 kV, 4.0 kV, 8.0 kV, 15.0 kV

Contact Discharge Voltage: 2.0 kV, 4.0 kV, 8.0 kV

Radiated Immunity, 8 0 MHz to 2.7 GHz and Proximity Fields

Radiated Immunity, Test Parameters		
Frequency Range	80 to 1000 MHz	1.0 to 2.7 GHz
Field Strength	10 V/m	10 V/m
Window Tested	NA	1
Modulation	1 kHz, 80%, AM	
Dwell Time	0.5 seconds	
Polarization of Applied Field	Horizontal and Vertical	

Radiated Immunity, Proximity Field Parameter			
Frequency (Hz)	Modulation	Level V/m	Test Distance
385	Pulse, 18 Hz, 50% DC	27	1.0 m
450	FM, 1 kHz Sine, ± 5 Hz Deviation	28	1.0 m
710, 745, 780	Pulse, 217 Hz, 50% DC	9	1.0 m
810, 870, 930	Pulse, 18 Hz, 50% DC	28	1.0 m
1720, 1845, 1970	Pulse, 217 Hz, 50% DC	28	1.0 m
2450	Pulse, 217 Hz, 50% DC	28	1.0 m
5240, 5500, 5785	Pulse, 217 Hz, 50% DC	9	1.0 m

Electrical Fast Transient / Burst

Transient Voltage: 0.5 kV, 1.0 kV, 2.0 kV
Transient Polarity: Positive and Negative
Repetition Rate: 100 kHz
Rise Time of Pulse: 5 nS ± 30%
Pulse Duration: 50 nS ± 30%
Burst Period: 300 ms ± 20%
Burst Duration: 15 ms ± 20%

Surge, Power Ports

Voltage: 0.5 kV, 1.0 kV Differential Mode
0.5 kV, 1.0 kV Line to Line Mode
0.5 kV, 1.0 kV, 2.0 kV Common Mode
Polarity: Positive and Negative
Pulse Phase: 0°, 90°, 180°, 270°
Open Circuit: Rise Time 1.2 µsec, Duration 50.0 µsec, Rep Rate 1 ppm
Short Circuit: Rise Time 8.0 µsec, Duration 20.0 µsec

Conducted Immunity Including ISM and Amateur Radio Bands
AC Mains and I/O Cables

Frequency Range, Test Level: 0.15 to 80 MHz, 10 Vms
ISM Test Frequencies: 6.765 to 6.795, 13.553 to 13.567
26.957 to 27.283, 40.660 to 40.700 MHz
Test Level: 6 Vrms

Power Frequency, Magnetic Immunity

Frequency: 50 Hz and 60 Hz
Applied Signal Level: 30 A/M RMS

VOLTAGE DIPS AND INTERRUPTS

100 VAC 60 Hz							
Specification	**Rated Voltage**	**Frequency (Hz)**	**Voltage Test Level (%)**	**Voltage Dip (%)**	**Test Voltage (Vac)**	**Duration (Periods)**	**Result**
0% UT for 0.5 Cycles @ 0°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 45°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 90°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 135°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 180°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 225°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 270°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 315°	100	60	0	100	0	0.5 Cycle	(1)
0% UT for 1 Cycle @ 0°	100	60	0	100	0	1 Cycle	(1)
70% UT for 30 Cycles @ 0°	100	60	70	30	70	30 Cycles	(1)
0% UT for 300 Cycles @ 0°	100	60	0	100	0	300 Cycles	(2)

220 VAC 60 Hz							
Specification	**Rated Voltage**	**Frequency (Hz)**	**Voltage Test Level (%)**	**Voltage Dip (%)**	**Test Voltage (Vac)**	**Duration (Periods)**	**Result**
0% UT for 0.5 Cycles @ 0°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 45°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 90°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 135°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 180°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 225°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 270°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 315°	220	60	0	100	0	0.5 Cycle	(1)
0% UT for 1 Cycle @ 0°	220	60	0	100	0	1 Cycle	(1)
70% UT for 30 Cycles @ 0°	220	60	70	30	154	30 Cycles	(1)
0% UT for 300 Cycles @ 0°	220	60	0	100	0	300 Cycles	(2)

240 VAC 50 Hz							
Specification	**Rated Voltage**	**Frequency (Hz)**	**Voltage Test Level (%)**	**Voltage Dip (%)**	**Test Voltage (Vac)**	**Duration (Periods)**	**Result**
0% UT for 0.5 Cycles @ 0°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 45°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 90°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 135°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 180°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 225°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 270°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 0.5 Cycles @ 315°	240	50	0	100	0	0.5 Cycle	(1)
0% UT for 1 Cycle @ 0°	240	50	0	100	0	1 Cycle	(1)
70% UT for 25 Cycles @ 0°	240	50	70	30	168	25 Cycles	(1)
0% UT for 250 Cycles @ 0°	240	50	0	100	0	250 Cycles	(2)

Close Field Proximity Test Levels *Based on 0.3 m Separation Distance*				
Test Frequency (MHz)	**Test Level (volts/meter)**	**Maximum Power (W)**	**Modulation (@ 50% duty cycle)**	**Communication Service (partial list)**
385	27	1.8	18 Hz	TETRA 400
450	28	2	FM (5 kHz deviation)	GMRS 460 FRS460
710, 745, 780	9	0.2	217 Hz	LTE
810, 870, 930	28	2	18 Hz	GSM 800
1720, 1845, 1970	28	2	217 Hz	GSM 1800
2450	28	2	217 Hz	RFID
5240, 5500, 5785	9	0.2	217 Hz	WLAN

GUIDANCE AND MANUFACTURER'S DECLARATION

The VuMAX HD is intended for use in the electromagnetic environment specified below. The customer or user of the VuMAX HD should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The VuMAX HD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The VuMAX HD is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

The VuMAX HD is intended for use in the electromagnetic environment specified below. The customer or user of the VuMAX HD should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge [ESD] IEC 61000-4-2	± 8kV Contact ± 15kV Air	± 8kV Contact ± 15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency [50/60 Hz] IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment

The VuMAX HD is intended for use in the electromagnetic environment specified below. The customer or user of the VuMAX HD should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	10 V/m 150 kHz to 80 MHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the VuMAX HD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio [cellular/cordless] telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VuMAX HD is used exceeds the applicable RF compliance level above, the VuMAX HD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VuMAX HD.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10V/m.

WARNINGS AND CAUTIONS

	**WARNING: AN INSTRUCTION THAT DRAWS ATTENTION TO RISK OF INJURY OR DEATH**

DANGER!

THE WATER PATH PROBE IS A TYPE B APPLIED PART AND PROVIDES A BASIC DEGREE OF PROTETION AGAINST ELECTRIC SHOCK AND HAS DIRECT EARTH CONNECTION. WHEN USING THE WATER PATH PROBE IN UBM MODE (35 OR 50 MHZ), THE USER MUST TAKE EVERY PRECAUTION TO PREVENT THE TRANSDUCER FROM TOUCHING THE EYE. CONTACT BETWEEN A MOVING TRANSDUCER AND THE EYE CAN CAUSE SEVERE INJURY.

WARNINGS

Switching on a cold instrument near 0° Celsius may cause permanent damage to the device. Allow the instrument to reach a normal room temperature for half a day in order to allow the internal elements to warm up and to avoid any thermal shock hazards when switched on. The cover will quickly reach room temperature, but not the internal circuitry.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Isolation from the supply mains may be achieved by disconnecting the main power cord from the supply outlet.

DO NOT disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.

DO NOT attempt to repair or service this instrument. Any repair or service to this instrument must be performed by experienced personnel who are trained by Sonomed Escalon. Attempts to repair or service the instrument may result in serious injury to the operator or patient.

Measurements should not be attempted when ocular integrity is questionable. The user needs to exhibit care in manipulating the measurement tip. Force should not be exerted against the eye.

Disconnect the AC POWER before cleaning the system.

If the device is used in the United States in the 240 volts mode, a Centered-Tapped Single-Phase 240V power supply must be used.

The transducers are fragile. Dropping or striking any probe can cause malfunctions; handle all probes with care. If a probe should be dropped, inspect it carefully for chips and cracks, and make a “test” scan on a known object. Damage to the front of the transducer will reduce efficiency, and may cause premature failure of the electronics or may cause damage to the cornea.
DO NOT USE PROBES IF TIP IS DAMAGED. ALWAYS EXAMINE PRIOR TO USE.

This device is not intended for fetal use.

Never autoclave a transducer or expose it to high heat.

Do not attempt to connect the device to any accessories or supplemental equipment other than that provided by Sonomed Escalon. This could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation. Equipment connected to the system must be IEC 60601-1 or IEC 60950 compliant. Additionally, do not load any additional software onto the system without prior authorization from Sonomed Escalon (doing so may void warranty). Connection of system with a network is responsibility of user, including assurance of data integrity and related protections.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on or off. Try to correct the interference using one or more of the following: Reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that to which the other devices(s) are connected and or/ consult the factory field service technician for help.

Portable radio frequency communications equipment (including antenna cables and external cables) should be used no closer than 12 inches (30 cm) to any part of the VuMAX HD, including cables supplied by SonomedEscalon. Otherwise, degradation of the performance of this device could result.

Modifications to this instrument are not allowed. This may cause unit damage, malfunction, electrical shock, fire, or personal and/or patient injury.

Do not use the device together with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.

CAUTIONS

PATIENT DATA IS NOT SAVED IF UNIT IS TURNED OFF BEFORE SAVING SCANS.
Data will be saved under the same patient name until another has been selected.

Care should be taken by user to minimize exposure of patient to ultrasound energy by keeping examinations as short as possible.

Position such that console is well ventilated with easy access to disconnect power cords, and do not block the power adapter in the event that disconnecting should be necessary.

The probe must be connected or disconnected only when the unit is switched OFF.

The unit should not be connected to a Multiple Power Switch Outlet (MPSO) which is also used to provide power to devices not intended to be used in the patient environment. Doing so may compromise electrical safety of the device.

Do not place the unit near heat sources such as a heater.

In order to prevent patient-to-patient transfer of infection, after each use disinfect the measurement tip following accepted clinical procedures. Refer to the Maintenance section regarding the use of disinfectants and for probe cleaning instructions.

Dispose of all products in accordance with local and national regulations and codes.

The VuMAX HD conforms to the emissions and immunity requirements IEC 60601-1-2:2014, Conducted Emissions, Group 1, Class B.

Essential performance of the VuMAX HD may be lost if the unit is adversely exposed to external electromagnetic disturbances resulting in loss of patient data. When tested for electromagnetic disturbances, the VuMAX HD did not exhibit malfunction or degradation of performance when subjected to power frequency magnetic fields of 50 Hz and 60 Hz, but it is recommended that use in close proximity to or stacking of other electronic devices should be avoided because it could result in improper operation. If such use is necessary, the VuMAX HD and other equipment should be observed to verify normal operations.

In the event adverse external electromagnetic disturbances causes the VuMAX HD to lockup, the unit may require a system reboot by restarting.

Third Party Equipment: The use of third-party equipment, cables or accessories, not made or authorized by Sonomed Escalon, invalidates the warranty of the unit, and adversely affect the unit's safe operation.

CYBER SECURITY RECOMMENDATIONS

VuMax HD systems incorporate Microsoft 10 as their software Operating System, and, as such, makes available to Operators the full scope of Microsoft Windows 10 security features as defense against cyber security threats. Failure to maintain cyber security could result in compromised device functionality, loss of data availability or integrity, or exposure of other connected devices or networks to security threats.

Sonomed Escalon recommends the following minimum procedures be followed in order to maintain a basic level of cyber security:

① **Utilize Device Only for Intended Use**. Limit or prohibit use of device for any purpose other than ophthalmic ultrasound, including internet browsing and email, to limit potential exposure to cyber security risks.

② **Verify Windows 10 Firewall is Enabled**. Devices are shipped from the factory with the Windows Firewall on by default. To make sure it hasn't been turned off, follow these steps:

1. Open Windows Firewall by clicking the **Start** button and then clicking the **Search** icon. In the search box, type **firewall**, and then click **Windows Firewall.**
2. In left pane, click **Turn Windows Firewall On or Off.** If prompted for an administrator password or confirmation, type password or provide confirmation.
3. Below each network location type, click **Turn On Windows Firewall**, and then click **OK**. It is recommended that the firewall be turned on for all network location types.

IMPORTANT: If device is connected to a network, ensure that the device is placed behind a strong network firewall.

③ **Verify Automatic Updating for Windows 10 Operating System Enabled.** With automatic updating, the Operator doesn't have to search for updates online or worry that critical fixes or device drivers for Windows might be missing from the system. Windows update automatically installs important updates as they become available. The Operator can also set Windows Update to install recommended updates automatically or to inform the Operator that they're available. The Operator can also choose whether to turn on Microsoft Update, which delivers updates for other Microsoft products. Optional updates, such as language packs and updates from Microsoft Update, aren't installed automatically. Windows Update won't add any apps to the system without prompting for permission.

To turn on automatic updating:

1. Open Windows Update by swiping in from the right edge of the screen (or, if using a mouse, pointing to the lower-right corner of the screen and moving the mouse pointer up), tapping or clicking **Settings**, tapping or clicking **Control Panel**, and then tapping or clicking **Windows Update.**
2. Tap or click **Change Settings**.
3. Under **Important Updates**, choose the option that you want.
4. Under **Recommended Updates**, select the **Give me recommended updates the same way I received important updates** check box, then click Apply.

IMPORTANT: In order for automatic Windows Update to function, the device must be continuously connected to the Internet. If the device is not connected, Windows updates will need to be performed manually. To do so, regularly go to Windows Update per step 1 above and then click **Check and Install Updates** button.

④ **Install Windows 10 Compatible Anti-Virus Program.** The Operator should utilize an antivirus and antimalware program, and keep it current by regularly downloading updates from the program manufacturer's website. Many of these programs update automatically and can help protect the system from spyware and malicious software.

⑤ **Enable Windows 10 BitLocker**. The Operator can use BitLocker Drive Encryption to help protect files on the entirety of the drive. BitLocker can help block hackers from accessing the system files they rely on to access sensitive data, or from accessing a disk drive by physically removing it from the system and installing it in a different one. New files are automatically encrypted when added to the disk drive that used BitLocker. However, if these files are copied to another drive or a different PC, they're automatically decrypted. BitLocker can encrypt the drive Windows is installed on (the operating system drive) as well as fixed data drives (such as internal hard drives). The Operator can also use BitLocker To Go to help protect all files stored on a removable data drive (such as an external hard drive or USB flash drive).

For more information on cyber security, please consult your IT support staff and/or visit Microsoft security www.microsoft.com/security.

WARRANTY

Sonomed Escalon warrants its products are free of defects of labor and material for two (2) years for consoles, one (1) year for probes and cables, and one (1) year for associated computer components such as monitors, keyboards, and mice.

The following items are not covered:

Physical damage to the console or probes due to misuse or shock.

Damage or data loss due to power failures or fluctuations. The use of a line-interactive UPS is recommended to avoid this type of failure.

Loss or corruption of data or software due to user error or the installation or use of any third-party hardware or software.

Damage to transducers caused by autoclaving or exposure to excessive heat.

Repairs not covered by warranty will be invoiced on the basis of parts and labor. At Sonomed Escalon's discretion, the damaged component may be exchanged at a flat rate.

Servicing of the unit may only be performed by Technicians certified by Sonomed Escalon. For additional information regarding system repair, maintenance, or exchange please contact US:

Sonomed Escalon
1979 Marcus Avenue, C105
Lake Success, NY 11042 USA
Tel: 800-227-1285
Fax: 516-354-5902
www.sonomedescalon.com

Any serious injury or incident occurring as a result of ophthalmic ultrasound use should be reported to Sonomed Escalon immediately. Patients and users should report serious incidents to the appropriate regulatory authorities.

NETWORKING

Sonomed Escalon does not provide support for the operation of this product in a network environment. Connection to and operation on any network is entirely the responsibility of the user. Where installation or use of any network hardware or software interferes with the normal operation of this Sonomed Escalon-supplied product, that product must be returned to normal operation at the user's expense. When the connection of this product to, or installation of Sonomed Escalon supplied software on, a network interferes with the operation of the network, the product must be removed from the network; alternatively, the problem may be resolved by the user in cooperation with the network owner, at their expense.

THIRD-PARTY SOFTWARE

Sonomed Escalon does not provide support for the use or installation of any software obtained from a third party on its products, including, but not limited to, operating system upgrades and device drivers. When software not supplied by Sonomed Escalon interferes with the operation of the system, the product will be returned to its original condition at the user's expense. Sonomed Escalon may occasionally furnish to users software not directly related to the functioning of its products. Such software is supplied as is, without warranty of any kind, and the availability of support for such software is at Sonomed Escalon's sole discretion.

SYMBOLS

	USB Port
	Do Not Dispose of Equipment in Normal Waste Stream
CE 0413	CE Mark; Device complies with the (EU) 93/42/EEC Medical Device Directive 93/42/EEC The number beside the symbol is the identification number of the Notified Body that certified the quality system under the Medical Device Directive
	Type BF Applied Part (B Scan probe / A Scan probe)
	Type B Applied Part (Water path [UBM] probe)
	Warnings and Cautions, Read Accompanying Documents
IPX7	Rating applies to ultrasound probes only. An IPX7 rating means the probes are protected against effects of temporary immersion in water. Do not immerse probe electrical connectors.
IPX1	Rating applies to VuMAX base unit only. An IPX1 rating means the device enclosure is resistant to the ingression of water at a flow rate of 1 mm/min for 10 minutes.
IPX6	Rating applies to foot pedal only. An IPX6 rating means the foot pedal can resist heavy sprays of high-pressure water.
	ETL Listing Mark
	Class II Equipment per IEC 60601-1
	Refer to Operators Manual