



VuPad™

An innovation in ultrasound
you can see and touch



OPERATOR'S MANUAL

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CONTACT INFORMATION

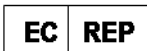


Sonomed Escalon™



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United States Federal law and European regulations restrict this device to use by, or on the order of, a physician. This device should only be used under the supervision of an experienced ophthalmic medical practitioner in a clinical setting. Before examining a patient, the user should become acquainted with the operating procedures, warnings and precautions set forth in the Operators Manual. The user should consult additional resources as necessary for further information regarding the proper application of ultrasound technology. If difficulty is experienced when operating the unit after carefully reviewing this Operators Manual, contact your local Sonomed Escalon distributor for assistance.

This instrument should be used in strict accordance with the instructions outlined in this Operators 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.

There are no user-serviceable parts within the VuPad 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.

OVERVIEW

DESCRIPTION

The VuPad™ is an 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 system intended for use in ophthalmic applications designed to capture images of the interior of the eye and make accurate measurements of the structures.

The VuPad™ is a stand-alone system that runs on a Windows 10 platform and may be networked (by the user) for interface with electronic medical records systems, printing, and other purposes. The system consists of the VuPad™ console, ultrasound probe(s) and transducer(s), and foot pedal.

The device is used by coupling the probe/transducer to the eye either through direct contact or immersion methods. Available modes are biometric A-scan, pachymeter, diagnostic A-scan, B-scan, UBM (ultrasound bio-microscope).

Biometric A-Scan

A-Scan is a noninvasive tool that produces 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.

Pachymeter

Pachymeter is a noninvasive tool that produces measurements of the thickness of the eye's cornea. It is used to perform corneal pachymetry prior to refractive surgery, for keratoconus screening, limbal relaxing incisions surgery and is useful in screening for patients suspected of developing glaucoma among other uses.

Diagnostic A-Scan

Diagnostic A-Scan is a noninvasive tool that enables 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 a noninvasive tool 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.

UBM/ Ultrasound Bio-Microscopy (UBM-Mode)

UBM is a noninvasive tool 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 VuPad™ is intended to be used to visualize and measure the eye and orbit using B-Scan and A-scan ultrasound.

CONTRAINDICATIONS

The VuPad™ is not intended for fetal use.

GETTING STARTED

SYSTEM COMPONENTS



Power On/Off

Ethernet

USB

Power Cable

UNPACKING

- ① Unpack contents from packaging.
- ② Connect power cord between console and wall outlet.
NOTE: Console may be propped on its stand or attached to a VESA mount.
CAUTION: Position such that console is well ventilated with easy access to disconnect power cords, as may be necessary.
- ③ Connect the probe cables to unit and place probes into probe holders.
NOTE: The same cable is used for all B-scan and UBM probes.
- ④ Power on console. System will boot up into a Windows 10 home screen and the VuPad icon can be selected to launch the program.
NOTE: Console may be powered off by pushing the power button.

CONSIDERATION WHEN JOINING TO NETWORK DOMAIN

The Vupad 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).

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

OPENING DISPLAY AND SETUP

- ① OPEN THE VUPAD PROGRAM by clicking on the VuPad Icon located on the desktop screen.

- ② CLICK ON THE “**CONFIGURE**” TAB. This will allow the user to set up defaults for the MD/Examiner by:
 - * Select “New MD/Examiner” tab and complete the requested information for MD/Examiner using the on-screen keyboard (or optional external Bluetooth keyboard). (see Fig. 1)
 - * The user can also designate any user as the “Default Examiner” or “Default Attending” (*required for Biometric a-scans*) by selecting the appropriate tab(s).
 - * The preferred lenses (IOL’s) can be selected by selecting the “Lenses” tab on the user setup screen. Pressing “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” key will become active and selecting this key will add the desired lens to the users preferred list. (see Fig. 2)
 - * Once all information has been entered, pressing the “OK” will return the user to the Lens screen. [Verify that the newly selected lens(s) appear in the table. Pressing “Close” will now return the user to the “M/D Examiner” screen.
 - * Pressing “Close” will return the user to the Patient Database screen.

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

Last Name	First Name	Middle Name	Specialty
Doctor	Test		
Durante	Barry		Cataract/Refractive
Escalon	Sonomed	Test	Cataract/Refractive

Fig. 1

MD/Examiner Setup Display:

Name: Enter Examiner Name

Type: Enter Examiner/Attending Phys./ Referring Phys.

Default Examiner: A “default” examiner can be entered for every exam.

NOTE: In order to perform A-scan biometry measurements, an “Attending” physician must be entered. Selecting a “Default Attending” will automatically assign this user for each exam.

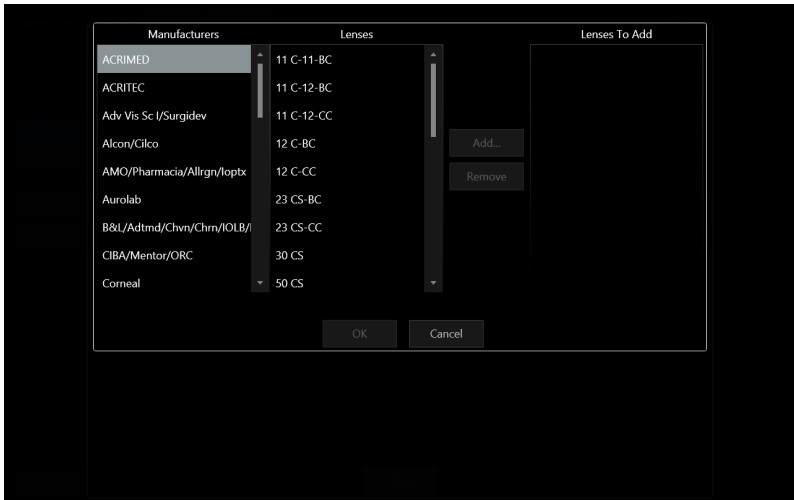


Fig. 2

Lens Selection Screen:

Manufacturer: Scroll and Select the Lens Manufacturer's Name.

Lenses: Scroll and Select the desired Lens Model.

NOTE: The "Lens Database" Tab (see Fig.1) includes over 1500 lenses and associated data which the user can update, by adding, deleting or editing lenses.

The "LENSES" Tab is the Examiner Lens Selection tab from which the Examiner must choose the desired lenses from for performing IOL calculations.

A-SCAN

PATIENT DATABASE

- ① **PATIENT:** Select the “NEW” tab located at the top left side of the database display screen.

NOTE: For previously entered patient, scroll through patient list, by sliding the scroll indicator just to the right of patient list until the desired patient name is displayed.

- ② **ENTER NEW PATIENT** Information into the appropriate fields (see Fig. 3) [Note: K-readings can be entered here or later if performing a-scan biometry.]..... Press “OK”

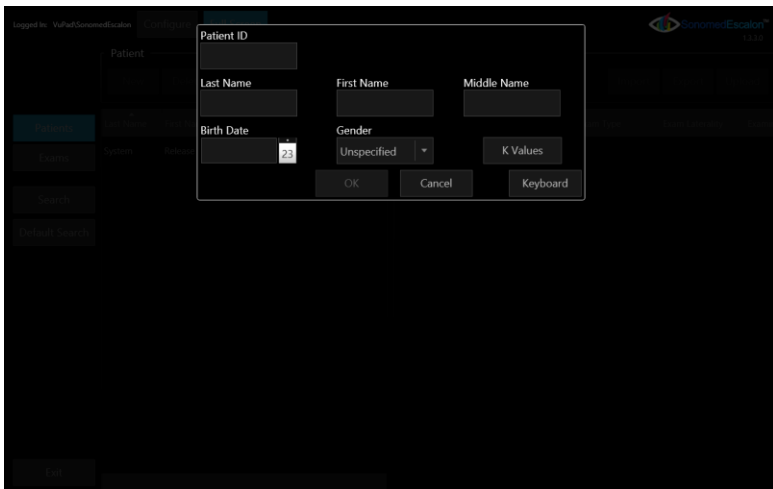
The image shows a screenshot of a software interface for entering a new patient. The background is dark with a grid of buttons. A white modal window is centered on the screen, titled "NEW PATIENT". The form contains the following fields: "Patient ID" (text input), "Last Name" (text input), "First Name" (text input), "Middle Name" (text input), "Birth Date" (calendar picker showing "23"), and "Gender" (dropdown menu showing "Unspecified"). There are also three buttons at the bottom: "OK", "Cancel", and "Keyboard". The top left of the screen shows "Logged In: Vahid.Governor@Education" and the top right shows the "Sonomed Escalon" logo.

Fig. 3

EXAM MODE

- ① **EXAM:** Select the “NEW” tab located at the top right side of the database display screen.
- ② **Verify Examiner** [Required], **Attending Phys** [Required], and **Referring Phys** (if needed) are entered.

- ③ **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 labeled “Teaching Case”]. Press “**OK**”
- ④ **ENTER PARAMETERS:** K-readings can be entered for either/both eyes. If the patient has had previous refractive surgery, pressing the “Post Refractive” tab will allow the user to select the formula and IOL Correction [Aramberri Double K, Laskany Myopic/Hyperopic] to apply to the lens power calculation. Then select the “**OK**” tab.

VERIFY CALIBRATION

- ① The **Verify Calibration** Window should be displayed if the “**Bio A**” tab had been selected previously.
 - **Select YES** to perform the calibration verification. The VuPad will start emitting an audio “beeping”. Place a drop of water onto the face of the a-scan probe and press the probe onto the calibration cylinder (located on left side probe holder). Once the correct pattern is accepted by the instrument, the beeping will stop and the message “Calibration Verified” will appear.
 - [Note: It may be necessary to increase the “Gain” control in order to achieve the desired pattern].
 - **Select NO** to bypass the calibration verification procedure.

EXAM MODE

- ① Select the desired **OD/OS** tab located on the top of the display. Then proceed as follows: (see Fig. 4)
 - * **SCAN** Tab: Select the desired mode (Cataract, Aphakic, etc.) for the eye to be examined. The user can also select “immersion” mode if using an Immersion Shell for biometry.
 - * **BIOMETRY** Tab: will display the collected data as the scans are performed and accepted.
 - * **SETTINGS** tab: will display the various velocities used for the selected mode. The user can adjust these values if needed by using the ▲ / ▼ symbols.

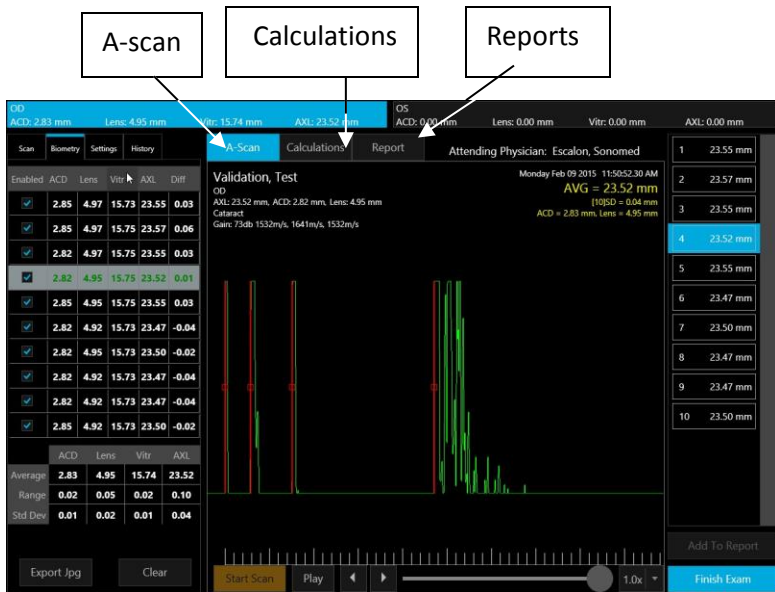


Fig. 4

- The "CONTINUOUS CAPTURE" tab, if selected, will allow the user to set the desired number of scans that the VuPad will obtain with a single press of the footswitch. If "Immersion" mode has been selected, TWO footswitch presses would be required to begin obtaining scans – once to activate the transducer for alignment and one to activate the algorithm for scan acceptance.

* **HISTORY** tab: records all previous a-scan exams [Date/Time/ Exam type] for the selected patient.

- ② For "Direct Contact" scanning, press the "START SCAN" tab at the bottom of the display (or press the footswitch). The VuPad will emit a continuous beeping sound indicating that the scan mode has been activated. Place the probe in contact with the cornea and instruct the patient to look at the RED FIXATION light at the tip of the probe. Once the proper alignment is achieved, the VuPad will begin to accept scans which will be shown on the right side of the display screen. Once the desired number of scans are accepted, the VuPad will cease emitting the beeping sound.
- For "Immersion" scanning, the user should press the "ALIGN PROBE" tab (or footswitch) until alignment is achieved. Once the user is satisfied that the probe is properly aligned, pressing the "START SCAN" tab (or footswitch a second time) will activate the scanning algorithm and begin to collect scan data.

- ③ Selecting the BIOMETRY tab, will permit the user to view all the data collected from the scan session including the ACD, LENS THICKNESS, VITREOUS DEPTH AND AXIAL LENGTH for all scans in the set.
 - The user can omit a scan from being included in the Average by un-checking the “Enabled” box located to the left of each data set. This does not delete the scan from the record.
 - The user can “Delete” a scan from the record by selecting and holding the individual scan data (for approximately 2 seconds) located on the right side of the display and selecting “delete” from the pop-up menu. This will delete the scan and all associated data from the record.

CALCULATION MODE

Once the user has reviewed and is satisfied with the scan results, the CALCULATIONS tab, located at the top of the measurement display screen, should be selected. (See Fig. 4)

- ① Enter the “Target” refraction and K-readings (if not entered previously)
- ② Average AXL and ACD should populate based on previous screen.
- ③ **LINK** tab will enable to user to display the same Formula or the same Lens for all 4 of the calculation tables.
- ④ **LENS** can be selected from the drop-down menu which will include all lens models previously added to user profile.
- ⑤ **Formulas** can be selected from the drop down menu which will include all formulas previously added to profile.
- ⑥ IOL table will display with the “Target” refraction entered previously at the center. The user can edit the center value by changing the value in the “Target” refraction field. (step 1 above).
- ⑦ Once all values are approved and accepted, the user should select the “**ADD TO REPORT**” tab located on the bottom right of the display.
- ⑧ 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 described above.
- ⑨ 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 (see Fig. 5) which includes the A-scan(s) and IOL calculations for each eye for which the measurement/calculations were performed. If required, the user can return to the calculation tables, 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 2 of 2, 3 of 3, etc.....

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 to return to the patient database screen.

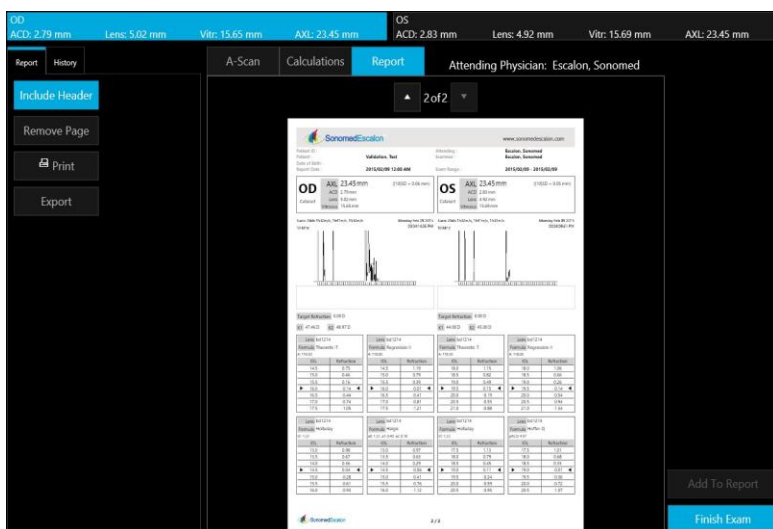


Fig. 5

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 ‘VuMaxHD Software’ icon (Fig. 6).

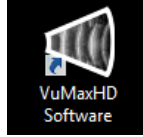


Fig. 6 - VuMAX HD Software Icon

- ③ **Patient Database Screen:** Upon launching the application the ‘Patient Database’ screen (Fig. 7) will display. Here you can add a new patient or find previously performed exams.

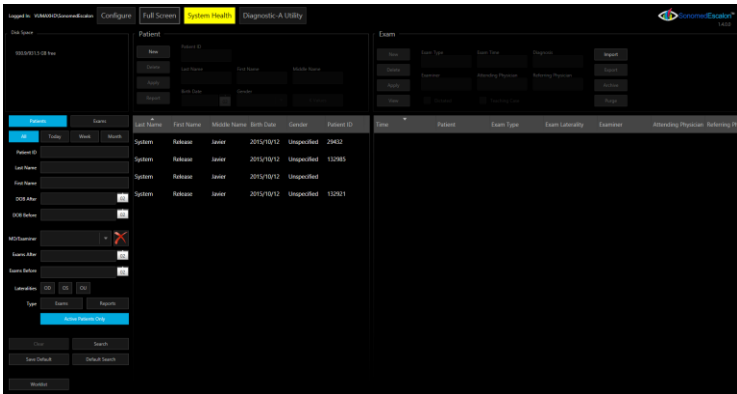


Fig. 7- Patient Database Screen

- ④ **Diagnostic A-Utility:** To start the Diagnostic A-Scan application, select the ‘Diagnostic A-Utility’ button (Fig. 8).

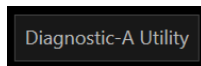


Fig. 8 - ‘Diagnostic-A Utility’ Button

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 (Fig. 9).

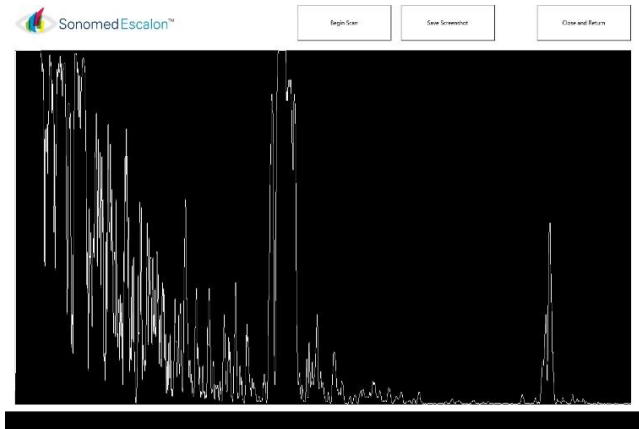


Fig. 9 - Diagnostic-A Utility Screen

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 (Fig. 10)

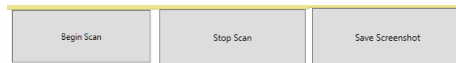


Fig. 10- ‘Begin Scan’ ‘Stop Scan’ and ‘Save’ Buttons

⑦ **Save As:** Upon selecting the ‘Save Screenshot’ button, a Windows ‘Save As’ screen (Fig. 11) 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.

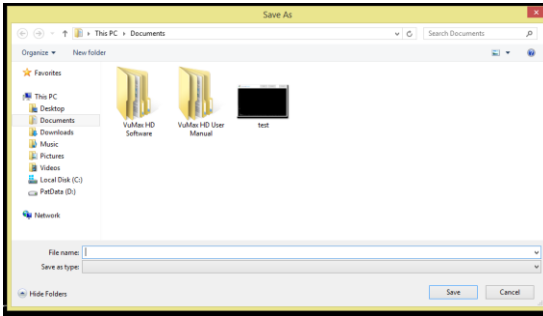


Fig. 11 'Save As' Window

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 Fig.12.

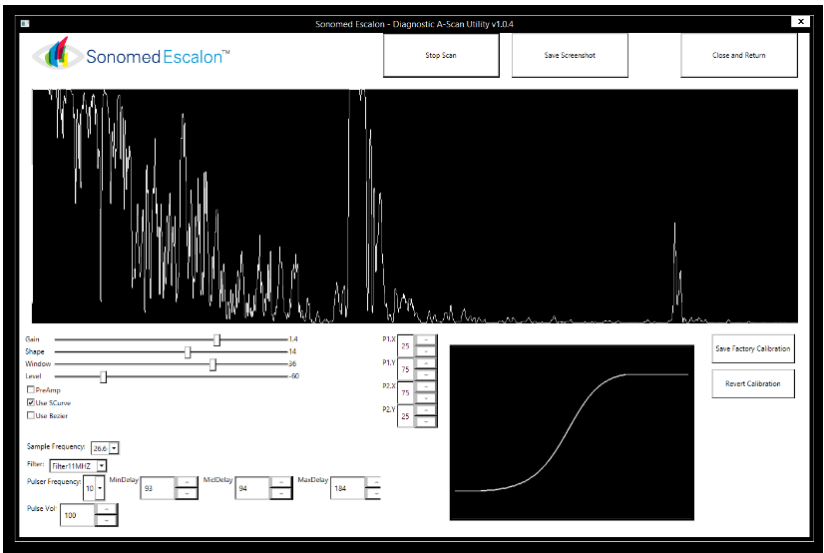


Fig. 12 Calibration Screen Window

PACHYMETRY

SELECT EXAM MODE

- ① **EXAM:** Select the “NEW” tab located at the top right side of the database display screen.
- ② **Verify Examiner** [Required], **Attending Phys** [Required], and **Referring Phys** (if needed) are entered.
- ③ **ENTER THE EXAM TYPE** [**Pach**] and Laterality [OD/OS]. [If the exam is to be used as a teaching case, place a checkmark in the box labeled “Teaching Case”]. Press “OK”

PERFORM EXAM

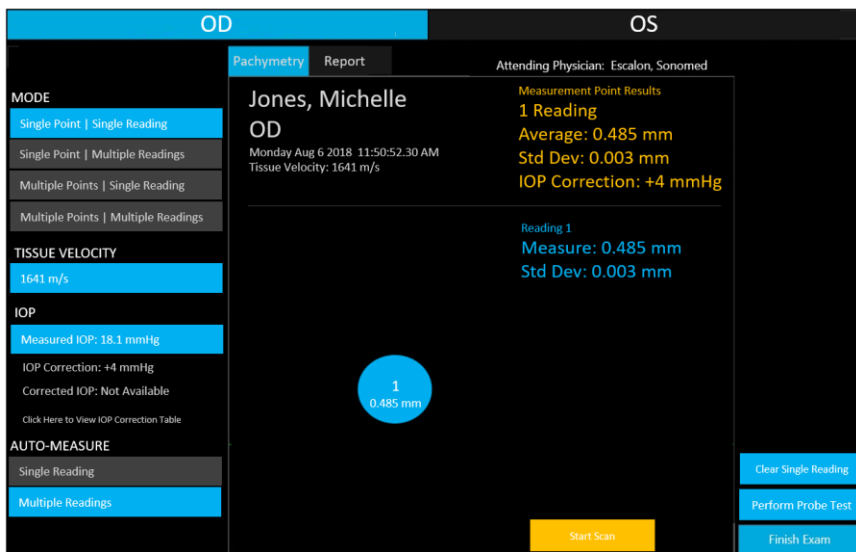


Fig. 13

- ① Select desired exam mode option: (Fig 13 and 14)
 - **Single Point | Single Reading** Provides for a single reading at a single point on cornea.
 - **Single Point | Multiple Readings** Provides for up to 5 readings at a single point on cornea.
 - **Multiple Points | Single Reading** Provides for a single reading at up to 9 points on cornea.
 - **Multiple Points | Multiple Readings** Provides for up to 5 readings at up to 9 points on cornea.

Note: If multiple points are to be scanned, select appropriate location on corneal map to first measure.
- ② Confirm Tissue Velocity is appropriate; tap to change as desired.
- ③ Enter measured IOP if corrected IOP based on corneal thickness is desired.
- ④ Select whether a single or multiple points should be automatically taken once system scan criteria are met.
- ⑤ Select “SCAN” button to start scan (or press foot pedal).
- ⑥ Repeat, as necessary, to measure all desired points. Readings can be cleared and repeated, if necessary.

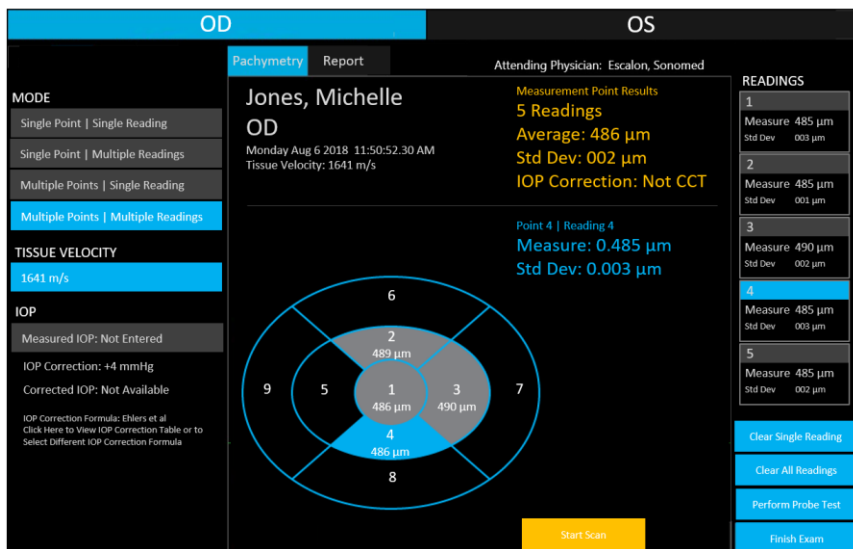


Fig 14

REPORT

① Select "Report" button to generate pachymetry report (Fig. 15).



Ideal Vision
123 Main Street
Anytown, USA 12345
215-514-8956

Patient ID	105481	Report Date	Sep 07 2018
Patient Name	Jones, Michelle	Attending Physician	Shatalov, Oleg
Date of Birth	Nov 13 1947	Examiner	Shatalov, Oleg
		Exam Range	Aug 08 2017 – Aug 08 2017

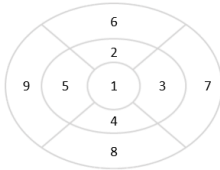
These are general comments regarding the exam...

OD

Monday Aug 6 2018 11:50:52.30 AM
Tissue Velocity: 1641 m/s

Measured IOP **20.1 mmHg**
IOP Correction **+4 mm Hg**
Corrected IOP **24.1 mmHg**

Using Ehlers et al IOP Correction Formula



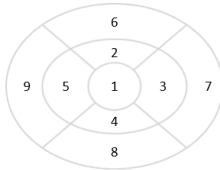
Reading	1	2	3	4	5	Avg	Std Dev	
Point 1	Measure 485	485	490	485	485	486	002	CCT
	Std Dev 002	001	001	002	003			
Point 2	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 3	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 4	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 5	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 6	Measure -	-	-	-	-	-	-	Limbus
	Std Dev -	-	-	-	-			
Point 7	Measure -	-	-	-	-	-	-	Limbus
	Std Dev -	-	-	-	-			
Point 8	Measure -	-	-	-	-	-	-	Limbus
	Std Dev -	-	-	-	-			
Point 9	Measure -	-	-	-	-	-	-	Limbus
	Std Dev -	-	-	-	-			

OS

Monday Aug 6 2018 11:50:52.30 AM
Tissue Velocity: 1641 m/s

Measured IOP **20.1 mmHg**
IOP Correction **+4 mm Hg**
Corrected IOP **24.1 mmHg**

Using Ehlers et al IOP Correction Formula



Reading	1	2	3	4	5	Avg	Std Dev	
Point 1	Measure 485	485	490	485	485	486	002	CCT
	Std Dev 002	001	001	002	003			
Point 2	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 3	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 4	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 5	Measure 485	485	490	485	485	486	002	
	Std Dev 002	001	001	002	003			
Point 6	Measure 472	470	471	471	471	471	001	Limbus
	Std Dev 001	002	001	001	002			
Point 7	Measure 468	465	462	462	468	465	003	Limbus
	Std Dev 002	002	003	003	002			
Point 8	Measure 472	470	471	471	471	471	001	Limbus
	Std Dev 001	002	001	001	002			
Point 9	Measure 468	465	462	462	468	465	003	Limbus
	Std Dev 002	002	003	003	002			

1/1

Fig 15

B-SCAN AND UBM

CONFIGURE SYSTEM

- ① After logging in by entering the administrator name and password, the home screen is the patient database, which shows a history of patients and their respective exams. From this screen, select the <Configure> button.
- ② **ENTER ASSOCIATE INFORMATION** by selecting the <New> button, entering information and clicking the <Apply> button. Each associate can be designated as an examiner, attending physician, and/or referring physician.
- ③ **ENTER ULTRASOUND INFORMATION** by selecting the Ultrasound tab and selecting the <Add...> button. Enter the frequency in MHz of any water path transducer(s).
- ④ **ENTER DIAGNOSES FOR REFERENCE ON EXAM RECORDS** by selecting the Diagnoses tab and selecting the <New Diagnosis> tab.

PATIENT DATABASE

Upon opening the VuPad 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:

- 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.
- 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 to actually delete a patient record.

- ④ **SELECT PATIENT** by highlighting the patient from the patient list – a history of any saved exams for the patient will appear in the exam list.
- 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 an EMR system, referrals, or creating presentations.
- ⑩ **PRINT REPORT** by selecting the <Report> button. In the Report screen, the images may be selected (across the patient's history of exams) and the format chosen for one, two, four, or six images per page.
NOTE: The report header may be toggled on or off by selecting the <Header> button.
- ⑪ **CONFIGURE SYSTEM** by selecting the <Configure> button to enter examiner, physician, and referring physician information, among other set-up tasks.

EXAM MODE

After selecting the <New Exam> button from the Patient Database screen, enter the exam information, the Exam screen is shown from which imaging can be performed.

- ① **SELECT THE PROBE FREQUENCY** to be used from the drop-down menu and select the <Refresh Probes> button.

Standard B-Scan Mode: 12 MHz or 20 MHz probes may be used.

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 particular structure of interest. Available image controls and preset scan modes are shown on the next page.

NOTE: Image controls may also be adjusted during or after a scan.









- ③ **PLACE PROBE INTO POSITION AND START SCANNING** by either depressing the footswitch or selecting the <New Scan> button. When the footswitch is pressed or <Stop Scan> button selected, a video clip of the prior 50 frames is captured.

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 **REVIEW SCAN** by selecting the Play button and selecting the playback rate (or scroll through video clip one frame at a time). 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.

- ⑤ **ANNOTATE SCAN** by selecting Tools tab and selecting the desired function. Annotations are saved with the associated video clip or image.

NOTE: A frame is automatically saved when an image is annotated.

ANNOTATIONS	
	Angle Measurement places adjustable angle edges onto image and displays angle in degrees.
	Arbitrary A-Scan allows user to see an A-scan trace along any vector.
	Linear Measurement places adjustable calipers onto image and displays distance.
	Pan allows user to move image while holding down the left mouse button.
	A-Scan displays an A-scan trace along the axis of a B-scan image. (B-scan only)
	Measurement Template displays approximate common measurements for UBM sulcus-to-sulcus video clips with ability to move measurement endpoints. (UBM-only)
	Refresh Measurements will reset measurements to those auto-generated by system. (UBM-only)
	Clear removes the highlighted annotation from the image.
Diagnosis	Add or Remove a diagnosis by selecting the appropriate buttons.
Notes	Add or Remove notes by selecting the appropriate buttons.

- ⑥ **EXPORT FRAME** by selecting Tools tab and selecting <Export JPG> button.
- ⑦ **USE NOMOGRAMS TO DETERMINE ICL LENS SIZING** by selecting the Tools tab and selecting the desired nomogram and entering required information to yield the resultant lens size.
- ⑧ **EXIT EXAM MODE** by selecting <Finish Exam> button.

IMAGE CONTROLS

TVG	Time Variable Gain (TVG) attenuates near field portion of scan sector.
Baseline	Affects low-level signal threshold to help reduce noise.
Zoom	Adjusts area of scan sector display on monitor.
Log Gain	Adjusts overall amplification of received signal.
Exp Gain	Adjusts overall signal amplitude in image with minimal effect on low-level noise (otherwise known as “E-Gain”).

UBM PRESET MODES

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.

B-SCAN PRESET MODES

Orbit	Optimized to image the orbit with 50° scan angle.
Deep Retina / Choroid	Optimized to view beyond the surface of the retina and into the choroid, with a 50° scan angle.

MAINTENANCE

SYSTEM CLEANING

Clean the VuPad™ probes with a damp cloth to remove gel and other debris. Use appropriate products to clean the cabling 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 from the probe, and to reduce the presence of microorganisms. Disinfection is performed after cleaning.

A-SCAN / B-SCAN / PACHYMETRY PROBES

① Cleaning of Probes:

- a) A few drops of common concentrated dishwashing detergent diluted in a liter of 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 water and allow to air dry or blot dry with a soft, lint-free cloth or gauze.

② Disinfection of Probes:

- 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 wipe dry with a soft, lint-free cloth or gauze. 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) The probe is hermetically sealed and, if necessary, the entire probe (up to the connector) may be immersed in either disinfecting solution (70% IPA or hydrogen peroxide). 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.

**** CAUTION: NEVER IMMERSER THE CONNECTOR AT THE END OF THE PROBE! ****

WATER PATH PROBES

① Cleaning of Water-Path Probes:

- a) Remove the “cap” that protects the rubber boot.
- b) A few drops of common concentrated dishwashing detergent diluted in a liter of warm tap water may be used. Lightly 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.
- c) The hard, plastic parts of the probe, including the protective cap, may be vigorously 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 boot.
- d) 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.
- e) Rinse the probe thoroughly with distilled or deionized water and allow to air dry or very lightly blot dry with a soft, lint-free cloth or gauze.

② Disinfection of Water-Path Probes:

- 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 wipe dry with a soft, lint-free cloth or gauze. 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) The probe is hermetically sealed and, if necessary, the entire probe (up to the connector) may be immersed in either disinfecting solution (70% IPA or hydrogen peroxide). 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.

**** CAUTION: NEVER IMMERSER THE CONNECTOR AT THE END OF THE PROBE! ****

- d) If necessary, the transducer may be detached from the probe and the two disinfected separately in either 70% IPA or hydrogen peroxide. 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.*

WARNINGS WHEN CLEANING WATER-PATH PROBES

- a) *Sodium Hypochlorite* (i.e. Bleach): Diluted (0.6% concentrations) and undiluted bleach solutions attack the gold plated surfaces of the probe, and once a breach has been made, the sensitivity of the transducer is diminished (proportional to the loss of gold plating). Therefore, cleaning and disinfection methods employing 0.6% concentrations, or more, of sodium hypochlorite should be avoided whenever possible.
- b) *Tap water*: Contaminants in common tap water have been found to attack and corrode the metal surfaces of the probe and transducer after extended use. The use of tap water, rather than sterile deionized water or distilled water is, therefore, contraindicated. After a probe is cleaned, soaked, or rinsed with tap water, rinse with distilled or deionized water and lightly wipe the surface clean of any residues.
- c) *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.

CAUTION:

Do not autoclave any probes; excessive temperatures will cause damage

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.

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

SPECIFICATIONS

A-SCAN SPECIFICATIONS	
Ultrasound Probes	Sealed 10 MHz focused transducer with standard probe (max length 5 ft cord)
Scan Modes	Direct contact or immersion Manual or automatic capture (cataract, dense cataract, aphakic, and pseudophakic)
Measurements	Anterior depth (ACD), lens thickness, vitreous, and axial length (AXI) Averages and standard deviation calculated for up to 10 scans per exam Configurable zone tissue velocities
IOL Formulas	Standard: Binkhorst, Regression-II, Theoretic/T, Holladay, Hoffer-Q, Haigis (optional); Post-Refractive: Laskany Myopic Regression, Laskany Kyperopic, Aramberri Double-K
Axial Resolution	0.0193 mm
Accuracy	±0.1 mm

UBM / B-SCAN SPECIFICATIONS	
Ultrasound Probes	B-Scan: HD series of sealed B-scan probes with focused transducers available in 12 MHz or 20 MHz frequencies (max length 6 ft cord) UBM: HD water path probe (max length 6 ft cord) with interchangeable focused transducers available in 35 MHz or 50 MHz frequencies and scan cap kit with four (4) different sizes
Image Rendering	Enhanced Focus Rendering™ (EFR™) with continuous interpolative zoom re-renders at each magnification level for optimized image quality (up to 8x zoom)
Scan Position Indicators	B-Scan One-click selection of transverse or longitudinal scan clock position with eye model confirmation (P/PE/EP/E/EA/O/CB/AX standardized labeling based on Acoustic Section Labeling Diagram from "Ultrasound of the Eye and Orbit", 2nd Edition, by Sandra Frazier Byrne and Ronald L. Green, MD) UBM: One-click selection of axial or longitudinal scan clock position with eye model confirmation User may add further free-form text for scan position details which are automatically annotated onto images and video clips
Scan Controls	A-Scan: Gain and sensitivity B-Scan / UBM: Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain (e-gain)

UBM / B-SCAN SPECIFICATIONS (cont'd)	
Preset Scan Settings	UBM: Selectable preset scan setting profiles to optimize image quality for each frequency probe: high resolution, sulcus-to-sulcus, angle detail, and motion picture
2D Scan Sampling	256 ray scan with 2048 sample points for each ray (524,288 sample points per sweep)
2D Video Clips	Capture and store 50-frame video clips at rates up to 20 frames per second (fps), depending upon scan setting. Store up to 12 video clips per exam and replay in real-time, scalable slow motion, or one frame at a time.
Images	Separately save any number of individual frames from video clips as images, complete with annotation(s)
A-Scan Trace	Superimpose A-scan trace onto images with a single button click with either arbitrary A-scan with caliper scan length adjustments or vector A-scan with adjustable vector
Annotation	Automatic annotation of images and video clips with patient and user identification, exam date, scan indicator position, transducer frequency, and scan settings; Unlimited measurements using linear calipers and angle measurement tool

PACHYMETER SPECIFICATIONS	
Ultrasound Probes	Sealed 20 MHz focused transducer with standard probe (max length 5 ft cord)
Scan Modes	Direct contact
Measurements	Single Reading – Single Point Multiple Reading – Single Point Single Reading – Multiple Points Multiple Reading – Multiple Points
Statistical Analysis	Average of 128 individual measures for each reading Standard deviation for each reading Average of up to 5 readings for each point Standard deviation of up to 5 readings for each point
Measurement Precision	± 1 micron
Measurement Accuracy	5 microns
Customizable Parameters	Corneal Velocity: 1620 – 1650 m/s Measurement Bias: 80 -120 % Intra-Ocular Pressure Correction (IOP) formula
Amplifier	Low Noise Automatic Gain Control Maximum Gain = 46 dB

GENERAL SPECIFICATIONS	
Patient Exam Records	Searchable patient database with exam record storage and expanded field set
User Profiles	Add unlimited number of users with user-selectable defaults and denotation of attending physician, referring physicians, and/or examiner
Reports	Detailed exam reports for printing or exporting
Export Feature	Export images (.jpg), video clips (.avi), and exam reports (.pdf)
Display	10.1" high-resolution monitor (1920 x 1080 pixel) with High-Definition Multimedia Interface (HDMI) and adjustable swivel and tilt
Connectivity	802.11n dual-band WiFi, Bluetooth 4.0, GigE Ethernet LAN, USB 3.0 ports
Hard Drive	500 GB SSD solid-state hard drive (1TB optional)
Printer	Any Windows-compatible printer
Operating System	Microsoft Windows 10
Power	100-120 / 200-240 V 4 / 2 A 60 / 50 Hz Auto-switching medical-grade power supply (250 W power consumption, typical) (max length 6 ft cord)
Operating Conditions	Operating Temperature: 41 to 104°F (5 to 40°C) Storage Temperature: -40 to 158°F (-40 to 70°C) Operating Relative Humidity: 0 to 90% non-condensing Storage Relative Humidity: 0 to 90% non-condensing Atmospheric Pressure: 70 to 101kPa
Controls	Foot pedal (max length 6 ft cord)
Dimension	13.3" x 8" x 2"

WIRELESS SPECIFICATIONS	Frequency band of operation: 5 GHz
Operating Frequency	5150 – 5350 MHz
Bandwidth	802.11 a/n/ac: 20/40/80/MHz
RF Output Power	23 dBm max. (5150 – 5725 MHz) IEEE 802.11 a/n/ac

ALARA SECTION AND EMISSIONS

(“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

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	
Pulse 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	
Pulse 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

Probe	20 MHz (Pachymeter) Transducer	
Mode	A-Mode	
Material	Ceramic	
Nominal Center Frequency	20 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	0.0683	4.02
Standard Deviation	0.00681	0.809
Limit	0.0973	7.47

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
	f _c [MHz]		7.80	7.80
	Z _{sp} [cm]		1.90	1.90
	Beam Dimensions	x ₆ [cm]		0.177
		y ₆ [cm]		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
	f _c [MHz]		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	
	f _c [MHz]		14.0	
	Z _{sp} [cm]		1.70	
	Beam Dimensions	x ₋₆ [cm]	0.0601	
		y ₋₆ [cm]	0.0605	
	PD [μS]		0.0650	
	PRF [Hz]		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	
	f _c [MHz]		24.095	
	Z _{sp} [cm]		1.000	
	Beam Dimensions	x ₋₆ [cm]	0.039	
		y ₋₆ [cm]	0.038	
	PD [μS]		0.043	
	PRF [Hz]		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]				
	f _c [MHz]		34.168	34.168	34.168
	Z _{sp} [cm]		1.000		
	Beam Dimensions	x ₆ [cm]			
		y ₆ [cm]			
	PD [μS]		0.056		
	PRF [Hz]		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 20 MHz Pachymeter Probe (s/n PD20.0-0108-0341)			
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		0.0760	4.91	3.69	
Associated Acoustic Parameters	Pr.3 [Mpa]		0.323		
	W ₀ [mW]				
	f _c [MHz]		17.9	17.9	17.9
	Z _{sp} [cm]		1.00		
	Beam Dimensions	x ₆ [cm]	0.153		
		y ₆ [cm]	0.142		
	PD [μS]		0.0780		
	PRF [Hz]		1.70E+4		
	EDS	Az [cm]	0.2		
Ele. [cm]		0.2			

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, 80 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 \pm 30%		
Pulse Duration:	50 nS \pm 30%		
Burst Period:	300 ms \pm 20%		
Burst Duration:	15 ms \pm 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 μ sec, Duration 50.0 μ sec, Rep Rate 1 ppm		
Short Circuit:	Rise Time 8.0 μ sec, Duration 20.0 μ sec		
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			
<i>Based on 0.3 m Separation Distance</i>			
Test Frequency (MHz)	Test Level (volts/meter)	Modulation (@ 50% duty cycle)	Communication Service (partial list)
385	27	18 Hz	TETRA 400
450	28	FM (5 kHz deviation)	GMRS/FRS
710, 745, 780	9	217 Hz	LTE
810, 870, 930	28	18 Hz	GSM 800
1720, 1845, 1970	28	217 Hz	GSM 1800
2450	28	217 Hz	RFID
5240, 5500, 5785	9	217 Hz	WLAN

GUIDANCE AND MANUFACTURER'S DECLARATION

<p>The VuPad is intended for use in the electromagnetic environment specified below. The customer or user of the VuPad should ensure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment Guidance
Radiated RF Emissions CISPR 11	Group 1	<p>The VuPad 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.</p> <p>The VuPad 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.</p>
Conducted RF Emissions CISPR 11	Class B	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

<p>The VuPad is intended for use in the electromagnetic environment specified below. The customer or user of the VuPad should ensure that it is used in such an environment.</p>			
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 VuPad is intended for use in the electromagnetic environment specified below. The customer or user of the VuPad 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the VuPad, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 1.2\sqrt{P}$ 800 MHz to 2.7 GHz</p> <p>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:</p> 
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 VuPad is used exceeds the applicable RF compliance level above, the VuPad should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VuPad.

^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 PROTECTION 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. 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 DAMAGE IS NOTICED.**

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 VuPad, including cables supplied by Sonomed Escalon. 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.

Probes 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 or operate in the presence of flammable anesthetics.

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, Care and Service 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 VuPad conforms to the emissions and immunity requirements IEC 60601-1-2:2014, Conducted Emissions, Group 1, Class B.

Essential performance of the VuPad 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 VuPad 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 VuPad and other equipment should be observed to verify normal operations.

In the event adverse external electromagnetic disturbances causes the VuPad 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

VuPad systems incorporate Microsoft 10 as the 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:

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


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 Mark; Device complies with New Approach Directives: 93/42/EEC Medical Devices
	Type BF Applied Part (B Scan Probe)
	Type B Applied Part (Water Path Probe / A Scan Probes / Pachymeter Probe)
	Warnings and Cautions, Read Accompanying Documents
IPX7	Protected Against Effects of Temporary Immersion in Water (Note: Rating Applies to Ultrasound Probes Only) Do not immerse probe electrical connectors.
IPX1	Rating applies to VuPad Base Unit only. An IPX1 designation means the device enclosure is resistant to the ingress of water at a flow rate of 1mm/min for 10 minutes.
	Class II Equipment per IEC EN 60601-1
	ETL Listing Mark
	Refer to Operator's Manual