



Sonomed Escalon™

MASTER-VU® **USB Ultrasound Systems**

A-SCAN AND B-SCAN



OPERATOR'S MANUAL

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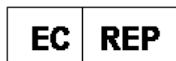
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United States Federal law and European regulations restrict the use of this medical device to, or on the order of, a physician. The Master-Vu ophthalmic ultrasound device is for use by trained professionals in optometry and ophthalmology in a clinical 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.

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 Master-Vu 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 *Master-Vu*[®] *B-Scan* is a diagnostic ophthalmic ultrasound intended for use in ophthalmic applications by imaging the internal structures of the eye. It consists of a sealed, liquid-filled posterior segment B-probe and cable, which connects to a standard PC (computer, referred to as the host PC). The standard *Master-Vu*[®] software effectively allows the PC to function as the control panel of a standard B-scan unit. The *Master-Vu*[®] *B-Scan* is supplied as a B-probe with an internal circuit board with pulser/receiver, control and data-communications electronics, which connects to the host PC, supplied by the user, by means of an included USB (universal serial bus) cable. To support the high data-transfer rate required for B-scan imaging, a USB-2 connection is mandatory. The standard *Master-Vu*[®] B-probe operates at an ultrasound frequency of 12 MHz.

Posterior segment scans are performed using the sealed B-probe which is applied, using a suitable acoustic coupling medium i.e, ultrasound transmission gel either to the closed eyelid or on the open eye, at the operator's professional discretion.

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

The *Master-Vu*[®] *A-Scan* is a diagnostic ophthalmic ultrasound intended for use in ophthalmic applications, by measuring internal structures of the eye along the visual axis for calculation of intraocular power. This allows 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 and the power of the cornea, a user selected formula can be used to calculate the power of the intraocular lens needed.

The *Master-Vu*[®] *A-Scan* is supplied as an A-probe with integral cable, a single-pedal foot switch with integral cable, base unit with an internal circuit board with pulser/receiver and data-communications electronics, and a USB cable. The software allows the PC to function as the control panel of the unit. The probe and foot switch connect to the base, which itself connects to the host PC using the supplied USB cable. The standard *Master-Vu* A-Probe operates at an ultrasound frequency of 10 MHz. Biometric A-scans are performed using the solid A-probe which is applied either directly to the cornea (contact technique) or indirectly using a standard scleral shell and BSS fluid (immersion technique).

The *Master-Vu*[®] software allows for saving and retrieval of patient data in computer files under the Microsoft Windows operating system. *This is not required by the system itself—it is possible to scan and print images repeatedly without saving anything—but some users may prefer to make saving a part of their standard operating procedure.* Users who do wish to save scan data are strongly advised to study this manual and become familiar with where and how such files are saved, in order to avoid losing/misplacing files.

The *Master-Vu*[®] software runs on the Microsoft Windows Operating System (up to Windows 10), and uses the features of the Windows graphical user interface to direct the operation of the system and maintain patient records. This operating system provides a user-friendly environment for clinical applications.

INDICATION FOR USE

The *Master-Vu*[®] systems are intended to be used to visualize and measure the eye and orbit using A-Scan and B-Scan ultrasound.

CONTRAINDICATIONS

The *Master-Vu*[®] ultrasounds are not intended for fetal use.

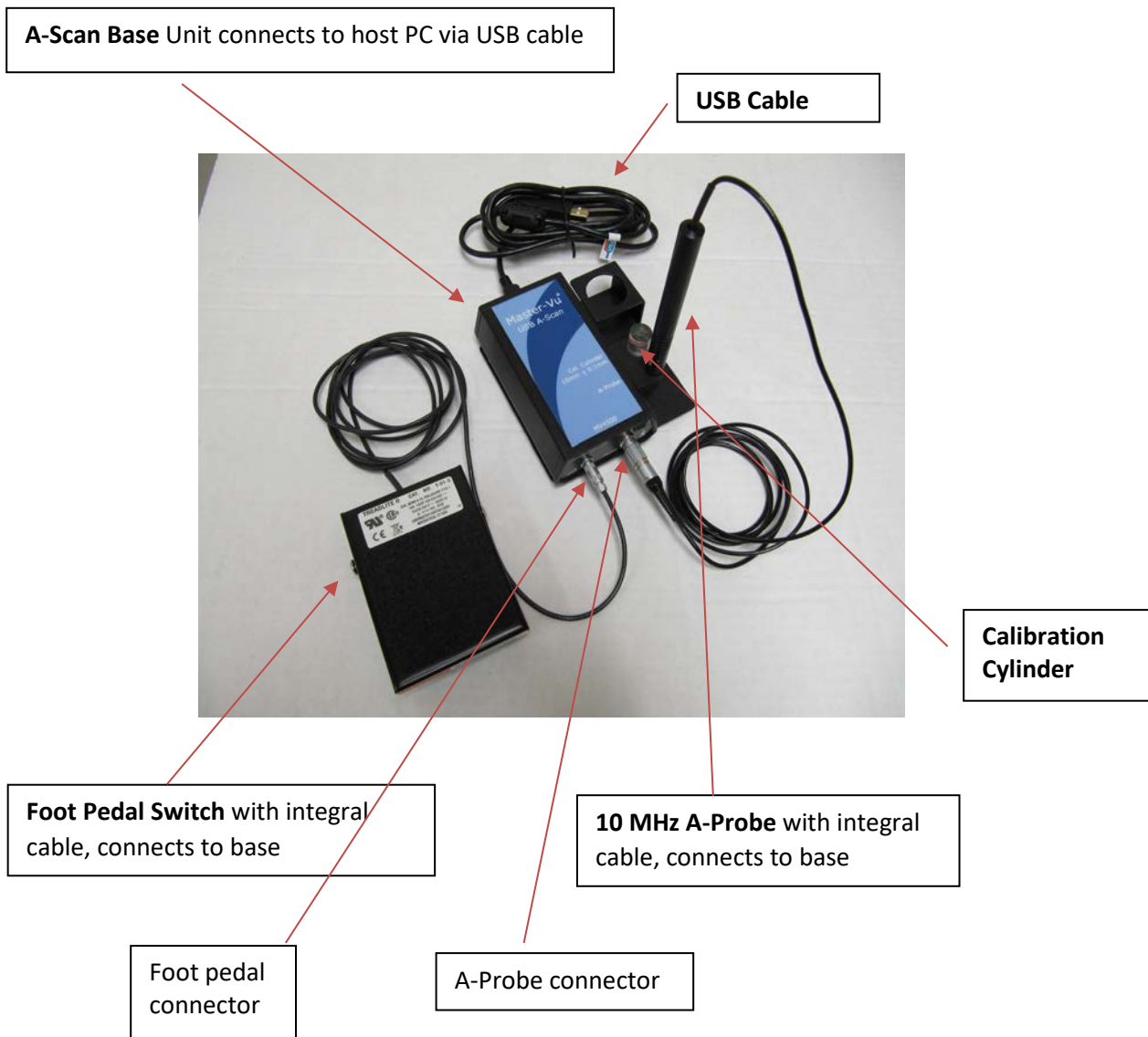
GETTING STARTED

SYSTEM AND COMPONENTS

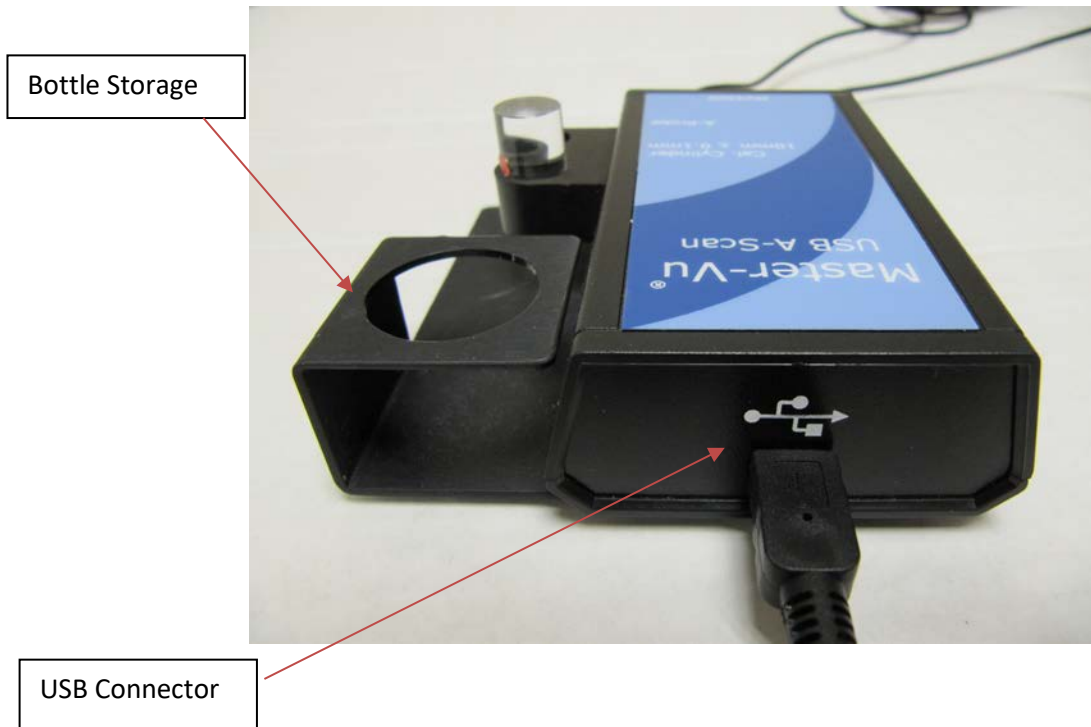
Master-Vu A-Scan Components

The Master-Vu A-Probe is a hand-held ultrasound device for ophthalmic use, with an integral cable. It connects to the compact A-Scan base unit complete with the A-Scan electronics, probe holder (to support the A-probe when not in use), calibration cylinder and bottle storage. A foot pedal switch unit, connects to the base, via its own integral cable. The included USB (universal serial bus) cable is used to connect the base to the host PC.

Master-Vu A-ScanTop/Front View



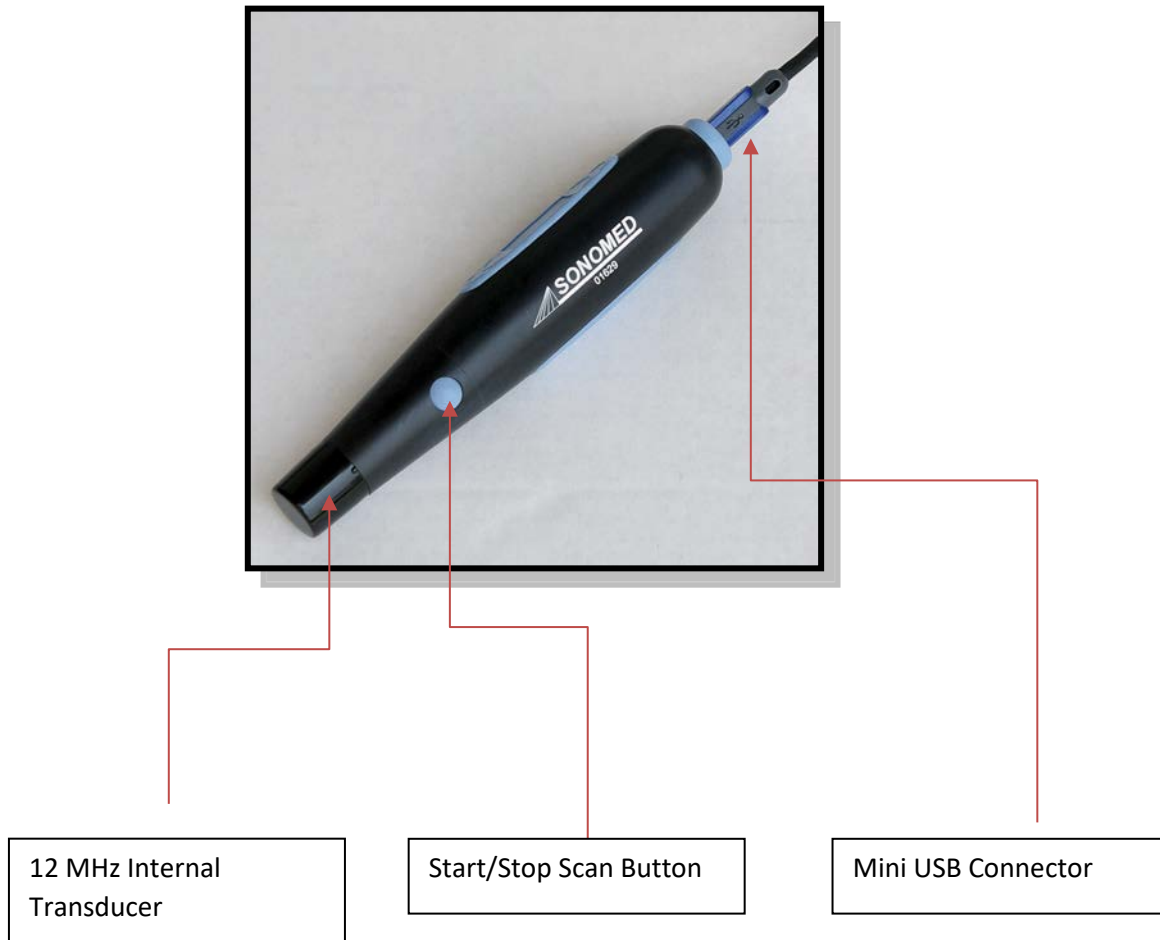
Master-Vu A-Scan Rear View



Master-Vu B-Scan Components

The Master-Vu B-Probe is a hand-held ultrasound device for ophthalmic use, with a built-in button that is used to start and stop scanning. The universal serial bus (USB) cable is used to connect the probe to the host PC. A USB-2 high speed connection is mandatory to support the high data-transfer rate required for B-scan imaging.

Master-Vu B-Probe



The USB cable has two connectors:

- Standard (larger) male USB Connector is for connecting the probe to host PC.
- Smaller male Mini-USB connector goes into the probe.

USB-2 Cable

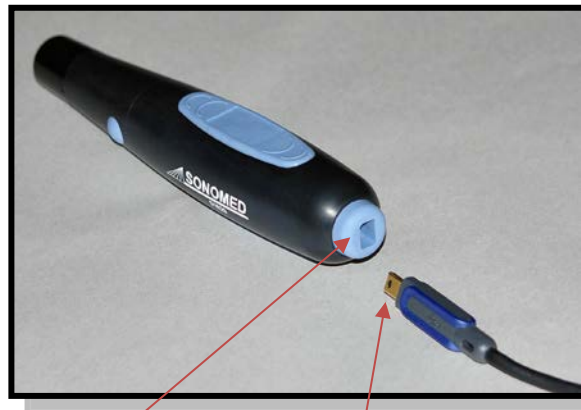


Standard USB Connector.
For connecting probe to Host PC.

Male Mini USB Connector
Connects to back of Probe.

- **To avoid damage to the connector and/or probe, Do not disconnect and re-connect the mini USB connector except when absolutely necessary.**
- **Insert Carefully!** The connector only **fits one way**. Wiggle the connector slightly while inserting, and do not attempt to push it in all the way until you can feel it engage with the female mini-USB connector inside the probe.

USB Connection to Probe



Female Mini USB Connector.
(inside the probe)

Male Mini USB Connector.

UNPACKING AND SETUP

1. Unpack contents from packaging and carefully examine all 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.
2. Place the host PC on a flat surface, positioned to ensure that the operator will be comfortable during use.
3. Connect the host PC hardware components (CPU, monitor, printer) according to the manufacturer's instructions and to the appropriate AC power source.
4. Turn on the host PC power, and wait until the Windows operating system has fully loaded and is ready to run programs.
5. Install host PC software components, i.e., printer driver, in accordance with the manufacturer's instructions.
6. Connect the supplied USB Flash Drive to an available USB port. Note the procedure to open the drive as it may vary depending on which version of Windows you have. Locate and double-click the file *MasterVuInstall.msi* to install the Sonomed *Master-Vu*[®] software. When the software installation process is complete, a new *Master-Vu* program icon should appear on the Windows desktop. **Do not run the Master-Vu program at this time.**
7. Connect the Master-Vu Probe (A or B) to an available USB-2 port on the host PC. A number of on-screen messages will be displayed while the probe drivers are being installed; this process can take several minutes. The exact sequence will depend on which version of Windows is used on the host PC. Under Windows XP, the *Found New Hardware Wizard* will appear twice, and you may be asked to confirm installation of the new drivers each time. Under Windows Vista, you may see a series of messages appear in a small message box at the bottom-right corner of the screen, finishing with a message saying your new devices are ready for use.

WARNING: Make sure Step 7 has completed before starting the program or the program will not function correctly. Do not run the Master-Vu program until this step has completed.

TIP: Once Windows indicates the device is ready to use on the first USB port, it is a good idea to unplug the probe and connect it to every other available USB-2 port on the host PC, allowing about 10 seconds each time for Windows to register the (already-installed) probe drivers to the new port.

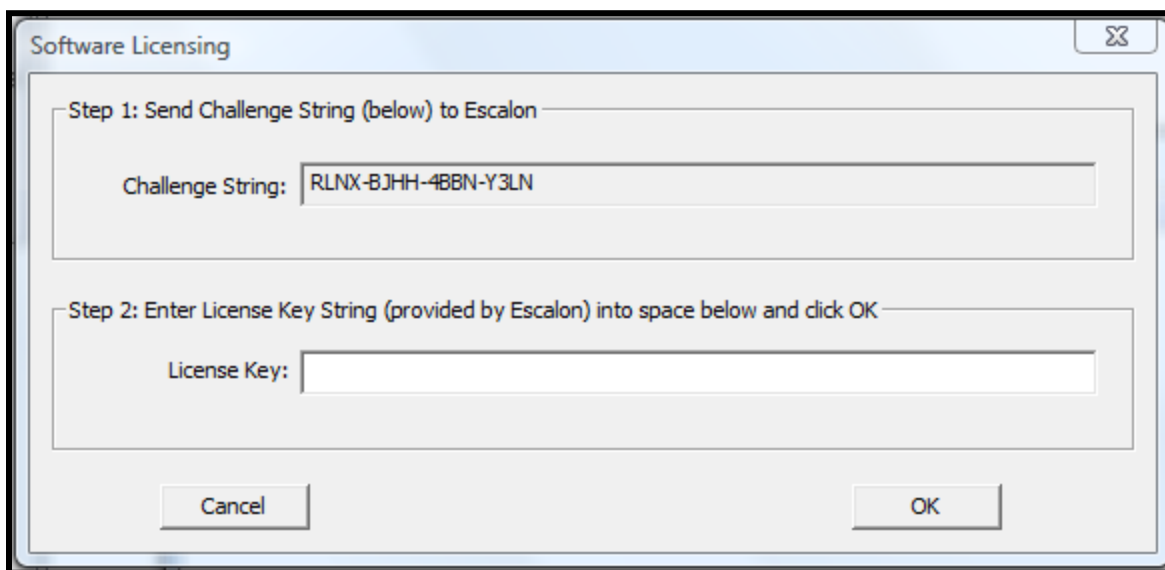
8. Run the Sonomed Master-Vu[®] software by double-clicking the icon (normally placed onto the Windows desktop by the software installer).

LICENSING

The Master-Vu program requires a *License Key* code to activate all of its functions. The B-Probe and the A-Scan base unit have License Key codes programmed into them at the factory. If you run the Master-Vu program with neither USB device connected, you will see a red warning message "View Only Mode - Save and Print are disabled."

If you would like to set up your PC as a *review station*—so you can review and save scans and also prepare and print reports without any probe connected—you will need to contact Sonomed to obtain a valid *License Key* code to license the PC itself. The procedure is as follows:

1. Run the Master-Vu program.
2. Hold down the CTRL key on the PC keyboard and, *while holding it down*, press the L key. This will bring up the Software Licensing dialog as shown below.



3. You will need to provide the *Challenge String* code displayed in the upper half of the dialog, and Sonomed will give you back a longer *License Key* code to enter in the lower half. Contact Sonomed at 1-800-227-1285 (USA) or +1 516 354 0900 (international), or by email to info@sonomedinc.com to request a license key.
4. Enter the License Key code provided by Sonomed in the lower half of the licensing dialog.
5. Click OK to close the Software Licensing dialog.

Challenge and License Key codes are designed to be easy to transcribe and to dictate over the phone. They always consist of groups of four letters or digits, separated by hyphens. (*Challenge* codes have four groups, *License Keys* have eight groups.) Letters are always capitalized, and you need not worry about confusing the letter O with the digit 0, or the letter I with the digit 1, because these letters and digits are never used.

Once you have entered a valid *License Key* code, you should not see the *Software Licensing* dialog again. You may, however, have to re-license the software after replacing major host PC components such as the main hard drive, or after re-installing the Windows operating system.

CONSIDERATION WHEN JOINING NETWORK DOMAIN

The device uses Windows OS 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.

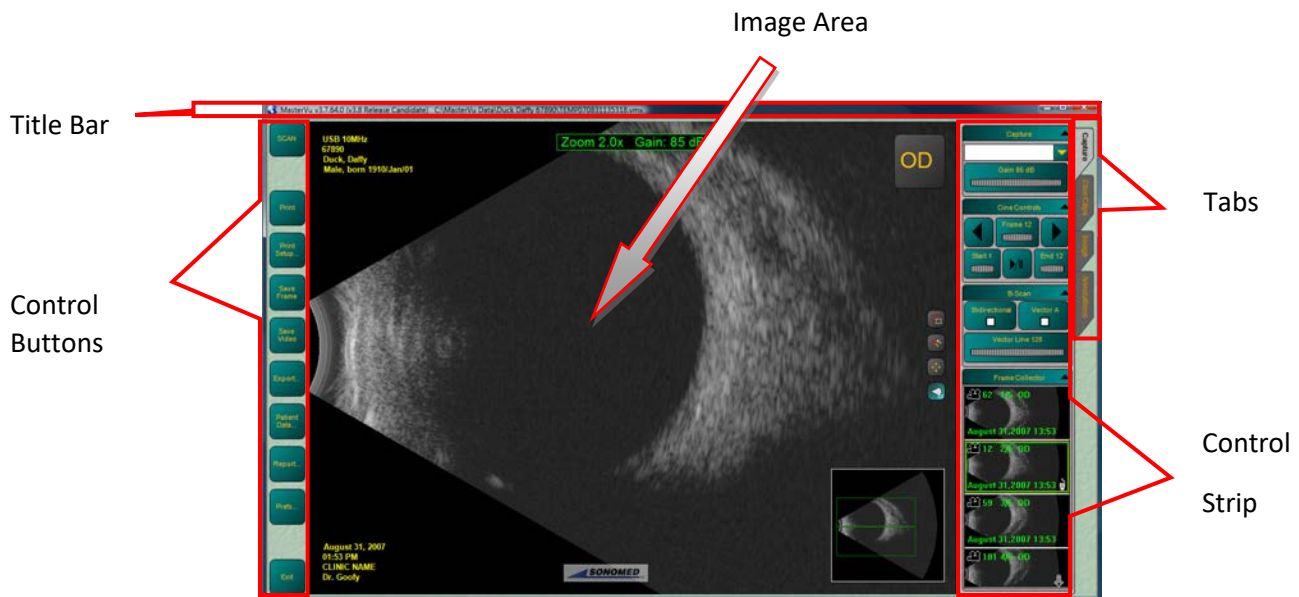
GETTING STARTED

Before using the Master-Vu system for the first time, ensure the following has been completed:

- Review warnings and cautions
- Install Master-Vu software
- Connect probe and allow drivers to install
- Run program and optionally enter License Key

B-Scan Mode Main Screen

In B-Scan mode, the *Master-Vu*® Main Screen (or *window*) is divided into five areas as shown:



The current live or recorded image appears in the **Image Area**. The **Control Buttons** trigger common actions such as scan/freeze, print, etc. The **Control Strip** can contain various groups of less commonly used controls, and you can select which groups appear by clicking in the **Tabs** section. The **Title Bar** displays the software version number and the *path* to the current scan or patient folder.

Cine Controls:

- Located under the **Capture** tab and the **Cine/Clips** tab.
- Displays currently-displayed frame number and frame count.
- The **Frame** scroll wheel allows you to select individual frames in a cine sequence. You can drag the wheel left/right with the mouse or use the vertical slider that appears in the **Image Area** when the **Frame** button is clicked.
- The **Start** and **End** scroll wheels define the segment of interest, which will be replayed when you click the **Play/Pause** button, or saved when you click **Save Video**. After scanning, drag the appropriate scroll wheels left or right to bracket the parts of the captured scan you are interested in keeping. Alternatively, a vertical slider appears in the **Image Area** when either the **Start** or **End** buttons are clicked.

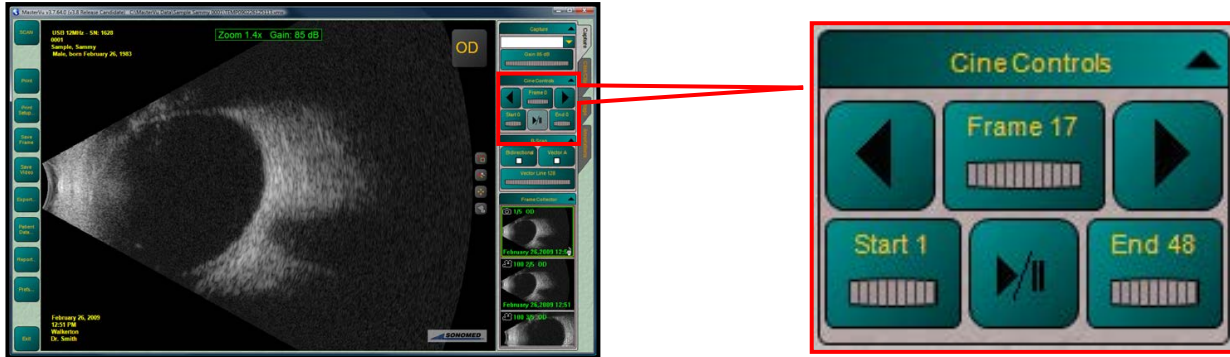
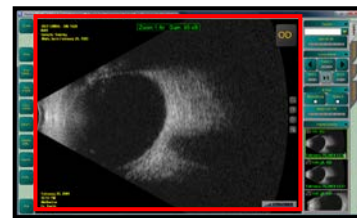


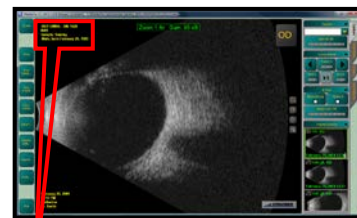
Image Area:

- The primary image is overlaid with various readouts and controls as described below.



Probe/preset and patient information:

- The upper-left corner text displays the name of the selected scan preset (your Master-Vu system will usually have only one preset, called "USB 12 MHz") and information about the currently-selected patient.
 - To change the scan preset, see Pg. 53
 - Use the **Patient Data...** button to change the patient's information (see Pgs. 32 and 33)



**USB 12MHz - SN: 1628
0001
Sample, Sammy
Male, born February 26, 1983**

Scan and clinic information:

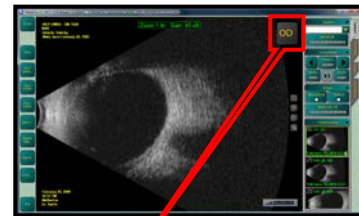
- The lower-left corner text displays scan date/time (filled in automatically when you start each scan), the name of your clinic/institution/department, and your name (user/operator name, person performing the scan).
 - **Make sure the host PC's clock and time zone are set correctly**, or scan times/dates may be wrong.
 - To change the other information, use the **Patient Data...** button (see Pgs. 32 and 33)



February 26, 2009
12:51 PM
Walkerton
Dr. Smith

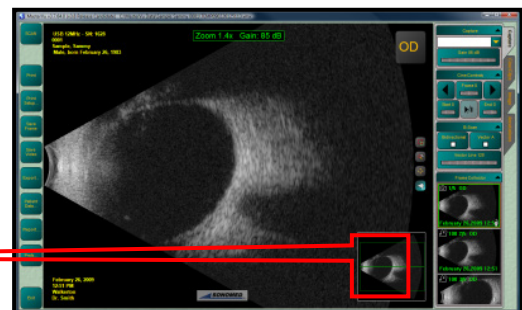
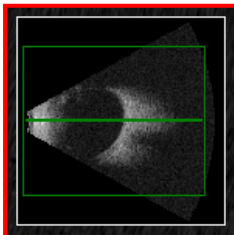
Scan Target Indicator:

- Indicates which eye was scanned. (OS/OD)
 - To change OS/OD, click once on the target indicator.
 - A list will appear, containing OS, OD.
 - Click once on the designator you want.



Overview:

- Displays entire scan, overlaid with a rectangle indicating the portion which is currently shown in the main Image Area.
- You can *pan* the main image by dragging the small rectangle.
- Use the *overview button* (see next page) to show or hide the overview.

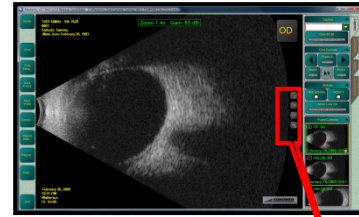


Area, Zoom, Pan and Overview Buttons:



Area Button

- When Area button is active (pushed in), you can zoom the display as follows: click mouse on area to be enlarged, drag mouse outward creating a box, then release. To resize image to normal size, double-click anywhere in Image Area.



Zoom Button:

- When Zoom button is active, you can zoom in and out by clicking anywhere in the Image Area and dragging upward to zoom in, or downward to zoom out.



Pan Button:

- When Pan button is active, you can pan (shift) the display by clicking anywhere in the Image Area and dragging in any direction.



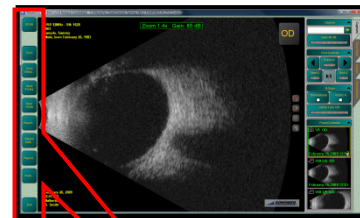
Overview Button:

- Switches overview display on and off.



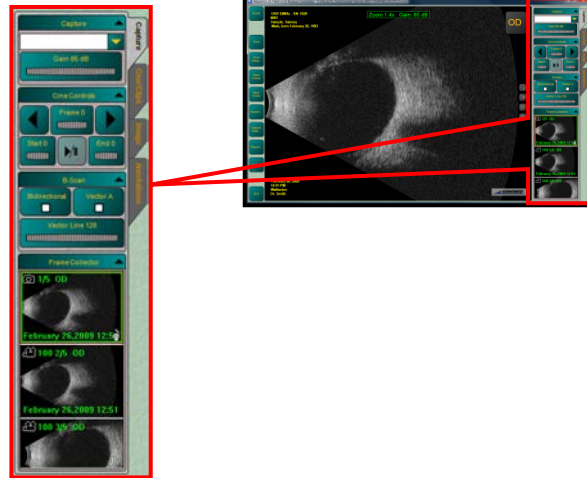
Control Buttons:

- **Scan** - starts/stops scanning — same as button on side of probe. Button text changes to "Freeze" while scanning.
- **Print** - prints current frame to previously-selected printer.
- **Print Setup** - lets you select a printer and page settings (Pg. 35).
- **Save Frame** - saves current frame to the Frame Collector.
- **Save Video** - saves current video to the Frame Collector.
- **Export** – save an image in BMP or JPG format, or a video as WMV. Many other export formats are available.
- **Patient Data** - enter patient information (name, DOB, physician, etc. (Pg. 32).
- **Report** - create reports with multiple images and text (Pg. 36).
- **Prefs...** - lets you customize settings such as clinic name, font size and language.
- **Exit** - closes program



Control Strip:

The *Control Strip*, down the right-hand side of the Master-Vu window, may contain various combinations of controls. You decide what appears in the control strip using three different mechanisms as follows:



Tab Selectors:

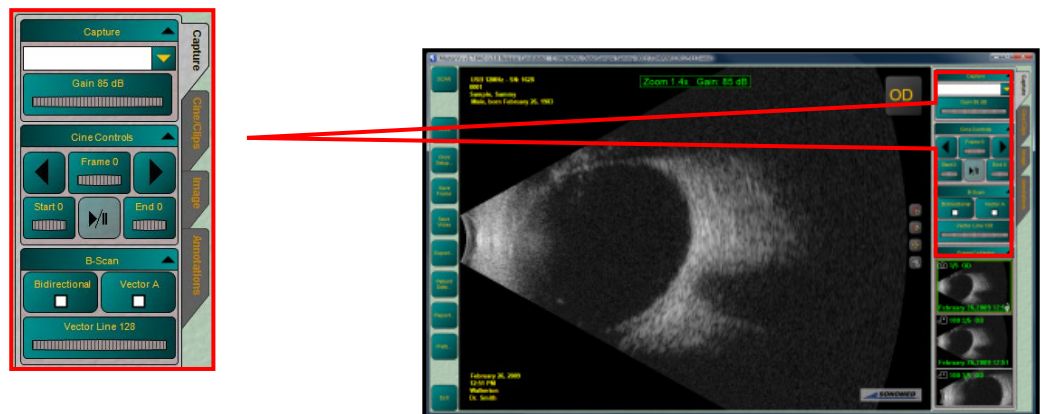
The four *Tab Selectors* (Capture, Cine/Clips, Image and Annotation) on the right allow you to select different sub-sets of the available controls, depending on what you're doing.

- **Capture** – control settings for capture parameters. (Pg. 52)
- **Cine/Clips** - for the selecting, loading and editing of previously saved scans. (Pg.52)
- **Image** - allows user to adjust image contrast, brightness and gain. (Pg. 53)
- **Annotations** - permits addition, editing or removal of various on-screen annotations. (Pg. 54)



Group Boxes and Heading Stripes:

- Controls are grouped into boxes, each with a colored heading stripe, and you can close up groups you don't need, to make space for other groups.
- To open or close a group, click on the *right half* of the group-heading stripe, near the black triangle.



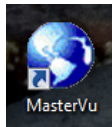
Daily Operations

Daily use of the Master-Vu will normally involve the following basic steps:

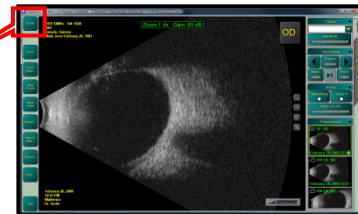
1. Connect probe
2. Run Master-Vu program
3. Create or select a patient folder
4. Modify patient and scan data
5. Scan, save and review scans
6. Print individual frames or
7. Print a report
8. Open another patient folder to review scans
9. Close Master-Vu program

1. Run Master-Vu Program

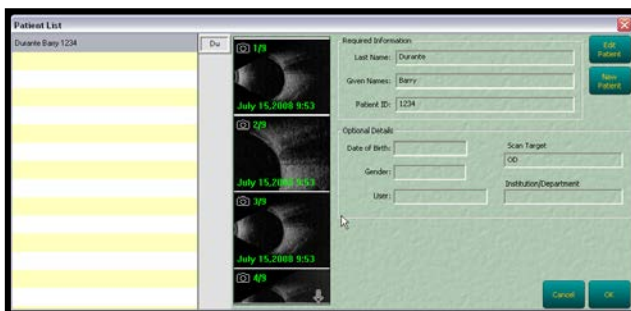
- Double-click on Desktop Icon:



- Master-Vu Main Screen opens:
Note: Scan button will only be activated (green color) when probe is plugged in and a patient is selected.



2. Create or Select a Patient Folder



Patient List dialog



Patient Data dialog

Create a NEW patient folder:

- Click **Patient Data** button. Patient List dialog opens (above, left).
- Click **New Patient** button. Patient Data dialog opens (above, right).
- Enter new patient's information. Only Last Name, Given Names and ID are mandatory. Other fields are optional
- Click OK. New Patient dialog closes
- Click OK. Patient List dialog closes. New patient data is in Patient Database. New patient data is displayed in Image Area text overlays.

Select an EXISTING patient folder:

- Click **Patient Data** button. Patient List dialog opens
- Click on a name within the patient list. *To scroll quickly through a long list:* click and drag the indicator just to the right of the patient list until it displays the first two letters of the last name you want.
- Click on the chosen patient, and then click OK. Patient information appears in the Image Area text overlays

3. Modify Patient and Scan Data

Information about the currently selected patient and scan are displayed as text overlays at the top-left and bottom-left corners of the primary image display. If the displayed information is incorrect, you can use the Patient Data button to correct it as follows.

Editing:

- Click **Patient Data** button. Patient List dialog opens
- Click on desired patient name
- Click **Edit Patient** button. Patient Data dialog opens
- Click on item(s) to be edited and make changes/corrections.
- Click OK. Patient Data dialog closes and user is returned to Patient List.
- Click OK. Revised patient data appears in Image Area text overlays.

Notes:

- If you change **Last Name, Given Name, or Patient ID**, the currently selected folder's information is revised with the changes you made when you click OK.
- If you change **Date of Birth, Gender, User or Institution/Department**, the currently selected patient folder's information will be revised when you click OK.
- Changes you make will affect only new scans. Previously saved scans, when recalled, will continue to show the older information.
- Ignore the **Scan Target** section of the Patient Data dialog. It is not used in Master-Vu.

4. Scan, Save and Review Scans

New Scan:

- Connect probe if not already connected.
- Click **Scan** Button and begin scanning. Button text changes to **Freeze**
- Click **Freeze** to stop scanning.



Save a Single Frame:

- Stop scanning.
- Use green slider in Frames Bar to locate desired frame.
- Click **Save Frame** button.
 - Saved frame will appear as a new image in Frame Collector.
 - Double-clicking the saved scan image will recall just the single saved frame to the main image display.



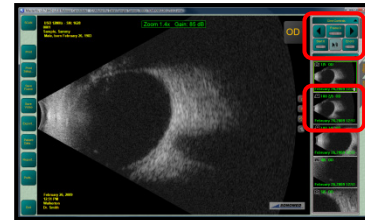
Save a Video (Cine sequence):

- Stop scanning.
- Use the Start and End scroll wheels in the Cine Controls panel to locate desired starting and ending frames. Use the Frame scroll wheel and the single advance/rewind buttons to locate desired "poster frame".
- Click **Save Video** button.
- Selected "poster frame" will appear as a new image in the Frame Collector.
- Double-clicking the saved scan image will recall the entire saved cine sequence to the main image display, with the "poster frame" initially selected.



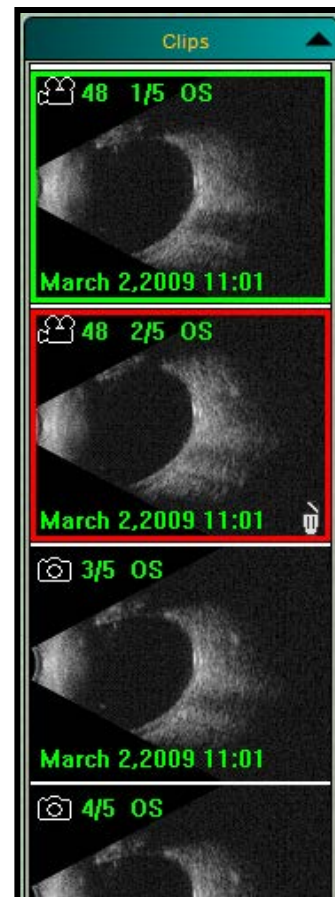
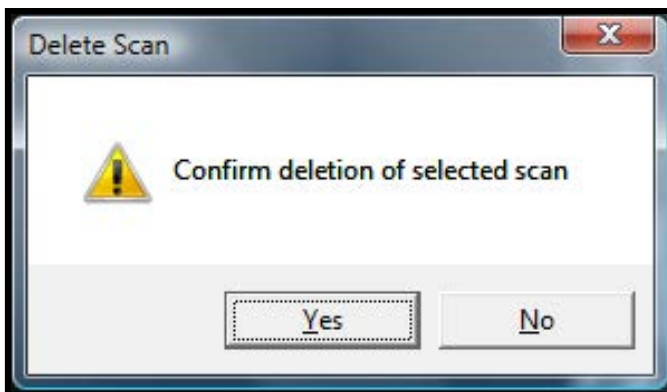
Recall a Saved Scan for Review:

- Double-click desired saved scan or frame in Frame Collector (OR drag it to left, into image area). Scan will load and appear in Image Area
- Cine clips only: Click **Play/Pause** button, and/or use Cine Controls to select frames.



Delete a Scan or Frame:

- Click on the scan to be deleted in the Frame Collector
 - A red outline will appear, indicating that the item is selected.
 - Click the small white "trash can" icon at the bottom right corner of the scan image. Delete Scan dialog will appear. Click Yes to delete the scan, or No if you did not intend to delete it.



5. Print Individual Frames

The frame printing feature works like an old-style video printer—it allows you to print the current contents of the Image Area to your printer. If you need to select a printer or change print settings such as page size, use the **Print Setup** button. After you have selected a printer once, you can use the **Print** button to print again to the same printer with the same settings. The selected printer will be remembered even if you quit and re-start Master-Vu.

Print Setup:

- Click on Print Setup button. A standard Windows print-setup dialog appears. What you see will depend on what version of Windows you have.
- Select Printer and whatever print settings you require
- Click Print in the print-setup dialog.



Print:

- Click the Print button. Image will automatically print to the previously selected printer; no print-setup dialog will appear.



6. Print A Report

The report printing feature allows you to create formatted reports containing multiple images together with comments.

- Click on Report Button; the main window will change to the *report-editing* layout:
 - The main image display will change to show a WYSIWYG ("what you see is what you get") view of the report to be printed.
 - The control buttons down the left-hand side of the Master-Vu program window will change.
 - The control strip down the right-hand side of the program window will change to show only the Frame Collector (headed "Clips").



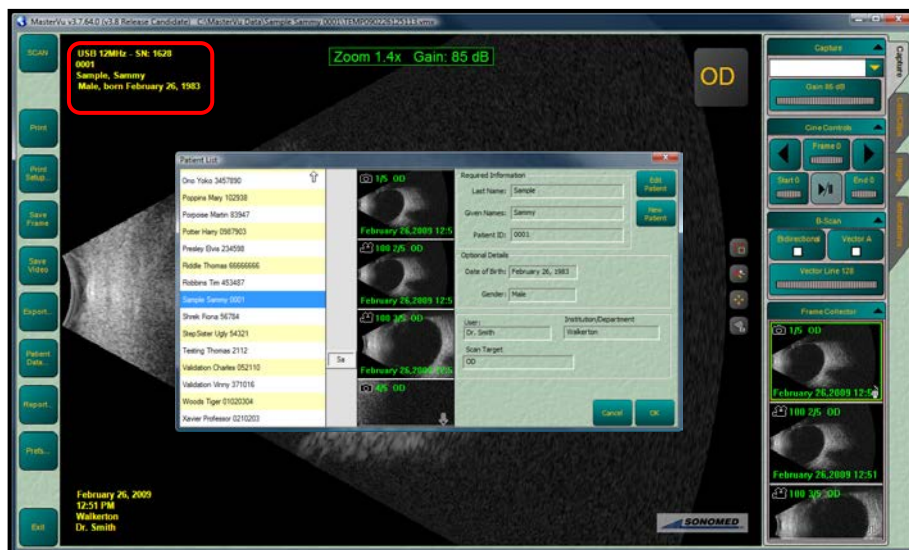
- To add images from the Frame Collector, double-click them or drag them to the gray images-area in the report.
- To edit text items (heading, patient details, image captions, comments, footer), double-click the text to bring up Edit Text dialog, change text and style (font, size etc.) as desired, then click OK.
- To quickly change the document view, use the Fit Width/Height buttons to re-size the report within the current dimensions of the Main Program Window.

- To adjust the document view, use the Zoom In/Out buttons or click-and-drag any area of the report not inside a text or image box.
- Functions of the control buttons:
 - **Save Report** - Saves the report to the current patient folder. The saved report will appear in the Frame Collector.
 - **Export Report** - Exports the current report as either a JPEG or Bitmap Image.
 - **Remove** - To remove an image, click once on the image to select it (red outline will appear to indicate selection) and click the Remove button.
 - **Print Setup** - Opens standard Windows print-setup dialog. What you see will depend on which version of Windows you have. Select printer and adjust print settings as you require, then click Print in the setup dialog to print.
 - **Print** - Once you have used Print Setup once, you can click the Print button to print again to the previously-selected printer without opening the print-setup dialog.
 - **IOL Data** - Opens the IOL Database dialog window. See p.4**Error! Bookmark not defined.** for details.
 - **Done** - switch back to the usual scan/review layout. Click this button when you are finished working with your report.

NOTE: For the Report Feature to display correctly, a printer capable of printing letter sized reports must be installed on the PC being used.

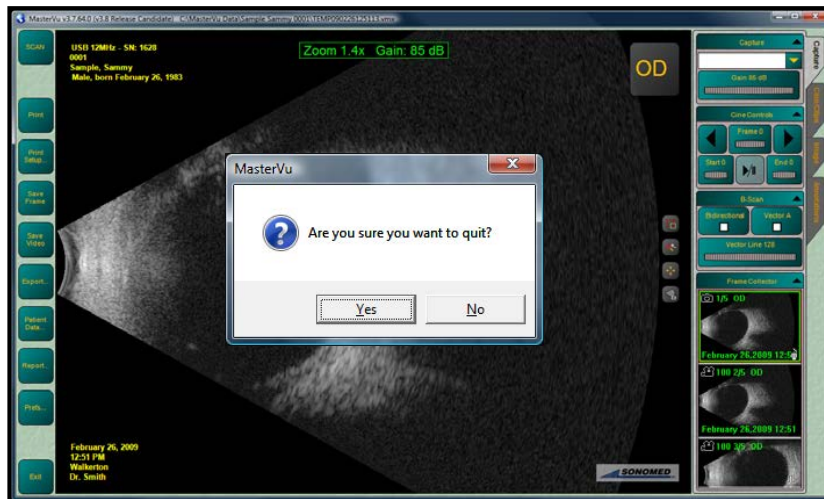
7. Open Another Patient Folder (to review scans)

- Click the Patient Data Button. The Patient List dialog opens.
- Click on another patient name in the list to select another patient, then click OK. The chosen patient is now selected. Image Area text overlays now show the chosen patient's data, and the chosen patient's saved scans will be available in the Frame Collector under the heading "Clips" on the right.
- Double-click any of the patient's saved scans to open and review them.



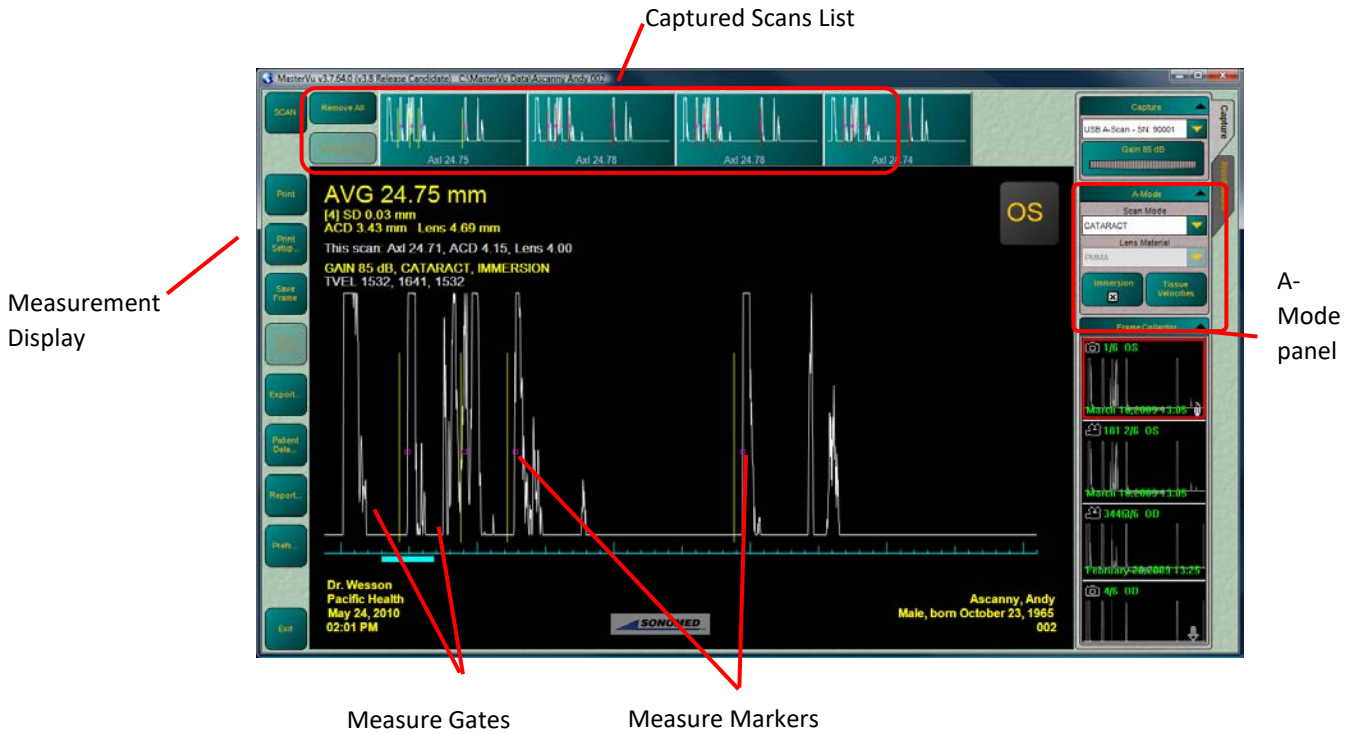
8. Close Master-Vu Program

- Click Exit button to close the Master-Vu program and return to Windows.
- If the current scan has been altered, but not yet saved, the Scan Contents Changed dialog may appear.
 - Click **Yes** to save the altered scan before closing the program.
 - Click **No** to close the program without saving any changes.
 - Click **Cancel** if you didn't mean to exit the program at all.
- If you don't see the Scan Contents Changed dialog, you will still be asked to confirm that you want to exit.
 - Click **Yes** to close program or **No** to keep program open.
 - You can also click the red "X" at the top of the dialog, which has the same effect as clicking the No button.



A-Scan Mode Main Screen

When an A-scan preset is selected, the Main Screen layout is changed slightly as shown:



Captured Scans List:

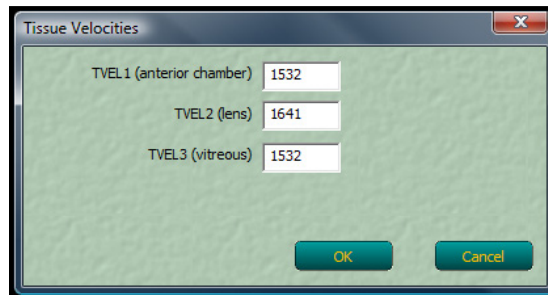
- Click any scan-segment icon to select it recall it to the main display.
- Remove Item/All buttons: Deletes the selected scan segment or clears all scans from the Captured Scans List.
- Measurement Display: Displays measurements for the individual scan segments as well as the average for all captured segments.

Primary Image Display:

- A-Scan graph: displays the current A-scan data.
- Measure Gates: can be dragged across the scan graph and used to indicate the starting point for Auto-Measuring.
- The Measure Markers indicate the point on the scan graph where the actual measurement is taking place.

A-Mode panel:

- **Scan Mode menu:** Used to select different eye conditions (cataract, dense cataract, etc.) as on the Pac-Scan.
- **Lens Material menu:** Used to select IOL material.
- **Immersion checkbox:** When checked, the program looks for a distinct corneal echo after the transmit pulse.
- **Tissue Velocities (TVEL):** This button will open a separate window which will allow you to modify the velocities used to calculate the speed of sound through the different elements of the eye.



Control features in A-mode

Foot switch:

The attached foot switch performs the same functions as the SCAN/FREEZE buttons.

- If an auto-measuring scan mode is selected, the foot switch will simply start and stop the scan.
- If a manual scan mode is selected, the first click of the foot switch will start a scan; on the second click, the scan will stop and a segment will be placed in the Captured Scans List.

Mouse scroll wheel and button combinations:

- The Gain control can be operated using the mouse scroll wheel. Simply click on the Gain control to activate it and use the wheel to modify its value.
- The Measure Gates can also be positioned with the mouse scroll wheel. Click on the desired Measure Gate, it will turn green indicating it is active. Use the scroll wheel to place it. Click anywhere on the screen (that is not a button) to deactivate it.

Also note that when a control is selected, a vertical slider appears in the Primary Image Display. Although the vertical slider is primarily used for touch-screen interfaces, mouse clicking the arrow buttons on either end of the vertical slider or simply clicking and dragging anywhere in the slider can also be used to set values.

How to verify calibration

1. Connect the A-scan probe.
2. In the Capture panel, in the drop-down menu, select "USB A-Scan – SN ..." This is currently the only probe preset that can be used for calibration. It may already be selected.
3. A Confirm Calibration window will appear. Click OK to continue calibration.



4. In the main window, a **Calibration NOT Verified** message appears. Click the SCAN button.
5. Using a drop of water to help with contact, touch the probe tip to the calibration block.
6. If the measurement is successful, the main display will freeze with the Measure Gates and Markers in place. The calibration button label will change to **Calibration Verified**.
7. If the calibration is not successful, scanning will continue. To abort, click **Freeze**.

Note: *Master-Vu*® will continue to function normally if the calibration is not verified.

1. How to Perform an A-Scan

- Click **Patient Data...** to select or create a patient.
- Select which eye you are scanning (OS/OD).
- Select the probe you would like to use in the **Preset** menu of the **Capture** panel – adjust the Gain if needed.
- In the A-Mode panel, select the **Scan Mode** and the **Lens Material**, if necessary.
- Click the **Immersion** checkbox if needed.
- Click **Scan** (or use foot switch) to begin scanning.
- If an auto-measuring mode is selected:
 - Scans meeting the capture criteria are placed in the Captured Scans List for later review. The auto-capture function is limited to 10 scan segments. This limit can be changed using the Prefs... button. If it is a difficult case and the markers don't go where you want them, the Measure Gates will become moveable when scanning stops. Simply click and drag them to the desired position. The Measure Marker(s) will adjust accordingly.
- If a manual mode is selected:
 - The A-Scan graph will show the current scan data until the **Freeze** button (or foot switch) is pressed. At this point, the program will capture a segment and place it in the Captured Scans List. This procedure can be repeated for multiple scan images. The Captured Scans List will **not** automatically be cleared each time you re-start, but **will** be cleared when you change OS/OD, switch to a different patient, or select a different **Scan Mode**.
- Click **Freeze** (or use foot switch) to stop scanning.
- Recall captured scans to the main display for review and optionally adjust the measurement gate positions. Click **Remove Item** to discard scans you don't want, until you are satisfied with the displayed Standard Deviation (SD).
- Save any scans you want to keep, by selecting them and using the **Save Frame** button. To create a biometry report, you should save at least one OS and one OD scan.

2. How to Enter Lens and Surgeon Information in the IOL Database

IOL Database Dialog Window

Manufacturer Section:
Used to select existing manufacturers or to create new ones.

Assigns the currently selected lens to the currently selected surgeon.

Lens List: Used to select or add a surgeon. The surgeon's preferred formula for IOL calculations can be selected here.

The screenshot shows the 'Edit IOL Database' dialog window. It is divided into several sections:

- Manufacturer Section:** Includes a dropdown for 'Manufacturer' (currently 'ACRIMED') and a text field for 'Description' (also 'ACRIMED'). Both have 'Add' and 'Update' buttons.
- Lens Section:** Includes a dropdown for 'Lens' (currently '11 C-11-BC'), a dropdown for 'Type' (currently 'Posterior'), and input fields for 'A' (118.00), 'ACD' (4.97), and 'SF' (1.22). Below these are fields for 'Optic Material' (PMMA), 'Haptic Material' (PMMA), 'Optic Size X' (6.00), 'Optic Size Y' (6.00), 'Haptic Angle' (0.00), and 'Length' (11.00). There is an 'Update' button.
- Dioptr Range Section:** Includes a dropdown for 'Dioptr Range' (currently '20.50 to 30.00 step 0.50') and input fields for 'Start' (20.50), 'End' (30.00), and 'Step' (0.50). There is an 'Update' button.
- Surgeon Section:** Includes a dropdown for 'Surgeon' (currently 'Sonomed Sample') and a dropdown for 'Formula' (currently 'Regression II'). Both have 'Add' and 'Update' buttons.
- Available Lenses Section:** Includes a dropdown for 'Available Lenses' (currently 'AC-60') and a table of constants:

A	ACD	SF	A0	A1	A2
114.50	2.92	-0.76	-0.91	0.40	0.10
Set Others	Set Others	Set Others	Set Others	Set Others	Set Others

 There is an 'Update' button.

Lens Section: Used to select or edit existing lenses or add new ones to the database. Only lenses associated with the selected manufacturer are available in the drop-down menu.

Dioptr Range for the currently selected lens. The range can be defined or edited in this section.

Lenses available to the currently selected surgeon.

IOL Database Dialog Window with New Surgeon and Default Lens Info

Click **Add** and enter the name of a new lens manufacturer here. Click **Update** when you are finished.

Click **Add** and enter the name of a new surgeon here. Select the preferred formula for IOL calculations. Click **Update** when you are finished.

This screenshot shows the dialog window with new entries:

- Manufacturer Section:** 'Manufacturer' is 'Dr. Schmidt' and 'Description' is 'Dr. Schmidt'. Both have 'Add' and 'Update' buttons.
- Lens Section:** 'Lens' is 'CTR 13/11', 'Type' is 'Posterior', 'A' is 118.50, 'ACD' is 5.26, 'SF' is 1.91. 'Optic Material' and 'Haptic Material' are PMMA, 'Optic Size X' and 'Y' are 11.00, 'Haptic Angle' is 0.00, and 'Length' is 13.00. There is an 'Update' button.
- Dioptr Range Section:** 'Dioptr Range' is '0.00 to 0.00 step 0.00', 'Start' is 0.00, 'End' is 0.00, and 'Step' is 0.00. There is an 'Update' button.
- Surgeon Section:** 'Surgeon' is 'Surgeon 3' and 'Formula' is 'Regression II'. Both have 'Add' and 'Update' buttons.
- Available Lenses Section:** 'Available Lenses' is 'CUSTOM'. The constants table is:

A	ACD	SF	A0	A1	A2
Set Others	Set Others	Set Others	Set Others	Set Others	Set Others

 There is an 'Update' button.

Click **Add** and enter the name of a new lens here. Click in the other info boxes to edit the contents. Click **Update** when you are finished.

Click **Add** and enter the dioptr range of the lens here. Click **Update** when you are finished.

Lenses associated with the currently selected surgeon will appear in this menu. All the lens values can be edited. Click **Update** when you are finished.

For creating custom lenses, these constants can be modified. Clicking "Set Others" will re-calculate the other constants based on the modified value.

For each section, clicking **Update** will create or edit the record in the database. The new entry will then be available for selection in the appropriate drop-down menu.

3. Adding a New Lens

- Click **Patient Data** to select a patient. The patient must have at least one scan in the Frame Collector or the **Report** button will not be active.
- Click **Report...** to open the report window.
- Click the **IOL Data** button. The IOL Data dialog window opens.
 - The database already contains many manufacturers and their lenses.
 - Sonomed Sample is the name of a sample surgeon that is created in the Lens List section to act as a guide.
- Note: New lenses can be added to existing manufacturers. If you wish to add a lens without creating a new manufacturer, select the existing company from the Manufacturer drop-down menu and skip to bullet 7.
- In the Manufacturer section, click **Add**. The auto-generated name: "Manufacturer XX" appears where "XX" represents the next sequential number.
- Click and highlight "Manufacturer XX" and enter the name of the new manufacturer. When you are finished, click **Update**.
 - The name in the drop-down menu above updates and displays the new name.
 - The entire Lens section is reset to default blank entries.
- In the Lens section, click **Add**. The auto-generated lens code "Lens XXXX" appears, where "XXXX" represents the next sequential number.
- Click and highlight "Lens XXXX" and enter the name of the new lens.
- Click and highlight to enter information for all the other lens attributes or use the drop-down menus as needed. When you are finished, click the **Update** button.
- In the Diopter Range section, click **Add**. Click and highlight to enter information for the Start, End and Step of the new lens diopter range. When you are finished, click **Update**.
 - The new diopter range appears the drop-down menu.

4. Adding a New Surgeon

- In the Lens list section, next to the Surgeon drop-down menu, click **Add**. The auto-generated "Surgeon XX" appears, where "XX" is the next sequential number.
- Click and highlight "Surgeon XX" and enter the name of the new surgeon.
- Using the drop-down menu under Formula, select the surgeon's preferred formula. When you are finished, click **Update**. The new surgeon appears in the drop-down menu.
- When filling out a report, all the formulas are available for use in the drop-down menu. The formula chosen here will appear only as the default favorite.

5. Adding a Lens to a Surgeon

- In the Manufacturer section, select a manufacturer from the drop-down menu.
- In the Lens section, select the preferred lens.
- In the Lens list section, select the surgeon.
- If the selected surgeon already has preferred lenses, they will appear in the Available Lenses drop-down menu.
- Click the **Add to Lens list** button.
- The newly chosen lens now appears in the drop-down menu.
- Repeat this procedure to add more lenses.
- There is no limit to how many lenses can appear in the lens list for a particular surgeon.
- When you are finished, click **Done**.

6. How to Create an A-Scan Report

Double-click to edit the header text.

Use this drop-down menu to select a surgeon. More surgeons can be added in the IOL Database dialog window.

This information is added automatically when an image is placed in the report. Double-click to edit the contents.

Click and drag the image to re-position it.

Click and drag the corner to re-size the image.

The screenshot shows a form with the following fields:

- CLINIC NAME (with a drop-down arrow)
- Patient Name: Ascanny, Andy
- Date of Birth: October 23, 1985
- Patient ID: 002
- Surgeon: (with a drop-down arrow)
- Report Date: May 24, 2010 03:19 PM

 Below the form are two A-scan reports for OD (Immersion, CATARACT) and OS (Immersion, CATARACT). Each report displays 'AVG 0.00 mm' and a graph of light intensity versus distance. Red arrows indicate that the reports can be repositioned and resized.

- Click **Patient Data...** to select a patient.
- Click **Report...** to open the report window.
- Make sure the patient has at least two saved A-scans (preferably one OS and one OD scan).
- In the **Report Template** menu, select the IOL2Eyes.txt template.
- Click and drag the saved A-scan(s) from the Frame Collector to the report template.
- Double-clicking a saved A-scan is the same as dragging it into the report.
- The OS and OD scans will be automatically positioned on the correct sides of the page.
- The patient information will be transferred to the appropriate info boxes.
- Using the **Surgeon** drop-down menu, select a surgeon. Preferred lenses and formulas will become available in the appropriate menus.
- Fill in the following information in the calculation table (see Figure below) by double-clicking on the green boxes. When you select a lens type, the values of the various IOL formula constants (A constant, SF, etc.) will automatically be filled in from the lens-types database. Enter the required data in top-down order as follows:
 - K1 and K2 values
 - Target Rx
 - Lens Type
 - IOL formula

The screenshot shows a software interface for IOL calculations. At the top, there are input fields for K1, K2, AXI (0.00), ACD (0.00), and Target Rx. Below this are two columns for 'Lens 1' and 'Lens 2', each with a 'Lens Name' dropdown and a 'Formula' dropdown. A red box highlights a formula selection menu with options 'A', 'a0', 'a1', and 'a2'. Below the formula menu are two 'Exact Power' tables, each with 'Power' and 'Ref' columns. Red callout boxes provide instructions: 'Double-click to enter K values.' points to K1 and K2; 'Double-click to enter Target Rx.' points to Target Rx; 'These values are entered automatically when an A-scan image is placed in the report.' points to AXI and ACD; 'The preferred formula of the selected surgeon is automatically entered here. All formulas are available in this drop-down menu.' points to the formula dropdowns; 'These constants will change based on the selected formula.' points to the 'A' formula option; 'The lenses available in this list are associated with the selected surgeon from step 6. More lenses can be added in the IOL Database dialog window.' points to the lens name dropdowns; and 'When all the required information is entered, the program will automatically perform the IOL calculations. If any values are changed, the calculation is repeated.' points to the 'Exact Power' tables.

- When all the required information is entered, the report will automatically calculate the values. If any of the values are changed, a re-calculation is performed.
- Edit the report in other ways as needed (e.g. heading and footer text, etc.)
- When you are satisfied with the report, click **Print** to print it to the default Windows printer, or **Print Setup...** to select a specific printer.
- Click **Done** to return to the Main Program Window.

CONTROL BUTTONS (left side of screen)

Scan

Click **Scan** to begin scanning. Scan button changes to read **Freeze**.

- Click **Freeze** to stop scanning.
- Click **Save Frame** to save a single image or **Save Video** to save a cine sequence.



Print

- Click Print button to send currently displayed frame to the previously selected printer.
- To select a printer, see Print Setup below.



Print Setup

Click **Print Setup** to open the usual Windows print-setup dialog.

- What you see will depend on which version of Windows you have.
- This allows you to select an available printer and adjust printing settings such as page size.
- Click **Apply** in the print-setup dialog to save the printer selection and settings, without actually printing.
- Click **Print** in the print-setup dialog to save the printer selection and settings, and print the current frame.



Save Frame

- To save a single frame after scanning:
 - Use the **green** slider on the Frames Bar to select the frame you want.
 - Click **Save Frame**.



Save Video

- To save a multi-frame cine sequence after scanning:
 - Use the two **red** sliders on the Frames Bar to define the first and last frames of the sequence you want to save.
 - Use the **green** slider to select the "poster frame"—the one which will initially be selected when you later re-load the saved data.
 - Click **Save Video**.



Export

- To export single images or cine sequences in standard file formats, click Export.
- A standard Windows file-save dialog will appear.
- Navigate to folder where you want to save your file.
- Select file type. Available types are BMP (Windows Bitmap image), JPEG (compressed single image), WMV (Windows Media Video, for cine sequences), Vumax files, Raw Image, Multiple Raw Images, Multiple JPEG Images, Multiple Bitmap Images, Multiple Raw RTC images single file or Single Raw RTC image.
- Click **Save**.



Patient Data

- Opens the Patient List Dialog, so you can:
 - Add a new patient to the database
 - Open an existing patient's folder
 - Edit a patient's information



Report

- The **Report** button switches the display into report-editing mode, allowing you to create and print reports with multiple images and text.



Prefs

- Clicking the **Prefs...** button will open the Preferences window. This allows you to customize various aspects of the program. Typically, a feature is set to either ON or OFF by clicking the appropriate button. If a value or name (i.e. clinic name) is entered, click the **Set to typed value** button. Note that some features or settings may require the user to exit and restart the program.



Exit

- Click **Exit** to close the Master-Vu software.
 - If you haven't yet saved the current scan, you will be asked if you want to save it before closing.
 - You will also have the opportunity to cancel closing the program, in case you clicked **Exit** accidentally.

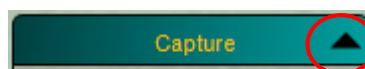


CONTROL STRIP (right side of screen)

The rectangular area down the right-hand side of the Master-Vu window is called the Control Strip. It features "tab" buttons along the right side, which select up to four different sets of controls for different tasks:

- To record new scans, use the **Capture** tab.
- To review saved images or edit and playback video, use the **Cine/Clips** tab.
- To adjust the image contrast, use the **Image** tab.
- To annotate images with graphical overlays such as measurement scales and arrows, use the Annotations tab.

Whichever tab you select, you will notice the various controls are organized into groups under a green group-heading stripe like this:



On smaller PC screens, you click on the black triangle on the right-hand side to close (collapse) some groups, to make room for others you need to use.

CAPTURE CONTROLS

Choose the **Capture** control set when you are ready to record new scans. It presents three control groups headed *Capture*, *Cine Controls*, and *B-Scan*. The controls in the Capture and B-Scan groups affect what data the system actually records. The Frame Collector for the currently selected patient is available under the Capture tab and the Cine/Clips tab.

CAPTURE:

- **Preset** – Selects a pre-defined combination of probe type and capture settings.
 - Click once to open the list of scan presets. (If you have only one probe, you may see only one preset in the list.)
 - Click on a preset name to select it and close the list.
- **Gain** – Reduces or increases the ultrasound power to reduce or increase echoes and saturation.
 - This scroll wheel control is calibrated in decibels (dB), and the default setting is 85 dB meaning "no sensitivity reduction".
 - Click anywhere in the body of the control and drag left to reduce the system gain, e.g. to avoid image saturation in foreign body cases.

CINE CONTROLS:

(These controls appear under both the Capture tab and the Cine/Clips tab.)

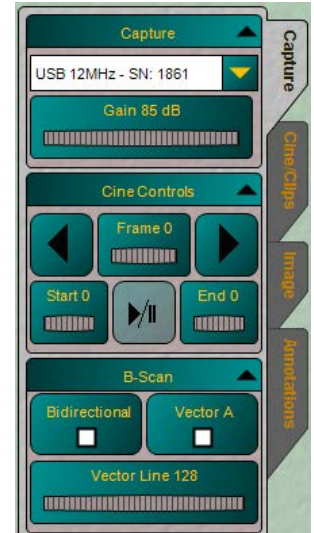
- **Frame** - Scroll control used to select an individual frame for display. The advance/rewind buttons are used for single-frame scrolling.
- **Start** and **End** - Scroll controls used to define the start and end points of the current cine loop.
- **Play/Pause** button - Plays and pauses the currently loaded cine.

B-SCAN:

- **Bidirectional Scan** – Captures image on both the upward and downward sweeps of the transducer. This doubles the frame rate, but may introduce some wobble into the display.
- **Vector A** – Activates vector A-scan display. You can drag the A-scan vector up or down with the mouse or use the Vector Line scroll wheel to select which image line is profiled in the A-scan graph.

CLIPS:

- The Frame Collector appears under each tab. It shows the saved scans for the currently-selected patient. The Cine Controls panel appears under both the Capture and the Cine/Clips tabs.



IMAGE

Choose the Image tab when you need to adjust the contrast for the main image display. It presents three control groups headed Image Controls, Image Presets, and Frame Collector. Unlike the controls in the Capture set, the Image controls affect only the display, not the recorded data.

Image Presets are specific combinations of the five image control settings, which you can create and save for later quick recall. These are distinct from the *capture presets* available in the Capture control set (previous page), which affect the recorded data and relate to choice of probe, zoom/pan, etc. *Image presets* can be used with any capture preset. They are saved even after you quit and re-start the Master-Vu program

IMAGE CONTROLS:

- *Gain* and *Contrast* controls adjust brightness and contrast across the entire image (all depths).
- *Near*, *Mid* and *Far* controls adjust the relative intensity of shallow, mid-depth, and deep echoes, respectively.
- To adjust these scroll wheel controls, click in the body of the control and *drag* left to reduce or right to increase the setting.

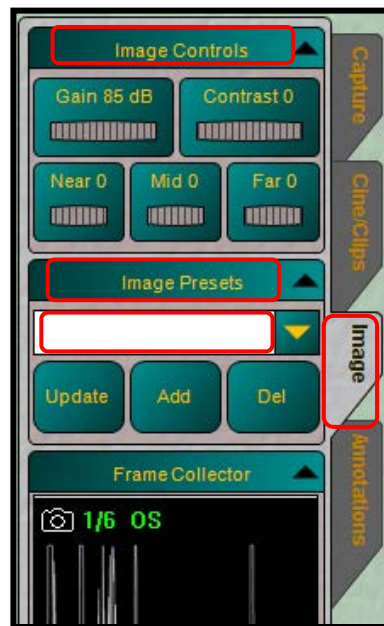


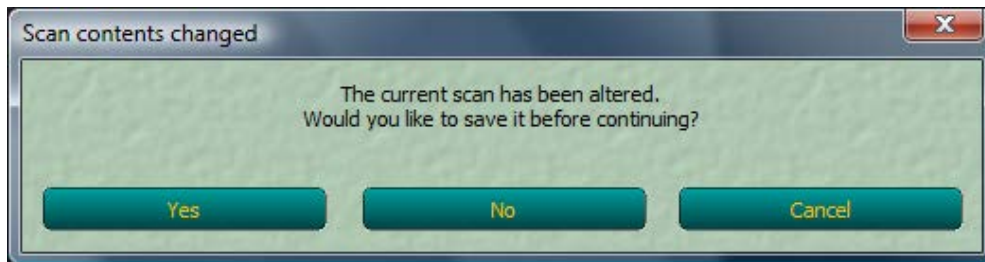
IMAGE PRESETS:

- Click once to open the list of image presets.
- If you select the preset named <Reset>, all the image controls will be returned to their default values. This preset cannot be overwritten or deleted.
- Click on a preset name to select it and close the list.
 - **Update** button: After changing any of the image control settings, use the *Update* button to modify (overwrite) the currently selected preset. (You will be prompted to confirm or cancel.)
 - **Add** button: When you find a combination of image control settings you would like to save, click the *Add* button to define a new image preset. You will be prompted to enter a name for the new preset, which will then be added to the list.
 - **Del** button: To delete an image preset, select it first, then click the *Del* button. You will be prompted to confirm or cancel deletion of the preset from the list.

ANNOTATIONS

Choose the Annotations Tab when you are reviewing scans and want to add overlay graphics such as measurement calipers, scales, arrows, etc. Overlay graphics do not affect the recorded data, but are saved along with the image data when you save a scan.

You may add overlays to a scan before saving it for the first time. You can also recall a previously saved scan to the main display for review, and add overlays at that time. You must then *save the scan again*—you may choose to save just the annotated frame or a longer cine (sub-) sequence—in order to save the annotations you have added. If at any time you forget to save after adding annotations to a scan, and attempt any operation which would destroy the work you have done (start a new scan, recall another saved scan, or close the program) the system will remind you by presenting the Scan Contents Changed dialog:



If you choose YES, the entire scan will automatically be saved. If you choose NO, the modified scan will be discarded. In either case, the program will proceed with whatever operation you originally requested. If you didn't want it, click Cancel.

ANNOTATION CONTROLS:

- Each of the first seven buttons in the Annotations group adds a new annotation to the current scan, as described in the detailed descriptions below.
- You can click once on any displayed annotation to *select* it—the color will change to indicate it is selected—and then remove it from the display by clicking the *Remove Selected* control, the icon is a trash can with a single item above it.
- You can also remove all annotations and start over by clicking the *Remove All* button, whose icon is a trash can with several icons above it.
- If you just want to hide the annotations temporarily, in order to see the underlying image more clearly without actually removing the annotations, click the *Hide/Show Overlays* button. Click again to re-display the annotations.

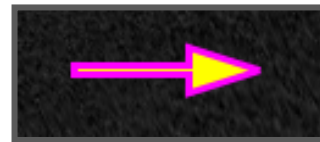


Frame overlays vs. Image overlays: Annotations are also called overlays, since they are graphical marks overlaid on top of the image. Calipers, arrows, and text overlays attach to specific frames, since they are usually used to mark image features which change from one frame to the next. Having added these "frame overlays" to a specific frame, you will notice they disappear if you use the Frames Bar controls to switch to a different frame, and reappear when you return to the frame to which they are attached. The scales and arbitrary A-scan overlays remain in place when you change frames; these attach to the ultrasound image irrespective of the frame. (In other words, frame overlays are fixed in space and time, whereas image overlays are fixed only in space.)

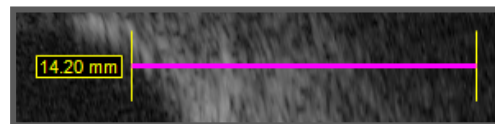
Avoid multiple overlays: Each time you add a new overlay, it will appear in a default location in the center of the image. If you add another overlay of the same kind without moving the first one, the second will be directly on top of the first and you will see only one. Make a point of moving each overlay immediately after adding it.

Editing (adjusting) overlays: All of the various overlays can be dragged using the mouse. As you roll the mouse pointer over the various parts of an overlay, bright colored outlines and other marks will appear to indicate what will happen if you click the mouse and drag from that point. This "visual feedback" takes four basic forms:

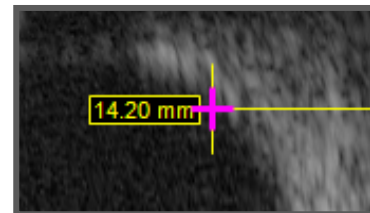
1. *Outline:* When an overlay is outlined, you can drag the entire overlay to a different location without changing its size or shape.



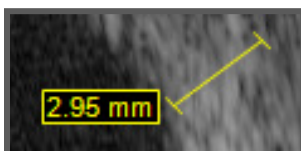
2. *Line:* When just one line is highlighted in color, you drag just this line (A-scan graph only) or the entire overlay (other types).



3. *Point:* A cross appearing over a point indicates that you can drag this point to re-shape the overlay.

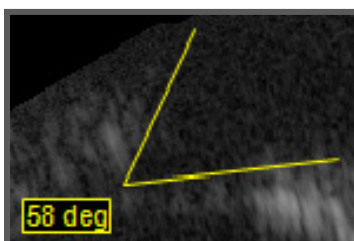


The specific kinds of overlays are activated by the individual buttons as follows.



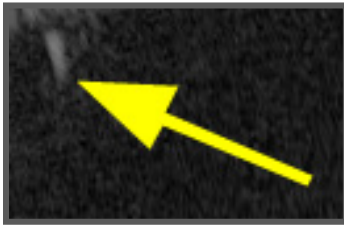
Distance Caliper – Measures distance between two points.

- Click on either end-point, hold and drag to new location.
- Click on the line, hold and drag entire caliper to new location.



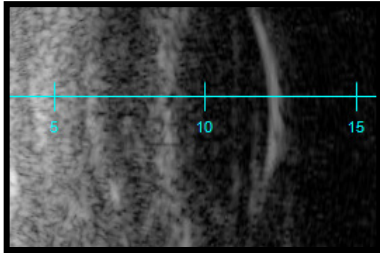
Angle Caliper – Measures the angle formed by three points.

- Click on either end-point, hold and drag to new location.
- Click on center-point, hold and drag to new location.
- Click on either line, hold and drag entire caliper to new location.



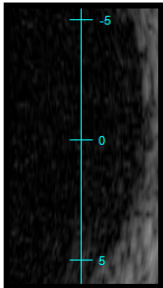
Arrow – Inserts arrow to point to a specific area or detail on scan.

- Click on end-points, hold and drag to new location. The breadth of the arrow will increase automatically along with its length.
- Click anywhere other than either end-point, hold and drag to move entire arrow to a new location.



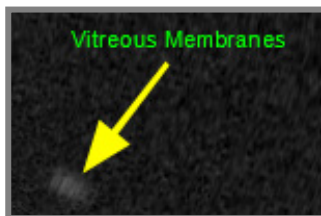
Horizontal Scale - Inserts horizontal scale with calibrated tick marks every 5 mm. The initial 0 mm point is located at the face of the transducer.

- Drag scale line to move it up/down
- Hold down the SHIFT key while dragging, to re-position the 0 mm point.



Vertical Scale - Inserts vertical scale with calibrated tick marks every 5 mm. The initial 0 mm point is the lateral center line of the scan.

- Drag scale line to move it left/right.
- Hold down SHIFT key while dragging, to re-position the 0 mm point.

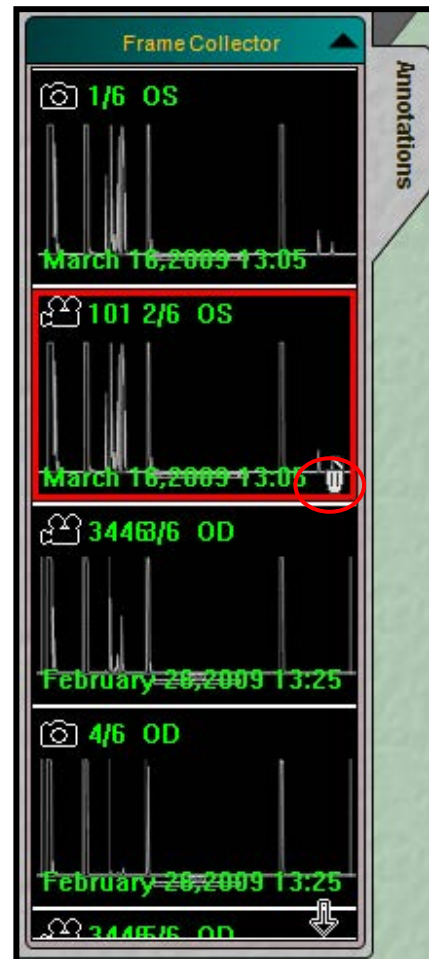


Text Label – Label specific areas or details on scan.

- Typically used along with arrow as shown.
- Click text, hold and drag to reposition.
- Double-click to pop up a text edit window to change the text.

CLIPS (Frame Collector)

- The Saved Scan List for the or currently selected patient appears under the group heading Clips, which appears in the Capture, Image and Annotation control sets, always at the bottom of the Control Strip.
- Scroll the list up/down by dragging any image up/down
 - List will continue to scroll after you release the mouse, until it reaches the end, or until you stop it with a single mouse click.
- To recall any saved scan to the main Image Area, double-click the scan's image in the Clips List, or drag it to the left.
- To delete any saved scan from the list:
 - Click once to select the clip -- a red outline box will appear around the scan image and a small "trash can" icon will appear at the bottom right corner.
 - Click once on the trash can icon -- a message box will pop up, asking you to confirm that you really want to delete the scan. Click Yes to delete, or No if you clicked the trash can icon by mistake.



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 *Master-Vu*® 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 probes 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 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

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 CABLES 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 for up to 10 minutes. Always rinse very thoroughly and allow to dry.
- FDA cleared disinfectants for low-level or high-level disinfection may be used 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.

Scan Type	Probe Type	Use	Patient Contact	Device Classification	Disinfection Level	Recommended	Method
A Scan	A 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 (Deionized 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.

* 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.

PRAGER SHELL CLEANING AND DISINFECTION

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 % H₂O₂). 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

Master-Vu General Specifications	
Personal Computer	Standard PC (desktop, laptop or tablet)
Operating System	Microsoft Windows up to 10
CPU	1 GHz clock (2 GHz or higher recommended), Pentium 4, Intel Core series or similar
RAM	1 GB (2GB recommended)
Available Disk Space	500 MB (Operating System) 50 to 100 GB (recommended)
Connectivity	USB: at least one available USB-2 port, direct to PC (not via a USB hub)
Monitor	17" Diagonal, 1280 x 1024 pixels (minimum), 24 bits/pixel
Power Requirement	5 volts DC, 500 mA max, supplied by host PC through provided USB cable
Display Resolution	1024 x 768 pixels or larger, 24 or 32 bits per pixel
Printer	Standard PC printer
Operating Conditions	Operating Temperature: 68 to 95°F (20 to 35°C) Storage Temperature: -40 to 149°F (-40 to 65°C) Operating Relative Humidity: 10 to 90% non-condensing Storage Relative Humidity: 5 to 95% non-condensing
Axial Sampling	Up to 2048 points
Lateral Sampling	256 lines (B-scan)
Pixel Separation	0.027 mm (B-scan)

A-Mode	
Transducer Frequency	10 MHz
Active Diameter	4.7 mm
Focal Length	25 mm
Operating Mode	Pulsed
Pulse Repetition Frequency	5880 Hz
Axial Resolution	0.193 mm
Scan Depth	45 mm

B-Mode	
Transducer Frequency	12 MHz
Active Diameter	6 mm
Focal Length	16 mm
Operating Mode	Pulsed
Pulse Repetition Frequency	3840 Hz
Axial Resolution	0.155 mm
Scan Depth	Up to 64 mm, 55 mm typical

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:

$$X = \bar{x} + K \cdot S_x$$

Where X is the upper output parameter limit, \bar{x} is the average of the measured output parameter, and S_x 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 $I_{SPTA.3}$ values below FDA limit values.

ACCURACY

The accuracy of the emissions figures is approximately 24.5% for all intensity values reported, 12.3% for all pressure values reported and 12.3% 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	12 MHz Transducer		10 MHz Transducer	
Mode	B-Mode		A-Mode	
Material	PZT		Lead Metaniobate	
Nominal Center Frequency	12 MHz		10 MHz	
Pulse Repetition Frequency	3840 Hz		5880 Hz	
Type	B-Scan (energy emitted during active scan)		A-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	0.201	0.408	0.186	0.7.82
Standard Deviation	0.00208	0.0262	0.00458	0.570
Limit	0.210	0.519	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	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	
	EBD	Az [cm]		0.47	
Ele. [cm]			0.47		

Transducer Model		Sonomed Escalon 12 MHz Probe (s/n 09065835)			
Operating Mode		B-Mode			
Application		Ophthalmic			
Acoustic Output		MI	I _{SPTA.3} [mW/cm ²]	I _{SPPA.3} [W/cm ²]	
Global Maximum Value		0.203	0.430	25.00	
Associated Acoustic Parameters	Pr.3 [Mpa]	0.656			
	W ₀ [mW]		0.194	0.194	
	f _c [MHz]	10.5	10.5	10.5	
	Z _{sp} [cm]	1.60		1.60	
	Beam Dimensions	x-6 [cm]			0.0756
		y-6 [cm]			0.0822
	PD [μS]	0.127		0.127	
	PRF [Hz]	3840		3840	
	EDS	Az [cm]		0.600	
Ele. [cm]			0.600		
Operating Control Conditions		Scan angle 60°	256 lines per frame	Frame rate 15Hz	

IMMUNITY TEST LEVELS

Electrostatic Discharge

Air Discharge Voltage: 2.0 kV, 4.0 kV, 8.0 kV
 Contact Discharge Voltage: 2.0 kV, 4.0 kV, 6.0 kV

Radiated, Radio-frequency, Electromagnetic Immunity 80 MHz to 2.5 GHz and Proximity Fields

Radiated Immunity, Test Parameters			
Frequency Range	80 to 200 MHz	200 to 1000 MHz	1000 to 2500 MHz
Field Strength	3 V/m	3 V/m	3 V/m
Modulation	1 kHz and 2Hz, 80%, AM		
Dwell Time	0.5 seconds		
Polarization of Applied Field	Horizontal and Vertical		

Radiated Immunity, Close Field Proximity Test Levels			
Frequency (MHz)	Modulation (@ 50% duty cycle)	Level V/m	Test Distance
385	18 Hz,	27	1.0 m
450	FM, 5 Hz Deviation	28	1.0 m
710, 745, 780	217 Hz	9	1.0 m
810, 870, 930	18 Hz	28	1.0 m
1720, 1845, 1970	217 Hz	28	1.0 m
2450	217 Hz	28	1.0 m
5240, 5500, 5785	217 Hz	9	1.0 m

Conducted, Radio-frequency, Electromagnetic Immunity

Frequency Range, Test Level: 0.15 to 80 MHz, 3 Vrms
 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: 3 Vrms

Power Frequency, Magnetic Immunity

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

GUIDANCE AND MANUFACTURER'S DECLARATION


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

Emissions Test	Compliance	Electromagnetic Environment Guidance
Radiated RF Emissions CISPR 11	Group 1	The Master-Vu 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. The Master-Vu 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.
Conducted RF Emissions CISPR 11	NA	
Harmonics IEC 61000-3-2	NA	
Flicker IEC 61000-3-3	NA	

The Master-Vu is intended for use in the electromagnetic environment specified below. The customer or user of the Master-Vu 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	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV 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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment

The Master-Vu is intended for use in the electromagnetic environment specified below. The customer or user of the Master-Vu 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Master-Vu, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3.5/V1)(\text{Sqrt } P)$ 150kHz to 80 MHz $d = (3.5/E1)(\text{Sqrt } P)$ 80Hz to 800 MHz $d = (7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 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 containing a transmitter or marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 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 Master-Vu is used exceeds the applicable RF compliance level above, the Master-Vu should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3Vrms.

Recommended Separations Distances for the Master-Vu.

The Master-Vu is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and Master-Vu as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz $d = (3.5/V1)(\text{Sqrt } P)$	Separation (m) 80 to 800 MHz $d = (3.5/E1)(\text{Sqrt } P)$	Separation (m) 800 MHz to 2.5 GHz $d = (7/E1)(\text{Sqrt } P)$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

WARNINGS AND CAUTIONS



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

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.

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 TO ENSURE PROBE INTEGRITY

This device is not intended for fetal use.

Never autoclave a probe or expose it to high heat.

Do not connect components not specified as system components. The PC used shall have an IEC 60601-1 or IEC 60950 compliant medical grade power supply or shall be used with a medically approved isolation transformer. 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. The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

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 the device 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 equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

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 device conforms to the emissions and immunity requirements IEC 60601-1-2, Conducted Emissions, Group 1, Class B.

Essential performance 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 Master-Vu devices 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 other electronic devices should be avoided because it could result in improper operation. If such use is necessary, the Master-Vu devices should be observed to verify normal operations. If the user notices unusual device behavior, particularly if such behavior is intermittent and associated with nearby usage of radio or TV transmitters, cell phones, or electrosurgical equipment, this could be an indication of electromagnetic interference. If such behavior occurs, the user should try moving the interfering equipment further from this device. Failure to do so could result in the equipment not functioning properly.

In the event adverse external electromagnetic disturbances causes the Master-Vu devices 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

Master-Vu systems incorporate Microsoft XP and above as the software Operating System, and, as such, makes available to Operators the full scope of Microsoft Windows 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 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 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 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 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).

WARRANTY

Sonomed Escalon warrants its products are free of defects of labor and material for two (2) years for electronics, and one (1) year for probes and cables.

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
	No user-serviceable parts
	CE Mark; Device complies with the EU 93/42/EEC Medical Device Directive
	Type B Applied Part Output is isolated from live parts by double or reinforced insulation
	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.
	Class II Equipment per IEC EN 60601-1
	ETL Listing Mark
	Refer to Operator's Manual