

UltraView XL

**Diagnostic Ultrasound Imaging System and Ultrasound
Biomicroscope**

Instructions for Use

UltraView XL IFU

Part Number 190-1001 Rev. G

The information contained in this document was accurate at the time of publication. Specifications are subject to change without notice. CLI reserves the right to modify the products described in this manual without notice and without incorporating those changes in any products already sold.

This product is sold for non-human use, only.

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System Requirements

Minimum system requirements

Windows 7 or Windows 10 Operating System

1. Display: Many display types and aspect ratios are possible with a given computer and monitor. Some possible display choices, moreover, do not result in square pixels. For correct image linearity, it is recommended that an aspect ratio be used that results in square pixels. The easiest way to achieve this is to select a monitor with a native (default) resolution larger (in each dimension) than 1177 x 756 pixels, which is the size of the UltraView XL application, and use the default display value.

Said another way, the UltraView XL application occupies a screen area of 1177 x 756 pixels. If the maximum screen resolution of your computer is, for example, 1600 x 900 pixels, then the application will occupy only a fraction of the display. If the resulting image size is smaller than desired, you may choose a lower screen resolution setting. This will result in a larger image. However, it is important to use a screen resolution that has the same, or very close to the same, aspect ratio. For example, a screen resolution of 1600 x 900 results in an aspect ratio of 1.777 ($1600 \div 900$). When selecting another screen resolution, choose one with the same or similar aspect ratio in order to preserve the viewing linearity of the image.

Note: The viewing aspect ratio has no effect on measurements. Measurements will be correct even though screen (viewing) linearity may be skewed.

2. CPU: The speed and cache of the CPU may affect the performance of the imaging system. Generally, the faster the CPU, the better the system performance. Because it is not feasible to test all PC configurations, no attempt has been made to determine all possible incompatibilities. However, the UltraView XL hardware and software have been designed to function with most computers, even those of modest performance speed. Generally, however, a CPU speed of 1.2GHz, or higher, is required. If a NetBook is used, however, some performance may be sacrificed.
3. High-speed memory: 2GB of high-speed memory (i.e., DDRAM) is required, more is advisable.
4. I/O: One USB 2.0 port

Note: A second USB port is needed if a footswitch is used.
5. Hard drive: Individual images require 512KB of memory to store. Cine files are 512KB multiplied by the number of frames and can be very large. Therefore, large hard drive capacities are recommended in order to store case files. Additionally, regular backup to a remote drive or storage media (CD-ROM, etc.) is highly recommended.

Windows 8.x Operating System

Windows 8.x may require additional high-speed memory to operate with the same efficiency as earlier OS.

Software Installation Instructions

See the ReadMe file included with the flash drive (or other media) that contains the application software and drivers.

Warnings and Cautions

CLI is not responsible for the safety and reliability of this instrument when:

- The instrument is not used in accordance with this IFU, including appendices hereto.
- Modifications or alterations are made to it by unauthorized dealers or other persons.

WARNINGS

WARNING: ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY AUTHORIZED DEALERS AND PERSONNEL THAT ARE TRAINED BY CLI SO THAT CORRECT OPERATION OF THE INSTRUMENT IS MAINTAINED.

WARNING: THIS INSTRUMENT IS NOT SUITED FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS, SUCH AS ETHER, OR GASES PROMOTING IGNITION OF FLAMMABLE GASES OR MATERIALS SUCH AS OXYGEN OR NITROUS OXIDE.

WARNING: TO AVOID INJURY TO ANIMALS WHEN USING THE IMMERSION-STYLE UBM PROBE (CLI C1500 SERIES PROBE FOR 35/50MHZ TRANSDUCERS), THE USER MUST MAINTAIN A SAFE DISTANCE BETWEEN THE MOVING TRANSDUCER AND THE ANIMAL.

WARNING: CARE MUST BE TAKEN TO ARRANGE THE CABLES FOR THE PROBE, FOOTSWITCH, USB INTERCONNECT, AND POWER SO AS NOT TO INTRODUCE A TRIPPING HAZARD FOR THE USER AND OTHERS IN THE IMMEDIATE VICINITY OF THE SYSTEM.

WARNING: DO NOT ATTEMPT TO USE ANY PROBES OR TRANSDUCERS OTHER THAN THOSE SUPPLIED WITH THE SYSTEM OR DIRECT REPLACEMENTS FROM CLI OR AN AUTHORIZED DISTRIBUTOR OF THE SYSTEM. USING ANOTHER MANUFACTURER'S PROBES OR TRANSDUCERS MAY DAMAGE THE INSTRUMENT AND/OR CAUSE INACCURATE IMAGING AND MEASUREMENT RESULTS.

WARNING: DO NOT ATTEMPT TO CHANGE ANY OF THE ULTRAVIEW XL FILES INSTALLED ON THE COMPUTER. ANY CHANGES CAN CAUSE THE INSTRUMENT TO MALFUNCTION AND CAUSE INACCURATE IMAGING AND MEASUREMENT RESULTS.

CAUTIONS

CAUTION: AVOID USING OTHER PC APPLICATIONS WHILE ULTRAVIEW XL IS IN OPERATION. UNEXPECTED MALFUNCTIONS MAY RESULT. IF MALFUNCTIONS DO OCCUR, CLOSE ULTRAVIEW XL , CLOSE THE OTHER APPLICATION, RESTART THE COMPUTER, AND RESTART ULTRAVIEW XL. CONFIRM PROPER OPERATION OF THE INSTRUMENT BEFORE RESUMING SCANNING OPERATIONS.

CAUTION: READ AND FOLLOW ALL CLEANING AND DISINFECTING INSTRUCTIONS FOR PROBES AND TRANSDUCERS FOUND IN THE APPENDICES.

CAUTION: ELECTRICAL INTERFERENCE TO THE INSTRUMENT MAY RESULT FROM STRONG RADIO FREQUENCY EMITTERS IN THE VICINITY OF THE INSTRUMENT. SUCH EMITTERS MAY INCLUDE RADIO AND/OR TELEVISION TRANSMITTERS OR HIGH-FREQUENCYING EMITTING SURGICAL EQUIPMENT EMITTING IN THE RANGE OF 5-50MHZ. IF SUCH INTERFERENCE DOES OCCUR, ROOM SHIELDING MAY BE NEEDED TO REDUCE INTERFERENCE.

CAUTION: AN EXCELLENT GROUNDING SYSTEM MUST BE APPLIED TO THE HOST PC SYSTEM.

CAUTION: CHECK THE AC MAINS SUPPLY FOR INTERFERENCE. IF INTERFERENCE IS SEEN, AN UNINTERRUPTABLE POWER SUPPLY (UPS) IS RECOMMENDED TO OPTIMIZE IMAGE PERFORMANCE.

CAUTION: THE 35 AND 50 MHZ TRANSDUCERS THAT MAY BE SUPPLIED WITH THIS INSTRUMENT ARE DELICATE AND FRAGILE. OBSERVE CAUTION WHEN HANDLING AND FOLLOW ALL INSTRUCTIONS IN THIS IFU REGARDING THEM. TRANSDUCERS CARRY A 90-DAY WARRANTY DUE TO THEIR FRAGILE NATURE AND SUSCEPTIBILITY TO MISHANDLING.

Warranties

LIMITED WARRANTY FOR PRODUCTS

CLI WARRANTS THAT ITS PRODUCTS, AS DELIVERED, SHALL CONFORM TO ITS SPECIFICATION AND BE FREE OF DEFECTS IN MATERIALS AND WORKMANSHIP WHEN USED IN ACCORDANCE WITH THEIR INTENDED USE. EXCEPT FOR THIN-FILM TRANSDUCERS WHICH ARE WARRANTED FOR 90 DAYS, SUCH WARRANTY SHALL EXTEND FOR A PERIOD OF THIRTEEN (13) MONTHS FROM THE PRODUCT'S ORIGINAL DATE OF SHIPMENT FROM CLI LOCATION. THIS WARRANTY SET FORTH DOES NOT APPLY TO SINGLE-USE AND OTHER NON-DURABLE SUPPLIES THAT MIGHT BE USED IN CONNECTION WITH THE PRODUCTS. FURTHER, THIS WARRANTY DOES NOT APPLY TO MODIFICATIONS MADE TO THE PRODUCTS BY CUSTOMER, OR DAMAGE TO PRODUCTS RESULTING FROM MODIFICATIONS OR REPAIRS EFFECTED BY CUSTOMER OR OTHER PERSONNEL NOT AUTHORIZED BY CLI TO PERFORM SUCH WORK. THIS WARRANTY SHALL NOT APPLY TO DAMAGE RESULTING FROM (I) LOSS OR DAMAGE IN TRANSIT, (II) UNREASONABLE USE, (III) CUSTOMER'S NEGLIGENCE, OR (IV) ACCIDENT. CLI RESERVES THE RIGHT TO EXAMINE THE ALLEGED DEFECTIVE GOODS TO DETERMINE WHETHER THE WARRANTY IS APPLICABLE.

LIMITED WARRANTY AND DISCLAIMER

CLI WARRANTS THAT ALL SERVICES SUPPLIED HEREUNDER WILL BE PERFORMED IN A WORKMANLIKE MANNER. EXCEPT FOR THE EXPRESS WARRANTIES PROVIDED TO CUSTOMER UNDER THE ABOVE "LIMITED WARRANTY FOR PRODUCTS", CLI MAKES NO OTHER WARRANTIES OR CONDITIONS, EXPRESSED OR IMPLIED, AS TO THE SERVICES OR PARTS SUPPLIED HEREUNDER, AND CLI EXPRESSLY DISCLAIMS ALL WARRANTIES OR CONDITIONS OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.

LIMITATION OF LIABILITY

CLI's LIABILITY UNDER THIS AGREEMENT IS LIMITED TO THE EXPENSE OF PROVIDING PRODUCT REPAIR ON CLI PREMISES. NEITHER CLI NOR ITS EMPLOYEES OR AGENTS SHALL BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION, BUSINESS INTERRUPTION, LOST PROFITS OR REVENUES, WAGES OR INJURY TO PERSONS OR PROPERTY. CUSTOMER AND CLI AGREE THAT THE SOLE AND EXCLUSIVE REMEDY FOR NONCONFORMING GOODS SHALL BE REPLACEMENT OF DEFECTIVE GOODS OR, AT CLI'S OPTION, REFUND OF THE PURCHASE PRICE TO CUSTOMER. THE PARTIES ACKNOWLEDGE THAT THE PRICE OF CLI'S PRODUCTS WOULD BE MUCH GREATER IF CLI UNDERTOOK MORE EXTENSIVE LIABILITY.

ANY ACTION BY CUSTOMER FOR ANY ALLEGED BREACH OF THE WARRANTY STATED IN THIS SECTION MUST BE BROUGHT WITHIN 90 CALENDAR DAYS AFTER THE END OF THE WARRANTY PERIOD.

Components of the System

The imaging system is composed of the following items:

1. One or more probes
2. Probe cable
3. Electronics box
4. USB cable
5. AC/DC Power supply/cable
6. Host PC (may be supplied by user)
7. Optional accessories (as ordered)

Assembling the System



IMPORTANT: IF THE ELECTRONICS ENCLOSURE (PN C92-005), IS EQUIPPED WITH A BATTERY PACK SEE README FILE AND SUPPLEMENTAL INFORMATION AT THE REAR OF THIS IFU.

All cables have unique connector ends and cannot be misconnected. Match connector types and connect all components: probe to probe cable, probe cable to electronics box (use the screws on the D-shell connector to firmly affix the connector to the electronics box), power supply to electronics box, power supply AC plug and converter to 115VAC mains outlet, USB cable from electronics box to computer.

Figure 1. Typical components comprising the ultrasound system: PC host, electronics enclosure, probe and power cables, and probes. The actual PC host may be a tower, desktop, laptop, netbook, tablet, or all-in-one system (shown).

The electronics box has one paddle switch (near the power connector) that activates/deactivates the AC power supply. An LED light is located adjacent to the switch that will illuminate when power to the box is activated.

Do not apply power to the system at this time.

Getting Started

If the software application program is not pre-installed on your computer, load the storage media (CD-ROM, memory stick, etc.) containing the UltraView XL program on the host PC, find and open the ReadMe File and follow the installation instructions.

After the UltraView XL application software is installed, or if it was pre-installed on your computer, power the electronics box (the LED will illuminate) and then launch the program by finding the shortcut icon on the Desktop, Start Menu or Taskbar and do one of the following:

Note: The Electronics Box MUST be powered prior to launching the application. If not, close the application, power the Electronics Box and re-launch the application.



- 1) Double left-click on the shortcut, or
- 2) Select the icon on the Taskbar, or
- 3) Select UltraView from the Start Menu depending on where the shortcut is (see installation instruction).

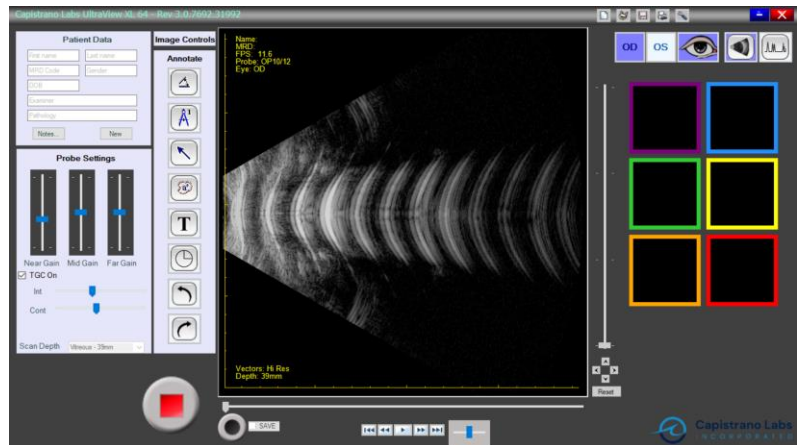
*Figure 2.
Application
shortcut*

The program will now launch and display the Main Screen of the application and associated graphical user interface (GUI).

Instructions for Using the Software Application

Main Screen

The Main Screen contains all controls typically needed to conduct an ultrasound examination. In addition to the central imaging area, the GUI is organized into several groupings as follows (clockwise from top-left corner):



- Patient Data
- Probe Settings
- Start/Record/Stop control button
- Cine recording bar and associated tools
- Snap Shots
- Image Controls
- Measurement controls
- Zoom and Pan control
- Right eye (OD) and left eye (OS) designation
- Top menu bar and icons

Note: In addition to the instructions in this manual, Tool Tips are also available for most controls. To display a Tool Tip, hover the pointer over a control for one second (1 sec.).

Tool Tips may be disabled, see Pg. 17.

Each of these control areas will be explained in the sections below.

Patient Data

To display the Patient Data fields, click within the gray header: "Patient Data". To put the box away, click the header again. The following fields are designated for patient exam information:

- First name of patient
- Last name of patient
- MRD Code (minimum of 5 digits are required)
- Gender of patient
- Date of birth (DOB) of patient (with numeric format of DD/MM/YYYY)
- Examiner name
- Pathology

Patient Data

First name	Last name
MRD Code	Gender
DOB	
Examiner	
Pathology	

Notes...

New

To enter data into any of these fields, place the cursor within the field, left-click the mouse (or other navigation tool), and begin typing (the field labels will be automatically cleared as typing begins).

Notes Button: Additional information concerning the patient or examination may be entered and saved with the examination by selecting the “Notes” button and entering the information in the text window provided.

New button: The “New” button will erase all patient information, images, image notations, measurements and any other data associated with an examination. The New button should only be actuated when all data has been saved from the previous examination, or it has been determined that no data is to be saved.

IMPORTANT: The NEW BUTTON erases all patient information, images, and all work performed on the current patient. Be sure to perform a save operation, if appropriate, before activating this button.

Probe Settings

This section of the GUI contains four controls with the following functions.

Gain Controls

To display the Gain Control fields, click within the gray header: “Probe Settings”. There are three vertical “sliders” that control the amount of digital TGC applied to the image data. Each slider has a default setting that places the slider approximately in the optimum TGC adjustment range for each probe. Grabbing (left-click-and-hold) the slider bar and lowering it will reduce gain, while raising the slider bar will increase gain. Each TGC control is explained below.

Near Gain: Increases and decreases gain in the portion of the image closest to the transducer.

Mid Gain: Increases and decreases gain in the central portion of the image. The default value is intended to provide maximum, noise-free echo strength in this region. Only small adjustments may be needed to further enhance the image.

Far Gain: Increases and decreases gain in the deepest region of the image. The default value is intended to provide optimum noise-free echo strength in this region. Small adjustments may be needed, however, to further enhance the image.

Scan Depth

To display the Gain Control fields, click within the gray header: “Probe Settings”. Selecting this field enables a drop-down menu of selectable scan depths (or “Ranges”). These depths are 18mm (Anterior-typical UBM scan depth), 39mm (typical vitreous/retina scan depth), 59 mm (typical retina/orbit scan depth), and 78 mm (maximum scan depth). To change scan depth:

- 1) Freeze the image (see below “Start/Record/Stop control button”).
- 2) Left-click on the down arrow of the Scan Depth field
- 3) Left click on the new depth

Note: Scan depth cannot be changed during live scanning.

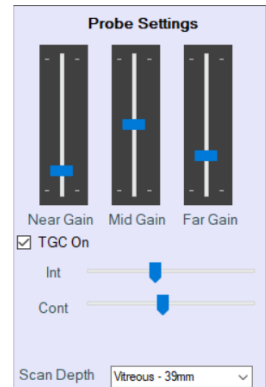


Figure 3. Probe Settings section of the GUI, containing gain controls and scan depth selections.

Start / Stop Control Button

At start-up, the imaging system is in a non-scanning state, the probe is not activated, and no image is displayed on the screen. To activate scanning, place the pointer over the Start button and left-click once. Alternatively, if a footswitch is used, depress the footswitch once to activate scanning.

If using a footswitch, depressing the footswitch while in live scanning mode will activate Cine. Depressing the footswitch a third time will stop the cine recording and freeze the image.



Figure 4. Start button in NON-SCANNING (FROZEN) state. Press to start scanning.



Figure 5. Stop button in SCANNING (IMAGING) state. Press to stop scanning.

NOTE: When using the footswitch, it is necessary to cycle through the cine feature in order to freeze the image. When using a mouse, or other pointer, the Freeze function can be activated directly by clicking on the red “Stop” button.

Cine Recording Bar and Associated Tools

The Cine feature includes the following features:

1. Up to 100 cines per eye: The cine bar is set to a length of 600 frames at the beginning of each examination. However, if more than 600 frames of cine recording are required for an examination, then an additional 600 frames of cine buffering will be AUTOMATICALLY ADDED ONCE THE INITIAL 600 FRAMES ARE FILLED. The total cine length will then be 1200 frames. If more frames are needed, an additional 600 frames will be allocated once the 1200 frames are used, and so forth. The addition of frames will be reflected in the position of the Cine Cursor.
2. Multiple cines: Each eye (OD/OS) is allocated its own cine feature.
3. Multiple cine snippets: The full cine recording may be comprised of many short movie segments (or “snippets”). Because the cine feature itself may be thousands of frames long, many individual snippets are possible. **However, a) a snippet must be at least two seconds in length before it is recognized and saved within the cine feature and b) the maximum length of any single snippet is 600 frames.** Regarding the 2-second delay, if the cine recording feature is accidentally activated and is subsequently deactivated within two seconds, no frames will be stored. Alternatively, one must record for at least two seconds in order for a snippet to be “recognized” and saved in cine memory. If a snippet is greater than two seconds, the initial two seconds will be included in the snippet (i.e., no frames are lost).
4. Selective archiving: It may be that a large number of snippets are recorded, but only a subset of these (or none) are suitable to be saved as part of the permanent record. **The default is that no snippets are archived, but a method is supplied (see below) to tag a snippet for archival.**



Figure 5. Cine controls for play/pause, frame-by-frame increment/decrement, and cine jump.

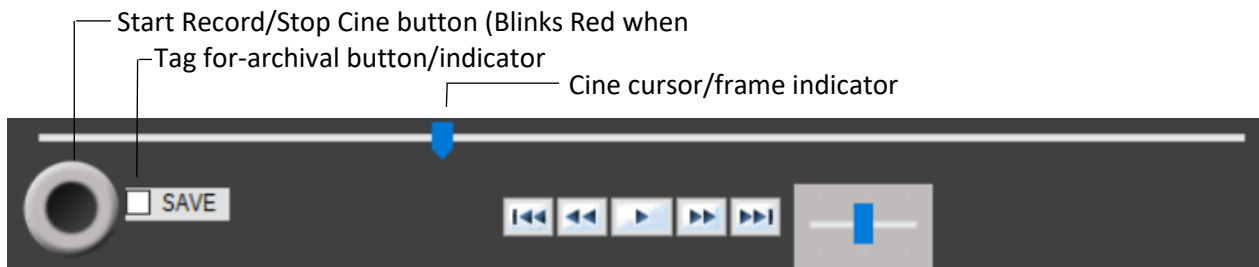


Figure 6. Cine bar and associated controls, including a control for tagging individual movies (snippets) for archival, a cursor to indicate frame position within the cine buffer, and individual play/pause and frame-by-frame increment/decrement controls.

Cine Controls

Start/Record/Stop Button

A cine snippet (movie segment) may only begin after initiating of live scanning. Once live scanning has started, a snippet may be recorded by either left-clicking round Start Record/ Stop button or by depressing the footswitch. To stop recording, left-click the Start Record/Stop button, or depress the footswitch again. To indicate that recording has begun, the Start Record/Stop button will blink red.

IMPORTANT: The maximum length of an individual snippet is 600 frames. The entire Cine (comprised of multiple snippets), however, may be much longer.

Cine Bar and Cine Cursor

When recording a cine, the cine cursor will move rightward along the cine bar, and will pause when recording is suspended. The color of the cine cursor is black during recording and when recording is paused. However, the cine cursor may be “grabbed” (left-click-and-hold the cursor, then drag the cursor) and positioned within previously recorded snippets. When this is done, the color of the cine cursor will change to cue the operator to the location of individual snippets within the bar.

Navigating within a Snippet

Standard navigation buttons are provided to move within a snippet. To play a recorded snippet, direct the mouse pointer to the cine cursor, grab and drag the cine cursor to the left until the desired snippet is found. Release the mouse button and click the play button. Activating Play will automatically move the cine cursor to the beginning of the snippet and begin playing from that point. Once playing, the play button will change to a pause button. Press the pause button to stop playback. Left and right double-arrowhead buttons will either decrement or increment the cine, respectively, frame by frame. The left-most and right-most buttons jump to the previous or next cine, respectively.

Note: As a shortcut, double-clicking the cine cursor within a snippet will place the cine cursor at the start of that snippet.

Playback Speed

To the right of the Cine controls, a small, slider window is present. Slow, medium, or fast playback speeds may be selected during playback. Selecting the Fast (far right of slider window) playback speed aids in the review of longer movies. Slower speeds (far left of slider window) aid in pausing the movie at particular frames.



Figure 7 Playback speed indicator (only visible during playback).

Tagging a Snippet for Archival

At the extreme left of the cine bar is the Archive Tag button. To tag a snippet for permanent archival, place the cine cursor within the snippet to be saved and then left-click the Archive Tag button. This button will illuminate when tagging is accomplished, and the button will re-illuminate whenever the cine cursor is dragged through this or any other tagged snippet.

Placing the cine cursor within a tagged snippet and again activating the Archive Tag button will un-tag the snippet (i.e., it will then NOT be archived along with the examination).

Image Snap Shots

An individual frozen image (either acquired from live scanning or from a paused snippet in playback) may be marked for archival by placing it within a Snap Shot. Clicking within an empty Snap Shot will transfer the image from the main window to the Snap Shot window and mark it for archival. Up to six images may be marked in this manner.

Clicking within a **filled Snap Shot** will activate a pop-up window with additional controls, as follows.

Down Arrow: replaces that Snap Shot with the current image in the main window.

Up Arrow: Places the Snap Shot image in the main window.

Printer Icon: Prints the Snap Shot.

Folder Icon/JPEG Save: Opens a save dialog box so that the Snap Shot may be saved individually in JPEG format.

Trashcan icon: Deletes the Snap Shot.

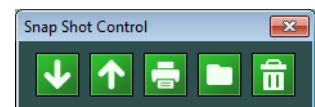


Figure 8. Snap Shot pop-up control window.

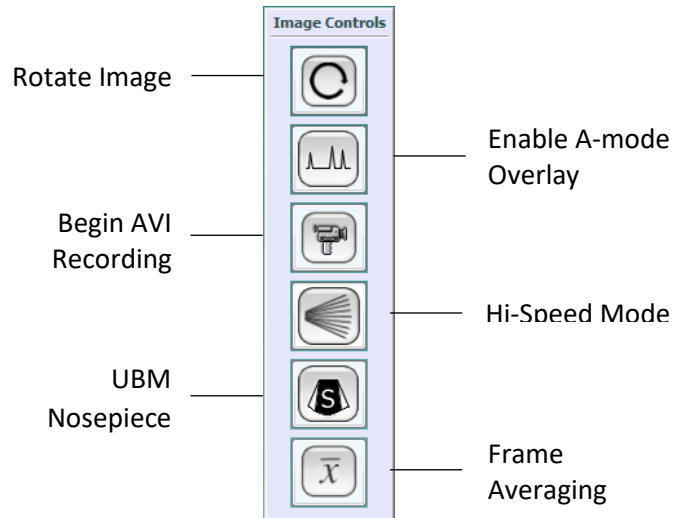
Note: Only images in the Snap Shot windows are saved when the Save button is selected. The large image in the Main Window is NOT saved.

Image Controls

For all Image Tools, first FREEZE the image, then click the Image Control header (if not already displayed), and then on the desired button to activate the feature. The background area of the button will highlight to indicate that it has been activated. Then follow these instructions.

Rotate Image

- 1) Activating the button will rotate the image 90 degrees from its default orientation.
- 2) De-activating the feature will return the image to the default orientation.



A-Mode Overlay

Activates an A-mode display of the center vector of the B-mode image. To select a different vector to display, place the pointer at any point along the desired A-mode line (or on any area of interest within the image) and left-click the pointer. The A-mode data from this new vector will now be displayed. A graphic line is drawn to delineate the vector used for the A-line data.

Whenever this feature is initially activated, the program will always display the center vector.

Saving to AVI from Cine

- 1) After recording one or more cines, place the cine curser within the cine from which the AVI movie will be based.
- 2) Select the AVI Recording button. A Save Dialog Box will open. If the AVI Recording button was activated accidentally, cancel out of the dialog box to return to the application.
- 3) Name the movie and navigate to the folder where you want the movie to be saved, then click Save. The cine curser will be placed at the beginning of the cine.
- 3) Select movie replay speed. Click movie button to continue.
- 4) Using the cine slider, set the starting frame. Click movie button to continue.
- 5) Using the cine slider, set the last frame. Click movie button to continue.
- 6) The AVI conversion will now be made and then the program returned to normal imaging mode.

NOTES:

1) These instructions are also displayed in the Image Controls box once the process is begun.

2) AVI movies from live scanning are not supported. A cine must first be made, then converted to AVI per the above instructions.

Hi-Speed Scan Mode

The default mode for scanning is High-Resolution mode (aka: Hi-Res mode). This refers to an imaging mode where images are formed using 256 vectors to form signal-dense, high detail images. Hi-Res scanning produces information-rich images and should be the mode used when high frame rates are not needed.

When high frame rates are needed to better delineate a fast moving structure, then activating this button will place the system in Hi-Speed, Standard Resolution imaging mode (aka: Hi-Speed mode). Hi-Speed mode roughly doubles the frame rate. In this mode, the image is built up from 128 vectors, which results in slightly less lateral resolution (only appreciated in zoomed images).

NOTES:

- 1) The frame rate is doubled in 35mm depth mode, but frame rates are less than doubled in other depths due to time of flight and signal processing considerations.
- 2) The actual frame rate is displayed within the image area.

Scan with Stand-off Attachment (Nosepiece)

This feature pertains the 35/50MHz UBM probe, only, and only when a Stand-off attachment is NOT used with the UBM probe (**see page 20-21, Using a Stand-off with the C1500 Series Probe**). The action of the button is to increase the scan angle from 25 degrees to 30 degrees and thereby provide a wider field of view. Activate this feature whenever a Stand-off is not used with the UBM probe and a wider view is needed.

Frame Averaging

Frame averaging takes data from the two most recent image frames and averages the echo data. It is useful in suppressing random noise within the image. Some “smearing” of the image may be appreciated when moving the probe. The image will stabilize once the probe is steadied on a target. Less smearing is evident if Hi-Speed mode is used (due to the higher frame rate).

Measurement Controls

For all Measurement Tools, first FREEZE the image, then click on the “Measurements” header (if not already displayed), and then on the desired button to activate the feature. The background area of the button will change color to indicate that it has been activated. Then follow these instructions.

Angle Measurement

- 1) Place the pointer at the first point along one arm of the angle and left-click the pointer
- 2) Place the second point at the vertex of the angle and left-click
- 3) Place the third point along the second arm of the angle and left-click
- 4) The angle measurement is displayed

Up to six angles may be measured per image. Use the Undo/Redo function as needed.

Distance Measurement

- 1) Find one-end point of the structure to be measured
- 2) Left-click at that point
- 3) Place the cursor to the opposite end of the structure and left-click again
- 4) The distance measurement is displayed

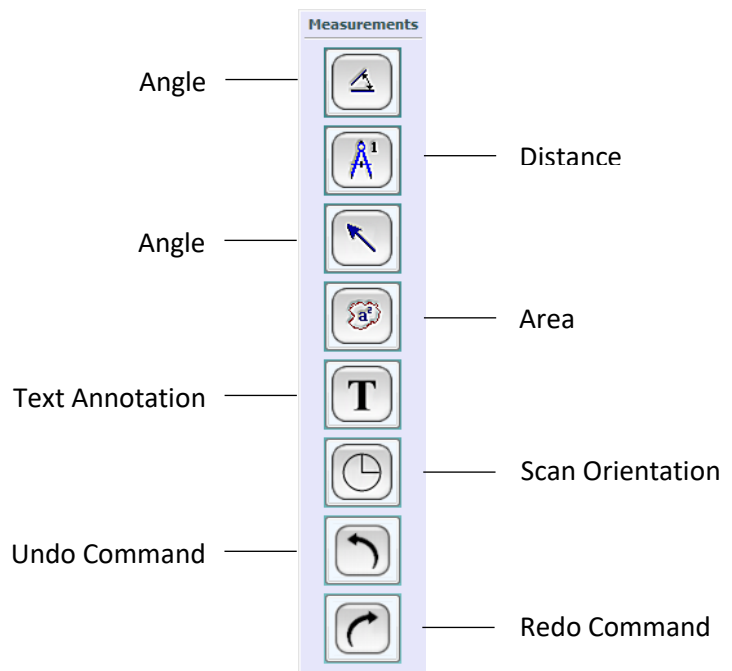
Up to six distance measurements may be made per image. Use the Undo/Redo function as needed.

Arrow Pointer (to highlight a structure in the image)

- 1) Place the cursor at some distance away from the structure to be highlighted
- 2) Left-click and drag the pointer toward the structure
- 3) Release the pointer

Use the Undo/Redo function as needed.

Note: The arrowhead is always placed at the end of the dragged line, not at its beginning.



Area Measurement

- 1) Identify the area to be measured
- 2) Delineate the perimeter of the area with a series of left-clicks of the pointer (an "X" is dropped along the perimeter with each click)
- 3) When the entire perimeter has been delineated, right-click within the area to connect the first and last points and draw the perimeter.
- 4) The area measurement will be displayed adjacent to the perimeter

Use the Undo/Redo function as needed.

Note: the more points used to delineate the area, the more accurate the measurement will be, especially when delineating irregular shapes.

Note: The pointer must be kept within the imaging area while all perimeter points are placed. If the pointer is taken out of the imaging area during the placement of perimeter points, the measurement will be completed (circumference closed). In this case, activate the Undo button and redraw the perimeter.

Add Text

- 1) Place the pointer within the image at the place where the text should *begin* and left-click the pointer
- 2) A text box will appear
- 3) Use the keyboard to write the desired text
- 4) Click OK
- 5) The text will appear within the image, starting at the click point in "1".

Scan Orientation

- 1) A window will be displayed with a clock-like graphic.
- 2) Left-click on a number within the "clock"
- 3) The window will close and place the chosen numeric orientation within the image data and will be archived along with the image when the examination is saved. This feature may be used to document the probe scan-plane orientation used to create the image.

Undo/Redo Function

These functions relate solely to the features found in the Measurement Controls, below, and act in the typical manner of undoing or redoing the most recent action(s). Both will undo/redo up to eight actions.

NOTE: For your convenience, the Reset button of the Pan/Zoom control will erase all measurements, text, and arrows in one action.

Zoom and Pan Control

With a frozen image, slide the Zoom Cursor upward to expand (zoom) the image the desired amount. Use the arrow keys to position the area of interest within the zoomed image. Activate the Reset button to return the image to its default (un-zoomed) state.



Right Eye (OD) and Left Eye (OS) Designation

Left-click and highlight “OD” to examine and temporarily archive images and movies of the right eye. Use “OS” to do the same for the left eye.

All Snap Shots and movies made for one eye are temporarily saved in memory when the other eye is selected for examination.

Switching between eyes will re-load any Snap Shots or cines already made for a given examination. Each eye has a full complement of Snap Shots (six per eye) and full cine (100 cines for each eye, as described earlier).



Grab and slide cursor up to zoom in, slide back down to zoom out.

Pan controls

Return to default

Figure 9. Pan and Zoom control panel.

Top Menu Bar and Icons

New Examination (same patient)

Activate this icon to erase all information, images, cines, and measurements for the current examination. PATIENT DATA and PATIENT NOTES ARE NOT ERASED.

Note: This is a convenient feature when an examination for a given patient already exists. The previous examination may be retrieved and, if desired, reviewed. Then, the New Examination icon may be activated to erase all previous information except the patient data and patient notes. This eliminates the need to re-enter patient data.

Note: If the Patient Notes from the previous examination are no longer pertinent, remember to delete or modify them for the new examination.

Open Archived Examination

Activates an OPEN dialog box for retrieving archived examinations from C:\Examinations.

Save Current Examination

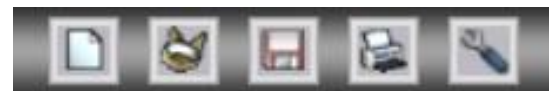
Archives all components of the examination to the folder C:\Examinations.

NOTE: With respect to images, only tagged Snippets of the cine feature and images in the Snap Shot windows are saved with the examination.

Print Current Examination Images

Prints all Snap Shot images and associated information.

Top Menu Bar



New Exam/Same Patient

Save Exam

System Setup

Open Archived Exam

Print Exam

System Setup

Opens a window (Control Options) containing links to parameters that may be configured by the user. These include the following.

Set Hardware

Opens a window of hardware configuration parameters. Most parameters are presented for informational purposes, only; however, any highlighted field may be changed.

Velocity (m/s): This parameter may be changed if the default is deemed incorrect for the tissue being scanned. To change the velocity, enter a new value and Write the file. The new velocity will now be used.

Warning: Using an incorrect velocity will result in incorrect measurement values. Use extreme caution when changing this value.

Sample Frequency (MHz): The sample frequency is associated with the depth of the scan. Associations are as follows:

80MHz = 18mm depth (UBM)
40MHz = 35mm depth
26.67 = 54mm depth
20MHz = 74mm depth

Selecting and Writing a new sample frequency will change the default depth of the scan when the program is launched. This default is probe-specific.

For Example, the 12MHz probe has a default depth of 35mm (40MHz Sample Frequency). To change the default depth to 54mm, change the sample frequency to 26.67MHz and Write the file. Do this with the appropriate probe attached to the system (in this case the 12MHz probe).

Display Offset: This control is for adjusting the centering of the mechanical movement of the transducer within the probe. The value "128" is the default value and should produce an image that is properly centered in the display. A useful way to assess the centering is to connect a probe, unfreeze the image and determine if the reverberation pattern is roughly centered within the display. If it is not well centered, then this parameter may be used to center the echoes as follows:

12MHz and 20MHz Probes

- 1) Determine if the reverberation pattern is below the centerline or above the centerline of the display.
- 2) If the reverberation line is above center, then numerically decreasing the offset will bring the reverberation pattern toward the center. The minimum value that may be used is "118".
- 3) If the reverberation line is below center, then numerically increasing the offset will bring the reverberation pattern toward the center. The maximum value that may be used is "138".

UBM Probe

Centering the UBM probe may be necessary to center the movement of the transducer within a Standoff (see "Using the Standoff (aka: Nosepiece) and Related Components"). If a Standoff is mounted to the probe and an audible clicking sound can be heard when the probe is activated, centering improvement is needed. Unfortunately, it is not possible to determine if the transducer is swinging too far to the left, or too far to the right by looking at the display (there is no reverberation pattern to use a cue). Imperfect centering is best appreciated when the standoff is removed and the probe is held such that the left and right motion is easily seen from the side. From this perspective, one can observe the extent of the motion and it is often possible to see if the overall motion of the transducer is biased to one side or the other. To adjust centering, do the following:

- 1) With the probe held such that the standoff locating pin is located on the right, observe the motion of the transducer.

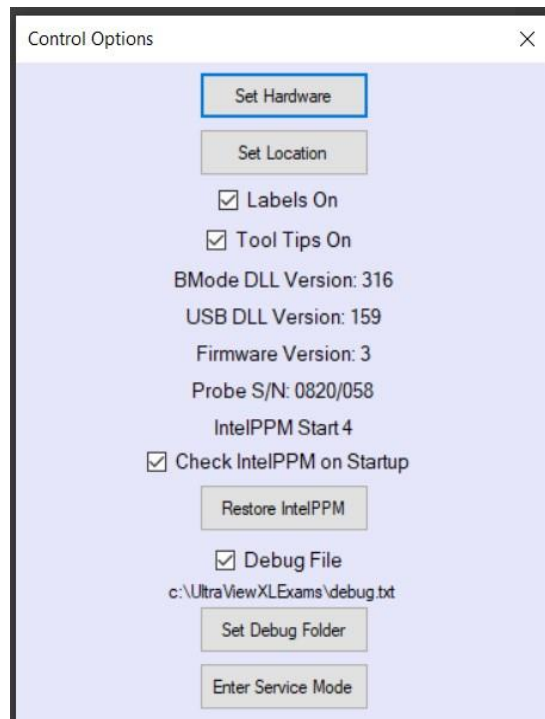


Figure 10. System Configuration.

- 2) If the motion is biased rightward (toward the locating pin) then numerically decrease Display Offset. Do this in small increments until the transducer appears to be well centered in its motion. It is not necessary to write the file each time a new value is tried. However, when optimal centering is achieved, write the file to retain the final value.
- 3) If the motion is biased leftward (away from the locating pin) then numerically increase Display Offset. Do this in small increments until the transducer appears to be well centered in its motion. It is not necessary to write the file each time a new value is tried. However, when optimal centering is achieved, write the file to retain the final value.
- 4) Attach the standoff and confirm that the “ticking” sound has ceased. If not, additional small adjustments are still needed. Make small numerical changes of 1-2 digits (either way) until ticking stops.

Note: If centering cannot be achieved in this manner, the probe may require service. Contact your sales representative.

Set Location

Opens a window from which a hospital, clinic, or other facility name may be entered. This name will be appended to all print-outs.

Labels On/Off

Unchecking this box will disable all labels normally present on the main imaging window. These labels will also be omitted from all printouts.

Tool Tips On/Off

Tool Tips provide instructions to the user for most controls. A Tool Tip window will pop up when the pointer is hovered over a control for one second.

To disable Tool Tips, uncheck the box.

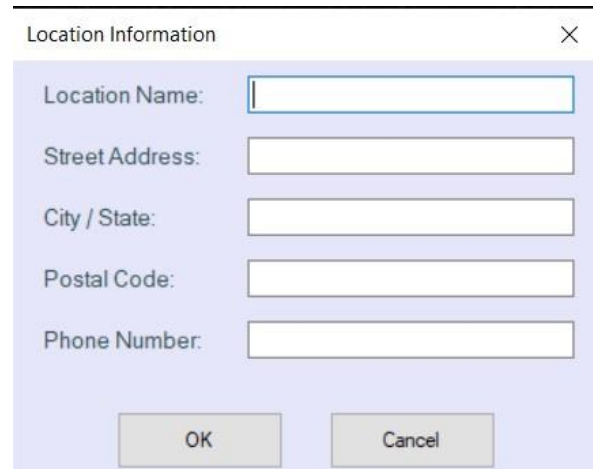


Figure 11. Hospital, clinic, office configuration window.

Restore IntelPPM

IntelPPM is a Windows device communication driver that if assigned a wrong value in the Registry may cause UltraView XL to not run correctly (USB Communication). Checking this box allows UltraView XL to check this value and adjust to optimum value.

Set Debug Folder

The Debug.txt file is an UltraView XL program file that is used for debugging program in the rare case of a system error. Checking this box allows UltraView to write the Debug file to the specified location. It is recommended to have this box checked as default. The Set Debug Folder button allows User to customize where the Debug.txt file is written.

Enter Service Mode

This button is to be used by Technical Support to enter into Hardware Configuration and change Probe Data Settings. Password Required.

Using the C1000 Series Probes

The C1000 series probes are intended for imaging the vitreous, retina, and orbit regions of the eye. These probes are available in three frequencies:

1. 10MHz: A general purpose probe suitable for the entire posterior segment of the eye and orbit.
2. 12MHz: A slightly higher frequency probe with superior resolution, but slightly less sensitivity than the 10MHz probe. It is best suited to examining the posterior 1/2 of the eye, especially peri retinal structures.
3. 20MHz: A probe with high axial resolution and lateral resolution, but significantly less sensitivity. It is best suited to retina examinations.

Handling Instructions

All probes must be handled with care. They especially must not be dropped on hard surfaces or be allowed to strike hard surfaces. If a probe is dropped, it may damage the internal workings of the probe, rendering it unusable until it has been repaired. Repair must be performed by authorized personnel, only.

If a probe is dropped, it is best to immediately test it for proper operation by attempting to scan with it on the ultrasound system. If the image is sharp and clear, the frame rates are normal, spatial geometry is correct, and there is no interruption of image acquisition, the operator may be reasonably assured that no damage has been done.

Avoid scratching the probe window, (i.e., the surface at the opposite end from the probe connector). This is the acoustic window through which the sound energy travels. Damaging this window may cause the device to image improperly. Deep gouges or cracks in the window may result in fluid leakage from the inside of the probe. This fluid is harmless to the user and patient; however, the probe must be repaired should a fluid leak occur. Failure to repair the probe can lead to damage to the internal workings of the probe (from loss of lubricating fluid).

Connecting the Probe to the Probe Cable

When connecting the probe to the probe cable, align the red dot on the probe cable connector with the scan plane indicator of the probe. With only slight adjustment, the connector should slide into the probe rear connector. Careful mating of these connectors should result in thousands of trouble-free connections. However, if the connectors do not mate after applying only moderate force, check that the pins of the probe connector are not bent. If bent pins are observed, call your authorized service agent for repair.

Cleaning and Disinfecting the C1000 Series Probes

Each of the C1000 probes is detachable from the probe cable, hermetically sealed, and can be vigorously cleaned and disinfected. If necessary, the entire probe may be immersed in disinfecting solution. However, this should only be done when the entire probe has been contaminated. When that is not the case, then it should only be necessary to immerse the portion of the probe that has been in contact with the patient, as follows:

1. Immerse the probe tip and approximately 2cm of the probe cover in either:
 - a. Cidex solution for 20 minutes, followed by a rinse of ethyl alcohol,
OR
 - b. Hydrogen Peroxide Solution 6% weight/weight (w/w) for ten minutes,
OR
 - c. Hygeol 1-20 (0.2% Sodium Hypochlorite and distilled water) for ten minutes,
OR
 - d. a solution of 0.6% Sodium Hypochlorite and distilled water for five minutes
2. For all of the above methods, rinse thoroughly with distilled water.
3. Wipe dry with a soft cloth.

Using the C1500 Series Probe (UBM)

The C1500 series probe is intended for imaging the anterior segment of the eye or similar shallow structures requiring high resolution and low tissue penetration except as noted (PN 190160). Three transducer frequencies are available, as follows:

1. 35MHz (PN: C190200): A good general purpose transducer for interrogating the entire anterior segment, including structures posterior to the iris. The best focus is 12-14mm from the transducer surface.
2. 50MHz (PN: C190210): A higher frequency transducer with superior resolution, but slightly less sensitivity than the 35MHz transducer. It is well suited to examinations related to glaucoma. The best focus is 12-14mm from the transducer surface.
3. 20MHz (PN: C190160): A transducer of lower frequency and (relatively) high sensitivity. It is best suited to retina examinations. The best focus is 20-30mm from the transducer surface. **A stand-off (nosepiece) is required when using this transducer for imaging the posterior segment of the eye. Contact your distributor for further information.**

Handling Instructions

All probes must be handled with care. They especially must not be dropped on hard surfaces or be allowed to strike hard surfaces. If a probe is dropped, it may damage the internal workings of the probe, rendering it unusable until it has been repaired. Repair must be performed by authorized personnel, only.

If a probe is dropped, it is best to immediately test it for proper operation by attempting to scan with it on the ultrasound system. If the image is sharp and clear, the frame rates are normal, spatial geometry is correct, and there is no interruption of image acquisition, the operator may be reasonably assured that no damage has been done.

The C1500 series probe is equipped with a protective cap, designed to shield the underlying rubber membrane from damage. Special care must be exercised when this cap is removed in order to avoid damage. Breaching of this membrane will result in leaking of the probe's internal lubrication fluid. This fluid is not harmful to either the operator or the patient. Operating the probe with a damaged, leaking membrane, however, may result in damage to the internal workings of the probe. If a leak is seen, do not use the probe and call your authorized service agent.

Connecting the Probe to the Probe Cable

When connecting the probe to the probe cable, align the red dot on the female probe cable connector with the scan plane indicator of the probe. With only slight adjustment, the connector should slide into the probe rear male connector. Careful mating of these connectors should result in thousands of trouble-free connections. However, if the connectors do not mate after applying only moderate force, check that the pins of the probe connector are not bent. If bent pins are observed, call your authorized service agent for repair.

Connecting/Disconnecting the 35 MHz or 50 MHz Transducer

The transducers for the C1500 series probe attach to the probe via a SMC connector. They are easily attached and detached with only light force.

1. To mount the transducer:
 - a. Check that a rubber O-Ring is present on the transducer - it is located just above the threads on the transducer. If an O-Ring is absent, use one of the spare O-Rings shipped with the transducer.
 - b. Using your fingers, only, mount and screw (clockwise) the transducer onto the probe.
 - c. A slight increase in resistance will be felt when the O-Ring makes contact with the probe's transducer connector. When the O-Ring makes this contact, tighten an additional $\frac{1}{4}$ turn. **DO NOT OVER TIGHTEN!**
2. To un-mount the transducer, only light counter-clockwise turning force should be required.

Warning: Never use any kind of tool to either tighten or loosen the transducer. Using a tool may damage the gold plating of the transducer or the transducer stalk on the probe.

Using the Stand-off (aka: Nosepiece) and Related Components

The Standoff, or “nosepiece”, is used to convert the water-path probe to a contact scanning probe (i.e., one not needing a water cup or bath to scan in). Being able to use this probe in this manner may be useful for some applications. The nosepiece and related accessories create a sealed water chamber through which the transducer transmits acoustic energy into the tissue. Using water and a thin membrane insure good acoustic matching to most tissues and causes only very minor attenuation of the sound wave.

Nosepiece Selection

Four lengths of nosepiece are available, each enabling its own focus position. **Focal distance is referenced from the membrane film** and can be found engraved on the nosepiece. The available focus distances are:

1. 1.5 - 2.5 mm (pn: 189240)
2. 3.0 - 4.0 mm (pn: 182930)
3. 4.5 - 5.5 mm (pn: 182920)
4. 6.0 - 7.0 mm (pn: 182910)

To select the proper nosepiece, first determine the estimated distance to the scanning target from the probe membrane. Now select the nosepiece with a focus distance that most closely matches the target depth.

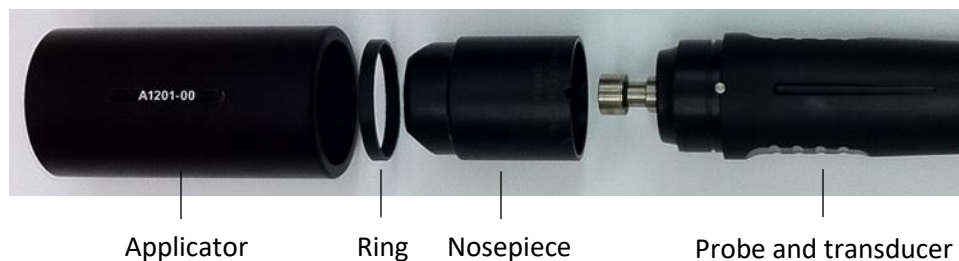


Figure 12. Expanded view of components used when attaching a nosepiece and membrane.

Attaching the Nosepiece

To attach the nosepiece and prepare it for scanning, follow these procedures:

1. Remove the transducer and then the protective cap from the probe. Reattach the transducer.
2. Locate and have available the chosen nosepiece, a small quantity of deionized or distilled water (e.g., in a needleless syringe), one membrane, the ring seal and the ring applicator.
3. Note that the nosepiece has a small notch on one end. When the nosepiece is seated onto the probe housing, this notch must be aligned with the short pin found on the probe. Now position the notched end of the nosepiece over the transducer and slide the nosepiece onto the probe housing. When finished, the pin should be fully seated in the notch (see Illustration at right).
4. Hold the probe upright (nosepiece up) and completely fill the nosepiece cavity with deionized or distilled water.



Figure 13. Nosepiece properly positioned on locating pin.

WARNING: Never use tap water to fill the nosepiece as impurities and minerals in tap water will damage the transducer.

5. Roughly center and place the membrane over the nosepiece opening. There should be no air, or only a very small bubble within the nosepiece at this time.
6. Using your fingers, center the ring over the membrane and press ring onto the nosepiece until it seats and captures the membrane on the nosepiece (see illustration at right).
7. Using the flat end of the applicator (not the notched end), place the applicator over the ring and firmly press the ring onto the nosepiece until it is fully seated against the shoulder of the nosepiece.
8. The UltraView XL system defaults to a scan angle appropriate for using the nosepiece. If the UBM Nosepiece button at right has been deactivated (for a wider scan angle), reactivate the button to enable the smaller scan angle.

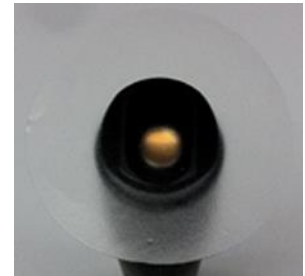


Figure 14. Membrane positioned over water-filled nosepiece.

Warning: Using the nosepiece with the wide scan angle will cause the transducer to knock against the sides of the nosepiece and may damage the transducer. See Troubleshooting section, below.

High-frequency, thin-film transducers are fragile. For maximum transducer life, NEVER LEAVE WATER IN THE NOSEPIECE OVERNIGHT OR FOR SIMILAR LONG PERIODS OF TIME.

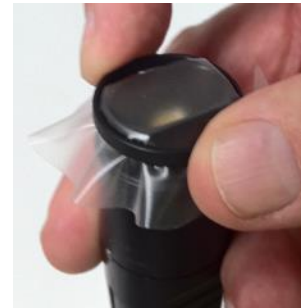


Figure 15. Hand-positioning the ring onto the nosepiece, capturing the membrane.

Removing the Nosepiece.

1. Grip the ring and carefully back it off the nosepiece.
2. Remove the membrane and empty the nosepiece of water.
3. Firmly grip the nosepiece and rock it back and forth while separating it from the probe housing. If the probe is wet and difficult to grasp, using a latex glove is helpful.

Troubleshooting

1. Bubbles under the membrane: Small bubbles are not generally a problem if the probe is used transducer-down. In this position, the bubble will migrate away from the window. Large bubbles should be avoided.
2. The transducer hits the wall of the standoff: Check that the Stand-off attachment button is not activated. If the problem persists, see System Configuration > HardwareSetup > DisplayOffset > UBM Probe (page 16) for an explanation of how to eliminate this problem by centering the motion of the transducer.



Figure 16. A fully seated film membrane on nosepiece.

Disinfecting the C1500 Series Probe

The following process is recommended to disinfect the CLI Series 1500 Probe.

1. Immerse the transducer and the probe tip, including rubber membrane, in
 - a. Cidex solution for 20 minutes, followed by a rinse of ethyl alcohol,
OR
 - b. Hydrogen Peroxide Solution 6% w/w for ten minutes,
OR
 - c. Hygeol 1-20 (0.2% Sodium Hypochlorite and distilled water) for ten minutes,
OR
 - d. a solution of 0.6% Sodium Hypochlorite and distilled water for five minutes.

Then (for all methods), rinse thoroughly with distilled water. Dab dry with soft cloth.



CAUTION: 0.6% solution of Sodium Hypochlorite and distilled water (“d” above) is the most severe disinfection method. Using this method will shorten the useful life of the transducer (but not the probe) and is only recommended when other methods are unavailable.

2. Store probe and transducer in an appropriate, clean container to be ready for next use.
3. Sterile saline solution or sterile distilled water may be used as a water path when performing eye scans.

If necessary, the transducer may be detached from the probe and the two disinfected separately in either of the above solutions. If this done, take care that the SMC connector of the probe and transducer are thoroughly dried before remounting the transducer to the probe; blow dry if necessary.



The internal surfaces of the transducer connections must be free of moisture prior to re-assembly. Metal surfaces may be gold-plated or titanium.



OTHER WARNINGS!

Testing has shown the following to be harmful to the probe and transducer.

1. Sodium Hypochlorite (i.e., bleach)

- ! • Diluted (0.6% concentrations) and undiluted bleach solutions attack the gold plated surfaces of the probe and, once a breach has been made, the sensitivity of the transducer is diminished (proportional to the loss of gold). Therefore, cleaning/disinfection methods employing 0.6% concentrations, or more, of Sodium Hypochlorite should be avoided when possible.

2. Tap Water

- ! • Contaminants in common tap water have been found to attack and corrode the metal surfaces of the probe and transducer. The use of tap water, rather than sterile deionized or distilled water is, therefore, contraindicated. Should the probe surfaces be soaked in or rinsed with tap water (e.g., accidentally), rinse with distilled or deionized water and lightly wipe the surfaces clean of any residues.

3. Abrasives

- ! • The gold plating on the transducer surface is very thin and cannot be thickened without negatively affecting transducer frequency and performance. Therefore, extreme care must be taken to avoid scratching or otherwise damaging the gold surface of the film. Never use any kind of abrasive cloth or tissue when wiping the transducer surface. Camera lens cleaning papers or soft gauze may be used. Apply no more force than is needed when wiping the transducer surfaces. Minor scratches to the gold surface will not damage performance. Contact the manufacturer only if the gold plating is breached and a silver color is seen in place of the gold.

Accessories for the C1500 Series Probe

P/N	DISCRIPTION
189240	Stand-Off, 1.5 – 2.5 mm, Water Path Probe
189230	Stand-Off, 3.0 – 4.0 mm, Water Path Probe
189220	Stand-Off, 4.5 – 5.5 mm, Water Path Probe
189210	Stand-Off, 6.0 – 7.0 mm, Water Path Probe

The stand-off is an attachment for the CLI 1500 series probe (water-path/UBM probe). It is used to create a **sealed water chamber** between the transducer and the eye surface. Use the standoff to convert the water-path probe to a contact scanning probe.

To use the stand-off, see the instructions in Using the Standoff and Related Components within this IFU. For convenience, a short description follows: mount the stand-off to the scanning end of the probe, fill the stand-off with distilled or deionized water, place membrane film (C189060) over nosepiece opening, use applicator (A1201-00) to apply ring seal (189055) to nosepiece.

The description for each stand-off specifies the location of the focal point of the transducer **beyond the contact membrane**. To decide which to use, the operator should determine how far the target is into the eye and choose the stand-off accordingly. For example, if the target is the ciliary body, it is approximately 2.0 mm from the scleral surface. Therefore, 189240 should be used.

A1201-00	Membrane Ring Applicator, Water Path Probe This item is used to apply O-ring 189055 (below) and is required in order to use any of the stand-offs. Only one is needed, even if all four stand-offs are bought. Five O-rings (189055) are included in the applicator.
C189060	Film, Qty 50, RB820, 3 Mil, 2" Diameter This membrane film is applied over the stand-off opening and is fixed to the nosepiece using the ring (189055). Film comes in packs of 50 pieces. Non-sterile.
C323000	Kit, O-Ring, 0.811 X 0.036 (replacement or spare O-rings for C1500 series probes). These provide a water seal, nosepiece-to-probe. Order as needed.
189055	Ring, Stand-Off, 0.972" I.D Diameter Five are included in A1201-00, so this pn is only for spares in the event all of the supplied O-rings are lost/damaged.

Note: When ordering Stand-offs, it is necessary to already have (or also order) one each of A1201-00 and C189060. When ordering multiple stand-offs, it is only necessary to order (or already have) one each of these items.

IFU SUPPLEMENT

Imaging System with Battery Pack (PN C92-005)

Summary Description



Figure 17. System example 1: All-in-one PC with external imaging electronics connected via USB. Requires AC-mains power.

This version of imaging electronics employs a lithium-ion battery pack to supply 6-7 hours of AC mains-free operation (see below). The product supports all CLI ophthalmic probes. There is no sacrifice in performance in order to accommodate battery operation. The product may also be used while connected to AC mains power.

Battery Performance

The battery pack consists of three 3.6V, 3350mAh (nominal) lithium-ion batteries which supply a total of 10.8 Volts (nominal). The chart below characterizes battery pack performance over time (full discharge/recharge cycles). This represents a worst-case scenario since most battery-only power sessions will not deplete the battery completely and partial depletions improve the performance profile described in the graph.

Testing with a C1000 series probe (10MHz, 12MHz, or 20MHz) indicates that the battery pack will power the probe *continuously* for up to five (5) hours for the first 300 *full discharge cycles*. Using a more realistic scenario in which the probe is acquiring data 15-25% of power ON time, battery power is then estimated to provide 6-7 hours

of use for the first 300 cycles and approximately 4+ hours use upon the 500th cycle. Again, partial discharge cycles improve the performance profile of the battery pack. Actual performance may vary.



Figure 2. System example 2: Laptop with external imaging electronics. This configuration can operate independent of AC-Mains power.

If used with a battery powered PC host (e.g., laptop or tablet computer), operation of the imaging engine and probe does not deplete the batteries of the PC host, thereby extending Mains-free operation of the entire *imaging system*.

TYPICAL CYCLE CHARACTERISTICS

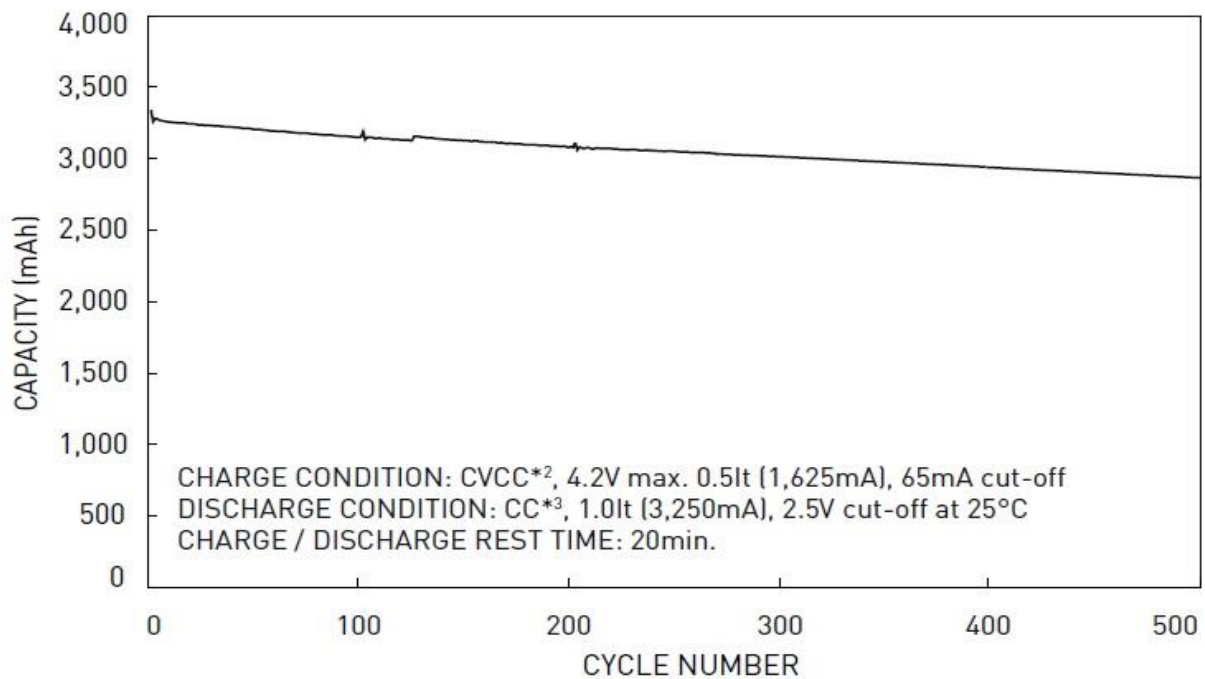


Figure 3. Discharge capacity of battery pack. Capacity remains stable over 500 full discharge cycles. Partial discharge cycles reduce the rate of decline in discharge capacity (Source: Panasonic).

Charging times consistently range near 3.0 hours following full discharge. Partial discharges will result in shorter recharge times. Charging is accomplished using the supplied AC/DC 20V power supply. Charging via the 5V USB connection is not supported.

Battery charge status is indicated by a series of LED lights on the power end-plate (see figure 4). Charge status is accessed by pressing the charge status button (labelled “PUSH” in the illustration below). Each LED represents approximately one hour of battery charge. When approximately ½ hour of battery charge remains, the final LED will blink.



Figure 4. Power end-plate containing ON/OFF switch, 12V IN, USB port, and charge status LEDs. LED colors are for reference, only, and are simulated.

IMPORTANT NOTICE: LEAVING THE BATTERY PACK IN A FULLY DISCHARGED STATE FOR AN EXTENDED PERIOD OF TIME MAY RESULT IN BATTERY FAILURE.

ALWAYS RE-CHARGE THE BATTERY PACK WITHIN 10 DAYS OF A FULL DISCHARGE. FAILURE TO DO SO MAY RENDER THE BATTERY PACK UNUSABLE. IF THIS SHOULD OCCUR (BATTERY PACK FAILURE) THE AC-MAINS WILL CONTINUE TO POWER THE SYSTEM, BUT THE UNIT MUST BE RETURNED TO THE MANUFACTURER FOR BATTERY PACK REPLACEMENT BEFORE MAINS-FREE OPERATION CAN BE RESTORED.

IF THE UNIT MUST BE STORED FOR AN EXTENDED PERIOD OF TIME, FIRST CHARGE THE BATTERIES FULLY, THEN PLACE IT IN STORAGE. CHECK BATTERIES EVERY SIX MONTHS AND RE-CHARGE AS NEEDED.

Imaging Features

When equipped with the appropriate software, probes and accessories, C92-005 is a full-function imaging system, including:

- 10MHz, 12MHz, and 20MHz vitreo-retinal probe compatibility
- 35/50MHz UBM probe compatibility
- B-mode, and A/B-mode operation

Input/Output

- B-mode ultrasound pulse/echo
- 12V IN (the supplied AC/DC power converter will supply up to 20V for rapid recharging of batteries)
- USB 2.0

Battery Replacement

Due to regulatory restrictions, should the batteries require replacement, the enclosure must be returned to the manufacturer for battery pack replacement and calibration.

Safety

The battery pack has been certified to United Nations testing protocol (UN/DOT38.3). A copy of the protocol may be seen at this link:

http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_D4B2D17039E706213B36C1B309D41DCF8B4A0200/filename/UN_Test_Manual_Lithium_Battery_Requirements.pdf).

Physical

Enclosure dimensions: 7.25in/18.4cm (L) x 3.25in/8.3cm (W) x 1.25in/3.2cm (H)
Weight: 1.25 lbs/0.57 kg



Figure 18. Enclosure. Images not to scale.