



Catalyst™ XL Ultrasound System

Version 1.4.4

User Manual

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CAUTIONS AND WARNINGS

READ CAREFULLY BEFORE USE!

Prescription Device Statement

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.

Appropriate Specialists

WARNING: The Catalyst XL system should only be used on the request by and under the direction of a licensed physician specialist.

System Use

WARNING: CATALYST SOFTWARE IS SUPPLIED ON EQUIPMENT PROVIDED BY HALO MEDICAL TECHNOLOGIES ONLY. CATALYST SOFTWARE SHOULD NEVER BE INSTALLED AND USED ON OTHER COMPUTERS OR MEDICAL EQUIPMENT SUPPLIED BY OTHER VENDORS. All equipment provided by Halo Medical Technologies is labeled with name, part number, and serial number. If there is a question about the authenticity of the equipment or software, DO NOT USE IT and contact Halo Medical Technologies Customer Service at (877) 686-8149.

WARNING: Only trained technicians should operate this device. The operator should read the User Manual entirely and refer to any additional training materials before using the device.

WARNING: Before the patient exam, inspect the USB Ultrasound Probe System for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. If physical damage exists, do not use for patient evaluation and call Halo Medical Technologies for servicing.

WARNING: Always use the transducer probe appropriate for the exam. Connect only one probe to the system at a time.

WARNING: Use the MidCRYSTL™ and HALO™ Probes with the Halo Medical Technologies Catalyst system ONLY.

WARNING: Catalyst software is warranted to work with MidCRYSTL and HALO probes ONLY.

WARNING: Always disconnect the probe from the system before maintenance or cleaning.

WARNING: The USB cable is an integral part of the probe assembly. DO NOT ATTEMPT to disconnect the USB cable from the probe.

WARNING: Keep the cable USB connector end dry at all times. Do not immerse the probe cable USB connector end in water. Make sure the USB connector is dry before connecting it to the Catalyst system.

WARNING: DO NOT ATTEMPT TO OPEN OR REPAIR the system or probes. ONLY trained Halo Medical Technologies technicians may service these devices.

WARNING: Any additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO Standard (e.g., IEC 60950 for Data Processing Equipment). Any and all configurations shall comply with the requirements for Medical Electrical Systems. Anyone connecting supplementary equipment to Medical Electrical Equipment configures a Medical System and is therefore responsible that the system complies with the requirements for Medical Electrical Systems.

CAUTION: Portable and mobile RF communications equipment may affect the normal function of the MidCRYSTL and HALO ultrasound probes.

CAUTION: Be careful when handling the USB probe. If the USB probe dropped on a hard surface it can be damaged.

CAUTION: Do not store the probe in the shipping case. It may become a source of infection.

To prevent damage to the probe, do not store in areas where it might be exposed to:

- Excessive vibration
- Excessive dust & dirt

Store the probe under the following ambient conditions:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Indications for Use

“Catalyst” is a diagnostic ultrasound system designed to be used for investigating disorders of the pelvic floor. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. MidCRYSTL and HALO probes allow for ultrasonography of the following: 1) on the surface of the perineum and/or abdomen, 2) endocavity, by inserting the endovaginal probe into the vagina, and 3) endocavity, by inserting the endoanal probe into the anal canal.

Target Populations

“**MidCRYSTL™ Endoanal and or Transrectal Probe**” (part number HMT-MCP) is a 360° ultrasound probe designed to be inserted into a patient's anal canal to investigate symptoms indicating the possibility of a defecation disorder as well as benign and malignant disease. It contains an ultrasonographic crystal which records images of the underlying muscle and tissue of the anal canal.

“**HALO™ Endovaginal Probe**” (part number HMT-VP) is a 360° ultrasound probe designed to be inserted into a patient's vagina to investigate symptoms in the pelvis. It contains an ultrasonographic crystal which records images of the underlying muscle and tissue.

“**HALO™ Surface/Curved Array Probe**” (part number HMT-SP) is a surface probe designed to be used superficially on intact skin, either transperineally or transabdominally, to investigate symptoms in the pelvic region. It contains an ultrasonographic crystal which records images of the underlying muscle and tissue.

The above probes are designed specifically for use with the HALO line of Catalyst™ Diagnostic Ultrasound System software (for full list of Halo Medical Technologies product part numbers and descriptions, see Appendix F):

- “**CATALYST XL System Software**” (part number CATXLP)
- “**CATALYST L System Software**” (part number CATLP)
- “**CATALYST Envoy System Software**” (part number CATEP)

Contraindications

The safety of the individual being tested is the sole responsibility of the physician performing the diagnostic study. The system is contraindicated for any patient with one or more of the following conditions:

- The system is not indicated for use on a patient who is pregnant
- Uncooperative patients
- Patients with GI bleeding
- Patients who are comatose or incapable of providing informed consent for the procedure
- For endoanal applications: It is inappropriate to insert the probe and perform an endoanal ultrasound procedure on individuals who have a degree of anal stenosis and/or have an anal canal deemed too narrow or short for its insertion, as is typical of infants

Safety Information

ALARA Declaration

Ultrasound is considered safe at low clinical levels for short exposure, as is typical of examinations performed with Catalyst ultrasound systems. At high levels and longer exposures, however, its safety is not completely understood. For this reason, always exercise caution when exposing patient to ultrasound. Always use the lowest transit power levels and minimize the time of exposure.

The potential benefits and risks of each examination should be considered. The *as low as reasonably achievable* (ALARA) principle should be observed when adjusting controls that affect the acoustic output and by considering transducer dwell times.

Further details on ALARA may be found in the AIUM publication "Medical Ultrasound Safety, Third Edition." (Publication available through online store at <http://www.aium.org/>)

Probe Cover Latex Warning

WARNING: To prevent infection and cross contamination between patients, always use a probe cover (sheath) during endocavity (endovaginal or endoanal) examinations. Use a HALO Medical Technologies non-latex probe cover (part number HMT-PC) or equivalent to avoid common and potentially dangerous, allergic reactions to latex.

Other probe covers may contain latex, natural rubber and talc, which may cause allergic reactions. For more information, see the Food and Drug Administration, "Allergic Reactions to Latex Containing Medical Devices," *FDA Medical Alert*, Pub. No. MDA91-1 (March 29, 1991).

Infection Control

WARNING: Follow all infection control policies/procedures established within the clinical institution to prevent any cross-contamination. Users must provide the highest level of infection control for patients, for co-workers, and for themselves at all times.

WARNING: Probes must be cleaned and disinfected after each use.

WARNING: The type of tissue contacted by the probe during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection. Be sure to follow the manufacturer's instructions.

WARNING: Using a non-recommended disinfection solution, incorrect solution strength, or immersing a probe deeper or for a period longer than recommended can damage or discolor the probe and will void the probe warranty.

WARNING: Do not immerse probes longer than one hour. Probes may be damaged by longer immersion times. Do not use heat or radiation to sterilize. This will permanently damage the probe and void the warranty.

WARNING: Disinfect probes using only liquid solutions. Using autoclave, gas (EtO), or other non-Interson-approved methods will damage the probe and void the warranty.

WARNING: Do not use a surgeon's brush when cleaning probes; even the use of soft brushes can damage the probe.

Cyber-Security

The Catalyst XL system has been designed with a closed architecture structure as a stand-alone device. If the system is connected to a network, the end user is responsible for all Cybersecurity aspects for information security, including but not limited to: confidentiality, integrity, availability, and accountability.

MidCRYSTL and HALO Probes Instructions for Preparation and Use

Please refer to separate "Halo Medical Technologies Ultrasound Probes Instructions for Preparation and Use" Document.

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I. INTRODUCTION

The “Catalyst” Ultrasound System is designed for aiding in the investigation of pelvic floor conditions. The system needs very little assembly prior to use. The specialized application software, as well as the additional Microsoft Office programs, are all pre-installed and tested on each system prior to delivery.

ACE Certification

Each probe goes through ACE™ (Automated Calibration Enhancement) Certification with the Catalyst software for optimal visual acuity at factory settings. This means the visual controls rarely if ever need to be adjusted during the endoanal examination.

System Components

The Catalyst system consists of the following:

- 1) Catalyst software pre-installed on a laptop or All-in-One Computer on Mobile Computer Cart with Microsoft Windows 8 Operating System, with separate mouse and power cable included
- 2) Optional MidCRYSTL endoanal ultrasound probe
- 2) Optional HALO endovaginal ultrasound probe
- 3) Optional HALO surface ultrasound probe
- 4) Optional wireless printer, if ordered

Assembly

For laptop computer configuration, plug the computer into a standard electrical outlet and attach separate mouse into open USB port on the computer. If a Bluetooth printer has been supplied as part of the purchase, it will be configured to operate with the Catalyst system after unpacking and quick assembly. (For All-in-One Cart configuration, see separate assembly instructions provided with cart.)

Starting the System

Plug in the selected HALO probe to the computer before opening the Catalyst software. Once the on-screen icons are in view, click on the **Halo** icon to open the on-screen Halo page. Locate the **Catalyst logo** icon and click on it to open Catalyst program.

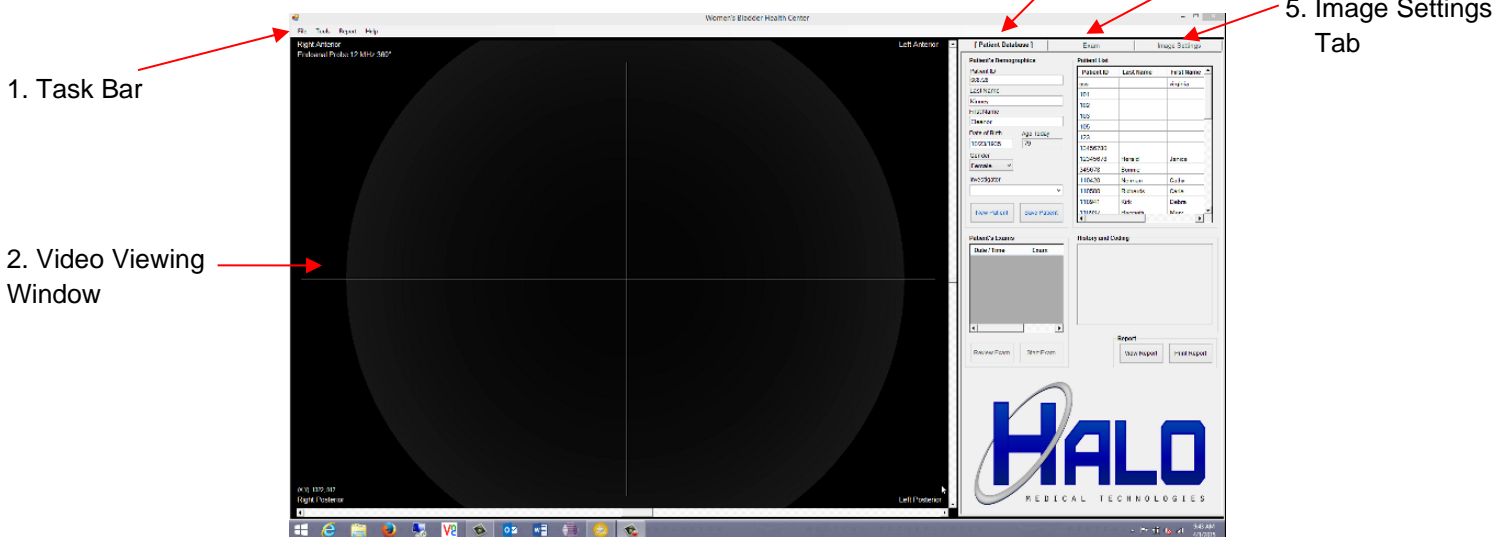
NOTE: Mouse Recommendation

Both the built-in thumb pad (laptop version) and the separate mouse will work to maneuver the screen cursor. However, it is recommended to use the separate mouse during examinations as the mouse takes less effort to precisely maneuver the cursor into position.

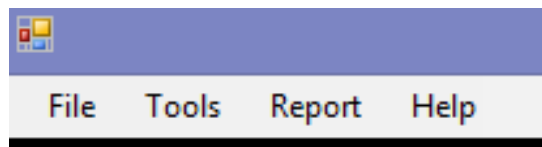
II. SCREEN SECTIONS

The Catalyst user interface is divided into five sections:

1. Task Bar, with pull down commands (always present)
2. Video Viewing Window (always present)
3. Patient Database Tab
4. Exam Tab
5. Image Settings Tab



III. TASK BAR



The Task Bar is always present at the top of the screen. It contains multiple drop-down menus for operating the Catalyst program.

File

Used to close the Catalyst program.

Tools

Contains several selections used to provide additional visual aids and controls while an exam is in progress. Selections are: Image Rotation, Show Diagonal Quadrants, Show Crosshairs, Scan Progress Bar Settings, Probe Button Enable, Puborectalis Outline Enable, Options, and Utilities.

Image Rotation

Allows recorded video display in video viewing window to be rotated 0, 90, 180, or 270 degrees. This can be useful if the video was recorded with the wrong orientation.

Show Diagonal Quadrants (shortcut: Ctl+Q)

When enabled, displays green diagonal crosshairs separating the four quadrants: Proximal, Left Lateral, Anterior, and Right Lateral. The program uses these quadrants to automatically report the locations of any measurement or annotation placed on an image. The Diagonal Quadrants will only be viewed when using the Exam tab and the probe is in scan or freeze mode. The Diagonal Quadrants are not burned into a recorded video image, so can be “turned off” when reviewing a video, if desired.

Show Crosshairs

When enabled, displays vertical and horizontal crosshairs to help orient image. Crosshairs can be “turned off” any time the video viewing window scrollbar is active. The Crosshairs are not burned into a recorded video image, so can be “turned off” when reviewing a video if desired, for example, when marking an image.

Scan Progress Bar Settings

Selectable icon and settings that indicate the probe's crystal is spinning (scanning). Choose between several icon styles, speeds, and sizes. The icons will only be visible when the probe is scanning.

Probe Button Enable

When enabled, pushing the button on the handle will alternately scan and freeze the image. When disabled (no check by command), the button is turned off. When off, scanning and freezing can only be performed using the on-screen “Scan/Freeze” button in the Exam Tab or by using the keyboard shortcut keys. (See Section XIII.)

Puborectalis Outline Enable

When enabled, the Puborectalis muscle outline will appear as a guide when using the MidCrystl™ endoanal ultrasound probe. It will disappear when either an image is frozen or when a video recording is started.

Options

Options provides four selections: 1) Patient name on image; 2) Puborectalis Outline Show/Hide on Image Right Click; 3) Enable Visual Styles, and 4) Area Measurement Settings. Area Measurement Settings allows you to select either Polynomial Interpolation (default) or Linear Interpolation along with graphic preferences for line style and color.

Utilities

Utilities is a tool used at the direction of a Halo Customer Service Engineer.

Report

Drop down list with the following options: Print, Preview, View Reports, Export Format and Path, and Facility Name. The Export Format and Path can be used to push a PDF report to a clinic's EMR system. Please contact Halo Customer Service for assistance.

Help

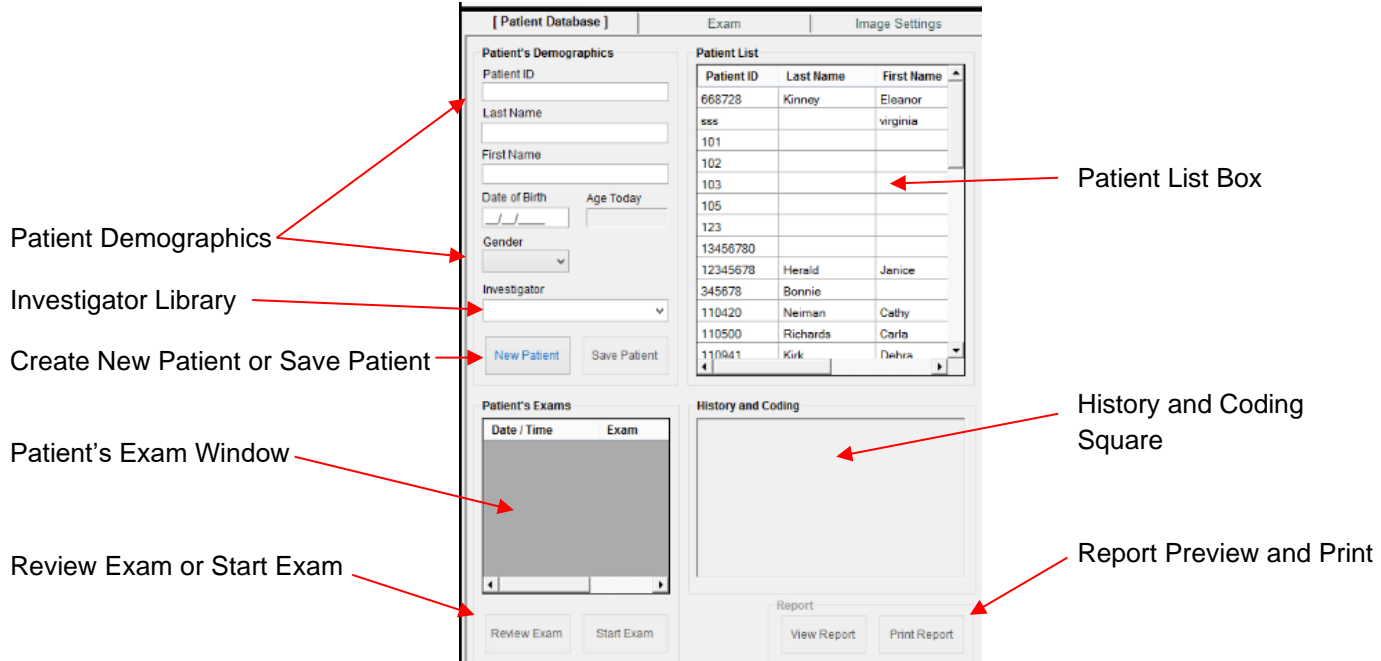
Provides information on software version installed for easy reference by Halo Customer Service.

IV. VIDEO VIEWING WINDOW

The video viewing window is always present on the left half of screen. Image selections, measurements, and annotations are performed within the window. Vertical crosshairs aid probe orientation. Quadrants are labeled: Right Anterior, Left Anterior, Right Posterior, and Left Posterior. The probe and MHz are indicated in the upper lefthand corner. Optionally, the patient's name can be displayed on the image in the lower lefthand corner.

V. PATIENT DATABASE TAB

The Patient Database Tab is the first of three tabs, and the start screen for the program. Use this tab to enter and manage patient information, search the patient database, and view or print reports.



Entering New Patient

Click the "New Patient" button.

Enter a Patient ID. *This is the only mandatory information required before performing an examination.*

Enter additional demographics if desired, then click "Save Patient." The "Age Today" window is automatically calculated once Date of Birth is entered.

Creating Investigator Library

If desired, create a list of selectable investigators to easily populate the investigator field. Right click in the Investigator box to bring up editor. Type-in the list of investigators' names. Click Save. To select an investigator, click on the down arrow (v) in the Investigator box and select desired name.

History and Coding Square

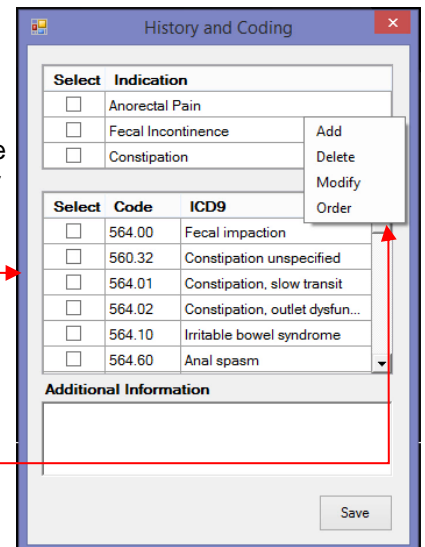
This section is only active AFTER patient data has been SAVED by clicking "Save Patient." The History and Coding Square allows general information about the patient's condition to be entered, along with billing information. This data will appear at the top of the patient report with the patient demographics. Data can be entered, added to, or edited in this square any time *after the patient data has been saved*.

Right-click anywhere in History and Coding Square and this box will appear:

After right-clicking in the Square, a box will appear with three windows:

1) pre-installed indication selections, 2) Pre-installed, ICD-9 Code selections, and 3) Additional Information text box. Check selections or type in text box.

It is possible to "Add, Delete, Modify, or Order" the pre-installed selections by right clicking within the Indication or ICD-9 Code windows.



Patient List Box

Each new patient is added to the Patient List. Patients are listed in the order of entry, with the newest patient listed at the top. By clicking on a column's heading (for example, "Last Name"), the list is rearranged in alphabetical or numerical order. By clicking on a column's heading again, the order will be reversed.

Reviewing the Patient List

Past patient information can be reviewed by clicking on the patient's name. Patient demographics, symptoms and exam history will populate the appropriate fields.

The screenshot shows the 'Patient Database' window with several tabs: 'Patient Database', 'Exam', and 'Image Settings'. The 'Patient Database' tab is active, displaying a 'Patient List' table and a 'Patient's Demographics' form.

Patient List Table:

Patient ID	Last Name	First Name
12345678	Herald	Janice
345678	Bonnie	
110420	Neiman	Cathy
110500	Richards	Celia
110941	Kirk	Debra
110937	Racciali	Mary
110935	Smith	June
110909	Parker	Debra
110897	Alameda	Rae
110896	Bowen	Abbey
110895	VonDuell	Helga
110891	Phalen	Jennifer
110880	D'Annunzio	Jacqueline

Patient's Demographics Form (for Patient ID 110941):

- Patient ID: 110941
- Last Name: Kirk
- First Name: Debra
- Date of Birth: 12/18/1946
- Age Today: 68
- Gender: Female
- Investigator: Jane Reed, MD

Patient's Exams 110941 Table:

Date / Time	Exam
09/24/2014 18:30	31

History and Coding 110941:

- Fecal Incontinence
- Radiation atrophy

Annotations:

- Click on patient name to retrieve information. (Points to 'Debra' in the Patient List)
- Patient information is displayed. (Points to the Patient's Demographics form)
- View or Print Report of previous exam(s). (Points to 'View Report' and 'Print Report' buttons)
- Review selected exam or start a new exam on the chosen patient. (Points to 'Review Exam' and 'Start Exam' buttons)
- List of saved exams, available for review. (Points to the Patient's Exams table)

Editing and Deleting Patient Information

To edit and/or delete the patient's demographics, right click on the patient's name and select "Initiate Edit" or "Delete Patient."

Patient's Exams Window – reviewing, deleting, and changing facility name

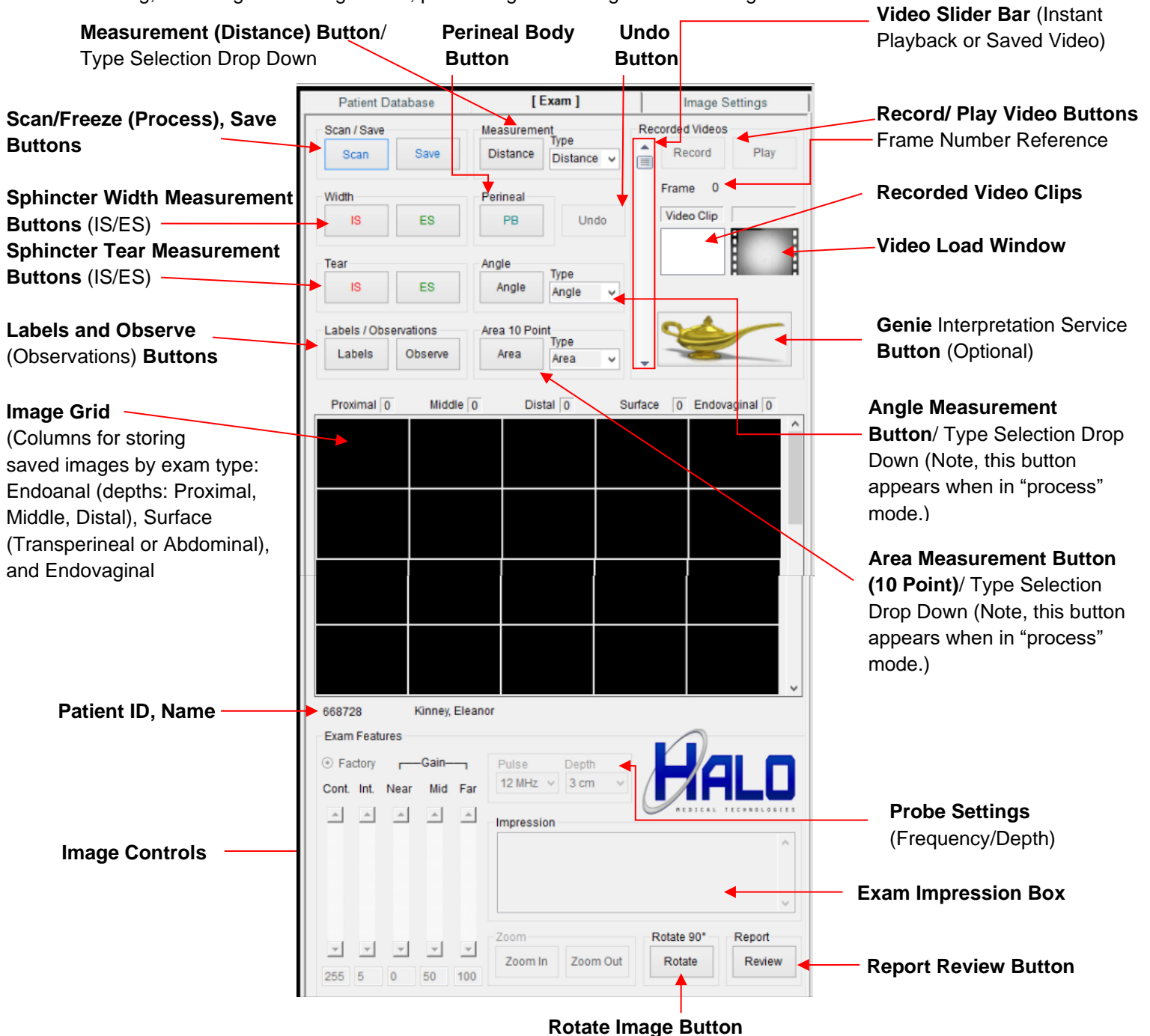
The Patient's Exams Window tracks multiple studies performed on the same patient. To see results of a past exam, click on the desired exam and then click "Review Exam." To delete a patient exam, right click on the highlight exam, and select delete. The Facility Name can also be changed by right clicking on a patient exam, if desired.

Starting an Exam (Moving to the Exam Tab)

After saving a new patient or selecting an existing patient from the database, the exam can be started. Simply click the "Start Exam" button or click on the "Exam" tab at the top of the screen.

VI. EXAM TAB

The Exam Tab provides all the tools for conducting and interpreting an exam, using one or more probes: scanning; recording and saving videos; processing and saving individual images.



Scan/Freeze/Process Button

The top button is "Scan/Freeze/Process". Click the "Scan" button to initiate a scan. Click the Scan button a second time to freeze the image. The button name will change to "Freeze," and a drop-down menu appears with selectable options that are specific for each type of probe:

- MidCrystl endoanal probe: depth selections are provided (proximal, middle, distal) which activate selectable, pre-installed observations for each depth and store each saved image in the appropriate column.
- Halo 90° endovaginal probe: endovaginal exam or introital (surface) exam
- Halo 360° endovaginal probe: endovaginal exam
- Halo surface probe: transperineal or abdominal exam

Once the depth or exam option is chosen, the menu box disappears, and the appropriate measurement and annotation buttons are activated. At this point, the image can be processed or simply saved by clicking the “Save” button. Saved images can be processed at any time.

When reviewing a saved video or saved exam, this button label changes to “Process,” with same functions for saving an image as in the “Scan/Freeze” mode.

Additional options in the dropdown menu are: Instant Playback, Resume Scan, or Cancel.

Instant Playback

“Instant Playback” allows a review of up to 60 seconds of past scanning. Use the Video Slider Bar to review the video. Note: this is not a permanently stored video. It is overwritten each time the scan button is clicked.

Resume Scan

To continue with the live scan after freezing an image, click “Resume Scan.” The Scan/Freeze button will change back to “Scan” and the on-screen image becomes live. If an image has not been saved, the system will ask, “Do you want to save image?” Click Yes or No.

Cancel

Clicking “Cancel” will simply reset the screen to the start position, without resuming scan.

Sphincter Width Measurement Buttons (IS/ES)

For endoanal ultrasound exams, these two buttons are used to measure the width of the internal sphincter (IS) and/or external sphincter (ES). Both the IS and ES buttons work the same way:

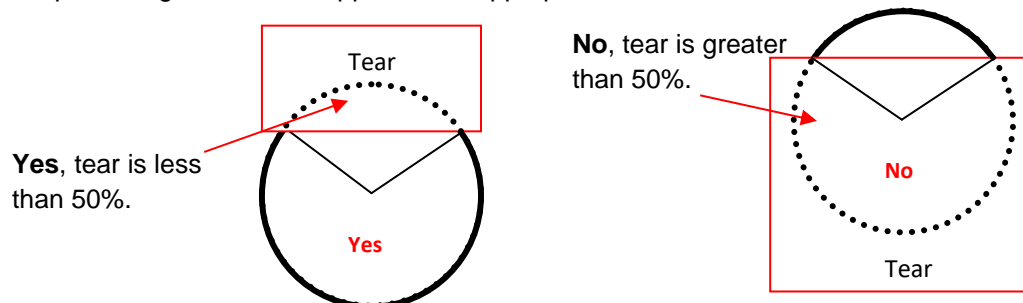
1. After freezing image, select appropriate depth. This activates the available measurement buttons.
2. Click the IS or ES width button.
3. In the video viewing window, place the cursor on the edge of the sphincter and click. It will leave a small white X.
4. Place the cursor on the opposite edge of the sphincter and click again.
5. As soon as the second X is placed, an arrow appears linking the two locations and providing a “Width” measurement with appropriate label and distance.
6. Continue with other measurements or annotations on the same image. Multiple measurements of the same type can be made without clicking the IS/ES Button again.
7. When done, click “Save” to save the image. A thumbnail of the image will appear in the image grid.

Sphincter Tear Measurement Buttons (IS/ES)

For endoanal ultrasound exams, these two buttons are used to measure the angle and % of a tear identified with the internal sphincter (IS) and/or external sphincter (ES). Both the IS and ES buttons work the same way:

1. After freezing image, select appropriate depth. This activates the available measurement buttons.
2. Click the IS or ES tear button.
3. In the video viewing window, place the cursor on the edge of the tear and click. It will leave a small white X.
4. Place the cursor on the opposite edge of the tear and click again.

- As soon as the second X is placed, an angle appears linking the two locations along with a pop-up box which asks if the tear is less than 50% of the entire sphincter. Click Yes or No. The degree and percentage of tear will appear, with appropriate label.



- Continue with other measurements or annotations on the same image.
- When done, click "Save" to save the image. A thumbnail of the image will appear in the image grid.

Measurement (Distance) Button/Type Selection Drop Down

For any type of exam, the Catalyst XL system makes it easy to measure distance (length) on a frozen image, and automatically have it labeled as desired.

- After freezing image, select appropriate depth or exam type. This activates the available measurement buttons.
- In the Measurement "Type" box, either type the label desired on the measurement, or select a pre-installed label from the drop-down menu. The "null" selection will make a measurement with no label.
- Click the Distance button.
- In the video viewing window, place the cursor on one edge of area to be measured and click. It will leave a small white X.
- Place the cursor on the other edge of the area to be measured and click again.
- As soon as the second X is placed, an arrow appears linking the two locations and provide a measurement with appropriate label and distance.
- Continue with other measurements or annotations on the same image. Multiple measurements of the same type can be made without clicking the Distance Button again.
- When done, click "Save" to save the image. A thumbnail of the image will appear in the image grid.
- Note: to add a label to the pre-installed list after typing the name in the Measurement box, simply right click and select "Add." To delete an item from the list: highlight it in the drop-down menu then right click and select "Delete."

Angle Measurement Button/Type Selection Drop Down

For any type of exam, the Catalyst XL system makes it easy to measure an angle on a frozen image, and automatically have it labeled as desired.

- After freezing image, select appropriate depth or exam type. This activates the available measurement buttons.
- Either click the Angle button (for a label of "Angle") OR use the Angle "Type" box to specify a different label. If specifying a label, either type the label desired in the "Type" box or select a pre-installed label from the drop-down menu. The "null" selection will make a measurement with no label.
- In the video viewing window, place the cursor on one edge of the angle to be measured and click. It will leave a small white X.
- Place the cursor on the other edge of the angle to be measured and click again.
- As soon as the second X is placed, an angle appears linking the two locations and provide a measurement with appropriate label and distance.

6. Continue with other measurements or annotations on the same image. Multiple measurements with the same label can be made without clicking the Angle Button again.
7. When done, click “Save” to save the image. A thumbnail of the image will appear in the image grid.
8. Note: to add a label to the pre-installed list after typing the name in the Angle box, simply right click and select “Add.” To delete an item from the list: highlight it in the drop-down menu then right click and select “Delete.”

Area Measurement Button (10 Point)/Type Selection Drop Down

For any type of exam, the Catalyst XL system makes it easy to measure a 10-point polygonal area on a frozen image, and automatically have it labeled as desired.

1. After freezing image, select appropriate depth or exam type. This activates the available measurement buttons.
2. Either click the Area button (for a label of “Area”) OR use the Area “Type” box to specify a different label. If specifying a label, either type the label desired in the “Type” box or select a pre-installed label from the drop-down menu. The “null” selection will make a measurement with no label.
3. In the video viewing window, place the cursor on one edge of area to be measured and click. It will leave a small, blue number 1.
4. Place the cursor on the next section of area to be measured and click. It will leave a small, blue number 2.
5. Continue making clicks around the area. After clicking number 10, a polygonal shape outline will appear with the area calculation. (The outline numbers disappear.)
6. Continue with other measurements or annotations on the same image. Multiple measurements with the same label can be made without clicking the Area Button again.
7. When done, click “Save” to save the image. A thumbnail of the image will appear in the image grid.
8. Note: to add a label to the pre-installed list after typing the name in the Area box, simply right click and select “Add.” To delete an item from the list: highlight it in the drop-down menu then right click and select “Delete.”

Perineal Body Measurement Button (PB)

During an endoanal ultrasound exam, the perineal body can be measured by laying a finger lightly along the posterior wall of the vagina, applying as little pressure as possible to avoid compressing the tissues. The fingertip will appear as a hyper-echoic half-moon image, anterior to the anal sphincters. The measurement should be made in the mid-anal canal:

1. After freezing image, select appropriate depth.
2. Click the Perineal Body Measurement Button (PB).
3. In the video viewing window, place the cursor at the posterior edge of fingertip ultrasound image and click. It will leave a small white X.
4. Place the cursor on the anterior mucosa of the anal canal (posterior edge of internal sphincter) and click. Measurement will appear with “Perineal Body” label.
5. Continue with other measurements or annotations on the same image. When done, click “Save” to save the image. A thumbnail of the marked image will appear in the image grid.
6. The measurement will appear in the report with an automatic comparison to the norms.

Label Button

The “Label” feature offers flexibility and customization. To create a label on a frozen image:

1. Click the Label Button. A pop-up box with pre-installed labels will appear.
2. Select the desired label or “make your own label” from the pop-up box.
 - a. To abort labeling, click “Labels” button again.
 - b. If incorrect label is selected, simply drag it off the right side of the image. The pop-up box will reappear to make another selection.
3. Drag and position the label on the image.

4. To place the image, either
 - a. Double click on the image, or
 - b. Right click on the image. Right clicking on the image brings up a text box to add comments if desired. Click save in the box to save the label. An asterisk [*] will appear by the label to indicate a comment has been saved with the label and will appear in the report.
5. Continue with additional markings on the image. When done, click “Save” to save the image. A thumbnail of the image will appear in the image grid.
6. To add/modify/delete/order the labels in the pop-up box, simply right click inside the box and follow the prompts.

Observe (Observations) Button

Observations can be made on any frozen image and saved. These will appear in the report in a table under the image. Pre-installed observations are provided that correspond to the type of exam selected after clicking the freeze button and for endoanal exams, these will correspond to the depth selected.

1. Click the Observe Button. A pop-up box with pre-installed observations will appear.
2. Either click on a desired observation or type your own.
3. To add/modify/delete a pre-installed observation in the pop-up box, simply right click inside the observation text box and follow the prompts.
4. To add a new observation, right click in a blank observation text box and type desired observation.
5. When done, click save in the Observe pop-up box.
6. Continue with additional markings on the image. When done, click “Save” to save the image. A thumbnail of the image will appear in the image grid.

Undo Button

The Undo button deletes misplaced measurements and labels before the image is saved. ***Once an image is saved any measurements and/or labels that were in place will become permanent.***

The Undo button functions by removing items one at a time, stepping backwards (last mark made is first mark removed).

Probe Settings

This shows the available frequencies and depths for each probe. The system will default to the optimized settings.

Exam Impression Box

To notate exam impressions, simply type comments into the box. Right click to “Save” impressions. (Impressions will also be auto-saved any time the “Save” button is clicked.) To edit Impressions after saving them, right click to Edit. Again, right click to “Save.” Impressions will appear in a separate table at the end of the report.

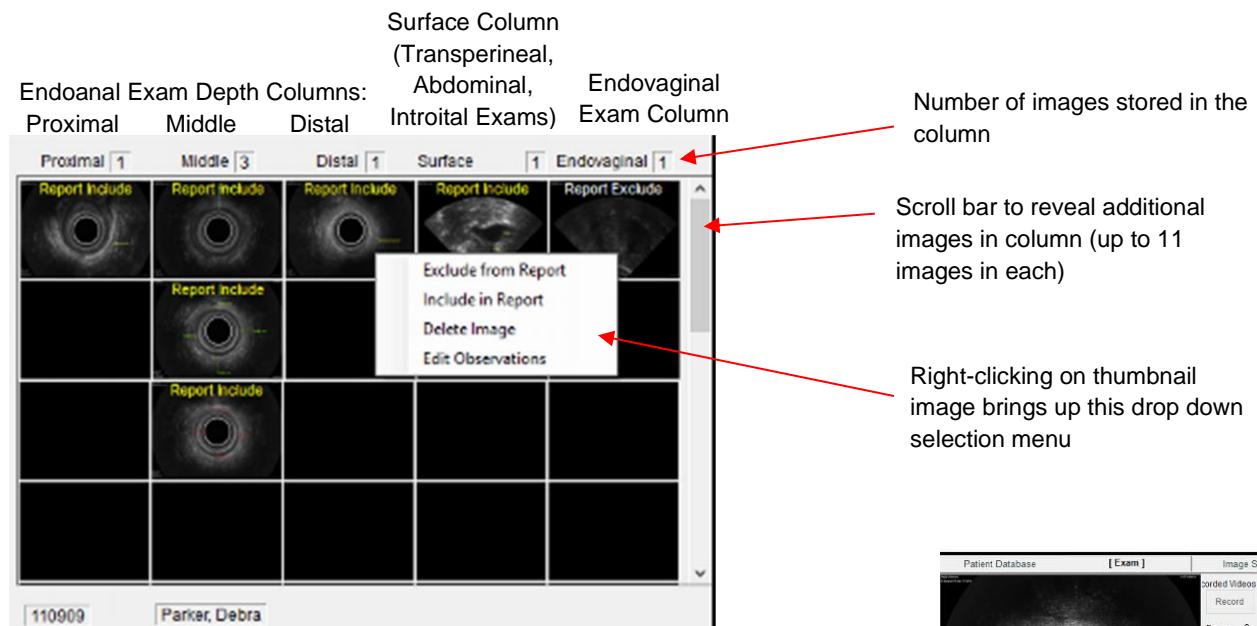
Rotate Image Button

To rotate an image during an exam (for instance, to change the orientation of the probe button to the image), simply click the “Rotate 90°” as many times as desired.

VII. IMAGE GRID

The Image Grid organizes images (thumbnails) after they have been saved by endoanal depth selected or exam type: Images in the grid can be easily recalled, analyzed and processed during or after a test. Each column can hold up to eleven images, for a total of 55 images. All images are saved as “Report Include” (yellow type). Right click on a thumbnail for the following:

- To exclude the image from the report (white type),
- To change an excluded image back to being included in the report,
- To delete the image (note: this permanently deletes the image and all annotations made on the image),
- To easily edit observations. (When selecting this function, the image will appear in the video viewing screen, and the observation box will appear.)



Working with Thumbnail Images

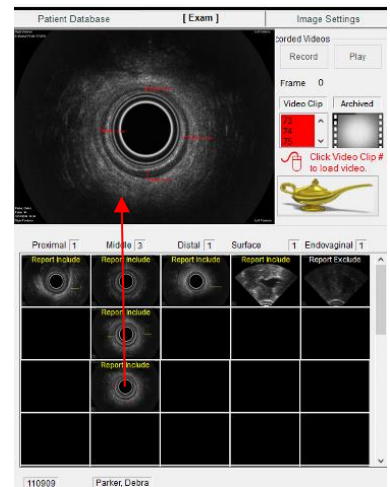
Click on a thumbnail image to preview it above the grid. Click on the preview image to display it in the Video Viewing Window, and then process the image in the same manner as a live image. Once processing is completed, click “Save” to save the image.

Note that both the original image and the newly processed image will be saved in the Image Grid. To delete the original image, simply right click on the thumbnail and select “Delete Image” from the drop down menu.

It is possible to do a quick comparison of two saved images by using this method:

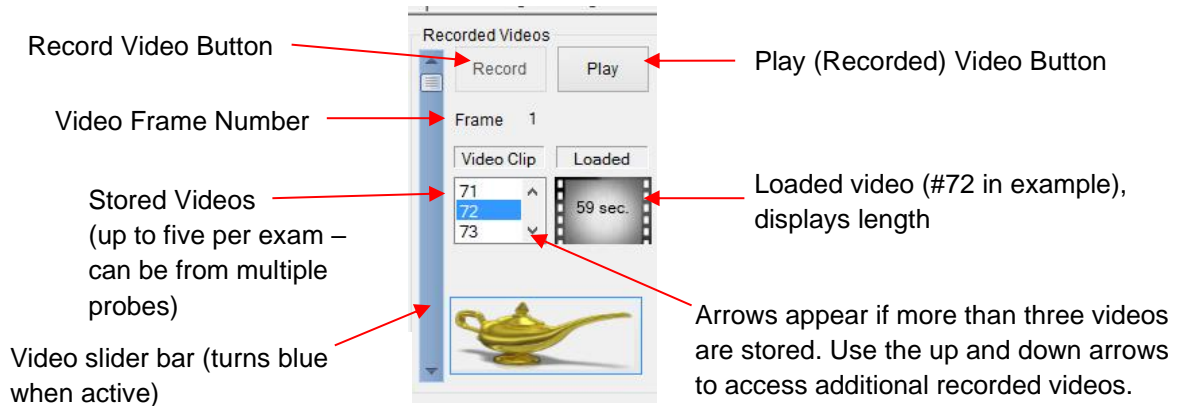
- 1) Click on the selected image to put it in the preview window, then click on it again to display it in the Video Viewing Window.
- 2) Click on the second image to display it in the preview window and compare it to the first image.

To remove the image from the preview window, right click on it. To remove the image from the Video Viewing Window, simply perform another function (such as loading a video, selecting another image to edit, or going back to the Patient Database tab).



VIII. RECORDING VIDEO

The Catalyst program supports recording up to five 60-second videos per examination. These videos are labeled and kept in a special archival program which is designed for playback at any time. Recorded videos can be marked, annotated, and edited in a similar manner to during the exam.



Recording a Video

Click the “Record” button. The button label turns to “Stop.” A green countdown bar appears on the right side of the Video Viewing Screen, which is a visual reminder of remaining time to complete the recording. In addition, a pre-recorded voice tells how many seconds are remaining, in 10 second increments.

The video will stop recording automatically at 60 seconds. Click “Stop” to end the recording earlier. A pop-up box will appear, asking “Do you want to save this video?” Click “Yes” to save, or “No” to discard. The video number will appear in the Video Clip window, and it will automatically load for immediate replay, if desired.

To continue scanning, click “Process,” and then choose “Resume Scan.”

IX. PLAYING BACK AND PROCESSING A RECORDED VIDEO

A recorded video can be processed much the same way as a live scan. To access a video recorded on a saved patient exam, see “Reviewing Past Exams Through the Patient Database Tab” below.

The pre-recorded video clips will appear in the Video Clip window. When the Video Clip window is red, no video has been selected. To load a video, double-click on the desired video number. When the video is loaded, the first video frame will appear in the Video Viewing Screen.

To play a loaded video, click “Play.” To freeze an image, click “Stop.” Once an image is frozen, it can be processed by clicking the “Process” button and marking the image as described on pages 12-15.

Another way to find a desired image is by using the Video Slider Bar. After loading a video, simply click on the slider bar and drag it up or down, or use the slider bar arrows to go frame by frame. Note: The frame number is a good reference tool for locating previously marked images. (The video frame is noted in the lower lefthand corner of the saved image.)

To load a different recorded video, simply click on that video number in the Video Clip window.

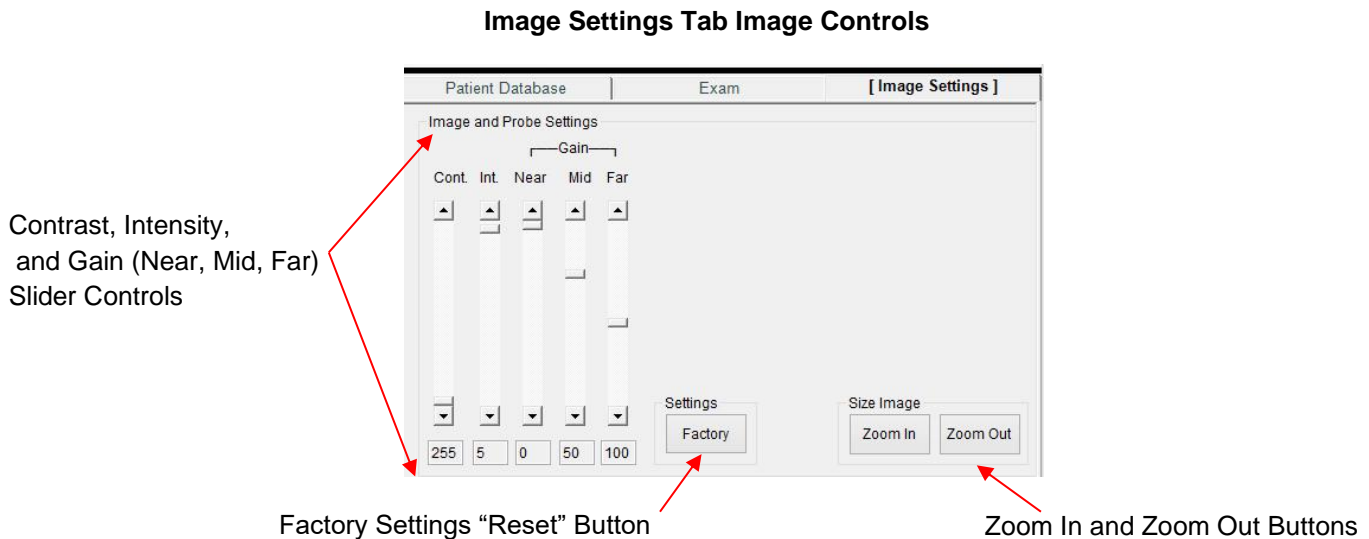
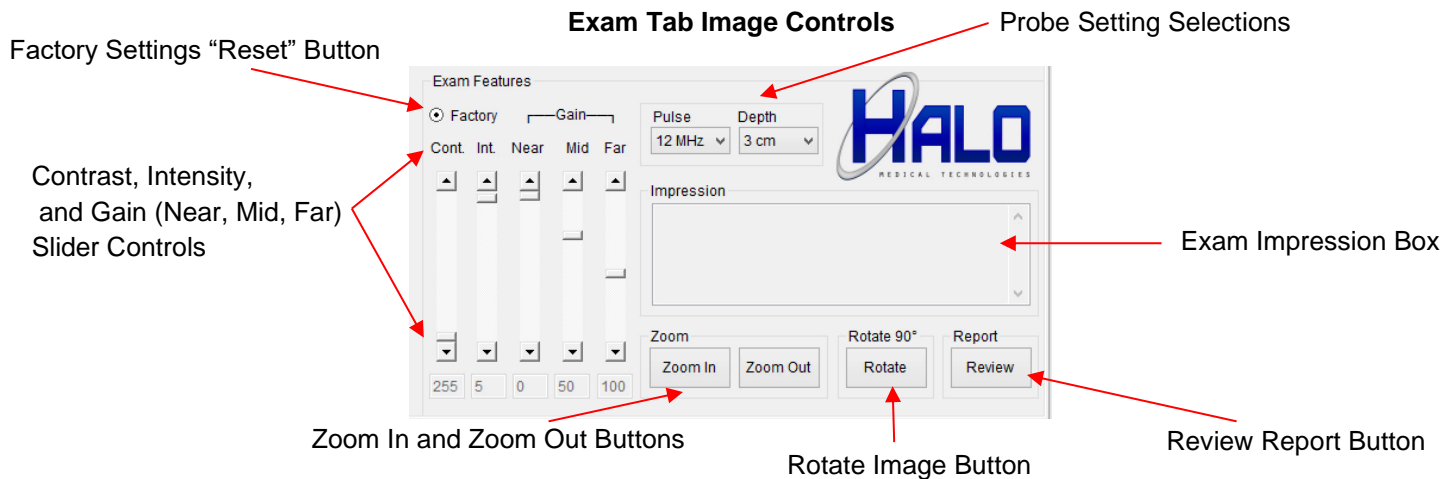
Reviewing Past Exams Through the Patient Database Tab

To review past exams from the Patient Database Tab, first select the exam from the Patient Database Tab: 1) highlight the patient name in the “Patient List,” 2) select the desired exam from the “Patient’s Exams” window, and 3) click “Review Exam.” **NOTE: When the Exam Tab is accessed through the “Review Exam” button, it is not possible to perform live scans.**

X. WORKING WITH IMAGE CONTROLS

NOTE: Each HALO probe has been ACE certified for optimal visual acuity in use with the Catalyst XL software. If settings have been changed, click the “Factory” button to restore ACE certified settings.

It is possible to adjust image settings in two areas of the Catalyst software interface, on the Exam Tab and on the Image Settings Tab. The Exam Tab allows adjustment of contrast, intensity, and gain controls. The Image Settings Tab allows adjustment of these controls, plus allows selection of available probe frequencies and depth for optimal viewing. (Note, it is possible to switch between Exam Tab and Image Settings Tab while scanning with the ultrasound probe.)



Adjusting the Contrast (Dynamic Range)

The Contrast Control (“Cont.”) is the first slide bar to the left and adjusts the overall contrast of the image. Slide this control up and down to increase and decrease the amount of contrast between light and dark areas of the image. Contrast can be adjusted during scanning, on frozen images, or on saved images and videos. Click “Factory” to restore original settings.

Adjusting the Intensity

The Intensity Control (“Int.”) is the second slide bar from the left and adjusts the overall intensity or brightness of the image. To darken the image, move the intensity slider up. To lighten the image, move it down. Intensity can be adjusted during scanning, on frozen images, or on saved images and videos. Click “Factory” to restore original settings.

Adjusting the Gain

The three gain controls on the right side of the “Probe and Image Settings” box allow adjustment for more or less gain in the far-field (**Far Gain**), mid-field (**Mid Gain**), or near-field (**Near Gain**). To add more gain, move the appropriate slider down. To reduce the gain, move the slider up. Gain can be adjusted during scanning, on frozen images, or on saved images and videos. Click “Factory” to restore original settings.

Zooming In and Out

It is possible to zoom in or zoom out on an image in the Video Viewing Window. Simply click on the “Zoom In” or “Zoom Out” Buttons under “Size Image” on either the Exam Tab or Image Settings Tab. Note: this function is not available after an image has been frozen or saved.

XI. REPORTS

Previewing and Printing Reports

Reports can be reviewed and printed from either the Patient Database Tab (see illus. on p.10), the Exam Tab (see illus. on p. 18), or from “Report” on the task bar.

To preview a report during an exam, or while post-processing an exam, click the “Review” Button in the lower righthand corner of the screen.

To generate an exam report from the Patient Database Tab, click on the patient’s name in the “Patient List” window to highlight it, then select the desired exam from the “Patient’s Exams” window. Reports are generated from a single exam, so if multiple exams have been created for one patients, it may be necessary to generate multiple reports. Click the “View Report” button under the “Notes” window to generate a report.

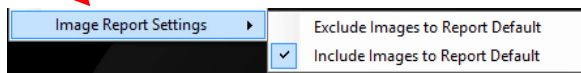
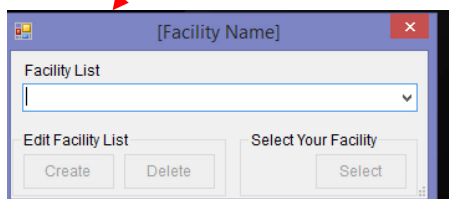
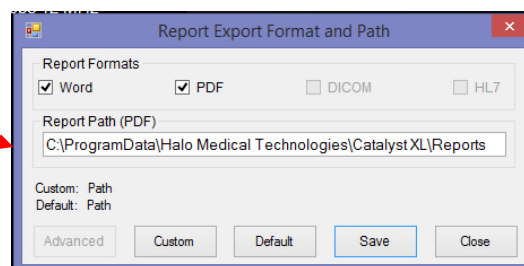
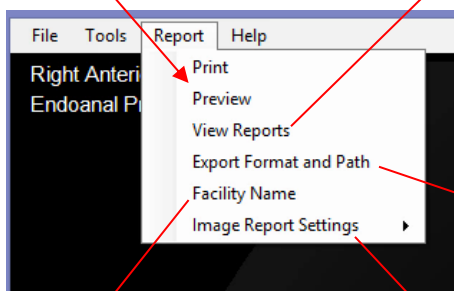
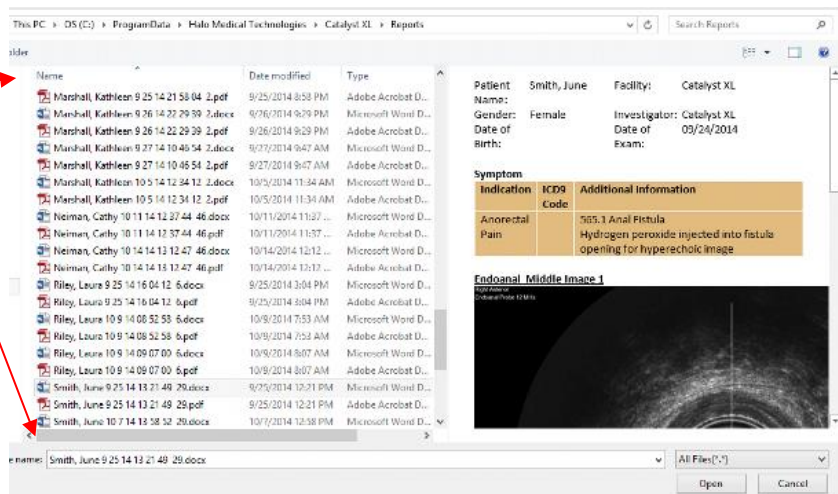
The “Review” and “View Report” buttons will generate a report in MSWord, which can be edited. The reports are saved in both MSWord and PDF formats. Reports can also be Reviewed and Printed from the tool task bar under “Report.”

Report Task Bar Features

The report database can be accessed from the “Report” selection on the task bar. The “Report” selection also provides additional ways to customize the report and to “push” the report to a designated EMR system location. These features are illustrated and described below.

Report names start with “Patient Last Name, Patient First Name, Date of Study” for easy retrieval. Reports are stored in MSWord and PDF format.

Print and Preview commands for currently selected exam.



Sending Reports to an EMR

Final reports can be sent to an EMR by using the “Export Format and Path” command found in the Report section of the Task Bar. To send a PDF report to an EMR, click “Custom” and enter the appropriate pathway, then click, “Save.” (Please call the Halo Service Support Center for assistance in assuring the correct EMR set-up.)


Adding and Changing the Facility Name

The Facility Name appears on the top of the Catalyst screen, and in the report heading. Create and select the desired facility name as follows:

1. Select “Facility Name” from the Report section on the Task Bar.
2. Type the desired name in the blank window.
3. Click the “Create” Button under “Edit Facility List.” The name will be added to the drop down list.
4. Click on the arrow to bring up the entire drop down list of pre-entered Facility names.
5. Click the desired name from the list.
6. Click on the “Select” Button under “Select Your Facility.”
7. A pop-up box will appear with your selection. Click “OK” to confirm your selection.

Note: To change the Facility Name on a saved patient exam, right click on the exam in the “Patient’s Exam” window, and select “Facility Modify.” Follow the directions in steps 2-7 above to change the name for that exam.

Sample Report Page



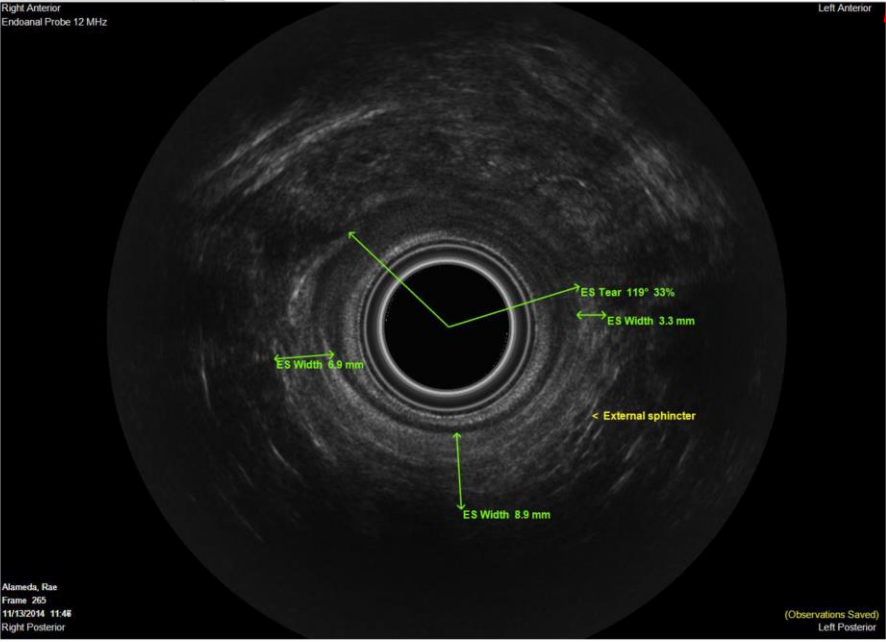
Ultrasound Report

November 13, 2014

Patient Name: Alameda, Rae
 Gender: Female
 Date of Birth: 01/01/1987

Facility: Catalyst XL
 Investigator: Catalyst User
 Date of Exam: 09/24/2014

Symptom		
Indication	ICD9 Code	Additional Information
Fecal Incontinence	787.62 Fecal smearing	G2/P2. 3rd degree laceration with first child delivery, approx. 2 years prior. Second child, one month prior.

Endoanal Middle Image 1


Measurement Type	Quadrant(s)	Value/mm	Degrees	Percentage
External Sphincter Tear	Anterior		119	33
External Sphincter Width	Left Lateral	3.3		
External Sphincter Width	Posterior	8.9		
External Sphincter Width	Right Lateral	6.9		

Label	Quadrant(s)	Comment
External sphincter	Left Lateral	

Observation
The external anal sphincter has a defect in the mid anal canal.

Alameda, Rae
Page 1 of 2

Page One Header

Image with markings, labeled for exam type and image number

Measurements with type, location, and values

Labels with location and stored comments

Observations

Patient Last Name, First Name on each page

Automatic page numbering

XII. USING MULTIPLE PROBES

The Catalyst system offers the unique ability to use multiple probes during one exam, facilitating a single report with a multi-compartmental approach to examining the pelvic floor. To change probes during an exam, unplug the current probe from the USB port. The following image will appear on the screen, identifying which probe has been disconnected, with selection buttons for choosing the next probe to be used:



Simply plug in the next probe to use and click the associated button. It does not matter what order these two steps are performed. Wait a few seconds to see that the Video Viewing Screen now properly identifies the new probe. If desired, change the default probe setting on the “Image Settings Tab” and begin scanning with the new probe.

XIII. KEYBOARD SHORTCUTS

The following keyboard shortcuts are available for basic operation of the Catalyst software, avoiding the use of the mouse during a study:

Key	Action
F1	Click to Scan and to Freeze/Process
Tab	Tabs down depth/exam type/function selection list (and continually scrolls)
Up/Down Arrows	Tabs up and down depth/exam type selection list
Enter	Selects from depth/exam type/function selection list
F2	Save Image
F3	Click to Record Video and to Stop Video Recording

Here is an example of performing a study using these keys without using a mouse:

1. Use the probe button or Click **F1** to start scanning
2. When ready, click **F3** to record a video
3. To save video, either
 - a. Record for 60 seconds, and then click **Enter** to “Save,” or
 - b. Record for desired length, click **F3** to stop recording, and click **Enter** to “Save”
4. Click **F1** to bring up depth/exam type/function selection list
5. Use **Tab** key or **Arrow** keys to select “Resume Scan”
6. Click **Enter** to resume scanning, and record additional videos in the same way
7. Post-process desired images when convenient

Appendix A

Indications for Use

System: Halo Medical Technologies, Catalyst™, MidCRYSTL™ Ultrasound System

Transducer: ER/12 MHz/ES 12MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = New Indication, P=Previously cleared by FDA; E=added under this appendix

*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

System: Halo Medical Technologies, Catalyst™, HALO™ Ultrasound System

Transducer: GP 3.5 MHz / AB 3.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = New Indication, P=Previously cleared by FDA; E=added under this appendix

*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

System: Halo Medical Technologies, Catalyst™, HALO™ Ultrasound System

Transducer: EC 7.5 MHz / EB 7.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B+CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative Neurological							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)							
	Small Organ (e.g. testicles, lymph nodes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N						
	Trans-urethral							
	Trans-esoph. (non-card.)							
	Muscular-Skeletal (Conventional)							
	Muscular-Skeletal (Superficial)							
	Intravascular							
	Invasive Diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)							
	Retroperitoneum							
	Female reproduction system and fetus (transcutaneous)							
	Superficial structures & pathologies							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = New Indication, P=Previously cleared by FDA; E=added under this appendix

*Examples of other modes may include: A-mode, Amplitude Doppler, 3-D

Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

Appendix B

Acoustic Output Format for Track 1 Autoscanning Mode

System: Halo Medical Technologies Catalyst™

Operating Mode: B

Transducer Model: GP 3.5 MHz/AB 3.5 MHz

Application(s): Abdominal, Small Organ

Acoustic Output			MI	I _{spta.3} (mW/cm ²)	I _{sspa.3} (W/cm ²)
Global Maximum Value			0.566	5.03	77.4
Associated Acoustic Parameter	Pr.3 (MPa)		0.976		
	W ₀ (mW)			37.2	37.2
	f _c (MHz)		2.98	2.98	2.98
	Z _{sp} (cm)		5.30		5.30
	Beam Dimensions	X-6 (cm)			0.386
		Y-6 (cm)			0.370
	PD (μsec)		0.405		0.405
	PRF (Hz)		3840		3840
	EBD	Az. (cm)		1.70	
		Ele. (cm)		1.70	
Operating Control Conditions	Image Rate 15 Hz				
	Operating Frequency				
	256 Lines/Sector				

Note: The statistical table above shows the worst-case indices for each probe type and operating condition that must be reported.

Acoustic Output Format for Track 1 Autoscanning Mode

System: Halo Medical Technologies Catalyst™
Transducer Model: EC 7.5 MHz / EB 7.5 MHz

Operating Mode: B
Application(s): Trans-vaginal

Acoustic Output			MI	I _{spta.3} (mW/cm ²)	I _{sspa.3} (W/cm ²)
Global Maximum Value			1.13	22.7	375
Associated Acoustic Parameter	Pr.3 (MPa)		2.42		
	W ₀ (mW)			17.9	17.9
	f _c (MHz)		4.61	4.61	4.61
	Z _{sp} (cm)		1.40		1.40
	Beam Dimension s	x-6 (cm)			0.166
		y-6 (cm)			0.169
	PD (μsec)		0.332		0.332
	PRF (Hz)		3840		3840
	EBD	Az. (cm)		2.000	
		Ele. (cm)		0.900	
Operating Control Conditions	Image Rate 15 Hz				
	90 Degree Scan Angle				
	256 Lines/Sector				

Note: The statistical table above shows the worst-case indices for each probe type and operating condition that must be reported.

Acoustic Output Format for Track 1**Autoscanning Mode****System:** Halo Medical Technologies Catalyst™**Operating Mode:** B**Transducer Model:** ER 12.0 MHz/ES 12.0 MHz**Application(s):** Trans-Rectal

Acoustic Output			MI	I _{spta.3} (mW/cm ²)	I _{sspa.3} (W/cm ²)
Global Maximum Value			0.462	0.644	112
Associated Acoustic Parameter	P _{r.3} (MPa)		1.44		
	W _o (mW)			1.20	1.20
	f _c (MHz)		9.70	9.70	9.70
	Z _{sp} (cm)		1.30		1.30
	Beam Dimensions	x-6 (cm)			0.0719
		y-6 (cm)			0.0914
	PD (μsec)		0.162		0.162
	PRF (Hz)		5120		5120
	EBD	Az. (cm)		6.28	
		Ele. (cm)		0.469	
Operating Control Conditions	Image Rate 10 Hz				
	Sector Offset = 1.0 cm				
	512 Lines/Scan				
	360° Total Scan Angle	

Note: The statistical table above shows the worst-case indices for each probe type and operating condition that must be reported.

Appendix C

Measurement Accuracy

B-mode

Transducers	Range & Accuracy	Distance (cm)		
		Horizontal	Vertical	Diagonal
EC 7.5 MHz / EB 7.5 MHz HALO™ Endovaginal Probe	<i>Range</i>	8-15	5-10	5-10
	<i>Accuracy</i>	+/- 5% or +/- 5 mm		
GP 3.5 MHz / AB 3.5 MHz HALO™ Surface Probe	<i>Range</i>	9-30	5-20	5-21
	<i>Accuracy</i>	+/- 5% or +/- 5 mm		

Appendix D

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue. The intensity value in the tissue, *In Situ*, has been estimated by using the following formula:

$$In\ Situ = Water [e^{-(0.23alf)}]$$

where: *In Situ* = *In Situ* Intensity Value

Water = Water Value Intensity

e = 2.7183

a = Attenuation Factor

Tissue	a(dB/cm-MHz)
--------	--------------

Brain	.53
-------	-----

Heart	.66
-------	-----

Kidney	.79
--------	-----

Liver	.43
-------	-----

Muscle	.55
--------	-----

l = skin line to measurement depth (cm)

f = Center frequency of the transducer/system/mode combination(MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *In Situ* intensity. An attenuation factor of 0.3 is used for general reporting purpose; therefore, the *In Situ* value which is commonly reported uses the formula:

$$In\ Situ\ (derated) = Water [e^{-(0.069lf)}]$$

Since this value is not the true *In Situ* intensity, the term “derated” is used.

The maximum derated and the maximum water values do not always occur at the same operating condition; therefore, the reported maximum water and derated values may not be related by the *In Situ* (derated) formula. For example: a multi-zone array transducer that has maximum water value intensities in its deepest zone. The same transducer may have its largest derated intensity in one if its shallowest focal zones.

Appendix E

Patient Privacy and Confidentiality

There are important steps that can be taken to safeguard data. Ultrasound images, patient data files, and reports may include identifying patient information. HIPAA regulations and other patient privacy and regulatory standards require that users take reasonable care to protect this information.

It is important that users comply with hospital or clinic HIPAA guidelines regarding privacy and safeguarding patient information. Ask these questions: What liability exists in the event the system laptop, computer, or storage device is stolen? What procedure is in place in the event the computer hard drive crashes? Ultimately, it is the user's responsibility to assure the security of their data.

Several strategies may be used to protect data:

- 1) Control the computer and storage devices at all times. They should be locked up when not under direct control of user.
- 2) Limit access to the computer to authorized users.
- 3) Password protect computer – require login.
- 4) Password protect any folders or files that include patient information. This should provide adequate encryption to prevent unauthorized viewing.
- 5) Regularly back up your data and store in a safe place.

Notes:

Catalyst software does not include electronic signature control and is not meant to substitute for an electronic medical record.

The Catalyst system has been designed with closed architecture software to be used as a standalone device. It is possible for users to connect the device to a network. In that event, the user is responsible for ensuring network information security with respect to cyber communications, including confidentiality, integrity, availability, and accountability of information.

Appendix F

Halo Medical Technologies Product Description and Part Numbers

Part No.	Product	Description
HMT-SYSAIO	All-In-One Catalyst System w/ mobile cart	360° Endoanal Ultrasound System
HMT-SYSLT	Catalyst System w/ Laptop	360° Endoanal Ultrasound System
HMT-AIO-PC	Halo Medical Technologies All-In-One PC	Minimum specs: 21" Full HD (1920 x 1080); IPS Backlit Wide Viewing Angle; i7 Processor; 8 GB Memory; 1 TB Hard Drive & Windows 8 Pro and MS Office for Business
HMT-MCCS	Mobile Computer Cart System	Custom cart with MidCRYSTL Probe Holder; VESA Mount for Secure & Easy Height Adjustment for Sitting or Standing; Wipe Holder and Storage Basket
HMT-TDL-17	Halo Medical Technologies 17in. Laptop	Minimum specs: Full HD (1920-1080); IPS Backlit Wide Viewing Angle; i7 Processor; 8GB Memory; 1TB Hard Drive; Windows 8 Pro and MS Office
HMT-TDL-15	Halo Medical Technologies 15in. Laptop	Minimum specs: 15.6" Laptop with HD (1366 x 768); LED Backlit; i5 Processor; 8 GB Memory; 500 GB; Windows 8 Pro OS and MS Office
HMT-CATXLP	Catalyst XL Software	Factory-installed on All-In-One or 17in. Laptop
HMT-CATLP	Catalyst L Software	Factory-installed on 15in. Laptop
HMT-MCP	MidCRYSTL Endoanal Probe	360° endoanal ultrasound probe
HMT-EVAGM	HALO Endovaginal/Introital Probe	90° endovaginal ultrasound probe
HMT-SURM2	HALO Curved Array/Surface	90° surface probe for transabdominal/transperineal applications
HMT-TRP-C	HALO Transrectal Probe	360° transrectal ultrasound probe, 12MHz
HMT-EVAG-G	HALO 360° Endovaginal Probe	360° endovaginal ultrasound probe, 7.5MHz
HMT-ESIPRO	Proctoscope and Rectal Balloon System	Rectal exam kit. Includes proctoscope, obturator, viewing window, rectal balloon sleeve with luer lock fitting
HMT-EPC	HALO Latex-free Endocavity Probe Covers	Latex-free, nonsterile, nonlubricated sheaths for endoanal and endovaginal probes, 20/package
HMT-SPC	HALO Latex-free Surface Probe Covers	Latex-free, nonsterile, nonlubricated sheaths for surface probes, 20/package
HMT - USGB	Parker Labs brand Aquasonic 100 Ultrasound Gel	Ultrasound gel, 0.25 Liter Bottles, 2 each bottles/package

Catalyst™ XL Ultrasound System

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