Reflex™

Ultrasound Bio-Microscope

User's Guide

Reichert
TECHNOLOGIES

© 2010 Reichert, Inc.

Reichert® is a registered trademark of Reichert, Inc.
Reflex® is a trademark of Reichert, Inc.
All other trademarks are property of their respective owners.

The information contained in this document was accurate at time of publication. Specifications are subject to change without notice. Reichert, Inc. reserves the right to make changes in the product described in this manual without notice and without incorporating those changes in any products already sold.
Federal law restricts this device to sale by or on the order of a physician.

ISO 9001 Certified – Reichert products are designed and manufactured under quality processes meeting ISO 9001 requirements.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, recording, or otherwise, without the prior written permission of Reichert, Inc.

Contents

Section **Page**

Warnings and Cautions 4

Symbols 6

Introduction 7

Getting Started

Unpacking Reflex 8

Turning On and Off 8

System Components 9

Available Accessories 9

Main Application Window 10

Menu Bar 11

Display Adjustments 12

Analysis Tools 14

Acquisition Console 15

Patient Exam

Patient Data 16

Preparing the Probe 16

Using the Eyecup 16

Using the *Optional* Nosepiece Standoff Kit 17

Preparing the Patient 18

Obtaining a Scan 19

Post Procedure Patient Care 19

Saving an Exam 21

Creating Sub-exams 21

Changing Probes During an Exam 21

Printing an Image 21

Options/Tools Menu

Edit Hospital/Clinic Info. 22

Compare to other Exam. 22

Advanced TGC Adjust 22

Image Label Style 22

Use On-screen Keyboard 23

Save Display Settings 23

Save JPEG snapshot 23

Save DICOM snapshot 23

Archive Selected Exams 23

Purge Scan Data Files 23

Instrument Setup 24

35/50MHz Probe Options 24

Print Setup 24

Print Scans Side-by-Side 25

About Reflex 25

Cleaning & Disinfection

External Cleaning 26

Probe Cleaning/Disinfecting 26

Troubleshooting

Touch Screen Calibration 27

Specifications

Specifications 29

Disposal 29

Guidance & Manufacturer's Declarations 30

Appendix A (Terms & Definitions) 32

End User Software License Agreement 33

Reichert Warranty 35

Warnings & Cautions

Reichert, Inc. (Reichert) is not responsible for the safety and reliability of this instrument when:

- Assembly, disassembly, repair, or modification is made by unauthorized dealers or persons
- Instrument is not used in accordance with this User's Guide.

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

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

WARNING: THIS INSTRUMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES, SUCH AS OXYGEN OR NITROUS OXIDE.

WARNING: UNITED STATES FEDERAL LAW AND EUROPEAN REGULATIONS REQUIRE THAT THIS DEVICE BE PURCHASED ONLY BY A PHYSICIAN OR A PERSON ACTING ON BEHALF OF A PHYSICIAN.

WARNING: TO AVOID INJURY TO THE PATIENT WHEN USING THE IMMERSION STYLE PROBE AND THE SCLERAL EYECUP, THE OPERATOR MUST READ THE INSTRUCTIONS IN THIS MANUAL AND TAKE EVERY PRECAUTION TO PREVENT CONTACT BETWEEN THE PROBE AND THE EYE.

WARNING: CARE MUST BE TAKEN TO ARRANGE THE CABLES FOR THE PROBE, FOOTSWITCH, AND POWER SUCH THAT THEY DO NOT PRESENT A TRIPPING HAZARD TO THE EXAMINER OR A DANGER TO THE PATIENT.

WARNING: DO NOT USE ANY OTHER PROBE WITH THE REFLEX THAN THOSE SUPPLIED BY REICHERT EXPRESSLY FOR USE WITH THE REFLEX. OTHER PROBES MAY NOT GENERATE ACCEPTABLY LOW ULTRASOUND ENERGY LEVELS WITH MEASUREMENT ACCURACY AND MAY CAUSE DAMAGE OR INJURY TO THE EYE.

WARNING: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE NEXT TO THE INPUT CORD RECEPTACLE OR DAMAGE TO THE UNIT MAY OCCUR.

WARNING: IT IS IMPORTANT TO MINIMIZE THE PATIENT'S EXPOSURE TO ULTRASOUND ENERGY TO A LEVEL AS LOW AS REASONABLY ACHIEVABLE (ALARA). THE AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE (AIUM) HAS A PUBLICATION “MEDICAL ULTRASOUND SAFETY” (1994) WHICH HAS MORE INFORMATION ON THIS TOPIC.

Warnings & Cautions (Continued)

CAUTION: AN INSTRUCTION THAT DRAWS ATTENTION TO THE RISK OF DAMAGE TO THE PRODUCT.

CAUTION: DO NOT INSTALL ANY ADDITIONAL SOFTWARE OTHER THAN WHAT WAS SUPPLIED WITH THE REFLEX. INSTALLATION OF ADDITIONAL SOFTWARE MAY CAUSE UNEXPECTED OPERATION OF THE REFLEX RESULTING IN MALFUNCTION OF THE REFLEX.

CAUTION: DO NOT USE SOLVENTS OR STRONG CLEANING SOLUTIONS ON ANY PART OF THIS INSTRUMENT AS DAMAGE TO THE UNIT MAY OCCUR.

CAUTION: USE OF AN AMMONIA BASED PRODUCT ON THE LIQUID CRYSTAL DISPLAY (LCD) MAY CAUSE DAMAGE TO THE DISPLAY.

CAUTION: THIS INSTRUMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES SUCH AS OXYGEN OR NITROUS OXIDE.

CAUTION: PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT MEDICAL ELECTRICAL EQUIPMENT.

CAUTION: THIS INSTRUMENT HAS ELECTROSTATIC DISCHARGE SENSITIVE DEVICES (ESDS) WHICH ARE SENSITIVE TO STATIC HIGH VOLTAGES STORED IN AND TRANSFERRED BY THE HUMAN BODY. OBSERVE CORRECT ESDS PRECAUTIONS OR PREMATURE MALFUNCTION OF THIS INSTRUMENT WILL OCCUR.

CAUTION: THIS INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND THAT IS CONNECTED TO THE RECEPTACLE OR DAMAGE TO THE UNIT MAY OCCUR. DO NOT DISABLE OR REMOVE THE GROUND PIN.

CAUTION: MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED INTO SERVICE ACCORDING TO EMC GUIDELINES PROVIDED IN THIS MANUAL.

CAUTION: THIS INSTRUMENT IS NOT TO BE USED NEAR HIGH FREQUENCY EMITTING SURGICAL EQUIPMENT OR MALFUNCTION OF THE REFLEX MAY OCCUR.

CAUTION: THE HIGH FREQUENCY PROBE SUPPLIED WITH THE UNIT EMPLOYS AN EXPOSED MOVING TRANSDUCER. THIS TRANSDUCER IS FRAGILE. TAKE EVERY PRECAUTION TO AVOID INADVERTENT CONTACT OR PHYSICAL SHOCK TO THE TRANSDUCER OR MALFUNCTION OF THE INSTRUMENT MAY OCCUR.

Symbol Information

The following symbols appear on the instrument.

⚠	Caution symbol indicating important information that are included in this User's Guide
🕮	Consult Instructions for Use symbol indicating important operating and maintenance instructions that are included in this User's Guide
🯅	Type B Product Classification Class 1 Equipment, Continuous Operation
∿	Alternating Current Power
I O	ON / OFF
🏭	Date of Manufacture
[REF]	Catalog Number
🗑	Waste of Electrical and Electronic Equipment
CE 0120	Compliance to Medical Device Directive 93/42/EEC
C SA US	Authorized mark given by CSA for conformance with electrical standards

FCC Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Introduction

The Reichert® Reflex™ Ultrasound Bio-Microscope is an ocular ultrasound imagining system designed for imaging the anterior chamber of the eye in real time. The system is designed to be compact, easy to move, set-up, and simple to use.

Intended Use

The Reflex is intended to be used for visualization by ultrasound of the eye and orbit.

About This Manual

This manual explains how to use the Reflex for patient examination and how to use the various tools for:

- Exam analysis
- Patient exam export
- Printing images.

This manual also provides help in resolving common problems.

For documentation on the Windows® operating system and other general aspects of the supplied personal computer (PC) please refer to the manufacturer of Windows® and the manufacturer of the PC.

Please retain this guide for future use and to share with other users. Additional copies can be obtained from your authorized Reichert, Inc. dealer or contact our customer service department at:

Tel: 716-686-4500
Fax: 176-686-4555
E-mail: info@reichert.com

Getting Started

Unpacking Reflex

1. Open the box and review the User's Guide and the contents of the box.
2. Unpack the Reflex, Support Stand, contents of the probe case, keyboard, and the foot pedal and controller from their packaging.
3. Review the contents and ensure that all parts were shipped with the unit. If any parts are missing, contact customer service at the phone number or address located in the *Introduction* section of this manual.
4. Attach the power cord and the Water Immersion Probe Cable to the unit and then secure the cables using the cable fasteners that were supplied with the computer.
5. Attach the Reflex to the supplied stand using the four attaching screws. (See instructions supplied with the stand.)
6. Plug the USB cable for the foot pedal interface module into one of the USB ports on the side of the Reflex and then plug the footswitch connector into the interface module.
7. Install the USB flash keyboard interface into one of the USB ports on the side of the unit. Ensure that new batteries are installed into the keyboard.
8. Attach the Water Immersion Probe into the end of the probe cable.
9. Install the Transducer onto the end of the Water Immersion Probe.
10. Remove the protective plastic cover from the touch screen.
11. Apply the correct input power to the unit (refer to the *Specifications* section of the manual) and then set the ON/OFF switch to the ON position.

CAUTION: WHEN UN-PLUGGING THE PROBE FROM THE CABLE, ENSURE THAT YOU GRASP AND PULL ON THE METAL CONNECTOR CLOSEST TO THE PROBE SO THAT DAMAGE TO THE CABLE DOES NOT OCCUR.

12. Select the value of the transducer at the start of the Reflex program.

Turning On and Off

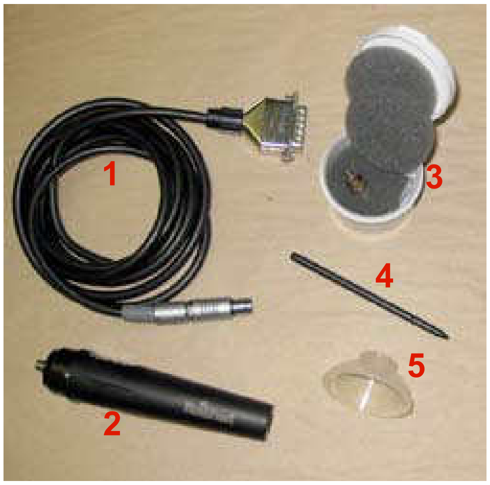
The power button is located on the side of the Reflex above the USB ports. Turning on the instrument will also start the Reflex software. Double tapping the **Reichert Reflex** icon on the Windows® desktop will also start the software.

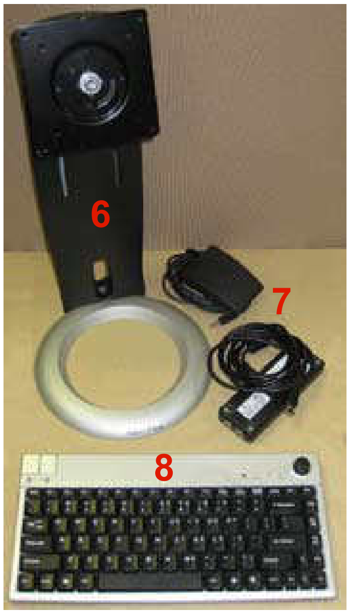
NOTICE: SHUT DOWN WINDOWS BEFORE TURNING OFF POWER SWITCH.

The power button is a mechanical switch not controlled by software. To power down the Reflex, close the application by tapping the X in the upper right corner of the screen, or by selecting Exit from the Tools/Options menu. Then from the Windows® desktop, tap the extreme lower edge of the screen to call up the Start menu. From the Start menu, select "Shut Down", and wait until Windows® indicates "it is safe to turn off the computer" before switching off the power.

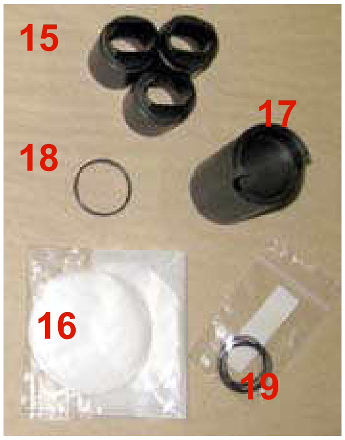
System Components

The Reflex consists of the following components (1 each):





ID	Description
1	Probe cable
2	Water Immersion probe
3	35 or 50 MHz Transducer
4	Stylus
5	Scleral Eyecup
6	Support stand
7	USB Foot pedal control (2 parts: footpedal & interface)
8	Wireless Keyboard
	User manual*
	Installation CD*
	Power cord**
	Medical grade Windows® based touchscreen PC*



Available Accessories

11	50 MHz transducer for Water Path Probe* (or 35 MHz transducer Water Path Probe)*	
12	10 MHz Sealed Oil Filled Probe*	
13	20 MHz Sealed Oil Filled Probe*	
14	Nosepiece Standoff Kit	
	15	Nosepiece Standoffs
	16	Nosepiece Membranes
	17	Membrane Applicator
	18	Nosepiece Ring
	19	Spare O-Ring Kit
20	UBM Probe Holder - attaches to the top left of the monitor and holds the probe vertical.	

*** Parts not shown in picture.**

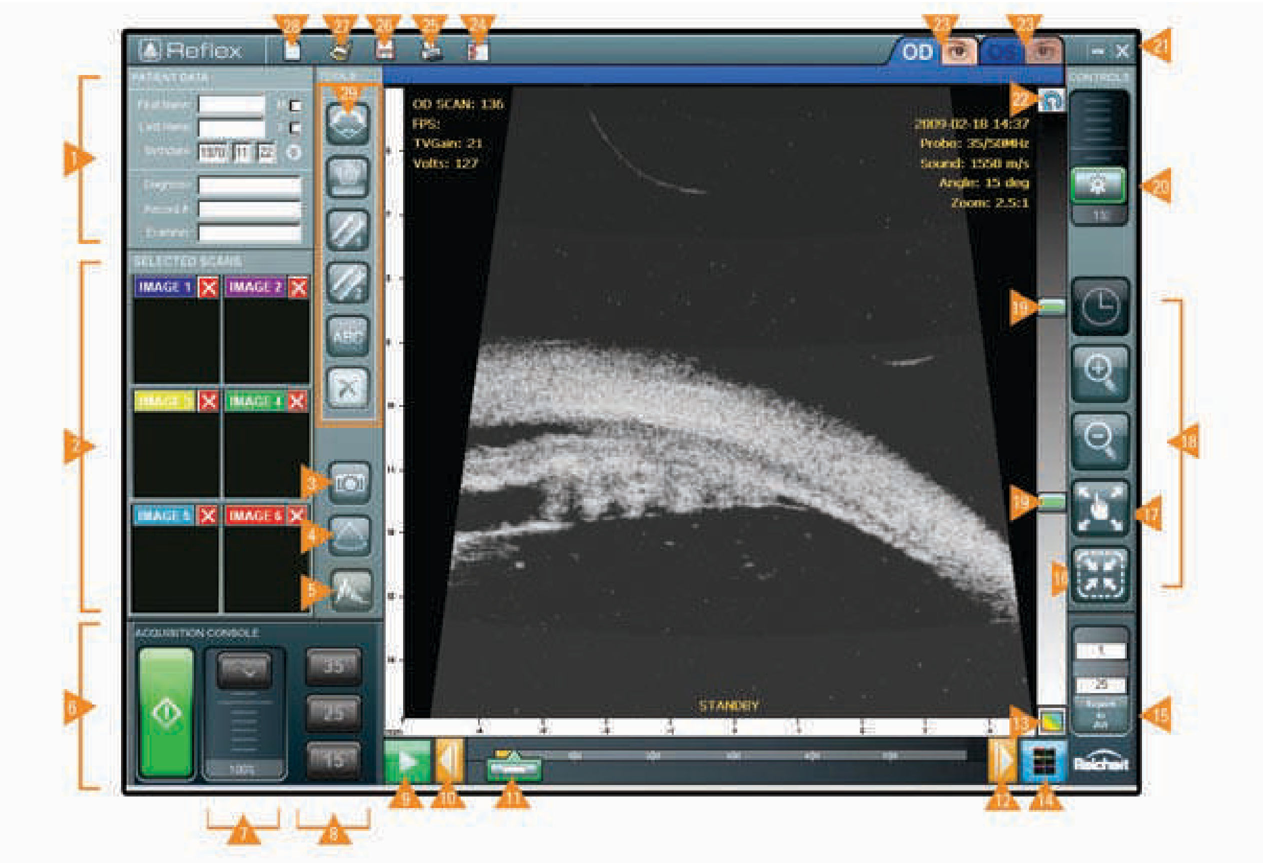
**** An alternate medical grade power cord for your region may need to be obtained as required by your local laws and ordinances for use with a medical grade device.**

Main Application Window

The main application window shown below is divided into five main areas:

- Menu bar across the top
- Patient data at the top left
- Acquisition tools at lower left
- Scan image screen and playback controls in the center
- Image tools to the right.

1 Patient Data
2 Exam Notes/ Selected Images
3 Export JPEG
4 Focus Line Overlay
5 A-Scan Display
6 Acquisition Idle/ On/Off
7 Probe Voltage
8 Scan Angle
9 Play
10 Frame Back
11 Scroll
12 Frame Forward
13 Color / B&W
14 Save Selected Scan
15 Export AVI
16 Reset
17 Centering
18 Zoom Buttons
19 Brightness Contrast
20 Gain
21 Exit
22 Rotate Image
23 OD/OS Select
24 Options/Tools
25 Print Exam
26 Save Exam
27 Open File
28 New File
29 Analysis Tools



OD SCAN: 136
FPS:
TVGain: 21
Volts: 127

2009-02-18 14:37
Probe: 35/50MHz
Sound: 1550 m/s
Angle: 15 deg
Zoom: 2.5:1

Reflex
OD
OS
PATIENT DATA
TOOLS
CONTROLS
SELECTED SCANS
IMAGE 1
IMAGE 2
IMAGE 3
IMAGE 4
IMAGE 5
IMAGE 6
ACQUISITION CONSOLE
35
25
15
100%
STANDBY
Reichert
28
27
26
25
24
23
23
21
22
29
20
1
19
19
18
17
16
2
3
4
5
6
15
13
9
10
11
12
14
7
8

Touchscreen notes:
When using the touchscreen it is recommended to use an appropriate stylus. This allows more accurate selection as well as helping to keep the screen free of fingerprints. When trying to make accurate selections such as when selecting points during scan analysis it is tempting to brace one's hand against the screen. This will be detected as a screen touch. To avoid this, use a longer stylus, and brace your wrist against the lower bezel of the display.

Getting Started (Continued)

Menu Bar

The menu bar contains options such as New, Open, Save and Print. Also included is a pull down menu for options/tools. At the top right of the Menu Bar are the icons for minimizing and exiting the program button. There is also OS and OD buttons.

New Exam

The New Exam button clears any existing scan data so that new exam data can be acquired.

Open Exam

The Open Exam button initiates a search screen to locate existing exams with the search criteria entered.

Save

The Save button is displayed when the current record is not saved so that it can be saved to a specific file name.

Print

Allows printing of the current record.

Menu

The Menu button displays a drop down menu of the available options for the records displayed.

Minimize

The minimize button allows access to the Windows® desktop without closing the Reflex program.

Exit

The exit button closes the Reflex program and returns to the Windows® desktop.

OS / OD

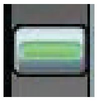
The OS/OD tabs allows selection of the right or the left eye exam screen.

Display Adjustments

The scan image window is the main area of the display.
This window changes between live images displayed briefly during acquisition and individual images displayed for analysis. The following tools are located around the perimeter of the scan window.

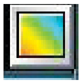
Gain

The Gain of the scan may be adjusted using the slider at the top right of the display.



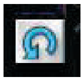
Brightness and Contrast

The range of grey or color used to generate the display may be adjusted. By dragging the sliders at the left of the screen the total range as well as the location of the range of grey or color may be adjusted.



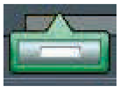
Color/Grey

Tap this button to toggle between the grey scale and false color display options.



Rotate

Tap this button to rotate the scan image 90 degrees. If the scan presentation is preferred horizontally or vertically, this button can change the orientation before scanning.



Scroll

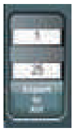
By moving the scroll slider any of the images captured during acquisition may be displayed for analysis. Forward and Reverse buttons are located at each end of the scroll bar to allow stepping through the exam one frame at a time.

Play

The Play button displays the scanned images in succession, producing a real time movie of the acquisition. Playback can be stopped at any time by tapping the Play button.

Movie Export

Above the Scan Select button is the Export to AVI tool. This will create a movie in .AVI format of the selected scans.



Getting Started (Continued)

Display Adjustments (Continued)

Orientation
Defines the angle of sweep the probe was oriented during the scan. The angle is displayed in clock hours (e.g., 4:00).

Zoom In
Select the Zoom In tool and then touch the screen in the center of the area of interest. The display will zoom to the defined area. While the zoom in tool is active tapping on the screen will zoom in the image. Zoom In mode can be cancelled by tapping the button once again.

Zoom Out
While the Zoom Out tool is active tapping on the screen will zoom out the image. Zoom Out mode can be cancelled by tapping the button once again.

Pan
The Pan button allows the displayed image to move in any direction on the screen. Press and hold the left mouse button and then move the mouse in the direction desired to move the image left, right, up, or down.

Reset Image
Tap the Reset Image button to size the image to its original size.

Selected Scans
Pressing the selected scans button saves the image into the save selected scans area. Thumbnails of these scans (up to a maximum of 6) will appear to the left of the screen in the selected scans area. Only these saved scans are part of the exam file. A sub exam can be created, raw scan data accessed, and more scans can then be saved. If saved, raw data can be re-opened.

Getting Started (Continued)

Analysis Tools The software provides several tools for analyzing and documenting images. Features in the image may be measured using the Angle, Area, and Caliper tools. The image may be labeled using the Label tool. A mouse can be used if greater precision is needed when using the analysis tools. The Angle, Area, Caliper1, and Caliper2 have adjustable points when performing analysis.

Angle

After selecting the Angle tool, tap the screen at 3 places with the middle point forming the vertex of the angle. Lines will appear on the screen joining the 3 points as well as an indication of the included angle in degrees. Angle mode can be cancelled by tapping the Angle button once again. T

Area

Select the area tool and tap at a minimum of three points around the desired area. Close the area with a single tap on the initial point. Area is reported in mm^2. Area mode can be cancelled by tapping the button once again.

Caliper1

Select the Distance1 tool and tap the screen at the 2 points to be measured. A line will be drawn on the screen between the two points and the distance displayed in mm. Distance1 mode can be cancelled by tapping the button once again.

Caliper2

Identical to Distance1, this second instance of the measurement tool allows the display of two distance measurements.

Label

Select the Label tool and tap the screen where you want the label to appear. A virtual keyboard will appear at the bottom of the screen allowing you to type in the label contents. Type in the text of the label and then tap Enter to complete the label entry. Label mode can be cancelled by pressing the ESC key. See the Options/Tools Menu section for available label styles.

Clear

Select the Clear button to delete the analysis tool overlays from the screen. This can be useful when saving the same image with different sets of analysis tools.

JPEG Export

The JPEG Export button saves the currently displayed screen as a JPEG. These can then be exported as needed.

Focus Line Overlay

Selecting this control will display a dotted line on the screen at the focal distance. Targets at this distance from the probe will be displayed with the best possible resolution and measurements taken along this line will be most accurate. This distance is a function of the probe type; consequently different probes should be used for anterior and posterior scans.

Analysis Tools (Continued)

A-Scan Display

Selecting this control will display an echo trace at the left side of the scan window. This trace indicates the strength of signal versus distance. Each sweep of the scan window contains multiple A-Scans. A specific A-Scan is selected by touching the screen in the location desired. This analysis tool is primarily used for measuring distances and areas at the areas of interest.

Acquisition Console

Idle/Start/Stop

Tap this button to enter the scanning idle state. Further taps will start and stop the acquisition of images. The footswitch may also be used to activate the acquisition functions.

Probe Voltage

The voltage of the beam may be adjusted using the slider next to the Idle/Start/Stop button. The default position is at the top for maximum voltage, however in some cases it may help to reduce voltage to obtain a better image. This is especially useful with postoperative IOL patients.

Scan Sweep Angle

The scan sweep angle allows three angles of view. Pressing the appropriate number sets the angle. Since the number of vectors remains constant, narrowing the angle increases the resolution. This can be useful when imaging a particular area of interest.

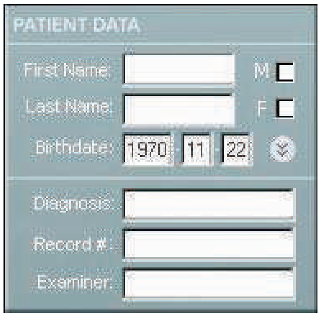
MHz (Probe)	Scan Sweep Angles
10	60, 40, 20
20	60, 40, 20
35*	35, 25, 15
50*	35, 25, 15

* Note: On the original version hardware, the scans will have scan angles of 30, 20, 10.

Patient Exam

Patient Data

To start a new exam, tap the new exam icon in the menu bar at the top of the screen. Tapping on any of the input fields will call up the virtual keyboard to allow input of the information if the "Use On-Screen Keyboard" option is selected. All fields are editable after saving data.

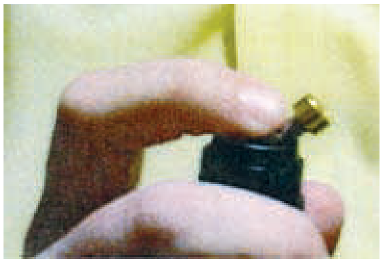


Birthdate: 1970 11 22

- **First Name** - enter the patient's first name (required)
- **Last Name** - enter the patient's last name (required)
- **Birthdate** - enter patient's year, month, and day of birth
- **Gender** - tap the appropriate checkbox (required)
- **Diagnosis** - Enter a diagnosis term
- **Record #** - Enter the reference number for the exam or patient
- **Examiner** - Enter the examining doctor's name
- **Exam Notes** - this field is normally hidden but can be called up and updated at any time by tapping on the two downward arrows in the Patient Information area.

To begin an exam for an existing patient, call up an existing exam for that patient, tap NEW EXAM at the top of the screen. Then tap YES on the pop-up asking if you wish to reuse the current patient data.

Preparing the Probe



The transducer may be installed or removed from the probe by pressing the scan head to one side as shown and turning the transducer counter-clockwise.

Note: The transducer should always be removed from the probe after an exam session and allowed to air dry before storage or reuse.

When using the eyecup simply attach the transducer (screw clockwise) onto the probe scan head finger-tight and it is ready.

Using the Eyecup

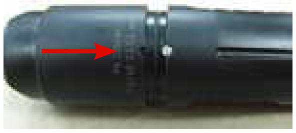
The optional eyecup is used to create a water bath on the eye for the immersion probe.

Note: Eyecups must be cleaned and disinfected after each exam to avoid contamination between eyes and between patients. Instructions are located in the *Cleaning & Disinfection* section on page 21.

Patient Exam (Continued)

Using the *Optional* Nosepiece Standoff Kit

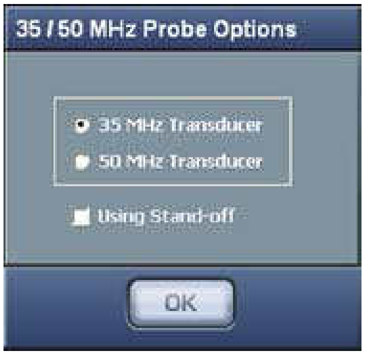
When using a nosepiece, the following procedure must also be followed:



1. Aligning the groove in the nosepiece with the metal pin on the water probe, slide the nosepiece carefully over the transducer and push until the pin is firmly seated into the nosepiece groove.
2. Place the probe in a vertical position. (The probe storage case can be used as a stand when preparing the probe. Disconnect the probe from the cable and use the foam in the case to hold the probe in a vertical position).
3. Fill the nosepiece with de-ionized or distilled water. This is most easily accomplished by filling it using a syringe (without a needle). For best results, fill the nosepiece completely with water.
4. Position one of the supplied membranes on the standoff and center it over the nosepiece opening. Using the applicator, push one of the supplied plastic rings over the membrane until it seats against the stop on the nosepiece.

Note: There should be little if any air trapped beneath the membrane after application. Any small air bubbles will float to the back of the transducer when the probe is in use.

Note: The standoff kit reduces the maximum angle and does not allow the highest scan sweep angle. The transducer will contact the sides of the standoff if the maximum scan sweep angle is selected. Please ensure that the "Using Stand-off" option is selected before starting the test or the transducer will contact the sides of the standoff and limit the scan sweep.

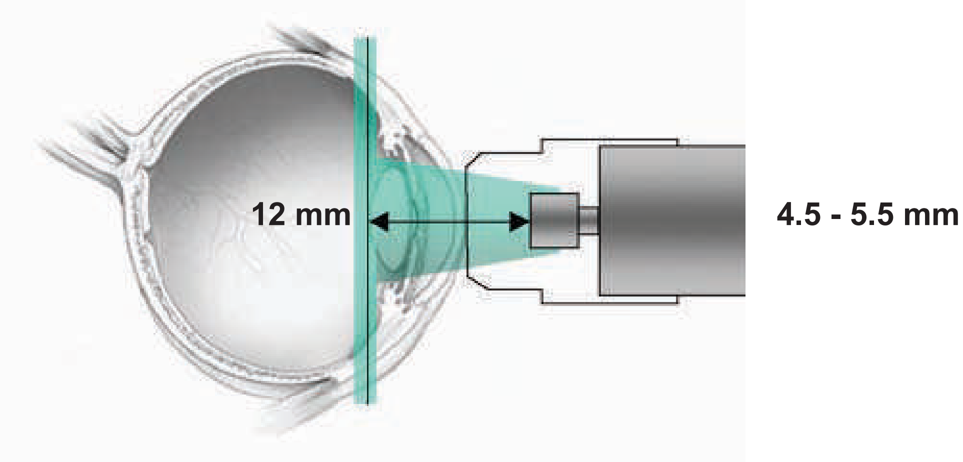


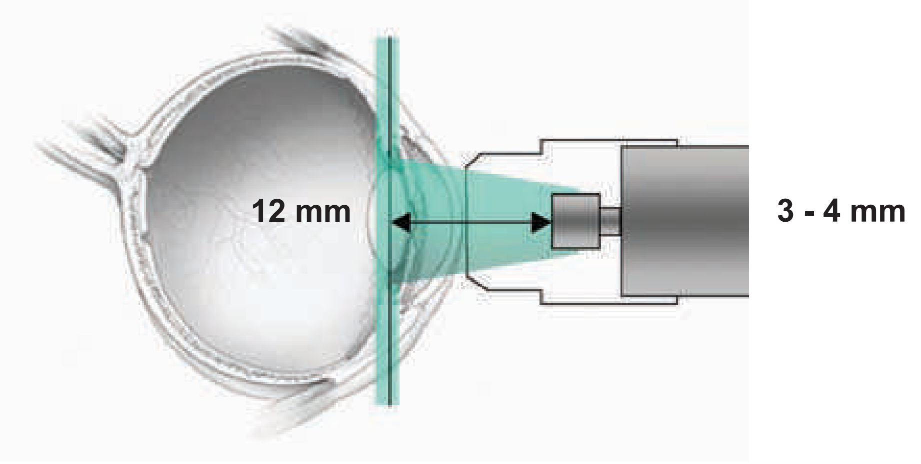
35 / 50 MHz Probe Options

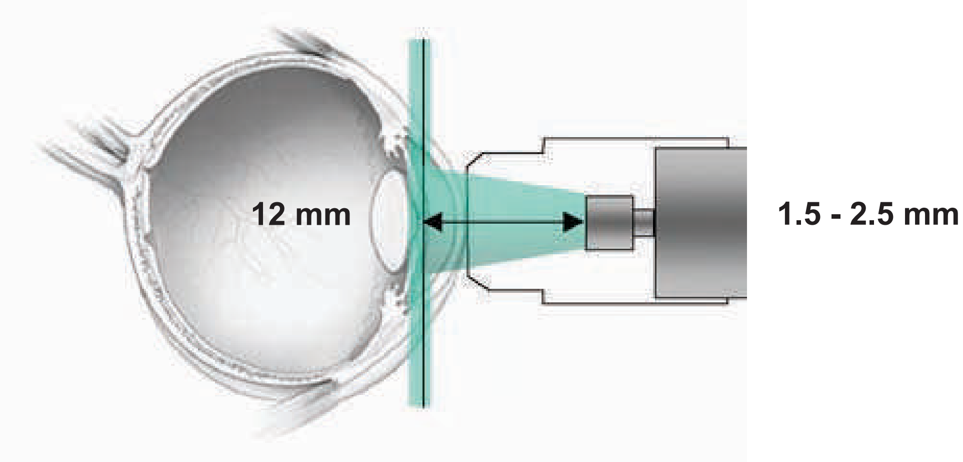
● 35 MHz Transducer
○ 50 MHz Transducer
☑ Using Stand-off

Using the *Optional* Nosepiece Standoff Kit (Continued)

The illustrations below are intended to show how the various standoff covers effect the optimum focus of the instrument. In all cases the 35 MHz transducer with a focal length of 12 mm is illustrated.







Preparing the Patient

- Place the patient in a reclining chair so that the patient is comfortable and laying almost flat.
- Apply a topical anesthetic to the patient's eye to be examined.
- Have the patient focus on a point on the ceiling with the fellow eye.

WARNING: MEASUREMENTS SHOULD NOT BE ATTEMPTED WHEN OCULAR INTEGRITY IS QUESTIONABLE. THE IMMERSION CUP MUST TOUCH THE EYE DURING OPERATION. CONSEQUENTLY, THE OPERATOR NEEDS TO EXHIBIT CARE IN PLACING THE CUP AND MANIPULATING THE PROBE. FORCE SHOULD NOT BE EXERTED AGAINST THE EYE.

Contact Scanning (For Water Path Scanning Without Immersion)

This scanning method applies when using one of the optional sealed Reflex probes or the water-path probe fitted with the nosepiece and membrane. (See the previous section on preparing the probe).

- For scanning the anterior portion of the eye with the 35 or 50 MHz probe, the membrane of the sealed (self contained) water path can be placed directly on the eye.

- For scanning the posterior portion of the eye using a low frequency (10 or 20 MHz) probe, the probe should be placed on the closed eyelid using an approved ultrasonic gel.

Immersion Scanning (For Sulcus-To-Sulcus Scanning)

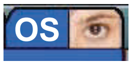
This scanning method is primarily used with the water bath and either the 35 or 50 MHz transducer.

- Insert a scleral eyecup securely under the eyelid.
- Fill the scleral eyecup, covering the eye to approximately three-quarters of an inch deep, with distilled water. The water is required for successful transmission of the ultrasound signals into the eye.

Patient Exam (Continued)

Obtaining a Scan

1. Select the eye to be examined by tapping the appropriate OS/OD button at the top of the screen.



2. Press the foot pedal once to place the unit in idle mode. Ensure the sweep angle is set to the minimum (10°) when using the nosepiece. The probe will begin scanning and an image will appear on the screen.

   Note: If performing a scan of the posterior chamber using a low frequency closed probe, apply coupling gel to the probe end and gently apply the probe to the closed eyelid. For scans of the anterior chamber using a higher frequency immersion probe, see the previous sections on use of either the eyecup or standoff.

3. Adjust the position of the probe over the eye until the image is satisfactory. You will find that the best tissue definition will be seen at the focal distance of the probe. It is not necessary to measure this distance as the focus line can be displayed on the image.
4. Press the foot pedal to begin capturing scans. Acquisition will continue for a maximum recording time of one minute. At any time a second press of the foot pedal will stop acquisition.
5. Lift the probe from the eye or the immersion cup. Scroll through the captured images using the slider at the bottom of the screen.
6. Tap the **Select Scan** button at the lower left of the screen to save the best images to the Selected Scans area as thumbnails.

Probe Cleaning and Disinfection

Refer to the ***Cleaning & Disinfection***, section in this manual for the cleaning and disinfection procedure and information.

Patient Exam (Continued)

Saving an Exam

To save an exam, tap the **Save Exam** icon in the menu bar at the top of the screen. When saving an exam, the patient data and the raw data for the scans in the **Selected Scans** thumbnail area (up to a maximum of six scans per eye side) will be saved as a single file. Any of the analysis tools used on the saved scans, or modifications to the display will be saved with the scan. Only the scans saved to the Selected Scans area are saved. Raw data can be saved for analysis at a latter time.

Scans may be exported as images in either JPEG or DICOM format. These images are not part of the saved exam file.

The entire group of scans or any part thereof may be exported as a movie file in .AVI format.

The exam folder can be archived to another PC or network server by using the Archive option in the Tools/Options menu.

Creating Sub-exams

For most users, the basic examination procedure with a single scan acquisition is sufficient. However, you can perform an exam with multiple sub-exams, each containing its own set of saved scans. To perform an exam that includes sub-exams you will need to prepare the patient and start the examination as described at the beginning of this section. You can then save the exam as described above. At this point clear the selected Scans area, continue the acquisition process, and again move the best scans to the Selected Scans area. Tapping the **Save Exam** icon will save a sub exam containing the current patient data and the new scans. The exam file name will have the next sequence number attached.

Sub-exams can also be created when opening an existing exam file. In this case any new instances of the analysis tools will be saved in the new sub-exam without effecting the original exam.

Changing Probes During an Exam

If it is necessary to change the probe for any reason during an exam it is important to first save the exam. When the new probe is attached the scan buffer and the Selected Scans area will be cleared.

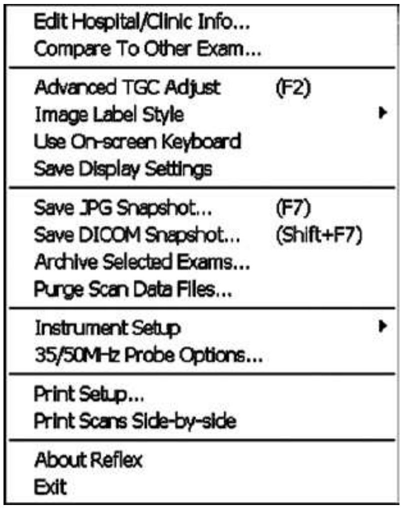
Printing an Image

Tapping the **Print** icon in the Menu Bar will send the highlighted images in the Selected Scans area to the printer. If no images are highlighted the currently displayed scan will be printed.

Options/Tools Menu

Options and Tools Menu

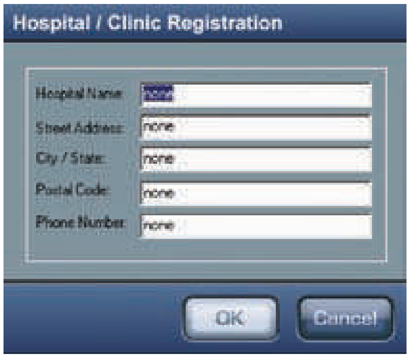
The Options and Tools menu provides the ability of the operator to add, edit, or modify information, options, and parameters of the Reflex. Refer to the menu shown.


Edit Hospital/Clinic Info...
Compare To Other Exam...
Advanced TGC Adjust (F2)
Image Label Style
Use On-screen Keyboard
Save Display Settings
Save JPG Snapshot... (F7)
Save DICOM Snapshot... (Shift+F7)
Archive Selected Exams...
Purge Scan Data Files...
Instrument Setup
35/50MHz Probe Options...
Print Setup...
Print Scans Side-by-side
About Reflex
Exit

Edit Hospital/Clinic Info..

Note: Protect your data by archiving it. Your exam database is stored on the hard drive of the unit. Good practice is to perform regular backups as described in the section of this manual titled "options/tools menu" to archive your data to a secure location.

Select this option to call up the Hospital / Clinic Registration window.


Hospital / Clinic Registration

Hospital Name: none
Street Address: none
City / State: none
Postal Code: none
Phone Number: none

The hospital info will be saved as part of the exam file and will appear on print outs of the scans.

Compare to other Exam..

When patient data is current on the screen and this option is selected, it will visually display a selected prior exam from the same patient in a side-by-side visual comparison. This comparison will provide a visual effect to determine changes between the two exams.

Advanced TGC Adjust (F2)

In some cases it may be desirable to use a TGC (time gain compensation) scheme other than the linear intensity increase with distance. The advanced TGC option allows a custom curve to be created defining gain versus distance. The most common application is to increase gain around the focal line to allow "focusing in" on a particular target, while reducing the surrounding noise. Click on the gain line and drag that point to describe the gain curve while observing the effect on the scan image.

Image Label Style

Select between Transparent, Opaque, and Invisible.

- **Transparent** - the label is displayed on a transparent background.
- **Opaque** - the label is displayed on an opaque background. This is useful when the label text is obscured by the image in the background.
- **Invisible** - this option makes all of the labels on the current scan invisible. This option is useful when printing a scan without labels.

Use On-screen Keyboard

The On-screen Keyboard is a virtual keyboard that will appear on the screen when the left mouse button is activated in any of the data fields in the Patient Data section or where text is required.

Note: This option must be set to ON before the On-screen Keyboard is active.

Save Display Settings

The current display settings can be saved at any time as the default settings. When the settings of the Reflex are set to the preferences of the user, this option can be selected to save the current settings as the default settings (e.g., gain, brightness/contrast, gray scale, etc).

Save JPEG snapshot.. (F7)

Select this option to create a JPEG format image file of the currently displayed image. The image file will be saved in the exam folder.

Save DICOM snapshot.. (Shift F7)

Select this option to create a DICOM format image file of the currently displayed image. The image file will be saved in the exam folder.

Archive Selected Exams..

If exam files need archiving, they can be archived on the computer or an external device such as a USB drive using this option. This option displays a pop-up window to locate the files by Name, surname, and by folder. The files can be selected individually, in multiples, or all selected. Once the files are selected and the Archive button is activated, the file is archived in the directory selected.

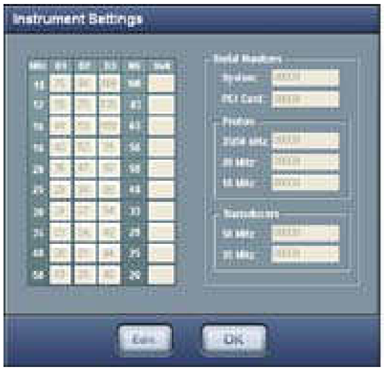
It is recommended to backup the exam files to an external location such as a PC or network server. This is best done by copying the files onto a USB flash memory which can then be transferred to the PC or server. The original files are not deleted by this operation but may be removed at the operator’s discretion using the Windows® Explorer.

Purge Scan Data Files..

If exam files are no longer needed, they can be purged from the computer using this option. This option displays a pop-up window to find the files by Name, surname, and by folder. The files can be selected individually, in multiples, or all selected. Once the files are selected and the Purge button is activated, the file is removed from its folder. Once these original data scan files are deleted, they are not retrievable. This option does not remove the examination files (e.g., patient data, and selected scan images).

Options/Tools Menu (Continued)

Instrument Setup



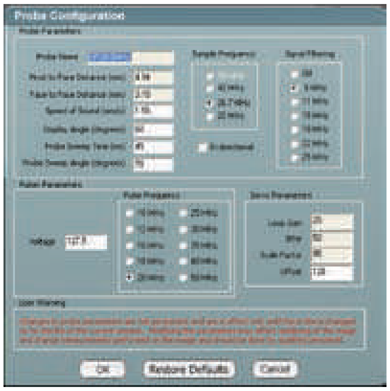
This option enables; changes to the instrument settings, probe calibration, and probe configuration.

Edit Instrument Settings

The instrument settings are set at the factory and should not need updating by the user. However, if a probe is replaced, there is a place to record the serial number in this screen.

Calibrate Probe

The probe calibration is a procedure that is performed at the factory and should not need updating by the user. This procedure is password protected and the password is only for authorized service personnel.



Configure Probe (For Advanced Users..)

This window is password protected and is used to modify the setup and configuration of the probe. This should only be performed by advanced users who fully understand the results of modifying the parameters in this screen. Several of the fields are displayed for information only and cannot be modified.

35/50MHz Probe Options

Selecting this option displays a window requesting the selection of either the 35 or the 50 Mhz Transducer. When selecting this option, ensure that the correct transducer is attached to the end of the probe.

Print Setup

This sub menu selects the printer and sets the print options such as paper size and orientation. The application is designed to output scanned images to any Windows® compatible USB printer. For details on setting up your printer, refer to the documentation supplied with the printer.

Options/Tools Menu (Continued)

Print Scans Side-by-side

This menu compares 2 scans side-by-side so that a visual comparison can be performed. This option allows the physician to determine if the health of the eye is improving or degrading.

About Reflex

Displays the following information:

- Toll Free Telephone Number
- The Company Telephone Number
- The Company Fax Number
- The Company Address
- The Software Revision of the Reflex.

Cleaning & Disinfection

External Cleaning

Clean the external surfaces of this instrument using a clean, soft cloth moistened with a mild detergent solution (1 cc of liquid dish soap to one liter of clean, filtered water (filtered below 5 microns)).

LCD Display Cleaning

Use a clean, soft cloth with neutral detergent or ethanol to clean the operator display. Do not use any chemical solvent, acidic, or alkali solution.

Probe Cleaning/Disinfecting

WARNING: IN ORDER TO PREVENT TRANSFER OF INFECTION, AFTER EACH USE DISINFECT THE PROBE AND IMMERSION CUP FOLLOWING ACCEPTED LOCAL CLINICAL PROCEDURES REGARDING THE USE OF DISINFECTANTS.

CAUTION: DO NOT STERILIZE THE PROBE USING AUTOCLAVING OR IRRADIATION. AFTER CLEANING OR DAMAGE TO THE PROBE MAY OCCUR.

CAUTION: DO NOT IMMERSE THE PROBE HANDLE, CONNECTING CABLE, OR THE MAIN PROBE UNIT IN LIQUID OR DAMAGE TO THE PROBE ASSEMBLY MAY OCCUR.

1. Clean the probe with a soft, clean cloth using an approved disinfectant; such as 70% isopropyl alcohol, cidex, 10% bleach solution, or a disinfection recommended by local regulations. Allow the unit to air dry.
2. Immerse the probe tip for 10 minutes in disinfectant. Approved disinfectants are 70% isopropyl alcohol, cidex, or a 10% bleach solution. The probe end may be immersed in liquid, but the probe handle, connecting cable and main unit cannot be immersed in any liquid.
3. Rinse the end of the probe thoroughly with sterile distilled water and dry the probe with a clean, lint-free cloth or tissue.

Note: Do not use the probe as a stylus.

Note: Always remove the transducer from the probe and allow to air dry before storing.

Note: Always store the probe when not being used in the provided case to protect it.

Note: Do not attempt to use the reflex if there is any indication that the probe or cables have been damaged and/or their physical integrity has been compromised.

4. If the probe tip has made contact with anything between exams, repeat disinfecting procedure. Ensure that no debris is present in the water path.
5. Put the probe and its accessories in the provided case for safe storage after cleaning and use.

Troubleshooting

This section describes troubleshooting and support information for the Reflex UBM.

Touch Screen Calibration

The Reflex UBM contains a touch screen. This touch screen can be re-calibrated as needed. To initiate the calibration program on the Reflex, perform the following procedure:

1. Press the Start button on the lower left of the screen.
2. Select “Programs,” “PenMount DMC9000 Utilities,” then “Control Panel.”
3. Under the “Calibrate” tab of the “PenMount Control Panel” there are two options: Standard Calibration and Advanced Calibration.
   Select either the Standard or the Advanced Calibration button.
   - Standard Calibration - requests touching the screen in 5 locations.
   - Advanced Calibration - requests touching the screen at 4, 9, 16, or 25 times.
4. Touch and hold the stylus on the screen at the requested locations as instructed.
5. After the calibration procedure is complete, close the “PenMount Control Panel.”

Troubleshooting (Continued)

The following chart provides details of common difficulties and solutions for the Reflex.

Definition	Probable Solution
Computer not starting.	Apply power to unit. Reboot computer.
Reflex Program not starting.	Shutdown and restart computer. Connect probe to unit.
Computer not responding to touch.	Shutdown and restart computer. Perform touch screen calibration.
Computer not responding to mouse.	Shutdown and restart computer. Plug USB mouse into USB port.
Computer not responding to keyboard.	Shutdown and restart computer. Change the batteries in the wireless keyboard.
CD is not reading media.	Push the CD closed. Use canned air to clean CD.
Printer is not responding.	Apply power to unit. Attach printer cable. Install printer driver. Install correct printer driver. Replace printer cartridges. Replace printer paper. Remove the printer paper jam.

If problems still persist, contact your local dealer or Reichert, Inc.

NOTE: Circuit diagrams, component parts list descriptions and calibration instructions are available only to the qualified personnel.

Specifications

Catalog Number:	16020
Electrical:	
Input	100-240 VAC, 50 - 60 Hz
Physical Dimensions:	
Width	15 in. (38.1 cm)
Height	15.5 - 20 in. (39.4 - 50.8 cm) (adjustable)
Depth	10 in. (25.4 cm)
Weight	23.5 lbs. (10.66 Kg)

The following specifications apply to the system when used with the water path probe in combination with the 35 MHz or 50 MHz thin film transducer and the 20 and 10 MHz Sealed Oil Filled Probes. Specifications are given in 35/50, 20, and 10 order.

Focus	12, 22, 18 (mm)
Accuracy	
Angular	1.0, 1.6, 1.6 (± deg.)
Distance	0.25, 0.40, 0.40 (± mm)
Area	1.25, 2.00, 2.00 (±mm^2)
Resolution	100, 150, 150 (μm, combined lateral & angular)
Probe ultrasound freq.	35 or 50, 20, 10 MHz

Storage Conditions:	
Temperature	50° to 95°F (10° to 35°C)
Humidity	10% - 90% relative humidity, non condensing
Operating Conditions:	
Temperature	59° to 95°F (15° to 35°C)
Humidity	20% - 80% relative humidity, non condensing

Classifications

Class II medical device per US-FDA classification
Class IIa medical device per European MDD 93/42EEC
Class III medical device per Canadian MDR SOR/98-282

Disposal

This product does not generate any environmentally hazardous residues. At the end of its product life, follow your local laws and ordinances regarding the proper disposal of this equipment.

Guidance & Manufacturer's Declarations

Acoustic Output Powers

For the standard 35MHz C190200 transducer, the following values apply:

Acoustic Output (35MHz C190200 transducer)			**MI**	**$I_{SPTA.3}$ (mW/cm^2)**	**$I_{SPPA.3}$ (W/cm^2)**
Global Maximum Value			0.0097±0.0015	0.00026±0.000008	0.040±0.0017
Associated Acoustic Parameters	$P_{r.3}$ (MPa)		0.038±0.007		
	W_c (mW)			0.000026±0.000005	0.000026±0.000005
	f_c (MHz)		15.0±0.6	15.0±0.6	15.0±0.6
	z_{sp} (cm)		1.1	1.1	1.1
	Beam Dimensions (cm)	x_{-6}		0.044±0.004	0.044±0.004
		y_{-6}		0.050±0.004	0.050±0.004
	PD (ms)		0.045±0.004		0.045±0.004
	PRF (Hz)		2560		2650
	EBD (cm)	Az		0.7	
		El		0.7	
Operator Controls			The acoustic output power may be reduced from the level shown here by moving the Probe Voltage slider down from full power.		

For the optional 50MHz C190210 transducer, the following values apply:

Acoustic Output (50MHz C190210 transducer)			**MI**	**$I_{SPTA.3}$ (mW/cm^2)**	**$I_{SPPA.3}$ (W/cm^2)**
Global Maximum Value			0.0083±0.0012	0.00024±0.000003	0.040±0.0010
Associated Acoustic Parameters	$P_{r.3}$ (MPa)		0.035±0.004		
	W_c (mW)			0.000029±0.000006	0.000029±0.000006
	f_c (MHz)		17.4±1.1	17.4±1.1	17.4±1.1
	z_{sp} (cm)		1.0	1.0	1.0
	Beam Dimensions (cm)	x_{-6}		0.044±0.005	0.044±0.005
		y_{-6}		0.047±0.003	0.047±0.003
	PD (ms)		0.042±0.002		0.042±0.002
	PRF (Hz)		2560		2650
	EBD (cm)	Az		0.7	
		El		0.7	
Operator Controls			The acoustic output power may be reduced from the level shown here by moving the Probe Voltage slider down from full power.		

Guidance & Manufacturer's Declarations (Continued)

Uncertainties on the values on page 27 are reported as ±1 standard deviation. The derated intensities were derived from those measured in water based on the measured center frequency of the acoustic signal (f_c, MHz) and the distance from the transducer to the point at which the intensity was measured (d, cm) using the formula: Derated Intensity = Measured Intensity $*e^{-0.069*fc*d}$.

In compliance with IEC61157 the peak rarefaction acoustic pressure (p_r) is less than 1 MPa; the output beam intensity (I_{ob}) is less than 20 mW/cm^2; and the spatial-peak temporal average derived intensity (I_{spta}) is less than 100 mW/cm^2.

Definitions

$I_{SPTA.3}$ - **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).

$I_{SPPA.3}$ - **derated spatial-peak pulse-average intensity** (watts per square centimeter).

MI - **Mechanical Index.**

$p_{r.3}$ - **derated peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

W_o - **ultrasonic power** (milliwatts). For the operating condition giving rise to $I_{SPTA.3}$, W_o is the total time-average power. For the operating condition giving rise to $I_{SPPA.3}$, Wo is the ultrasonic power associated with the transmit pattern giving rise to the $I_{SPPA.3}$ value.

f_c - **center frequency** (MHz). For MI and $I_{SPPA.3}$, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter.

z_{sp} - axial distance at which the reported parameter is measured (centimeters).

x_{-6}, y_{-6} - are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} is found (centimeters).

PD - **pulse duration** (microseconds)

PRF - **pulse repetition frequency** (Hz)

EBD - **entrance beam dimensions** for the azimuthal and elevational planes (centimeters).

Appendix A

Terms and Definitions

A-Scan	The transmission and reception of ultrasound along a single axis or vector. The result is displayed as an oscilloscope–like trace showing amplitude and distance.
Exam	The data set consisting of up to 12 scanned images, image analysis, and patient data. Each exam is stored as a separate file.
Foot pedal	Allows the user to control scan acquisition in a hands-free manner.
Idle	An active scanning state in which the images are not saved. Usually used during setup before starting acquisition.
Export AVI	Display output of an Individual scan. Images may be exported in either JPEG or DICOM formats.
Movie	Display option in which the scanned images are replayed in real time. Movies may be output in AVI format.
Probe	A handheld sweeping ultrasound transducer that sends pulses and receives ultrasonic echoes during a scan sweep.
Tap	A momentary touch of the touch screen.
Touch	A continuous touch of the touchscreen normally used as part of a drag command to adjust or move an item on the screen.
Vector	A group of 2048 reflection samples from a single ultrasonic pulse, ranging from near (closest to the probe) to deepest (farthest from the probe).

End User Software License Agreement

CAREFULLY READ THE FOLLOWING TERMS AND CONDITIONS BEFORE USING THIS PRODUCT. IT CONTAINS SOFTWARE, THE USE OF WHICH IS LICENSED BY REICHERT, INC. TO YOU, THE ORIGINAL END USER, FOR YOUR USE ONLY AS SET FORTH BELOW. IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT, DO NOT USE THE SOFTWARE. USING ANY PART OF THE SOFTWARE INDICATES THAT YOU ACCEPT THESE TERMS.

Software products included with this product that are not Reichert products are licensed to you by the software provider. Refer to the license contained in the provider's product for the terms of use before using such products.

LICENSE: Reichert, Inc. grants you a non-exclusive license to use the accompanying software program(s) (the "Software") subject to the terms and restrictions set forth in this License Agreement. You are not permitted to lease or rent (except under separate mutually agreeable terms set forth in writing), distribute or sub-license the Software or to use the Software in a time-sharing arrangement or in any other unauthorized manner. Further, no license is granted to you in the human readable code of the Software (source code). Except as provided below, this License Agreement does not grant you any rights to patents, copyrights, trade secrets, trademarks, or any other rights in respect to the Software.

The Software is licensed to be used on any personal computer and/or any Reflex, provided that the Software is used only in connection with Reflex. With respect to the Desktop Software, you may reproduce and provide one (1) copy of such Software for each personal computer or Reflex on which such Software is used as permitted hereunder. With respect to the Device Software, you may use such Software only on one (1) Reflex. Otherwise, the Software and supporting documentation may be copied only as essential for backup or archive purposes in support of your use of the Software as permitted hereunder. You must reproduce and include all copyright notices and any other proprietary rights notices appearing on the Software on any copies that you make.

Notwithstanding any other provision of this License Agreement, this License Agreement shall not be deemed to apply to the Adobe® Acrobat® Reader software, Palm Inc. software, or any other applications software licensed to you by third parties that is included on the same media as Reichert's Software ("Other Software") if the Other Software provides that the use of the Other Software is subject to the terms and conditions of the third party's license agreement.

NO ASSIGNMENT; NO REVERSE ENGINEERING: You may transfer the Software and this License Agreement to another party if the other party agrees in writing to accept the terms and conditions of this License Agreement. If you transfer the Software, you must at the same time either transfer all copies of the Software as well as the supporting documentation to the same party or destroy any such materials not transferred. Except as set forth above, you may not transfer or assign the Software or your rights under this License Agreement.

Modification, reverse engineering, reverse compiling, or disassembly of the Software is expressly prohibited. However, if you are a European Union ("EU") resident, information necessary to achieve interoperability of the Software with other programs within the meaning of the EU Directive on the Legal Protection of Computer Programs is available to you from Reichert, Inc. upon written request.

EXPORT RESTRICTIONS: You agree that you will not export or re-export the Software or accompanying documentation (or any copies thereof) or any products utilizing the Software or such documentation in violation of any applicable laws or regulations of the United States or the country in which you obtained them.

TRADE SECRETS; TITLE: You acknowledge and agree that the structure, sequence and organization of the Software are the valuable trade secrets of Reichert, Inc. and its suppliers. You agree to hold such trade secrets in confidence. You further acknowledge and agree that Reichert, Inc. holds ownership of, the title, the Software and all subsequent copies, regardless of the form or media.

TERM AND TERMINATION: This License Agreement is effective until terminated. You may terminate it at any time by destroying the Software and documentation together with all copies and merged portions in any form. It will also terminate immediately if you fail to comply with any term or condition of this License Agreement. Upon such termination you agree to destroy the Software and documentation, together with all copies.

End User Software License Agreement

GOVERNING LAW: This License Agreement shall be governed by the laws of the State of New York and by the laws of the United States, excluding their conflicts of laws principles. The United Nations Convention on Contracts for the International Sale of Goods (1980) is hereby excluded in its entirety from application to this License Agreement.

LIMITED WARRANTY; LIMITATION OF LIABILITY: All warranties and limitations of liability applicable to the Software are as stated on the Limited Warranty Card or in the product manual accompanying the Software. Such warranties and limitations of liability are incorporated herein in their entirety by this reference.

SEVERABILITY: In the event any provision of this License Agreement is found to be invalid, illegal or unenforceable, the validity, legality and enforceability of any of the remaining provisions shall not in any way be affected or impaired and a valid, legal and enforceable provision of similar intent and economic impact shall be substituted.

ENTIRE AGREEMENT: This License Agreement sets forth the entire understanding and agreement between you and Reichert, Inc., supersedes all prior agreements, whether written or oral, with respect to the Software, and may be amended only in a writing signed by both parties.

Reichert, Inc.
3362 Walden Ave
Depew, NY 14043
USA

Toll Free: 888-849-8955
Phone: 716-686-4500
Email: info@reichert.com
www.reichert.com

Reichert Warranty

This product is warranted by Reichert, Inc. (herein after referred to as Reichert) against defective material and workmanship under normal use for a period of one year from the date of invoice to the original purchaser. (An authorized dealer shall not be considered an original purchaser.) Under this warranty, Reichert's sole obligation is to repair or replace the defective part or product at Reichert's discretion.

This warranty applies to new products and does not apply to a product that has been tampered with, altered in any way, misused, damaged by accident or negligence, or which has had the serial number removed, altered or effaced. Nor shall this warranty be extended to a product installed or operated in a manner not in accordance with the applicable Reichert instruction manual, nor to a product which has been sold, serviced, installed or repaired other than by a Reichert factory, Technical Service Center, or authorized Reichert Dealer.

Lamps, bulbs, charts, cards and other expendable items are not covered by this warranty.

All claims under this warranty must be in writing and directed to the Reichert factory, Technical Service Center, or authorized instrument dealer making the original sale and must be accompanied by a copy of the purchaser's invoice.

This warranty is in lieu of all other warranties implied or expressed. All implied warranties of merchantability or fitness for a particular use are hereby disclaimed. No representative or other person is authorized to make any other obligations for Reichert. Reichert shall not be liable for any special, incidental, or consequent damages for any negligence, breach of warranty, strict liability or any other damages resulting from or relating to design, manufacture, sale, use or handling of the product.

Patent Warranty

If notified promptly, in writing, of any action brought against the purchaser based on a claim that the instrument infringes a U.S. Patent, Reichert will defend such action at its expense and will pay costs and damages awarded in any such action, provided that Reichert shall have sole control of the defense of any such action with information and assistance (at Reichert's expense) for such defense, and of all negotiation for the settlement and compromise thereof.

Product Changes

Reichert reserves the right to make changes in design or to make additions to or improvements in its products without obligation to add such to products previously manufactured.

Claims for Shortages

We use extreme care in selection, checking, rechecking and packing to eliminate the possibility of error. If any shipping errors are discovered:

1. Carefully go through the packing materials to be sure nothing was inadvertently overlooked when the unit was unpacked.
2. Call the dealer you purchased the product from and report the shortage. The materials are packed at the factory and none should be missing if the box has never been opened.
3. Claims must be filed within 30 days of purchase.

Claims for Damages in Transit

Our shipping responsibility ceases with the safe delivery in good condition to the transportation company. Claims for loss or damage in transit should be made promptly and directly to the transportation company.

If, upon delivery, the outside of the packing case shows evidence of rough handling or damage, the transportation company's agent should be requested to make a "Received in Bad Order" notation on the delivery receipt. If within 48 hours of delivery, concealed damage is noted upon unpacking the shipment and no exterior evidence of rough handling is apparent, the transportation company should be requested to make out a "Bad Order" report. This procedure is necessary in order for the dealer to maintain the right of recovery from the carrier.

www.mercoframes.com

MERCOFRAMES