Ocular Response Analyzer®

User's Guide



AMETEK®
ULTRA PRECISION TECHNOLOGIES

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The information contained in this document was accurate at time of publication. Specifications subject to change without notice. Reichert Technologies 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.

The analysis tab of Ocular Response Analyzer software contains features that have not yet been cleared by the US FDA. Access to these features cannot be provided to users in the USA as of the date of this manual.

ISO 9001/13485 Certified – Reichert products are designed and manufactured under quality processes meeting ISO 9001/13485 requirements.

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

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Warnings and Cautions

Reichert Technologies (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: 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: THIS INSTRUMENT SHOULD BE USED IN STRICT ACCORDANCE WITH THE INSTRUCTIONS OUTLINED IN THIS USER'S GUIDE. THE SAFETY OF THE OPERATOR AND THE PERFORMANCE OF THE INSTRUMENT CANNOT BE GUARANTEED IF USED IN A MANNER NOT SPECIFIED BY REICHERT TECHNOLOGIES.

WARNING: USE OF THE ORA IS CONTRAINDICATED IN INSTANCES OF:

- ULCERATED CORNEAS
- FOLLOWING KERATOPLASTY
- FOLLOWING PENETRATING TRAUMA

WARNING: DO NOT REPAIR OR SERVICE THIS INSTRUMENT WITHOUT AUTHORIZATION FROM THE MANUFACTURER. ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY EXPERIENCED PERSONNEL OR DEALERS WHO ARE TRAINED BY REICHERT OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: MODIFICATIONS TO THIS INSTRUMENT IS NOT ALLOWED. ANY MODIFICATION TO THIS UNIT MUST BE AUTHORIZED BY REICHERT OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: IF THIS INSTRUMENT IS MODIFIED, APPROPRIATE INSPECTION AND TESTING MUST BE CONDUCTED TO ENSURE CONTINUED SAFE USE OF THIS INSTRUMENT.

WARNING: THE INTERNAL CIRCUITRY OF THIS INSTRUMENT CONTAINS ELECTROSTATIC DISCHARGE SENSITIVE DEVICES (ESDS) THAT MAY BE SENSITIVE TO STATIC CHARGES PRODUCED BY THE HUMAN BODY. DO NOT REMOVE THE COVERS WITHOUT TAKING PROPER PRECAUTIONS.

WARNING: THIS INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON THE POWER INPUT CONNECTOR OR THE UNIT'S POWER CORD OR DAMAGE TO IT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE OR DAMAGE TO THE INSTRUMENT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH OR DAMAGE TO THE OCULAR RESPONSE ANALYZER AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

WARNING: THE AREA SURROUNDING THE OCULAR RESPONSE ANALYZER NOSEPIECE MAY CREATE A "PINCH HAZARD." DO NOT PLACE FINGERS INTO THE OPENING SURROUNDING THE NOSEPIECE.

WARNING: THE USE OF ACCESSORIES OR CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF THOSE SOLD BY THE MANUFACTURER AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE EQUIPMENT OR SYSTEM.

WARNING: THE EQUIPMENT OR SYSTEM SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT OR SYSTEM SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

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

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



CAUTION: THE INTERNAL CIRCUITRY OF THE INSTRUMENT CONTAINS ELECTROSTATIC DISCHARGE SENSITIVE DEVICES (ESDS) THAT MAY BE SENSITIVE TO STATIC CHARGES PRODUCED BY THE HUMAN BODY. DO NOT REMOVE THE COVERS WITHOUT TAKING PROPER PRECAUTIONS.

CAUTION: DO NOT USE SOLVENTS OR STRONG CLEANING SOLUTIONS ON ANY PART OF THE INSTRUMENT OR DAMAGE TO THE UNIT MAY OCCUR. SEE THE MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTIONS.

CAUTION: USE OF AMMONIA BASED CLEANERS ON THE LIQUID CRYSTAL DISPLAY (LCD) MAY CAUSE DAMAGE TO THE DISPLAY. SEE MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTION.

CAUTION: MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THE ACCOMPANYING DOCUMENTS.

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

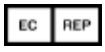
CAUTION: THIS INSTRUMENT IS NOT TO BE USED NEAR HIGH-FREQUENCY EMITTING SURGICAL EQUIPMENT.

CAUTION: THIS INSTRUMENT IS NOT INTENDED TO BE CONNECTED TO EQUIPMENT OUTSIDE THE CONTROL OF REICHERT INC.

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

Symbol Information

The following symbols appear on the instrument:

	CAUTION - Consult accompanying documents
	Type B Product Classification
	Alternating Current
	Protective Earth
	On / Off
	Date of Manufacture
	Manufacturer
	Waste of Electrical and Electronic Equipment
	Authorized to mark given by Intertek ETL Semko for conformance with electrical standards
REF	Catalog Number
SN	Serial Number
	Accompanying Documents must be consulted
	Accompanying Documents must be consulted
	Fragile Contents in Shipping Container - handle with care
	Keep Dry - Package shall be kept away from rain
	Authorized Representative in European Community
	This Way Up - Indicates the correct upright position of package

Introduction

Congratulations on your purchase of the Ocular Response Analyzer.

The Ocular Response Analyzer, part numbers 16070 and 16071, are revolutionary instruments designed to measure the intraocular pressure of the eye and biomechanical properties of the cornea in one simple, fast measurement. The instrument has an innovative automatic alignment system that eliminates operator subjectivity and provides precise, repeatable measurements.

This User's Guide is designed as a training and reference manual for operation, maintenance, and troubleshooting. We recommend that you read it carefully prior to use and follow the instructions in the guide to ensure optimum performance of your new instrument. If used properly, the Ocular Response Analyzer (also referred to in this manual as "ORA") will provide you with fast, accurate and reliable measurements for many years. Properly trained eyecare professionals such as ophthalmologists, optometrists, opticians and eye care technicians should operate this instrument. This unit should only be used by personnel knowledgeable of its operation and use.

Please retain this guide for future reference and to share with other users. For additional copies of this manual or questions related to the ORA, contact your local authorized Reichert, Inc. dealer or contact our Customer Service department directly at:

Tel: 716-686-4500
Fax: 716-686-4555
E-mail: reichert.information@ametek.com

Indications for Use

The ORA is intended to measure the intraocular pressure of the eye and the biomechanical response of the cornea.

Contraindications

Use of the ORA is contraindicated in instances of:

- Ulcerated corneas
- Following Keratoplasty
- Following penetrating trauma



Unpacking and Assembly

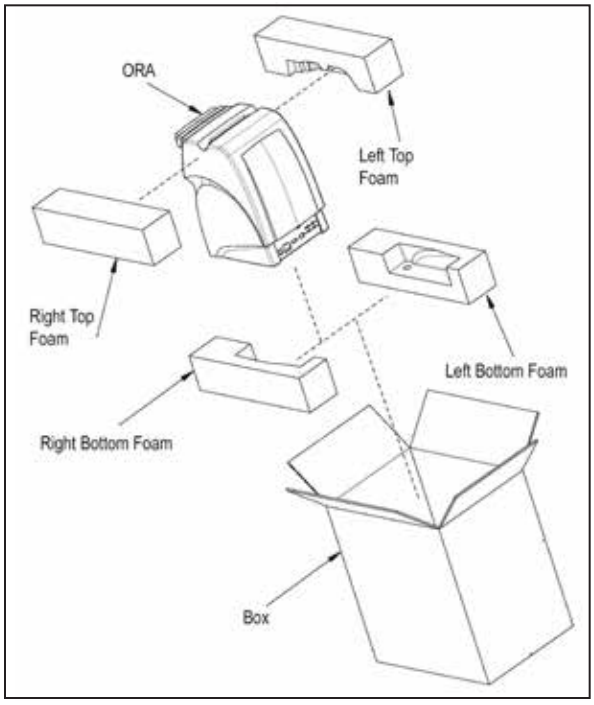
Great care has been taken to deliver your instrument to you. The packaging was specially designed to transport this device. The ORA is packaged in two boxes; one contains the display, and the other contains the unit. Please retain the packaging for future use in case transportation is required.

WARNING: DO NOT APPLY INPUT POWER TO THE UNIT UNTIL COMPLETE ASSEMBLY IS PERFORMED OR DAMAGE TO THE OCULAR RESPONSE ANALYZER AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

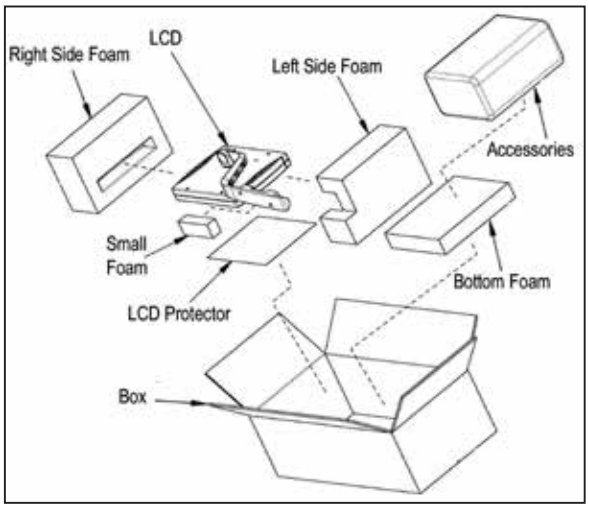
1. Open the Main Unit Box and carefully place the unit on an adjustable height instrument stand in a clean, dry, temperature controlled environment (Refer to the Specifications section in this manual). Keep away from direct sunlight, bright lights, and Infrared (IR) light-generating devices. Refer to the Unpacking Main Unit figure that details the box and contents.
2. Open the LCD Box and carefully remove the LCD and Attach the LCD Mounting Arm to the top of the ORA using the two (2) screws and washers that were sent with the LCD. Refer to the Unpacking LCD and the LCD Assembly figures.

Note: Ensure that the LCD cable is not pinched between the LCD Mounting Arm and the top of the ORA when the LCD Mounting Arm is attached.

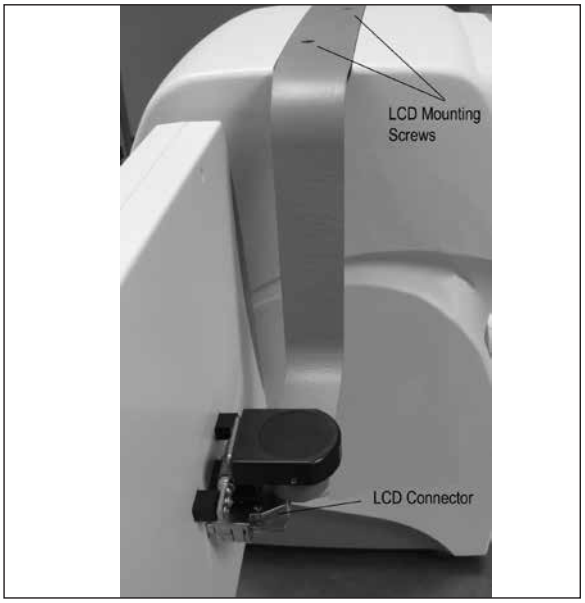
3. Attach the connector from the ORA to the LCD and tighten the screws on the connector to secure it firmly onto the LCD.
4. Put the packaging in a safe place in case future transportation is required.



Unpacking Main Unit



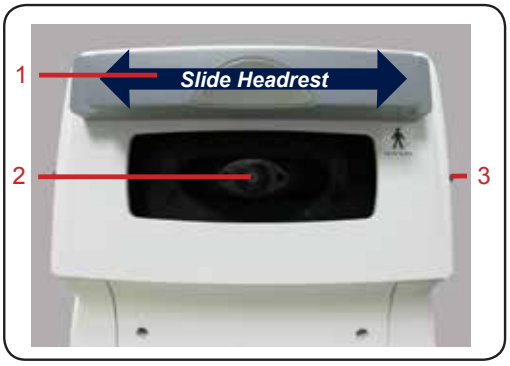
Unpacking LCD



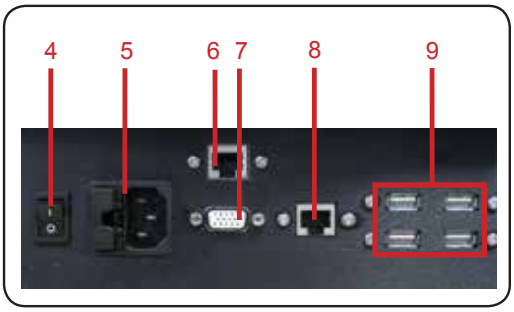
LCD Assembly

System Part Identification

1. **Forehead Rest:** Comfortable left/right sliding headrest for patient positioning and stabilization.
2. **Nosepiece:** Air tube where “air puff” originates. Green LED patient fixation target is visible inside this tube.
3. **Canthus Marks:** Alignment marks for proper positioning of instrument-to-patient-eye height.
4. **On / Off Switch:** Rocker-switch used to turn the instrument ON and OFF. Pressing the “I” is ON.
5. **Power Input Receptacle and Fuse Holder:** Input for AC power cord and location of fuses.
6. **Calibration Port:** Service Port for connection to Reichert Service equipment.
7. **Video Output:** Connection port for external monitor.
8. **Ethernet Connection:** Port for connection to a LAN (local area network).
9. **USB Interfaces:** Communication port for connection of peripheral devices (4 inputs).
10. **LCD Touch Screen:** User Interface for operating the instrument and displaying data.
11. **Chinrest Assembly*:** Integrated chinrest option of the 16071 model Ocular Response Analyzer. (* Assembly on the Ocular Response Analyzer, P/N 16071.)



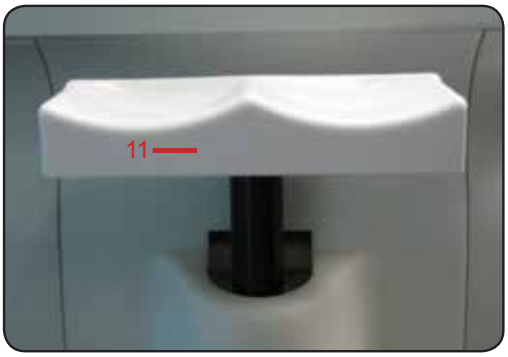
Patient Interface



Connections & Power



LCD Touch Screen



Chin Rest Assembly

Accessories

The items listed below should be included in the package. If any of these items are missing, please contact the Reichert Customer Service Department. Contact information can be found on the back page.

- Allen Wrench (P/N X76481)
  (For attaching the LCD Screen.)
- MSCR CAP Screws - 3 pcs (P/N X76368)
- Washer SPLK - 3 pcs (P/N X76381)
- Dust Cover (P/N 16070-012)
- Power Cord - 110V (P/N WCBL10018) or
  Power Cord - 230V (P/N WCBL10027)
- User’s Guide (P/N 16070-101)

Application of Input Power

1. Insert the female end of the Power Cord into the Power Input Receptacle (Item 5, previous page) located on the back of the instrument near the bottom.
2. Plug the male end of the power cord into a wall outlet of the appropriate voltage. Input voltage must not exceed the range specified on the instrument data plate. An appropriate wall socket adapter may be required depending on your wall-outlet style.
3. Remove the plastic screen protector from the screen (if it was not removed during unpacking).

Note: When powering up the Ocular Response Analyzer, do not touch the LCD screen until the device is fully booted up or the touch screen control program will be disabled.



4. Press the “I” on the On / Off Switch (Item 4, previous page) to apply power to the instrument.
5. After the On / Off Switch is ON, the unit will automatically initiate the ORA software. The screen to the right will be displayed.

Note: Ensure the date, time and time zone settings are correct for your location or the accuracy of patient data record keeping will be adversely affected.

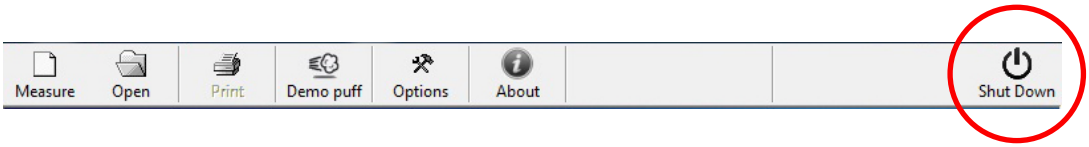
CAUTION: IF CONNECTION TO A NETWORK IS NECESSARY, CONNECT ONLY TO A SECURE NETWORK THAT HAS VIRUS AND MALWARE PROTECTION.

Instrument Shutdown

1. At the top of the ORA program in the title bar is an icon labeled “Shutdown”. Click on the Shutdown icon and wait until the LCD Screen powers off.

Note: Also shutdown using the standard windows shutdown under the start button.

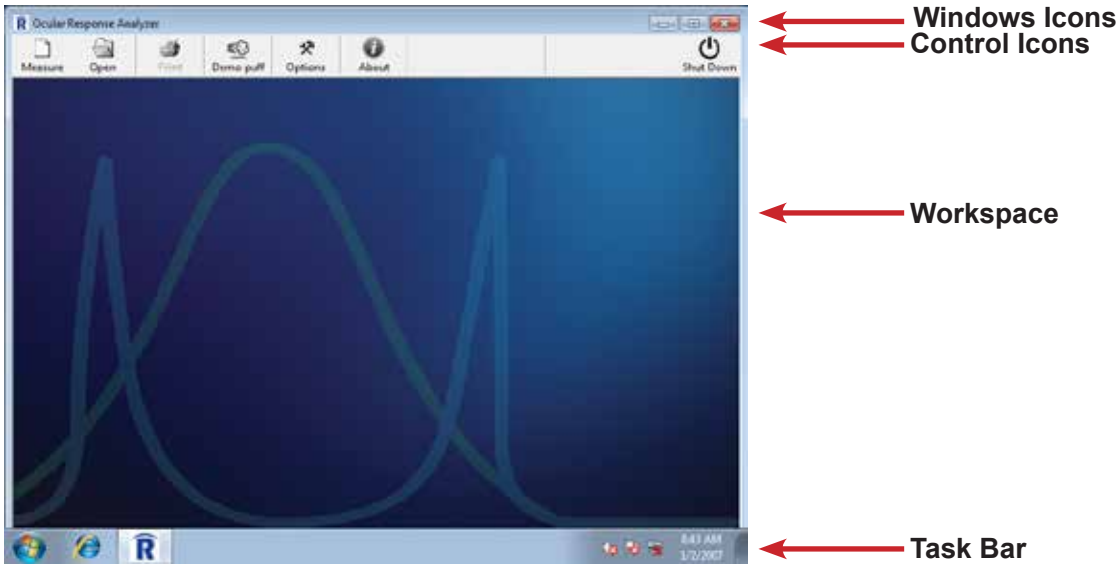
2. After the LCD Screen is dark, press the “0” on the On / Off Switch (Item 4, previous page) to disconnect power from the instrument.



Using the Software

The Ocular Response Analyzer PC software package controls the functions of the measurement head and allows for archiving of measurement data.

Initial Screen



Control Icon Buttons

The control buttons initiate the main functions of the software.

Windows Icons	Icons that minimize, maximize, or close the main menu screen.
Control Icons	Menu options for initiating main tasks and options in the ORA software.
Workspace	Display area for waveform and measurement data.
Task Bar	Tray displaying Windows operating software and options.

Control Icon Functions



Measure

The Measure function has two options, the normal mode and the quick mode.

Normal Measure: This mode requires operators to enter patient information before proceeding to the measure screen. All measurement data taken in Normal mode will be archived into the database.

Quick Measure: This mode immediately goes to the measure mode for quick measurements without patient data required.

Open

When the Open function is selected, a window is displayed to Open Patient Data where prior patient data records are stored.

Print

This option is only active when data is displayed to allow printing the data. An external printer is required with the printer drivers installed using removable media. A Windows 7®, 32-bit Embedded compatible printer is recommended.

Demo Puff

Enables operators to demonstrate the air-puff to patients before beginning an exam.

Options

Enables operators to modify various system settings:

- **General** - Maximum # of measures per eye, file locations, and database backup options.
- **Practice Info** - Doctor's name and Practice name information.
- **Tables** - Enables operators to edit database groups and races.
- **Views Layout** - Enables/disables selection of information on the patient database window.

About

Contains information about the Ocular Response Analyzer software package and has an option to view System Information about the embedded computer system.

Keyboard

An on-screen keyboard is available when not using a USB keyboard. To display the on-screen keyboard touch the field requiring information and the keyboard will appear on the LCD screen

Measure

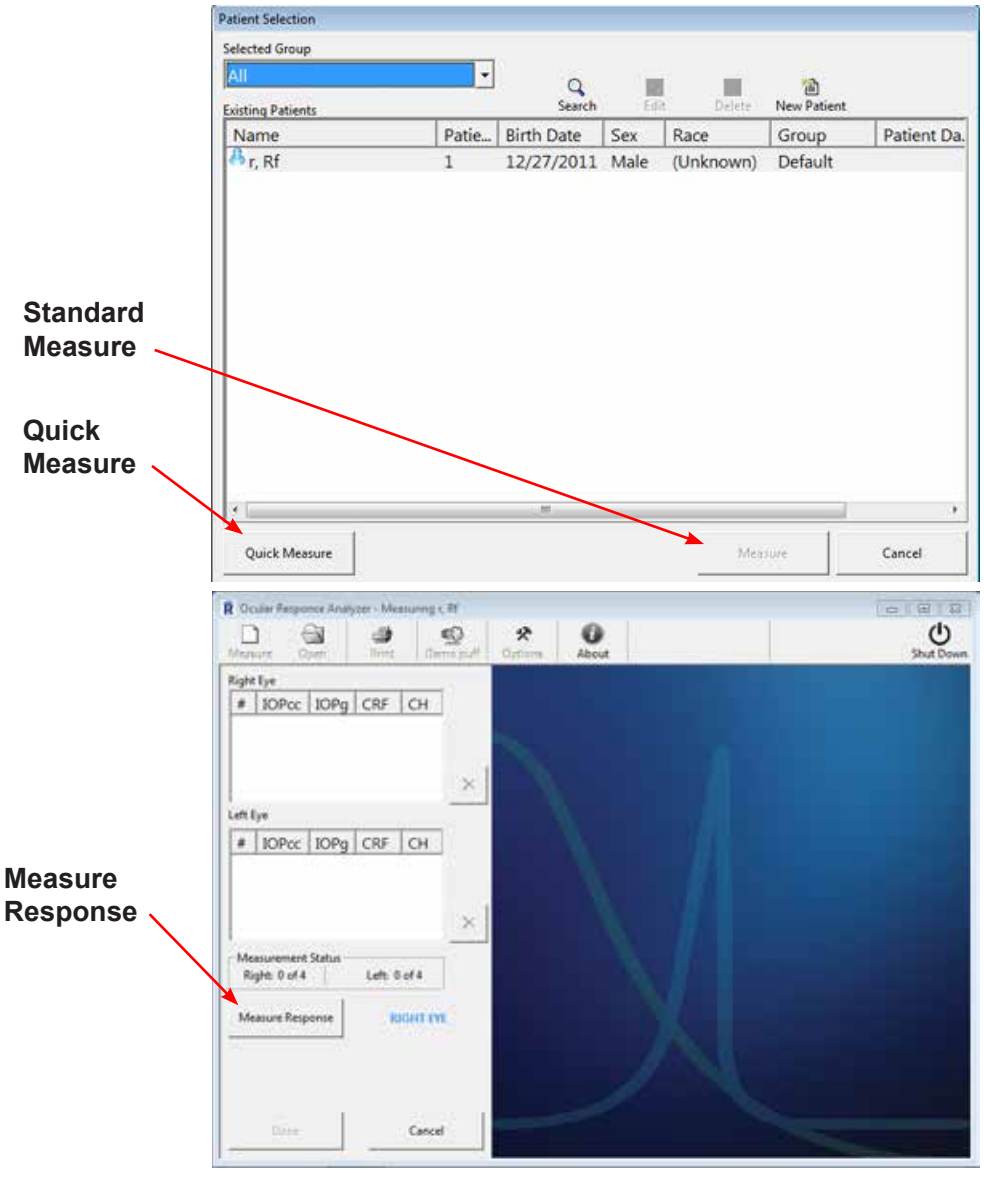
The Measure mode has two methods of measuring, the normal Measure mode and the Quick Measure mode.

Normal Measure: Enables a measurement by selecting an existing patient before progressing to the measurement screen. Existing Patients are displayed by group and new patients can be added by selecting the New Patient icon.

Quick Measure: This button skips past the request for patient information and goes directly to the measurement screen.

Measure Response

The button that initiates an automated alignment and measurement.

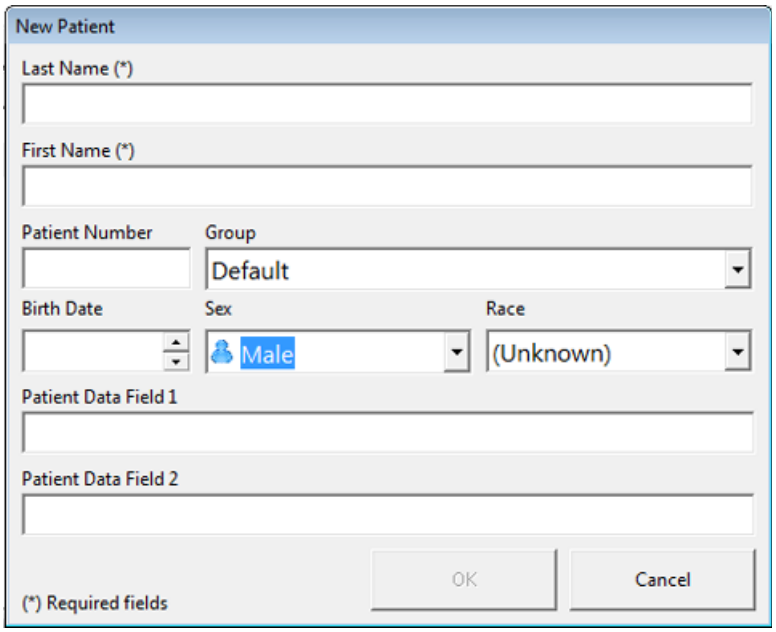


Measure (continued)

New Patient

When this option is selected, a window is displayed for entering patient information. The fields with an asterisk (*) require information entered.

Note: An on-screen keyboard may be displayed on the LCD Screen by touching a field requiring information when not using a USB keyboard.

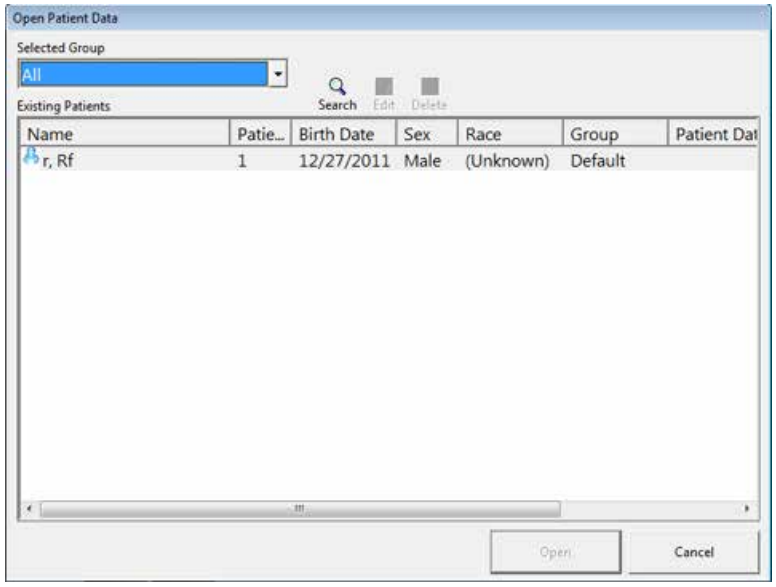


Open

The Open window shows a list of previous patient exams.

Search

Patient data can be found using the Search button. When Search is activated, type a name in the highlighted search field and the patient record will be displayed.



Edit

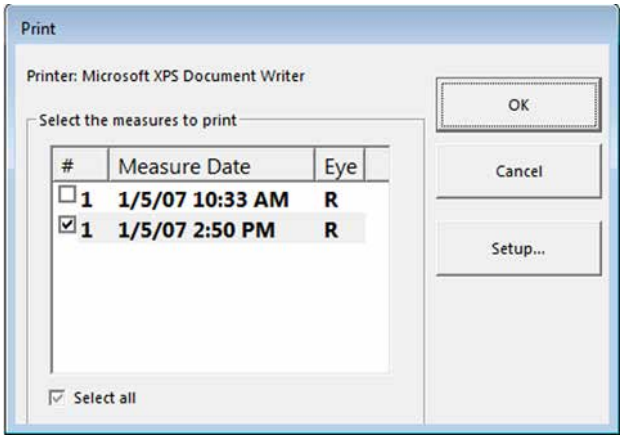
Allows editing of previously saved patient data.

Delete

This option deletes the selected patient record.

Print

Patient data can be printed from the main window when viewing patient records. To print a record, select the box next to the record and press OK.



Demo Puff

Before measuring a patient it may be helpful for operators to demonstrate the air puff so that the patient will know what to expect. With the patient seated comfortably in front of the instrument the operator should instruct the patient to hold a hand a few inches in front of the air tube, where the red fixation lights are visible.

Initiating the Demo Puff

1. Select Demo Puff to bring up the Demo Puff Dialog Window.
2. Click the Demo button to initiate the air puff.

Note: The button can be pressed as many times as desired.

3. Click the Close button when finished.



System Options

To modify system settings, click on the Options button. There are four tabs containing various system setting options.

Options

The Options window provides settings for features in the ORA software:

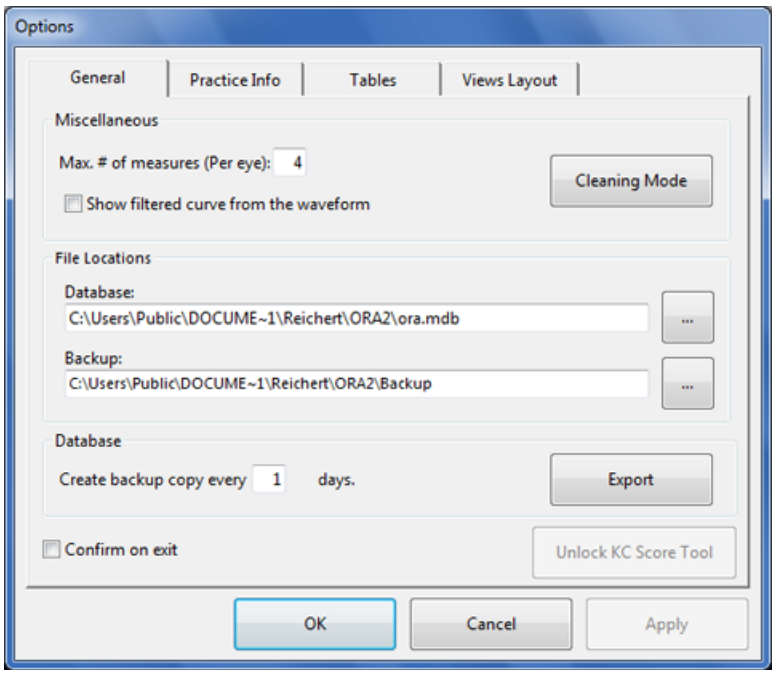
General

- The maximum number of measurements per eye can be set (maximum of four).
- The Ocular Response Analyzer uses a mathematical signal filter to calculate IOPg, IOPcc, CH, and CRF values from the raw measurement signal. Turn the Filtered Signal on or off by clicking the check box “Show filtered curve from waveform.”
- The Clean button moves the airtube assembly forward so that you can clean the parts of the optical path as indicated in the Cleaning and Maintenance section of this manual.
- The default database is located at:
  C:\Users\Public\Documents\Reichert\ORA2|ora.mdb;
  and the Backup Database location is located at:
  C:\Users\Public\Documents\Reichert\ORA2|Backup.mdb.

Note: Databases can be stored on a shared network drive and accessed from any PC with the software installed and users can rename the database, create multiple databases, or change the location of databases if desired. Click the button to the right of the database path to select the desired database.

Automatic backup feature: A Backup Location for databases can be specified and the desired backup frequency can be set.

Export button: Operators may desire to export data from the database in order to manipulate it in other windows-based programs such as spreadsheets or statistical packages. This can be accomplished quickly and easily using the Export function as indicated in the Export Data Function section of this manual.



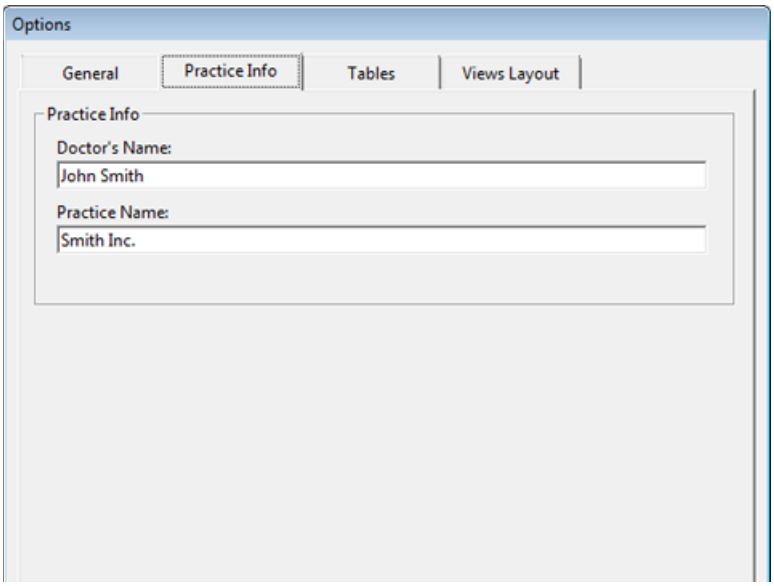
- To prevent accidentally closing the software, users can enable the Confirm on Exit check box at the bottom of the General Tab.
- The Keratoconus Match Index features can be enabled by clicking the Unlock KC Score Tool button as indicated in the Activating the Analysis Tab section of this manual.

Options (continued)

Practice Information

The Information tab enables users to modify the Doctor's Name and Practice name. This information is stored in the database and appears on the printout.

- Enter the Doctor's name (or the clinician's name if applicable)
- Enter the Practice Name.

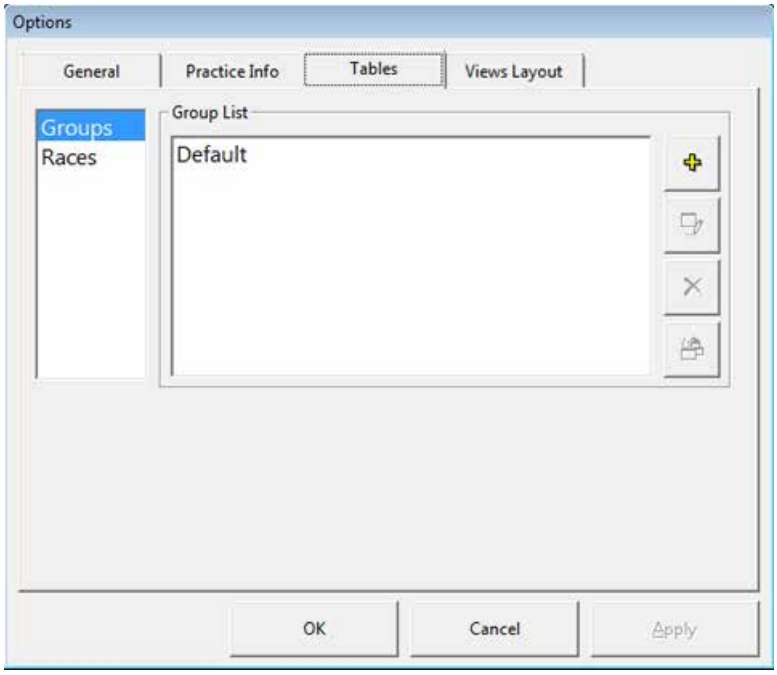


Tables

The Tables tab allows users to select the category patient data is stored. The default options are Groups and Race.

- To Add a categories, press the add (+) button (top button).
- To Edit a category, select the button with the pencil (second from the top button).
- To Delete a category, highlight the category and then press the Delete (x) button (Second from the bottom button).
- To Reassign a category, highlight the category and then press the Reassign button (bottom button).

Note: Once the categories are created, the patient data can be moved from one category to another in the edit patient data screen.

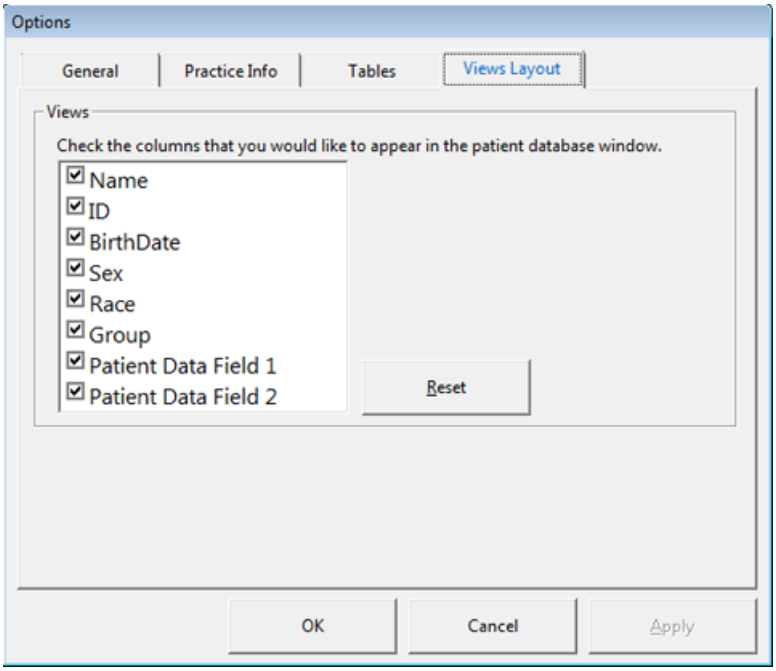


Options (Continued)

Views Layout

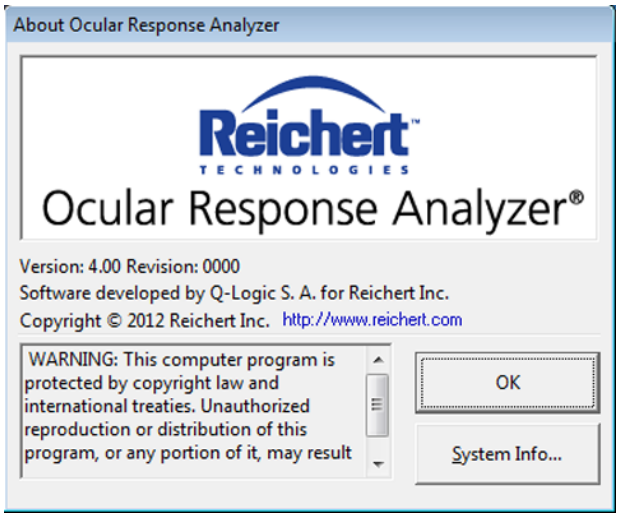
The Views Layout tab enables users to configure the categories that will be visible in the patient data window. Users should check the options that they wish to see when they are viewing, sorting, or searching the patient database.

Note: Patient Data Field 1 and Patient Data Field 2 are comment related fields available to notate information about the patient, history, or miscellaneous other information as needed for the patient file. The fields are capable of 256 alpha-numeric characters and can be edited in the edit patient data screen.



About

The About screen located on the main menu contains information about the Ocular Response Analyzer software package and has an option to view the System Information and its properties.



Patient Positioning

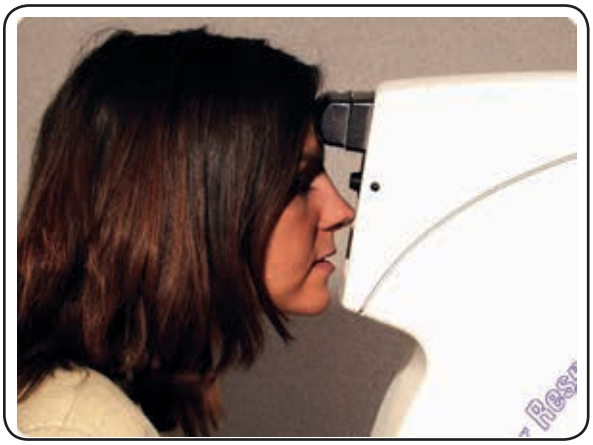
Proper patient positioning promotes fast and accurate measurements. Patients should remove contact lenses, loosen tight collars and ties, and be relaxed. Operators should inform patients that nothing will touch their eye and that they will only feel a very gentle puff of air. It may be helpful to demonstrate the air puff to patients before the exam.



The Ocular Response Analyzer features a left / right sliding forehead rest that enables the software to automatically determine which eye is being measured. It must be positioned completely to one side or to the other in order to take a measurement.

A properly-positioned patient will easily see the fixation cues. The fixation target is a green light, located inside the air tube, surrounded by four red LED lights. If a patient is able to see any of the red lights, the automatic alignment system will bring the green fixation target into view.

Set the height of the table so the canthus marks on the sides of the instrument are level with the patient's eyes.



Correct Patient Positioning

Patients should lean forward slightly so that the center of their forehead rests in the middle of the rubber forehead pad. The patient's head should contact the headrest straight-on; perpendicular to the front of the instrument (not turned to the side). In addition, the patient's nose and chin should be inward, towards the front surface of the unit.

To ensure fast and accurate results operators should instruct the patient to blink a few times and hold both eyes open immediately before clicking the **Measure Response** button. Inform the patient to look directly at the green light once it is in view, and hold steady.



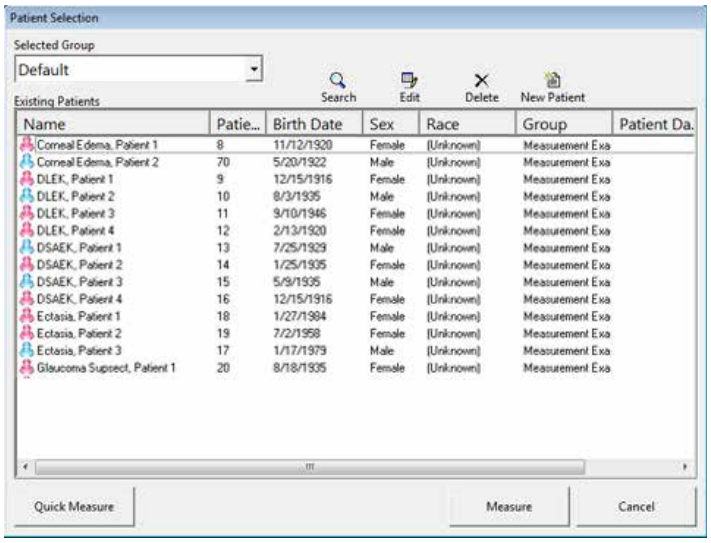
Incorrect Patient Positioning

Observe the photo on the left. Notice the distance between the patient's chin and the front of the instrument. The instrument is too low, causing the patient to rest her head in a downward-facing manner. In this instance, the patient may not be able to see the fixation target, and the alignment system may not be able to find the patient's eye.

Patient Data Entry/Patient Selection

1. Click on the Measure icon and the Patient Selection window will appear.

Note: If you already have existing Patient's, the Patient Selection Window will display the list.

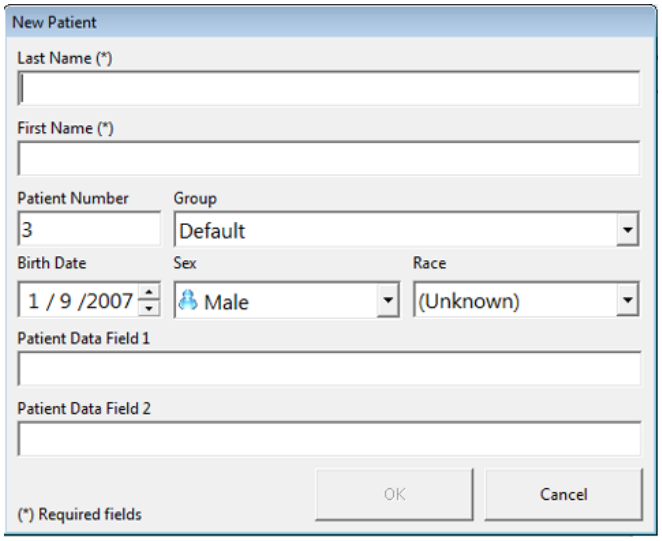


2. Click the New Patient button to enter a new patient into the database.
3. The New Patient window will appear.

Note: All fields indicated by an asterisk (*) are required.

Note: The Patient Number field automatically generates a sequential Patient Number.

Note: Patient Data Field 1 and Patient Data Field 2 are open text fields for additional identification information.



4. When all the information is entered, click OK to save it.
5. The Patient Selection window will appear again, now with the new patient added to the list.
6. Double click the patient name or click the Measure button to proceed to the Measure Screen (see page 22).

Note: Operators can sort the list in ascending or descending order by clicking on the category header. The categories can be selected to be displayed or not displayed in the Views Layout Tab (see page 19).

Patient names can be displayed all at once, or a specific Group can be viewed. The Group Function is used to create separate patient data archives. New Group names can be added by clicking the down arrow next to the Selected Group list and then choosing "Add new..."

Quick Measurement Mode

Click the Quick Measure button at the lower left of the Patient Selection screen.

Measurements made in Quick Mode cannot be printed. However, patient information and results can be saved afterwards, allowing the device to be used as a screening instrument, but providing the flexibility to save the patient data if remarkable results are discovered.

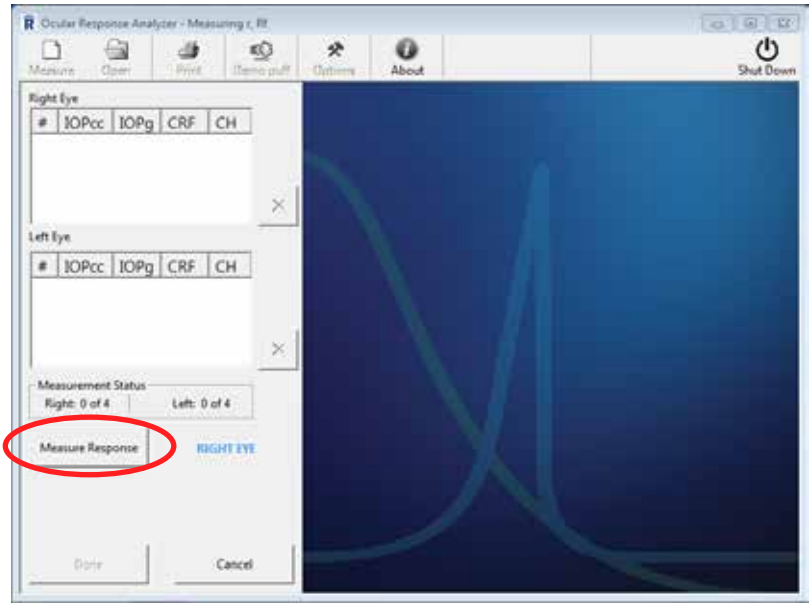
Note: This immediately brings up the Measurement Window, bypassing the entry of patient information.

Initiating a Measurement

1. Enter a new Patient or select an existing Patient from the Patient Selection Window.
2. Click the Measure Icon.
3. The instrument will prepare for a measurement.
4. Slide the headrest to one side and then ask the patient to put their head against the headrest and look at the green light. Refer to Patient Positioning.
5. Click the Measure Response button and the ORA will take a measurement.

Note: Refer to the Measurement section in this manual for more information about how to determine if the measurement is a reliable reading.

6. Repeat the measurement process for the other eye as needed.



Taking Multiple Measurements on the Same Eye



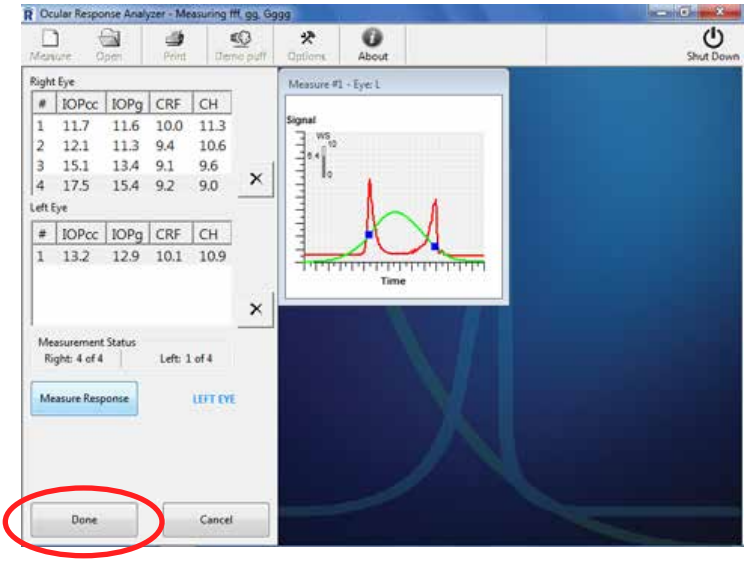
It is recommended that operators take multiple measurements on each eye so that the signals can be evaluated for consistency to ensure accurate results. A maximum of four signals and measurement result lines can be displayed at once.

When multiple measurements are taken, the signal with the highest waveform score will automatically be selected as the signal that the final results will be based on.

Operators may need to take additional measurements, deleting unacceptable signals, until acceptable results are obtained.

Eyes with irregular corneas or pathology may make obtaining a reliable signal more difficult. Some eyes may never produce “normal” signals.

Measuring the Second Eye



After completing the number of desired measurements on the first eye, operators should slide the headrest fully to the other side and reposition the patient for measurements on the second eye.

Once the patient is repositioned, simply click the Measure Response button again. When the first measurement for the second eye is taken, the measurement signal will appear on the screen.

Operators can click on the left or right eye data windows to switch back and forth between the signals from either eye.

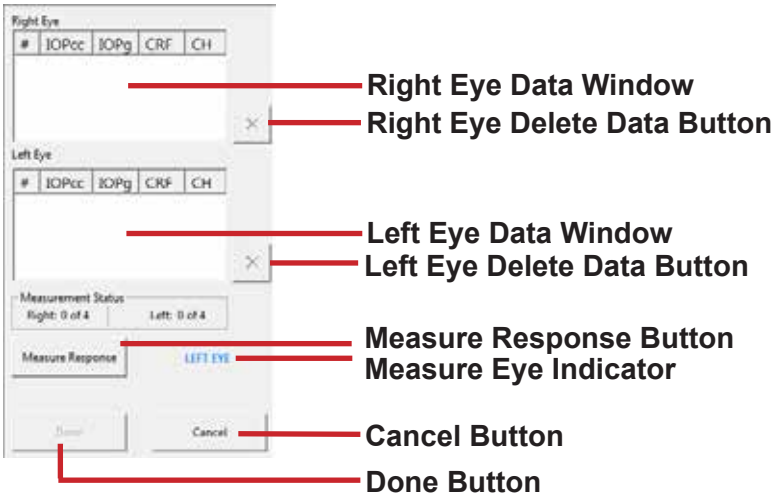
When the desired number of measurements has been obtained for both eyes, the operator must click the Done button to proceed to the Results Window.

Measurement Window

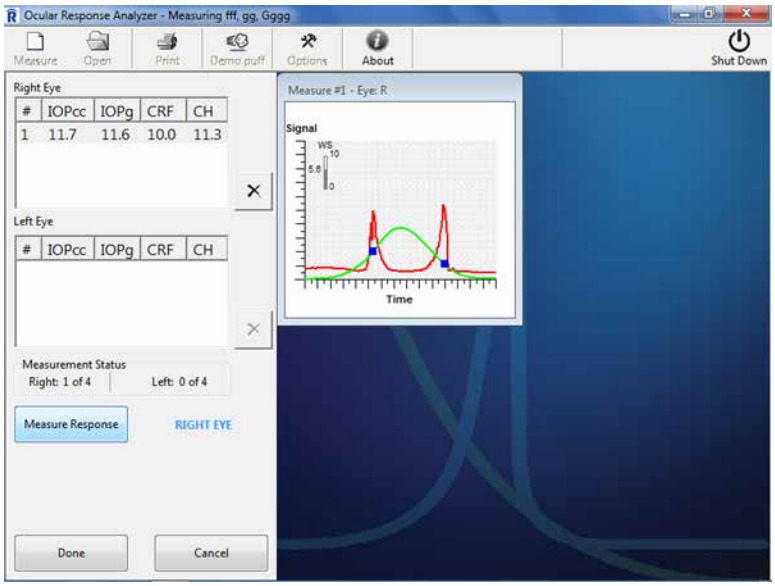
The Measurement Window enables operators to initiate a measurement and to see the resultant numerical data. The Measure Response button initiates automated alignment and measurement.

Measurements

The measurement data appears in the right or left eye data window, depending on which eye was measured. Up to four measurements can be taken per eye.



To ensure the reliability of the measurement data, operators should look at the Waveform Score (WS) in the signal window. The waveform score is presented on a scale of zero (0) to ten (10). The higher the number, the more reliable the measurement data will be. Unreliable signals can be deleted by highlighting the desired measurement values and then clicking the delete button (x).



Open Icon

The **Open** button displays a list of measured patients. When the patient is selected, the measurement data is displayed in the Results tab window.

This window automatically appears after taking patient measurements and clicking the **Done** button. Operators can also access this mode by clicking the **Open Icon** or selecting **Open** from the **File Menu** and then choosing the patient to be reviewed. If multiple measurements were taken, only the results from the measurements with the highest waveform score for each eye will be displayed.

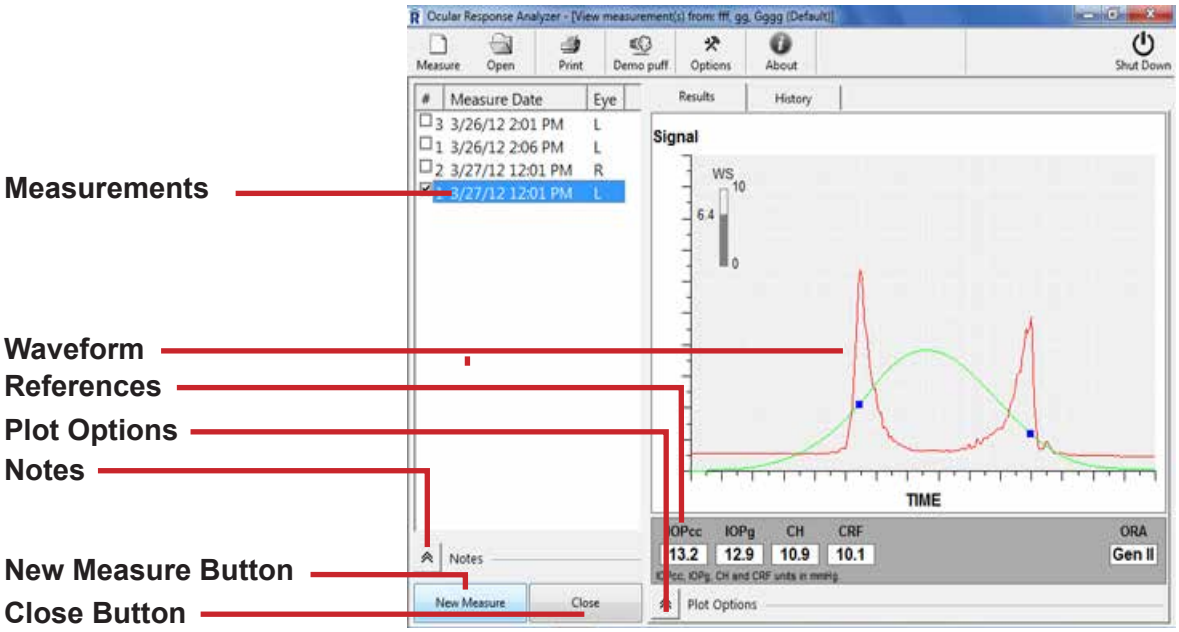
Measurement Data

This screen contains a powerful patient data analysis tool that displays patient data in a number of formats. Detailed descriptions of the features, functions, and buttons are provided below.

Measurements
The measurement section displays the historical measurements recorded for the patient. The date, time, and eye are displayed for each measurement. To display the graph of the measurement, select the record.

Note: The waveform for the selected measurement is displayed and measurement data corresponding to a specific measurement is displayed below the waveform. Operators can click on any line in the list or measurements to view the numerical data for that measurement.

Notes
Notes of a record can be edited by selecting the Notes icon. When this icon is selected a drop-down menu is displayed for the Medications, Conditions, and Exam Notes 1 and 2 fields that will allow modification of the information in any of these field.



Measurement Data (continued)

Plot Options

In this window, operators can select Waveform, Overlay, or Sequential mode.

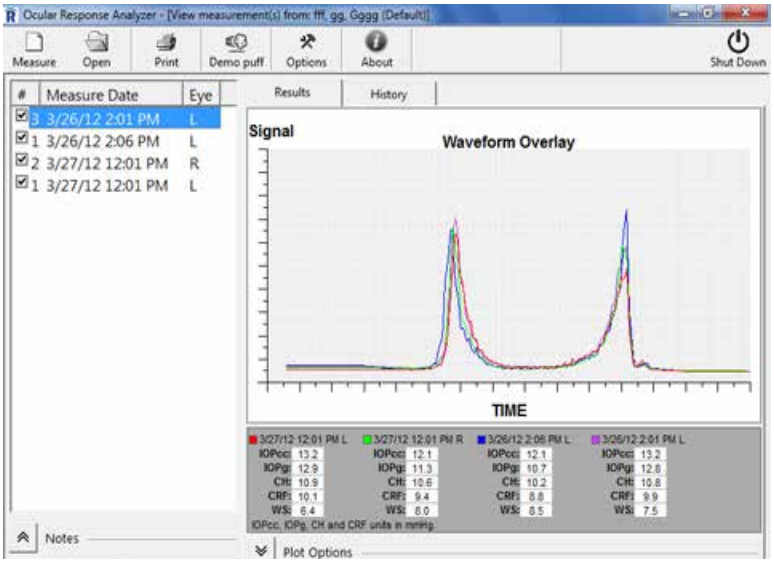
Waveform

This is the default view, showing the waveform from the selected measurement and the CH, CRF, IOPg and IOPcc data for this measurement in the references window.

Overlay

Operators can view up to four signals from the same subject simultaneously superimposed over one another.

Operators must manually select signals by clicking on the desired check boxes in the measurement history list.



Overlay Option

Each signal appears in a different color. The colors are automatically assigned by the software in a sequential manner, depending on the order of the selection of signals.

The measure date and time are displayed above the waveform data below the waveform window.

Measurement Data (continued)

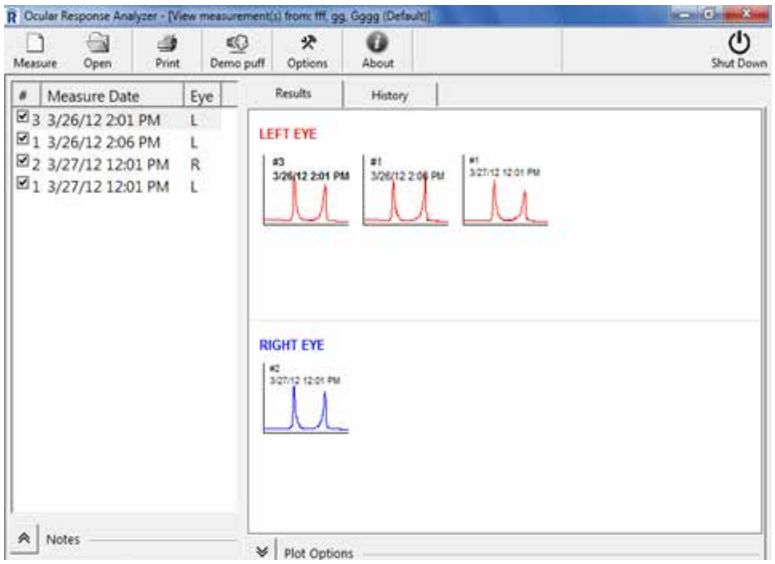
Plot Options (continued)

Sequential
Operators can select up to 10 signals for each eye on the same subject and display them in date/time sequential order.

Operators must manually select signals by clicking on the desired check boxes in the measurement history list.

Left eye signals appear in red. Right eye signals appear in blue.

The signals will be displayed in date/time sequential order, regardless of the order they are selected.



Sequential Option

New Measure Button
Click to begin a new measurement session on the patient whose data is being reviewed.

Close Button
Click to close the View Measurement Window.



New Measure Close

Print Icon

Measurement data can also be printed using the **Print** button, accessible from this screen. See the Printing Patient Data section of this guide for details.

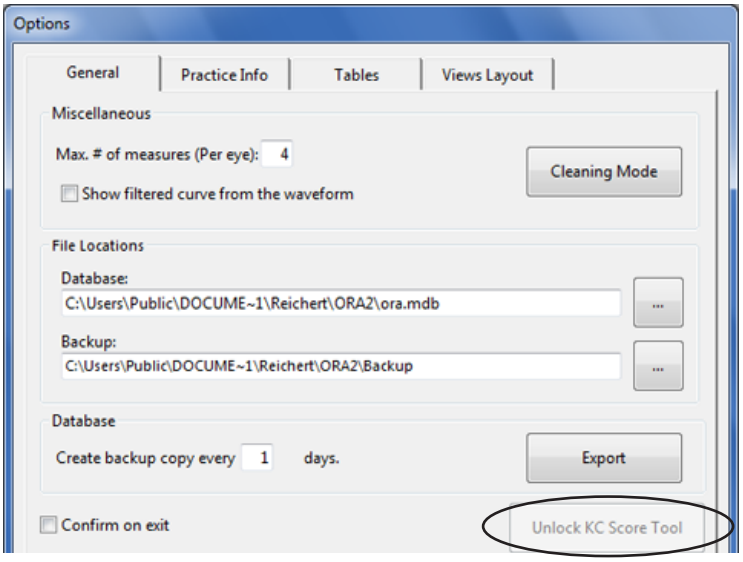
Activating the Analysis Tab

Note: New Ocular Response Analyzer systems may come pre-configured with the Analysis tab already activated (if this option was ordered before it was sent from the factory). In this case, the instructions for unlocking the analysis tab on this page can be disregarded.

NOTE: THE ANALYSIS TAB OF OCULAR RESPONSE ANALYZER SOFTWARE CONTAINS FEATURES THAT HAVE NOT YET BEEN CLEARED BY THE US FDA. ACCESS TO THESE FEATURES CANNOT BE PROVIDED TO USERS IN THE USA.

1. Go to the Options menu and click on the General tab, click the Unlock KC Score Tool button.
2. A window with an installation ID will appear.





Note: When the Installation ID is displayed, contact Reichert or to your Reichert Authorized Distributor to obtain the matching unlock code for activation of the Analysis Tab.

3. Enter the Unlock Code.
4. Once activated, the Analysis Tab will appear next to the Results and History tabs in the software.

Note: ***The data presented on this tab will only be generated for measurements taken after the installation of the software with this option.*** If you have upgraded a pre-existing system software, the previously acquired data will not be retroactively updated to display the new indices provided on the analysis tab. However, all of the previous data will remain intact and will be accessible.

Each Ocular Response Analyzer measurement signal generates a total of 37 waveform parameters. These parameters are mathematical representations of waveform shape characteristics such as peak height, area, slopes, etc. Different eyes can generate significantly different waveforms shapes. Eyes with certain pathologies share common waveform features.

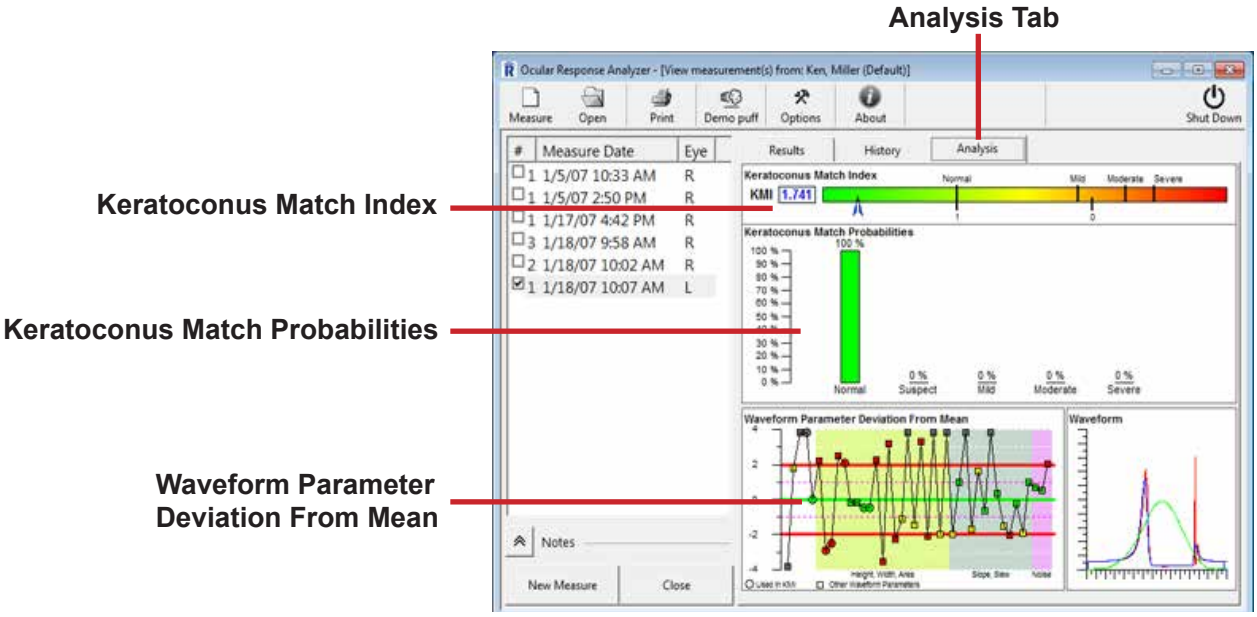
The analysis tab of Ocular Response Analyzer software features indices for assessing the similarity of a subject's measurement waveform to the characteristics of waveforms from various keratoconus populations. Data from 5 reference populations are utilized in this analysis: Normal, Suspect, Mild, Moderate, and Severe keratoconus eyes.

Activating the Analysis Tab (continued)

For a given measurement, each of the 42 Ocular Response Analyzer parameters (37 waveform parameters, Waveform score, CH, CRF, IOPg, IOPcc) are plotted against a normalized average value of each parameter for a normal reference population on the Waveform Parameter Deviation From Mean plot.

A selected group of 7 waveform parameters are utilized to present a Keratoconus Match Index (KMI) and the Keratoconus Match Probability (KMP). These software features describe how similar the measurement in question is to Ocular Response Analyzer waveforms gathered from the reference populations.

Note: The Ocular Response Analyzer does not diagnose disease. The KMI and KMP merely represent the similarity of Ocular Response Analyzer waveform characteristics to data from reference populations. This is not a substitute for a clinical evaluation and the opinion of experienced medical professionals.



Activating the Analysis Tab (continued)

Waveform Parameter Deviation From Mean

The Waveform Parameter Deviation from Mean plot provides a graphical representation of all Ocular Response Analyzer measurement parameters for a measurement waveform plotted against normative data. By quickly glancing at this graphic, users can see if the measurement signal in question is typical of a normal eye or not. The green line down the center represents the normalized average value of each parameter for an 836 eye normal population. The dashed and solid red lines represent one and two standard deviations from the mean of the normal population respectively.

Waveform parameter data points represented in green are less than one standard deviation from the mean. Data points in yellow and red are more than one or more than two standard deviations from the mean respectively. Data points that are represented by small squares are not used in the KMI and KMP calculations. Data points represented by small circles are used in the KMI and KMP calculations. Data points displayed in black are more than six standard deviations from the mean of the normal population and are outside of the plot range.

Note: There is no “directionality” associated with the data points on the WAVEFORM PARAMETER DEVIATION FROM THE MEAN plot. Data points may fall above or below the green line. When there are waveform parameter data points that are more than one or two standard deviations from the mean, it does not necessarily indicate that there is something clinically “wrong” with the eye in question. It simply means that the waveform generated from that eye has characteristics that are significantly different from the average of a normal population.

Keratoconus Match Index (KMI)

The Keratoconus Match Index is a composite value that represents the similarity of the waveform from an eye to the average waveform characteristics of various Keratoconus eyes.

The average value for the normal population is 1 and the average value for the combined keratoconus populations (suspect, mild, moderate, and severe) is 0. As with any statistical data, there is a distribution around the mean. Therefore, a normal eye may have a value higher or lower than 1 and a keratoconus eye may have a value higher or lower than zero.

The value of the eye being measured will be displayed graphically and numerically on the KMI reference scale.

Keratoconus Match Probabilities

The KMI is a single number, but as with any medical data, presence of disease, or severity of disease is not “black and white” or “binary”. There are distributions surrounding the KMI values for all the keratoconus reference populations. The Keratoconus Match Probabilities (KMP) further demonstrate how a given measurement matches the reference population data. It is very common for a measurement waveform to have characteristics that match multiple populations. As such, the KMP shows which population the measurement in question matches best, but also shows the percentage match to the other surrounding populations.

Note: Again, it is important to note that the KMI and KMP do not diagnose keratoconus. Eyes without keratoconus, such as post refractive surgery eyes, may share measurement characteristics with keratoconus eyes, but this does not imply that the cornea is ectatic. There is no substitute for a full clinical evaluation and the opinion of an experienced medical professional.

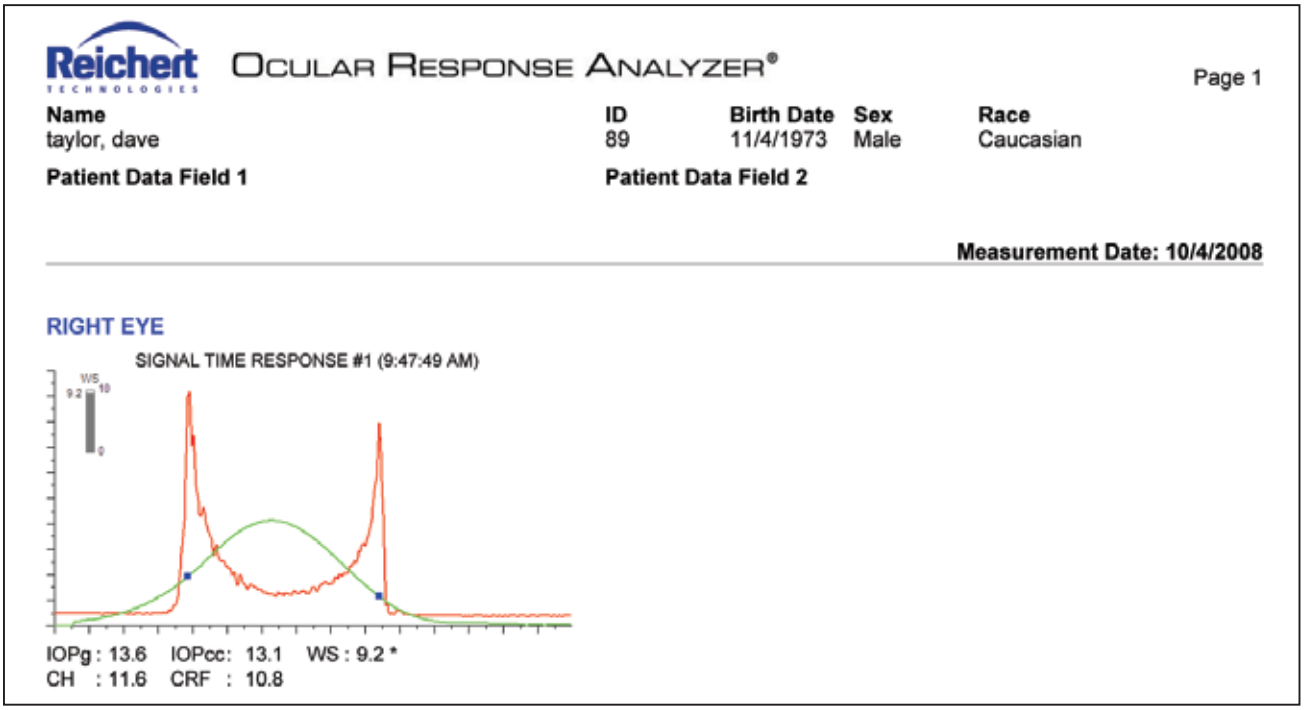
Printing Measurement Data

Operators can print patient data by pressing the Print button or selecting Print from the File Menu, after which, the print dialog box will appear.

Review Window with Print Dialog Box

Operators can click the print icon to print data from the Results, History, or Analysis tabs. An example of a printout from the Results tab for one right eye measurement is shown below. To Print the data, select the record and then OK.

Sample Print Out



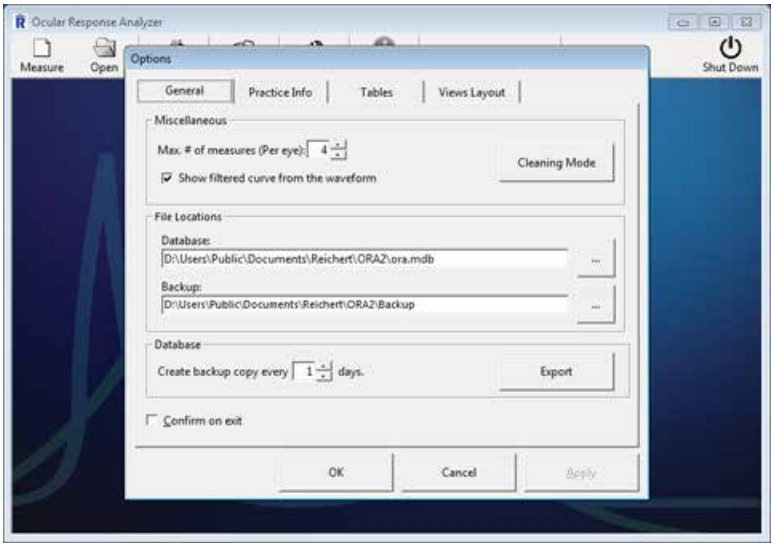
Export Data Function

Operators may desire to export data from the database in order to manipulate it in other windows-based programs such as spreadsheets or statistical packages. This can be accomplished quickly and easily using the Export function.

Export Wizard

The Export Wizard can be accessed by selecting Options and then Export.

The Welcome to Export Wizard screen appears. Click the Next button to continue.



Select Patient

Operators can select the Group, Sex, and Race of the patient data to be exported. Individual patients can be included or excluded from the export by clicking on the check boxes next to the names. All patient data for the selected Group, Sex, and Race can be included by clicking the Select All check box.

Click the Next button to continue.



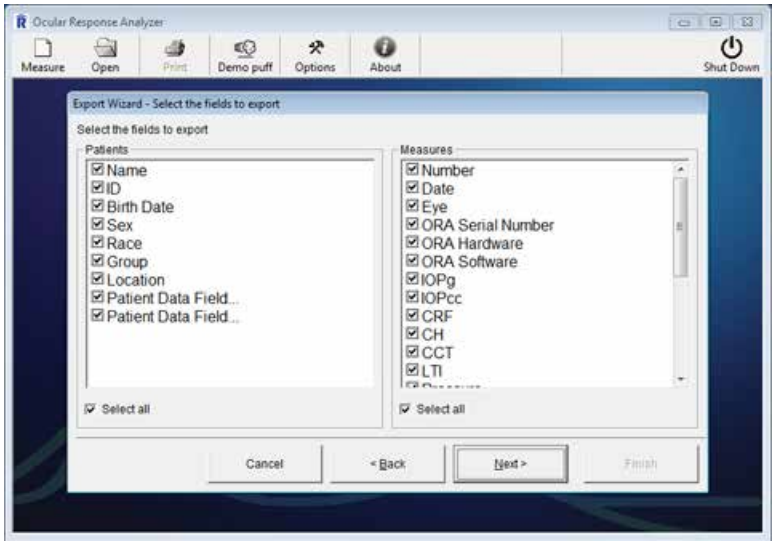
Export Data Function (continued)

Field Data

Operators can now choose which fields are to be included in the export by checking or unchecking the boxes next to each field name. There is a box for each piece of data that the software archives with each measurement.

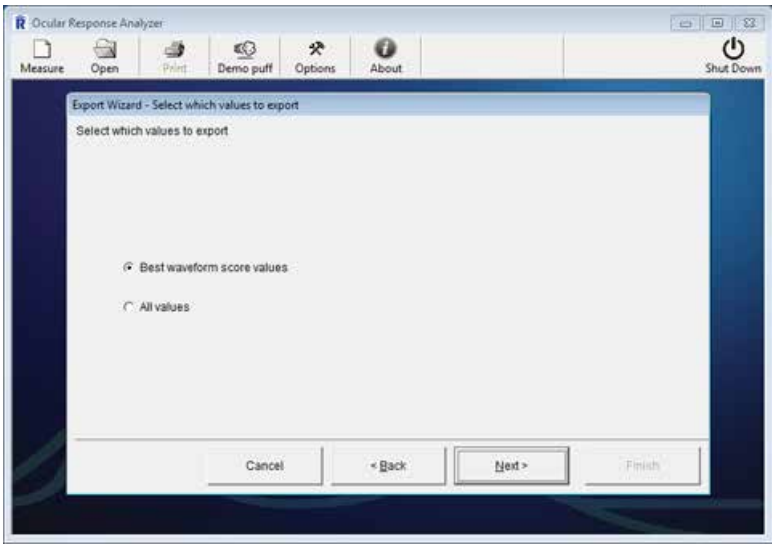
Click the Next button to continue.

NOT shown here, operators will have the option to export All Values or only the Best Signal Values. Even when All Values are exported, the Best Signal Values for each eye, for each measurement session, are identified in the export file.



Export Values

Select the option for the type of values.



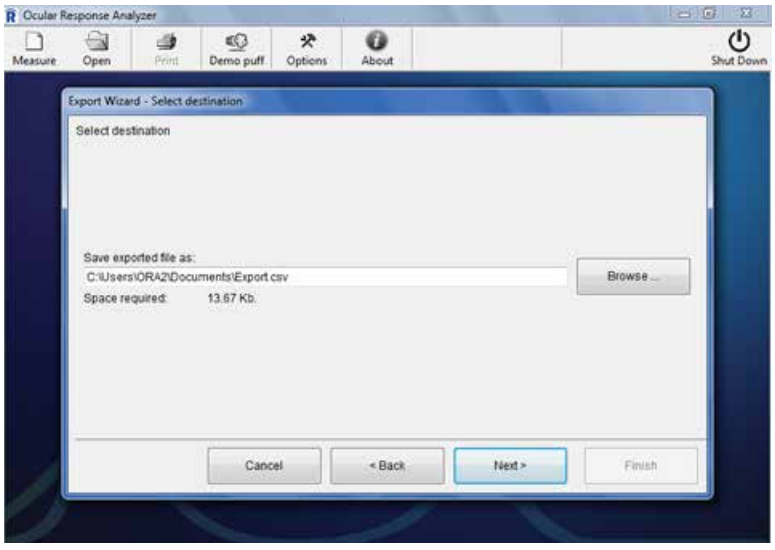
Destination

Once the export has been configured, the operator must choose where to locate the export file.

The default save location is: D:\Users\ORA2\Documents\Exports.csv

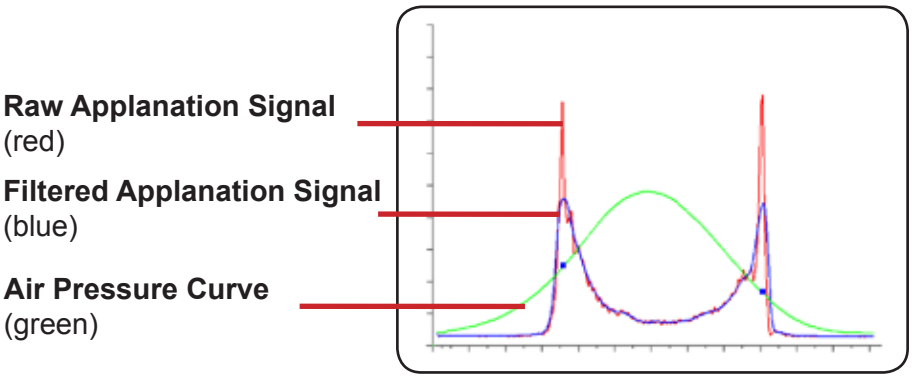
This location can be changed by clicking the Browse button next to the path field and browsing the computer for the desired location. Once the desired location has been identified click the Next button.

The export will take place and the file will be saved in the chosen location. The Export Wizard should indicate Export finished successfully. Click the Finish button to close the Export Wizard.



Ocular Response Analyzer Waveforms

The Ocular Response Analyzer makes measurements by applanating the cornea with a puff of air and monitoring the shape of the cornea with an electro-optical detection system. The waveform that is produced as a result of the measurement process is displayed, and should be analyzed by the operator, after each measurement. Operators should understand the waveform in order to ensure reliable results when making patient measurements.



The above curves are the following:

- The green curve represents the pressure of the air on the cornea.
- The red curve indicates the raw signal of the applanation detection system.
- The blue curve is a filtered version of the red curve, designed to identify the “optimum point of applanation” in less than ideal signals.
- The filtered curve can be turned on or off in the **Tools / Options** menu. The default setting is off.

The optical signal collected during the inward and outward applanation events causes the two “spikes” on either side of the pressure curve. The applanation pressure is determined by drawing a line down from the peak of each applanation spike to the intersection of the green pressure curve. These points are graphically indicated in the Ocular Response Analyzer software by blue squares. The outward applanation pressure will always occur at a lower position on the pressure curve than the inward applanation pressure due to Corneal Hysteresis (CH). Corneas with higher hysteresis will cause a greater discrepancy in the vertical offset of these two pressure points.

The pressure curve will always be fairly symmetrical. The height of the curve will vary depending on the amount of pressure required to applanate a particular eye. Eyes with high intraocular pressure will cause a higher curve.

The applanation signal curves, particularly the raw signal curve, may vary significantly in appearance from measurement to measurement. Ideally, the peak-amplitude (height) of the applanation signals (spikes) will be above the green curve. Both spikes should have a clearly defined and relatively well-centered high point (peak). The spikes should be similar in amplitude (they will rarely be identical). In normal eyes, the signals will be symmetrical and relatively free of “noise.”

Cleaning and Maintenance

CAUTION: DO NOT USE STRONG CLEANING SOLUTIONS OR SOLVENTS, SUCH AS ALCOHOL, ON ANY PART OF THE OCULAR RESPONSE ANALYZER, UNLESS OTHERWISE SPECIFIED, OR DAMAGE TO THE UNIT MAY OCCUR.

External Cleaning Including LCD, Housing, and Buttons

Gently clean any dirt or contaminants off the LCD screen using a lint-free cotton cloth lightly dampened with a mild cleaning solution that is safe for plastic. Be sure to wipe off any residual solution using a lint-free cotton cloth.

Forehead Rest Cleaning and Patient Contact Area Cleaning

For hygienic reasons the forehead rest should be cleaned with a sterile alcohol wipe after each patient. In addition, operators should wipe the front surface of the housing with alcohol wipes, as required, based on patient contact.

Air-Tube Cleaning

WARNING: AFTER CLEANING THE INSIDE OF THE AIRTUBE, PRESS THE DEMO PUFF ICON LOCATED ON THE OPERATOR'S SCREEN SO THAT ANY CONTAMINANTS ARE SAFELY REMOVED FROM INSIDE THE AIRTUBE.

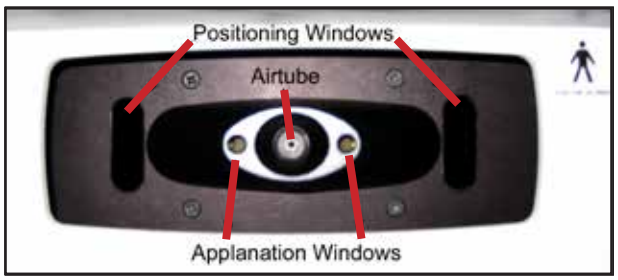
The inside of the air tube can become partially obstructed by contaminates. In severe cases, the green fixation light will become blurry or dim. Contamination inside the air-tube will cause signal quality degradation. To clean the air tube, use a Pipe Cleaner and slide it in and out of the air-tube a few times to remove any contaminants inside the air-tube. Refer to the image on the right. Press the demo puff button on the tools menu of the software a few times to blow any contaminates out of the tube.



Pipe Cleaners

Positioning and Applanation Window Cleaning

Contaminants on the positioning windows of the Ocular Response Analyzer, such as tear-splatter, may interfere with the Ocular Response Analyzer's ability to align and measure, or result in unreliable readings.



The Positioning Windows and Applanation windows should be cleaned using a clean, soft, cotton-tipped swab that is lightly moistened with lens cleaner. After the windows are cleaned, dry the surfaces using only clean, dry compressed air at less than 90 psig (620 kPa) (also referred to as "canned air").

Fuse Replacement

Fuses are located in a holder next to the power input, near the bottom of the instrument. If fuse replacement is required, only replace with equivalent fuses (see the specifications section).

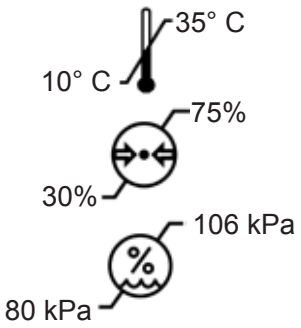
Troubleshooting

COMPLAINT	POSSIBLE SOLUTION
The Ocular Response Analyzer Will Not Turn On or Respond.	Ensure power cord is properly seated in the power input receptacle on the side of the Ocular Response Analyzer and the on/off switch is in the “up” position (I is depressed).
	Check the fuses located in the fuse holder of the input power module of the Ocular Response Analyzer. Replace fuses if required. See page 32 for fuse specifications.
	If the Ocular Response Analyzer measurement head is not moving restart the unit using the power switch.
The Ocular Response Analyzer Will Not Find Eye. (Moves Straight Out, Then Moves Straight Back.)	There may be contaminants on the positioning windows. See the maintenance section for cleaning instructions.
	External light may be interfering with the positioning system. Identify the source and remove or reposition.
	Infrared (IR) light from other instruments or devices may be interfering with the positioning system. Identify sources of IR and remove the source.
The Ocular Response Analyzer Is Able To Measure One Eye But Not The Other.	External light may be interfering with the positioning system. Identify the source and remove or reposition.
	Infrared (IR) light from other instruments or devices may be interfering with the positioning system. Identify sources of IR and remove the source.
The Ocular Response Analyzer Attempts To Align But Will Not Take A Measurement.	Typically a patient positioning problem. The following are common patient positioning problems: Patient too high; patient too low; patient head not straight-on (head turned to side); patient chin too far away from front of instrument; patient forehead not firmly against headrest; patient not keeping eye open; patient not fixating on green target. See patient positioning instructions for proper patient positioning.
Frequent Questionable Signals and/or Atypical Measurement Results.	There may be contaminants on the positioning windows or inside the air tube. See the maintenance section of this guide for cleaning instructions.
Error Messages and Error Codes.	The Ocular Response Analyzer software may display a variety of error messages or codes. There are too many to list in this guide. Some of these codes are related to operator error and others are related to instrument or software failures. If an error message is displayed on the screen, operators should follow the instructions to correct the problem. If the problem persists, contact Reichert or your authorized Reichert distributor.

For all other problems or questions please contact Reichert Technical Support. Contact information is provided on the back page of this manual.

Specifications

Catalog Number 16070

Physical Dimensions (With Display Mounted)
Size: Weight, unpacked: 37 lbs. (16.8 Kg) Height: 18.5 in. (47 cm) Width: 26.8 in (68 cm) Depth: 13 in (33 cm)
Electrical
Voltage: 100-240 VAC, 50 - 60 Hz Current: 1.5 A Watts: 40-75 VA Fuses: Slo-Blo(T), 2.5 Amp, 250V, glass type, 5x20mm
The following specifications apply to the tonometer. Range 0-60 mmHg Display Resolution +/- 0.10 mmHg **Note :** The accuracy complies with ISO 8612 Tonometer Standard
The following specifications apply to the Operating System. Windows 7® 32-bit, Embedded
Operational Conditions
Environmental: The environmental conditions are as follows:
Operating: Temperature: 10° to 35 °C (50° to 95 °F) Relative Air Humidity: 30% to 75% Atmospheric Pressure: 80 kPa (23.6 in. Hg) to 106 kPa (31.3 in. Hg) Transportation & Storage: Temperature: -40° to 21 °C (-40° to 70 °F) Relative Air Humidity: 10% to 80% (non-condensing) Atmospheric Pressure: 70 kPa (20.6 in. Hg) to 106 kPa (31.3 in. Hg) 
Exposure to extreme temperature conditions indicated above must not exceed 15 weeks.

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.

Software Revision

The software can be obtained by contacting Reichert, Inc.
The serial number identifies the manufacture date and will provide access to the software version.

Classifications

The Ocular Response Analyzer is classified as Class 1 equipment. Class 1 Equipment is equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to a protective earth conductor in the fixed wiring of the installation in such a way which accessible metal parts cannot become live in the event of a failure of the basic insulation.

The Ocular Response Analyzer is classified as Type B Equipment. Type B equipment provides an adequate degree of protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protective earth connection.

The Ocular Response Analyzer is classified as IPXO Equipment. IPXO equipment is equipment enclosed without protection against ingress of water.

According to the mode of operation, the Ocular Response Analyzer is a continuous operation instrument.

Federal Law restricts this device to sale by or on the order of a physician.

Table 201 – Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Equipment and Systems

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Ocular Response Analyzer is intended for use in the electromagnetic environment specified below. The customer or user of the Ocular Response Analyzer should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance -
RF Emissions CISPR 11	Group 1 Class B	The Ocular Response Analyzer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Class A	The Ocular Response Analyzer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building for domestic power.
Flicker IEC 61000-3-3	Complies	

Table 202 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Equipment and Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Ocular Response Analyzer is suitable for use in electromagnetic environment specified below. The customer or user of the Ocular Response Analyzer should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±4kV Contact* ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%. * ESD contact events over 4kV on the Back Panel communication ports may cause the computer system to re-boot. Even though this may be an inconvenience to the user, it does not affect safety and effectiveness of the instrument.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical residential, commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the Ocular Response Analyzer requires continued operation during power mains interruptions, it is recommended that the Ocular Response Analyzer be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical residential, commercial or hospital environment.

Table 204 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Equipment and Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Ocular Response Analyzer is intended for use in the electromagnetic environment specified below. The customer or user of the Ocular Response Analyzer should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	NA	Portable and mobile RF communications equipment should be no closer to any part of the Ocular Response Analyzer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: d=(3.5/V1)(Sqrt P) d=(3.5/V1)(Sqrt P) 80 to 800 MHz d=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz @ 3V/m	(E1)=3V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. The measured field strength in the location in which the ME Equipment or ME System should be observed to verify normal operation. If abnormal performance is observed, additional measures many be necessary, such as re-orienting or relocating the ME Equipment or ME System.

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less then [V1] V/m.

Table 206 – Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Ocular Response Analyzer for ME Equipment and ME Systems that are NOT Life-supporting.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended Separation Distances for between

Portable and Mobile RF Communications Equipment and the Ocular Response Analyzer

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

Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz d=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800 MHz d=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz d=(7/E1)(Sqrt P)
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Reichert Warranty

This product is warranted by Reichert Technologies. (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.

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