Ocular Response Analyzer® G3

Auto Tonometer + Corneal Hysteresis

User's Guide

AMETEK®
ULTRA PRECISION TECHNOLOGIES

Reichert®
TECHNOLOGIES

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

Introduction

Congratulations on your purchase of the Reichert® Ocular Response Analyzer® G3 (Model 16170).

The Ocular Response Analyzer G3 (ORA) is a revolutionary instrument 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 G3 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 Ocular Response Analyzer G3, 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 for the purpose of aiding in the diagnosis and monitoring of glaucoma.

Contraindications

None known.

Principle of Operation

The Ocular Response Analyzer G3 utilizes a patented dynamic bi-directional applanation process to measure the Intraocular Pressure (IOP) of the eye, and also an indicator of corneal biomechanical properties called Corneal Hysteresis (CH), which is an indication of corneal viscoelastic properties.

The Ocular Response Analyzer G3 utilizes a rapid air impulse to apply force to the cornea, and an advanced electro-optical system to monitor the deformation. The precisely metered collimated-air-pulse causes the cornea to move inwards, past applanation, and into a slight concavity. The air pump shuts off and, as the pressure decreases, the cornea begins to return to its normal configuration. In the process, it once again passes through an applanated state.

The applanation detection system monitors the cornea throughout the entire process, which takes only milliseconds. Two independent pressure values are derived from the inward and outward applanation events. Viscous damping in the cornea causes delays in the inward and outward applanation events, resulting in two different pressure values.

The average of these two applanation events provides a repeatable, Goldmann-correlated IOP measurement (IOPg). The difference between these two pressure values is Corneal Hysteresis (CH). The ability to measure this CH effect is the key to understanding the biomechanical properties of the cornea and their influence on the IOP measurement process.

Contents

Contents (continued)

Warnings & Cautions

Reichert Technologies® 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: 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 ARE 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: TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH OR DAMAGE TO THIS INSTRUMENT 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: THIS INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON POWER INPUT CONNECTOR OR THE UNIT'S POWER CORD OF THIS INSTRUMENT OR DAMAGE TO IT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

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.

WARNING: DO NOT PLACE FINGERS INTO THE OPENING SURROUNDING THE NOSEPIECE.

WARNING: RISK OF EXACERBATED INJURY OR SENSITIVITY FROM APPLANATING AIR PUFF. ALTHOUGH NON-CONTACT TONOMETRY HAS NOT BEEN SHOWN TO BE INJURIOUS. APPLY CLINICAL JUDGEMENT BEFORE DIRECTING USE OF THIS INSTRUMENT IMMEDIATELY AFTER PENETRATING CORNEAL SURGERY, TRAUMATIC OCULAR INJURY, OR OTHER SIMILAR CORNEAL CONDITION.

Warnings & Cautions (continued)

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: THIS INSTRUMENT IS NOT INTENDED TO BE CONNECTED TO EQUIPMENT OUTSIDE THE CONTROL OF REICHERT TECHNOLOGIES OR MUST BE TESTED TO AN APPLICABLE IEC OR ISO STANDARDS.

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

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 THIS DOCUMENT.

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

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

CAUTION: USE OF ACCESSORIES AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY REICHERT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THE INSTRUMENT AND RESULT IN IMPROPER OPERATION.

CAUTION: PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE INSTRUMENT, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS INSTRUMENT COULD RESULT.

Symbol Information

Symbol Information

The following symbols appear on the instrument:


Caution symbol indicating important operating and maintenance instructions that are included in this User's Guide


Type B Applied Part


Alternating Current Power


Protective Earth Connection


ON / OFF

Date of Manufacture


Manufacturer

REF Catalog Number

SN Serial Number


Waste of Electrical and Electronic Equipment

Compliance to Medical Device Directive 93/42/EEC

Authorized to mark given by Intertek ETL Semko for conformance with electrical standards


Accompanying Documents must be consulted

Authorized Representative in European Community


Fragile Contents in Shipping Container - handle with care


Keep Dry - Package shall be kept away from rain


This Way Up - Indicates correct upright position of package

Instrument Setup

Great care has been taken to deliver your new Ocular Response Analyzer G3 to you safely. The container and packaging was specially designed to transport this unit. Please retain the packaging in case future transportation is required.

Inner Box

Opened Inner Box

Shipping Protector

Unpacking Instructions

Please remove the packaging material from the instrument in the following manner (Refer to images on left).

The instrument is packaged in a shipping container to protect the instrument from damage during shipment. Please read the User's Guide before operating the unit. A Quick Reference Card is provided for your convenience and reference during operation of the unit.

1. Remove the accessories from the shipping container.

   Accessories box contains:
   - Printer Paper (P/N 12430-887)
   - Dust Cover (P/N 16050-089)
   - Quick Reference Card (P/N 16170-104)
   - User's Guide (P/N 16170-101)
   - Forehead Rest Pad (Spare) (P/N 16050-170)
   - Power Cord (P/N RCBL10040 - 110V) or
     (P/N RCBL10041 - 230V)
     Note: Power cord not to exceed 10 ft.
   - Package of Pipe Cleaners - (P/N 16170-004)
   - Package of Cotton Swabs (P/N 16170-005)

2. Remove the Top Foam (4 corners) from the shipping container.
3. Locate the handles on the sides of the inner box and remove the inner box.
4. Lay the inner box on its side and remove the tape.
5. Remove the foam top and bottom inserts from the inner box.
6. Lift the Ocular Response Analyzer G3 out of the inner box.
7. Take the Ocular Response Analyzer G3 out of the plastic bag and set the unit on a secure table.
8. Place the packing material in a safe place so that if transportation is required in the future, it will be available.

Shipping Protector

The Ocular Response Analyzer G3 comes with a shipping protector installed on the patient's side of the instrument. This protector ensures that the motor does not get damaged during shipping. It is **EXTREMELY** important that this plastic shim is saved and installed anytime the unit is shipped to prevent damage to the motor and malfunction of the unit, most likely an M15 motor error.

CAUTION: IT IS VERY IMPORTANT TO REMOVE THE SHIPPING PROTECTOR BEFORE OPERATING THE UNIT.

1. Pull the plastic Shipping Protector up and out of the opening on patient side of the instrument.

IMPORTANT: Do **not** throw away the Shipping Protector! Keep it with the rest of the packaging material so that it can be re-installed if future shipment is necessary.

2. Continue with the instrument setup as indicated in the User's Guide.

Note: Anytime the unit is shipped, this plastic Shipping Protector must be reinstalled, to prevent any damage to the unit.

Instrument Setup (continued)

Application of Input Power

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

WARNING: POSITION THIS INSTRUMENT SO THAT IT IS NOT DIFFICULT TO OPERATE THE DISCONNECTION DEVICE (PLUG).

1. After the unit is in its secure location, apply the correct input voltage to the instrument using the Power Cord from the Accessory Tray.
2. Press down on the "|" located on the ON/OFF Switch. The power inlet is located on the underside of the unit (Refer to page 11, item 8, for its location).

Note: The unit will auto puff as a part of the start up procedure.

3. Read the User's Guide and the Quick Reference Card before operating this instrument.

WARNING: DO NOT REMOVE THE OUTSIDE COVERS OF THE UNIT OR ATTEMPT TO REPAIR ANY INTERNAL PARTS. REPAIR AND SERVICE OF THE UNIT MUST BE PERFORMED BY EXPERIENCED PERSONNEL OR DEALERS THAT ARE TRAINED BY REICHERT.

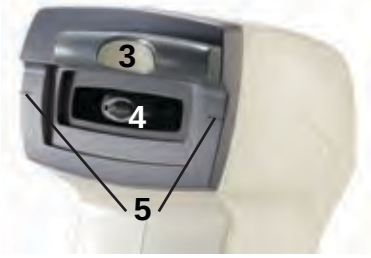
CAUTION: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE NEXT TO THE INPUT CORD RECEPTACLE OR DAMAGE TO THE UNIT MAY OCCUR.

CAUTION: FOR CONTINUED PROTECTION AGAINST THE RISK OF FIRE, ANY REPLACEMENT OF DAMAGED FUSES MUST BE IN ACCORDANCE WITH THE RATING AS INDICATED IN THE SPECIFICATIONS SECTION OF THIS MANUAL.

Disconnection of Input Power

1. At any time, the power switch can be set to OFF. The unit does not have a power down sequence. To terminate operation of this instrument, press the ON / OFF switch to the OFF position (O).
2. If this instrument is intended to be OFF for an extended period of time, it can be disconnected from power by detaching the power cord from the its receptacle.

Instrument Setup (continued)



Parts Identification

1. **Operator Display:** Displays measurement data.
2. **Printer Door:** Door (push to open) to access printer paper.
3. **Forehead Rest:** Alignment mechanism that moves right or left for correct patient positioning.
4. **Nosepiece Objective:** Patient fixation and measurement point.
5. **Canthus Alignment Marks (right and left side):** Alignment mark used to indicate proper instrument height. Should be aligned with the patient's eyes.
6. **ON/OFF Switch:** Switch that controls input power to the unit. "O" indicates OFF, and "|" indicates "ON."
7. **RS232C Port:** Communication port for the export of data.
8. **Main Power Connector and Fuse Holder:** Connection point for input power and the fuses. Press the top tab and bottom tab together on the fuse panel to remove the fuse holder and fuses. It is located on the underside of the unit.
9. **Printer:** Internal thermal printer.

Accessories

- Chinrest (P/N 16049)

Components

- Printer Paper (P/N 12430-887)
- Dust Cover (P/N 16050-089)
- Quick Reference Card (P/N 16170-104)
- Forehead Rest Pad (Spare) (P/N 16050-170)
- Power Cord (P/N RCBL10040 - 110V) or (P/N RCBL10041 - 230)
- Package of Pipe Cleaners - (P/N 16170-004)
- Package of Cotton Swabs (P/N 16170-005)

Instrument Setup (continued)

Icon Definition

The Ocular Response Analyzer G3 incorporates a user-friendly icon/menu-based operating system that will increase the speed of measurements, training and use. Listed below are the icons that are used during the operation of this instrument.

Icon Description


MAIN MENU — Accesses secondary level menus such as setup and help.


SINGLE MEASURE — Initiates a single-puff measurement process.


MULTIPLE MEASURE — Initiates a triple-puff or quadruple-puff measurement process.


DEMO PUFF — Allows patient to feel a soft demonstration air puff.


CLEAR DATA — Clears the current measurement data.


PRINT — Sends data to the printer and/or the RS232C port.


CANCEL — Cancels measurement process.


SELECT — Confirms entry.


BACK — Returns to preceding screen.


ANALYSIS - Displays a graphical analysis of the current measurement data.


CH HISTOGRAM - Displays current CH measurement compared to a normal population distribution.

OD WAVEFORM - Shows the best waveform for the Right Eye

OS WAVEFORM - Shows the best waveform for the Left Eye


SERVICE — Displays service information.


SERVICE HISTOGRAM - Displays a histogram of the last 400 measurements.

Instrument Setup (continued)

Default Settings

The Ocular Response Analyzer G3 has default settings that are set at the factory. To view a summary of these settings, refer to the following page. To view a detailed definition and explanation of each setting, refer to the individual setup sections in the Instrument Setup section of the manual.

CAUTION: DO NOT USE A POINTED OBJECT TO TOUCH THE SCREEN OR DAMAGE TO THE DISPLAY MAY RESULT.

Follow these steps to customize the default settings:

1. Tap the MAIN MENU icon.
2. Tap the appropriate setup category (e.g., Printout Setup).
3. Tap the desired parameter to select it.
4. Tap the BACK icon to return to the previous menu screen.
5. Tap the BACK icon on the main Settings screen to return to the main screen.

Instrument Setup (continued)

Default Settings (continued)

This instrument is sent from the factory with default settings. These settings can be changed to suit the needs of the individual operator. A summary of these settings is given below with the default selections shown in bold type. To customize these settings, follow the steps provided on page 12, Instrument Setup, Default Settings.

Setup Options

This instrument has the following default settings:

Tonometer Setup: (page 15)

Pressure: **mmHg,** kPa

Averaging: **Intelligent,** Straight

Printout Setup: (page 15)

Date Format:	**MDY,** DMY, YMD
Time Format:	**AM/PM,** 24 HR
Date:	12/18/2007
Time:	05:00PM
Printer:	**On,** Off
Practice:	**Reichert**

Communication Port Setup: (page 16)

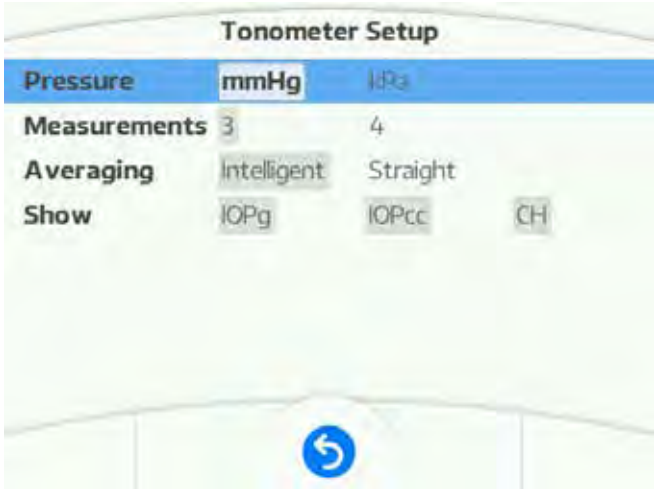
Baud:	2400, 4800, 9600, **19200**
Parity:	**None,** Even, Odd
Data Bits:	7, **8**
Stop Bits:	**1,** 2

General Setup: (page 17)

Language:	**Eng,** Fra, Deu, Esp, Por, Ita
Tone:	**On,** Off
Sleep:	**5,** 10, 15, 20, Off
Brightness:	* * * * * * * * * * *
Eye Title:	**Right/Left,** OD/OS

Instrument Setup (continued)

Tonometer Setup

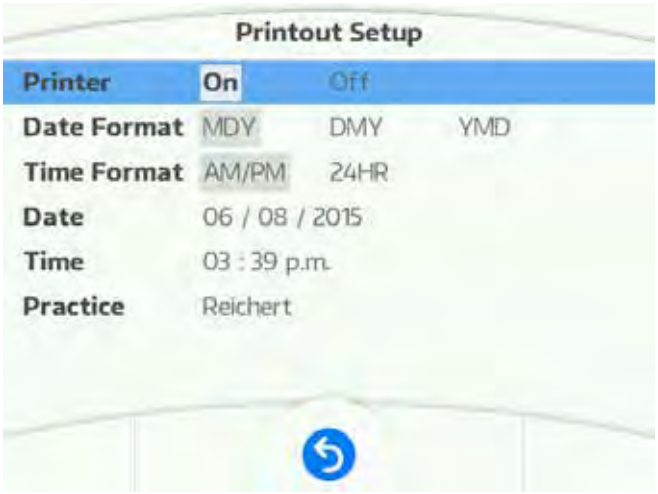


The following options are available in the Tonometer Setup menu:

Settings	Options
PRESSURE	Choose either mmHg (millimeter of mercury), or kPa (kilopascal).
MEASUREMENTS	Choose either 3 or 4 measurements for the multi-measure button function.
AVERAGING	Choose either Intelligent or Straight averaging. Refer to the Measurement Results section of this manual.
SHOW	Choose one, two, or all three of the options to be displayed. Options are IOPg, IOPcc, and CH. Refer to the Measurement Results section of this manual. **Note:** At least one must be selected. It is not possible to turn off all three.

Instrument Setup (continued)

Printout Setup



The following options are available in the Printout Setup menu:

Settings	Options
PRINTER	Option that sets the printer to print (ON) or not to print (OFF) when the PRINT icon is touched.
DATE FORMAT	Choose the date format to display on the printer paper: D=Day, M=Month, Y=Year.
TIME FORMAT	Choose the time format: AM/PM or 24 HR.
DATE	Change the current date. Touch to select a date field and use the PLUS (+) or MINUS (-) icons to modify the value.
TIME	Change the current time. Touch to select a time field and use the PLUS (+) or MINUS (-) icons to modify the value.
PRACTICE	Up to 29 characters (letters and numbers) can be printed at the bottom of the printer paper. To change the characters, use the PLUS and MINUS icons to scroll through the alphabet. Once you find the letter you need, touch the RIGHT or LEFT icon to move horizontally to the next letter. To exit, touch the SELECT icon, then the RETURN icon.

Instrument Setup (continued)

Communications Port Setup

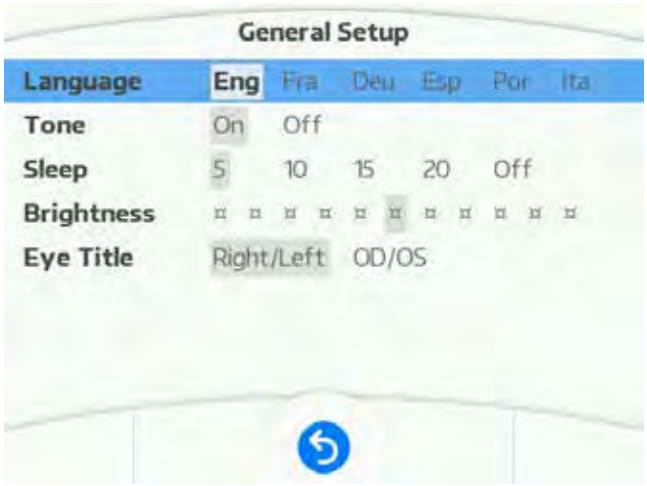
The Ocular Response Analyzer G3 can transfer data to an external device, such as a computer, through the RS232C port.

The following options are available in the Communications Setup menu:

Settings	Options
BAUD	Serial transmission data rate, transfers in bits per second (bps).
PARITY	Bits added to data transmission used to detect transmission errors. None, Even, or Odd are the available options.
DATA BITS	Number of bits that make up data transmission signal. Usually 7 or 8 bits in length.
STOP BITS	Number of bits added to the end of the data transmission signal to indicate the end of transmission. Usually 1, 1.5, or 2 bits in length.

Instrument Setup (continued)

General Setup



The following options are available in the General Setup menu:

Settings	Options
LANGUAGE	Sets the language that appears on the Operator Display.
TONE	Sets the audible tone indicator (“beep”) to be audible (ON) or silent (OFF). **Note:** Any time a selection is made on the touch screen, a beep will sound if the option is set to “ON”.
SLEEP	Sets the duration of time (5, 10, 15, 20 minutes, or OFF) that the instrument is inactive before it enters the “sleep” mode (the Operator Display goes blank when the “sleep” mode is active). To illuminate (“wake”) the Operator Display after the “Sleep” mode is active, touch the screen. **Note:** When unit comes out of sleep mode, any measurements that were not cleared prior to the activation of the sleep mode will still appear, but the measurement buttons will be disabled in order to prevent accidentally combining data from two different patients. Any previous measurements must be output or cleared before taking new readings.
BRIGHTNESS	Adjusts the brightness of the Operator Display by touching the desired level.
EYE TITLE	Select either Right/Left or OD/OS.

Instructions For Use

Definitions & Interpretation of Measurement Values

- IOPcc - Corneal Compensated IOP. A Goldmann correlated IOP measurement that takes the biomechanical properties of the cornea into consideration providing an indication of intraocular pressure that is less influenced by properties such as corneal viscoelasticity and thickness.
- CH - Corneal Hysteresis is a function of corneal viscoelastic damping that reflects the ability of the corneal tissue to absorb and dissipate energy. It is indicative of corneal biomechanical properties.
- IOPg - Goldmann-correlated IOP. IOPg is strongly correlated with the results obtained from an expertly executed, properly calibrated Goldmann Applanation Tonometer (GAT).
- Waveform Score – The Waveform Score is an indicator of measurement reliability on a scale of 0 to 10 (0 being lowest, 10 being highest). The higher the Waveform Score, the more reliable the measurement data. If the Waveform Score is below 3, the measurement will appear orange on the screen. It is recommended that you take an additional measurement.

Note: When IOPcc is higher than IOPg, this indicates that the IOP for this patient may be understated using traditional methods of tonometry. When IOPcc is lower than IOPg, this indicates that the IOP for this patient may be overstated when using traditional methods of tonometry.

Boot Up

When power is applied to the Ocular Response Analyzer G3, it initially performs a system check. During the system check, the unit will puff. After completion of the system check, the title screen will be displayed.

Note: The unit will puff during the start up sequence.

Alignment & Measurement

From this screen operators may choose to enter the MAIN MENU, demonstrate the airpuff to the patient, or begin the measurement process. To measure, move the Forehead Rest fully to the left or right until it locks into position if it is not already in this position.

Demo Puff

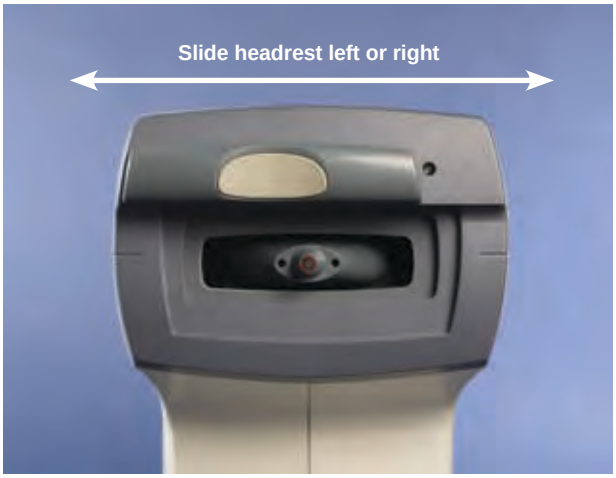
Pressing the DEMO PUFF icon initiates a sample air puff. This can be used to demonstrate the air puff to the patient. Suggest patient to hold their hand about 3 inches in front of the nosepiece so they can feel the air puff. After each time the DEMO PUFF icon is pressed and the air puff is delivered, an internal check of the Ocular Response Analyzer G3's systems is conducted to ensure optimum performance of your instrument.

Note: The DEMO PUFF icon will not display if there is measurement data displayed on the screen.

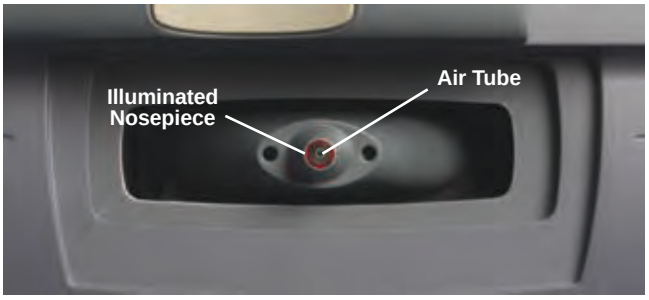
If the forehead rest is not in position, the icons will be inactive, and the message in the image below will appear.

The side that is ready to measure will become blue, indicating the unit is ready to measure that eye.

Alignment and Measurement (continued)

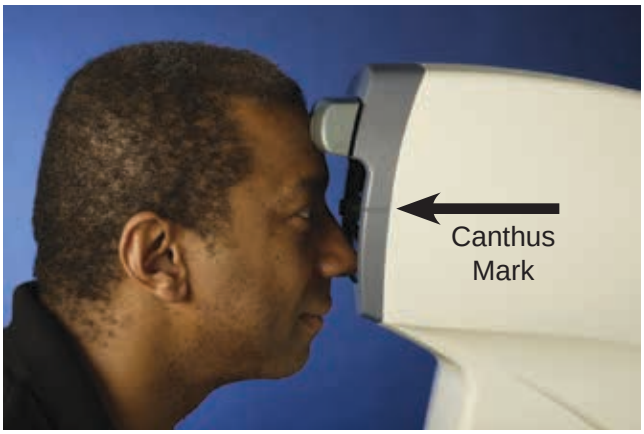


The Ocular Response Analyzer G3 features a left/right sliding forehead rest that enables the instrument to determine which eye is being measured. It must be positioned completely to one side or to the other in order to take a measurement. Position the forehead rest to the desired position before beginning the measurement process.



A properly positioned patient will easily see the fixation cues. The fixation target is a green light, located inside the air tube, surrounded by a ring of red lights. In order to take a measurement, patients must be fixating on the green light. If a patient is able to see any of the lights (red or green) then patient position is adequate. If any red lights can be seen, the automatic alignment system will bring the green fixation target into view. The measurement will be made automatically.

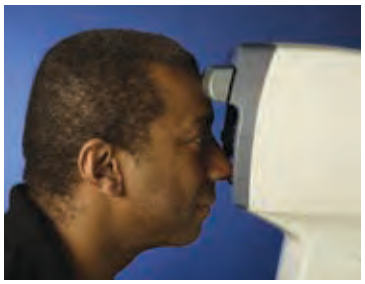
Alignment and Measurement (continued)



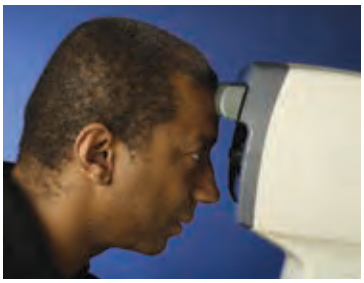
Correct Patient Positioning

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

Patients should lean forward slightly so that the center of their forehead rests in the middle of the forehead pad. The patient's head should contact the headrest straight-on; perpendicular to the front of the instrument (not turned to the side). Ensure the patient's chin is not too far from the front of the instrument, or the alignment system may not be able to reach the eye.



Proper Patient Alignment
(Chin Close to Unit)



Improper Patient Alignment
(Chin Moved Away From Unit)

Observe the photo on the right. Notice the distance between the patient's chin and the front of the instrument. The instrument is too low, causing the patient to rest his 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 reach the patient's eye.

Alignment & Measurement (continued)

To take a measurement, simply touch one of the measurement icons.

- Touching the SINGLE MEASURE icon will initiate a measurement with one puff.
- Touching the MULTI MEASURE icon will initiate a measurement with three or four sequential puffs, depending on menu settings.

Note: Between each measurement, the unit will align to the eye briefly, then measure.

Note: To ensure fast and accurate results operators should instruct the patient to blink a few times and hold both eyes open immediately before measurement. Remind the patient to look directly at the green light and hold steady.

Alignment & Measurement (continued)

During the alignment and measurement process, the Operator Display will show the position of the airtube with respect to the center of the patient's cornea. As the positioning system aligns to the apex of the eye, the measuring icon will move to the middle of the screen and align over the center of the eye graphic. Once the positioning system is aligned the air puff(s) is delivered to the eye and the measurement results are automatically displayed.

Note: If the instrument is unable to properly align to the patient's eye and take a measurement (e.g., it keeps aligning but never takes a reading), it may be necessary to ask the patient to:

- Remain still and try not to move or blink frequently
- Open his/her eyes wider
- Reposition his or her head per the instructions indicated on screen.

Alignment & Measurement (continued)

Measurement Count
The eye icons below the eye titles (Right and Left, or OD and OS) will be filled in to indicate the number of measurements that have been made.

When using the single measurement function, an eye icon will become filled after each measurement. If more than 3 individual measurements are made on the same eye, all three eye icons will remain filled and the measurement results will continue to be updated based on the averaging methodology described in the Measurement Results section of this manual.

When using the multi measure function, all eye icons will appear filled after the measurement process is complete.

Pressing the multi measure icon again will result in a new set of measurements, replacing any data displayed for the eye being measured.

Measurement Results

Intelligent Averaging of Data

The Ocular Response Analyzer G3 features an intelligent averaging system, based on the waveform score, to help ensure the most reliable measurements are displayed. The system works in the following manner:

Single Measurements

If a single measurement is taken on an eye, the IOPcc, CH, IOPg and Score for that measurement will be displayed regardless of the Waveform Score. If the Waveform Score is low, another measurement should be taken.

Multiple Measurements in Intelligent Averaging Mode

If multiple measurements are made on an eye, the displayed result will be an average of the measurements with Waveform Scores that are within 1 number of the highest score obtained. Any measurement in a series of measurements with a Waveform Score more than 1 below the highest Waveform Score will be discarded. Results from any measurement that produces a score more than 1 number higher than all other measurements obtained will be displayed based on this result alone.

Note: The intelligent averaging process updates the displayed results in “real time.” Results from each measurement in a series of measurements are not displayed individually.

Straight Averaging of Data

When the straight averaging option is selected in the setup menu, the displayed result will be an average of all measurements regardless of the score.

Multiple Measurements Using the Multi Measurement Button

When using the multi measurement mode the displayed result will be a straight average. If the multi measurement button is pressed again, the process will start over, clearing the previous measurements, and replacing any stored values for that eye.

Multiple Measurements Using the Single Measurement Button

When taking multiple measurements using the single measurement button the displayed results will continue to be updated based on a straight average of all measurements made, up to the amount of measurements selected in the tonometer setup menu (3 or 4).

Once the maximum number of measurements have been made (3 or 4), an additional measurement will replace the measurement with the lowest Waveform Score, so that only 3 or 4 measurements are averaged together. Each following measurement will continue to replace the measurement with the lowest Waveform Score.

Measurement Results (continued)

Examples - Intelligent Averaging

Please refer to the table below for some scenarios that demonstrate how the intelligent averaging process determines the displayed result

	Measurement A	Measurement B	Measurement C	Measurement D
Individual IOPcc	17.5	11.0	16.0	16.5
Individual IOPg	13.0	8.0	12.0	12.7
Individual CH	12.0	9.8	12.4	11.2
Individual Score	9.5	3.0	9.0	8.5
Displayed IOPcc	17.5	17.5	16.8	16.7
Displayed IOPg	13.0	13.0	12.5	12.6
Displayed CH	12.0	12.0	12.2	11.8
Displayed Score	9.5	9.5	9.3	9.0

Measurement A - A single measurement taken

The first measurement results in a good score. Since it was the only measurement made, the displayed results are based on this measurement.

Measurement B - An additional measurement taken after Measurement A

A second measurement is made that resulted in an individual score more than 1-number lower than measurement A. As such, the intelligent averaging system disregards this value and the displayed results do not change.

Measurement C - A third measurement taken after Measurement B

A third measurement is made that resulted in an individual score that is within 1 of the highest Score (measurement A). The displayed results are now an average of measurement A and measurement C. The displayed values are updated in real time, such that the operator never sees the individual results from measurement C.

Measurement D - A fourth measurement taken after Measurement C

A fourth measurement is made that resulted in a score that is within 1 of the highest Score (measurement A). The displayed result is now an average of measurements A, C, and D. The displayed values are updated in real time, such that the operator never sees the individual results from measurement D.

Note: If the triple measurement function were used to obtain results A, B, and C, the process would end after result C. An additional press of the triple measurement button would clear the results and start the process over. An additional single measurement would continue to update the results based on the averaging technique.

Note: It is important to clear on-screen results after concluding with a patient to prevent “blending” of measurement results from patient to patient.

Note: If the unit goes into sleep mode, any measurements that were not cleared out prior to sleep mode must be printed, transferred, or cleared before taking new readings.

Measurement Results (continued)

Examples - Straight Averaging

Please refer to the table below for some scenarios that demonstrate how the straight averaging process determines the displayed result

	Measurement A	Measurement B	Measurement C	Measurement D
Individual IOPcc	17.5	11.0	16.0	16.5
Individual IOPg	13.0	8.0	12.0	12.7
Individual CH	12.0	9.8	12.4	11.2
Individual Score	9.5	3.0	9.0	8.5
Displayed IOPcc	17.5	14.3	14.8	15.3
Displayed IOPg	13.0	10.5	11.0	11.4
Displayed CH	12.0	10.9	11.4	11.3
Displayed Score	9.5	6.3	7.2	7.5

Measurement A - A single measurement taken
The first measurement results in a good score. Since it was the only measurement taken the displayed results are based on this measurement.

Measurement B - An additional measurement taken after Measurement A
A second measurement is made. The two measurements are averaged and displayed.

Measurement C - A third measurement taken after Measurement B
A third measurement is made. All three measurements are averaged and displayed.

Measurement D - A fourth measurement taken after Measurement C
A fourth measurement is made. All four measurements are averaged and displayed.

Note: It is important to clear on-screen results after concluding with a patient to prevent “blending” of measurement results from patient to patient.

Note: If the unit goes into sleep mode, any measurements that were not cleared out prior to sleep mode must be printed, transferred, or cleared before taking new readings.

Note: Once the maximum number of measurements have been made (3 or 4), an additional measurement will replace the measurement with the lowest Waveform Score, so that only 3 or 4 measurements are averaged together. Each following measurement will continue to replace the measurement with the lowest Waveform Score.

Measurement Results (continued)

IOPcc, IOPg, or CH
Whichever options that have been selected in the Tonometer Setup in the Settings menu will be displayed. All other values will be hidden from view. You can still view the results of the hidden values for the current measurement by pressing the field for that value. Pressing the field again will hide it again.

Note: You cannot hide a value that was selected in the Tonometer Setup.

The displayed values will be printed out and exported, regardless of what was selected in the Tonometer Setup.

Once you erase the data and take another reading, the results displayed will be those selected in the Tonometer Setup.

Measuring the Next Eye

There are several options available at this point:

a. The Forehead Rest may be slid to the opposite side to continue taking measurements on the other eye.
b. All data may be cleared and additional measurements taken on the same eye (touch the CLEAR icon).
c. The data can be printed by touching the PRINT icon.

Note: The instrument will print out the data from both eyes if the PRINT icon is touched after both eyes are measured.

Note: Measurement data should always be printed or cleared after a patient is completed. Leaving readings on the screen can result in “mixing” of data when the next patient is measured.

Note: If the unit goes into sleep mode, any measurements that were not cleared out prior to sleep mode must be printed, transferred, or cleared before taking new readings.

Sleep Mode

The unit will go into sleep mode after the specified amount of time selected in the Setup Menu. When the unit comes out of sleep mode, any measurements that were not cleared out prior to sleep mode will appear on the screen, but the measurement buttons will be disabled in order to prevent accidentally combining data from two different patients.

While the measurement buttons are disabled, the Analysis button is still functional, so that the data can be viewed.

If disabled measurement buttons appear, the data must be printed, transferred, or cleared before taking new readings.

Low Waveform Scores

An advanced signal “scoring” process is employed in the Ocular Response Analyzer G3 to objectively determine the reliability of the measurement data. On a scale of 0 to 10, the higher the score, the more reliable the measurement data.

Any measurement values identified with a “low waveform score” will be indicated in orange text, and on the bar graph beneath the measurements. Take additional measurements to replace results with low waveform scores.

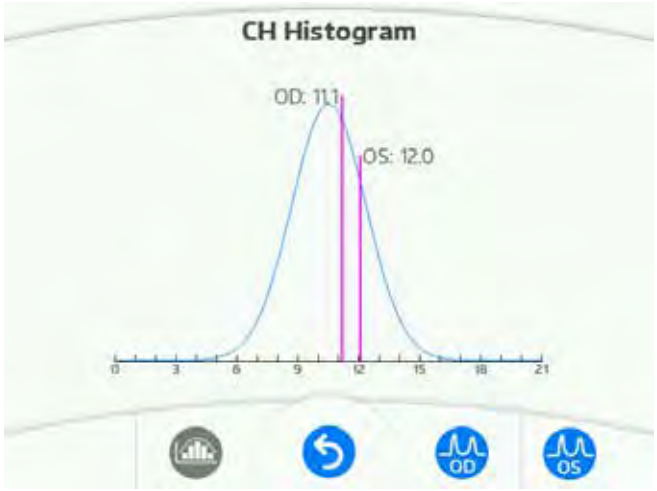
Note: It is possible that post refractive surgery eyes and eyes with pathologies may produce consistently low measurement scores. The values based on the highest obtainable scores should be considered reliable.

Analysis Screens

Tapping the ANALYSIS icon will display the analysis screen. On the Analysis screen the CH Histogram, as well as the Left and Right eye Waveforms can be viewed.

Note: When a chart is displayed, the icon will be disabled since it is the current chart and is an inactive button. Only the icons that can be selected will be in blue.

CH Histogram



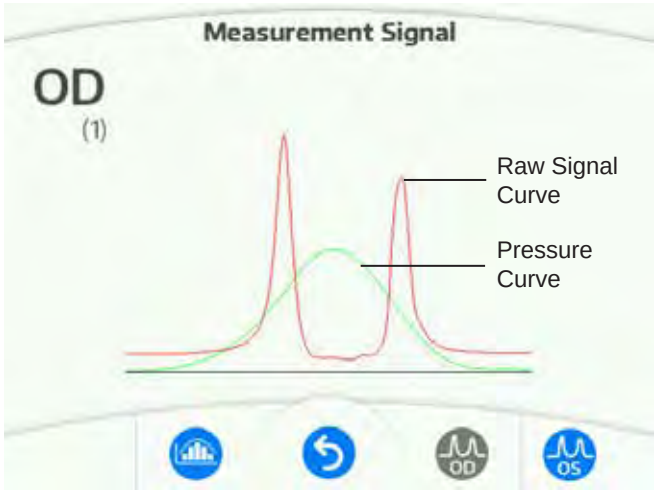
The CH Histogram displays a distribution of normal population CH values, and the CH results for the patient being measured with respect to the normal distribution*.

* The reference population is comprised of 840 eyes (340 Male and 500 female) for CH measured during 2002 and 2003. Ethnic breakdown of the population is as follows: 18 African American, 264 Asian, 496 Hispanic, and 62 Caucasian. No minimum or maximum “cut-off” values were established for hysteresis or IOP in the reference population. Observed Corneal Hysteresis and IOP values ranged from 4-18 mmHg and 6-26 mmHg respectively. Inferences for values outside of this range remain speculative.

Instructions For Use (continued)

Analysis Screens (continued)

OD/OS Measurement Signal



The measurement signals based on the best waveform score obtained can be seen by tapping the corresponding icon, either OD or OS. This signal displays the Applanation Curve (red line) and the Pressure Curve (green line).

The Ocular Response Analyzer G3 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.

The illustrated curves are the following:

- The green curve represents the pressure of the air on the cornea.
- The red curve indicates the signal of the applanation detection system.

The optical signal collected during the inward and outward applanation events causes the two "peaks" 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. 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 green 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 red applanation signal curve may vary significantly in appearance from measurement to measurement. Ideally, the amplitude (height) of the applanation peaks will be above the green curve. Both peaks should have a clearly defined and relatively well-centered high point. The peaks should be *similar* in amplitude (they will rarely be identical). In normal eyes, the signals will be symmetrical and relatively free of "noise."

Positioning Error Messages

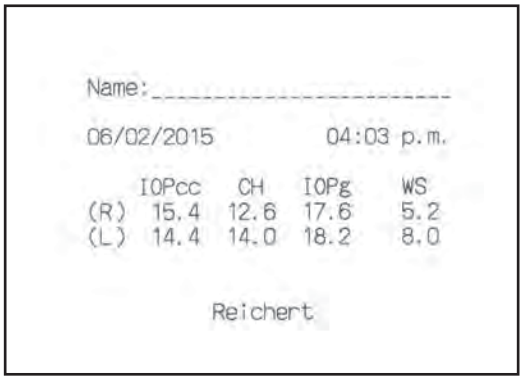
If the patient is not properly positioned, the Ocular Response Analyzer G3 may not be able to align and measure. Should this occur, the nosepiece will return to the home position, and the screen will display an error message indicating the reason for the incomplete measurement.

Should this situation arise, reposition the patient and proceed with the next measurement.

Printing Measurement Data

Touch the PRINT icon to print a paper copy of the measurement data and/or output the measurement data via the RS232C port. A sample printout is shown below.

Note: Only the displayed values will print out. Any hidden values will not be printed.



Sample Printout

If you decide not to make a printout, touch the CLEAR DATA icon. This will clear all data from the memory and the screen. The instrument is now ready for the next patient.

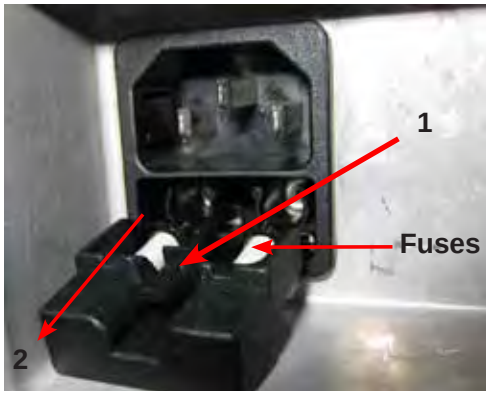
Cleaning & Maintenance

Fuses

WARNING: DISCONNECT POWER BEFORE ATTEMPTING TO REMOVE THE FUSES OR SERIOUS INJURY OR DEATH MAY OCCUR.

Replace the fuses in the Power Input Module with the fuses indicated in the Specifications section of this manual.

1. Remove input power to the instrument.
2. Press down on the tab in the middle of the Power Input Module to release the Fuse Holder. Refer to item 1.
3. Pull the fuse holder out of the input module. Refer to item 2.
4. Install new fuses that are indicated in the Specification section of this manual into the Fuse Holder.
5. Push the Fuse Holder into the Power Input Module until it snaps into place.



Fuse Location

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)).

Forehead Rest Cleaning

For hygienic reasons, the Forehead Rest may be cleaned with a clean cloth moistened with a mild detergent solution (1 cc of liquid dish soap to one liter of clean, filtered water (filtered below 5 microns)) or a sterile alcohol (isopropyl or ethanol) wipe.

Note: Replacement Forehead Rest Pads can be purchased through your local authorized Reichert dealer under P/N 16050-170.

Operator Display Cleaning

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

Printer Paper

To change the printer paper, remove the printer paper door to expose the printer paper compartment. Remove the cardboard roll and place a new roll of thermal printer inside the printer paper compartment as shown below. To order replacement thermal paper, call your local dealer and ask for Reichert replacement paper.


Printer Paper Replacement

Cleaning & Maintenance (continued)

Positioning Windows and Airtube Cleaning

WARNING: TO REDUCE THE RISK OF INJURY, BE SURE THERE IS NO PATIENT OR OTHER PERSON LOOKING INTO THE AIRTUBE DURING THIS CLEANING PROCEDURE.

CAUTION: DO NOT USE SOLVENTS OR STRONG CLEANING SOLUTIONS ON THE ALIGNMENT WINDOWS OR DAMAGE TO THE WINDOWS WILL OCCUR.

When the Positioning Windows or the Applanation Windows become occluded with contaminants, degradation of the positioning signal occurs. When signal degradation occurs, the system may not recognize or position at the center of the eye. Consequently, the instrument will not find the center of the eye or align off center, which may prevent the unit from taking a measurement or can cause low waveform score readings.

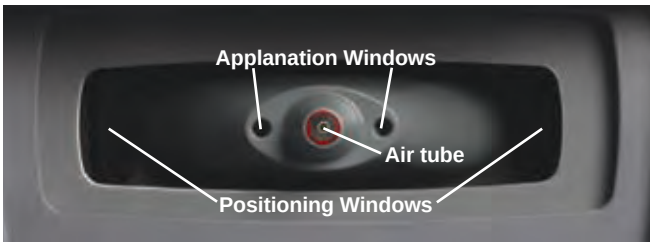
Every 30 days, the on-screen display will remind the user to clean the instrument.

Note: Any time during cleaning press the DEMO PUFF icon to initiate a single puff.

1. Press the SELECT icon to Enter Cleaning mode if reminder appeared, or the Cleaning mode may be entered at any time from the main screen by pressing the MAIN MENU icon then selecting Cleaning Procedure.

Note: If the cleaning mode is not entered after the 30 day reminder by the user pressing the BACK icon, then the 30 day reminder counter will be reset.

2. The nosepiece will advance for easy cleaning access.
3. Locate the Positioning Windows and the Applanation Windows and wipe the outside surfaces with a clean, long handle cotton-tip swab moistened with a lens cleaner or alcohol (isopropyl or ethanol).
4. Remove any remaining dust or foreign particles using only clean, dry, compressed air at less than 90 psig (620 kPa).



Positioning Windows

5. Using a Pipe Cleaner, slide it in and out of the Airtube a few times to remove any contaminants inside the Airtube.

CAUTION: BE SURE THERE IS NO PIPE CLEANER OR OTHER OBJECT IN THE AIRTUBE BEFORE PUFFING THE INSTRUMENT.


Pipe Cleaners

6. When cleaning is completed, press the SELECT icon and the Ocular Response Analyzer G3 will initiate a series of puffs to clear potential contaminants from the airtube and the nosepiece will return to normal position.

Cleaning & Maintenance (continued)

Forehead Rest Pad Replacement

The Ocular Response Analyzer G3 has a removable Forehead Rest Pad, to allow for easier replacement of the pad.

On the bottom part of the Forehead Rest Pad, there is a small indent, which is to allow room to grip the pad with your finger. Refer to Figure CL-1.

1. Grip the Forehead Rest Pad with your fingers at the Indent at the bottom of the pad. Refer to Figure CL-2.
2. Gently remove the Forehead Rest Pad by peeling it away from the Headrest. Refer to Figure CL-3.
3. Install a new Forehead Rest Pad by pressing it onto the grooves of the Headrest. Refer to Figure CL-4.

Note: Be sure the new Forehead Rest Pad is completely and firmly pressed down. If it is not, it could fall off.

Note: If you have the old style Headrest Assembly and need to replace the Headrest, please contact Reichert.

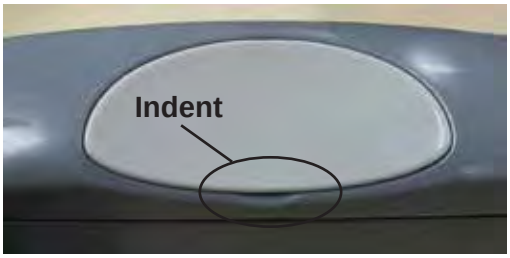


Figure CL-1. Forehead Rest Pad Indent

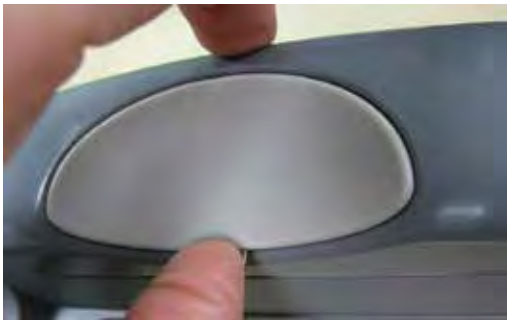


Figure CL-2. Grip Forehead Rest Pad

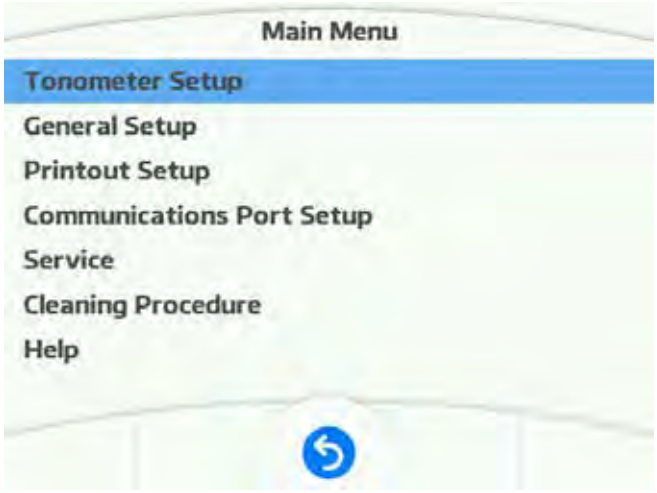
Figure CL-3. Remove Forehead Rest Pad

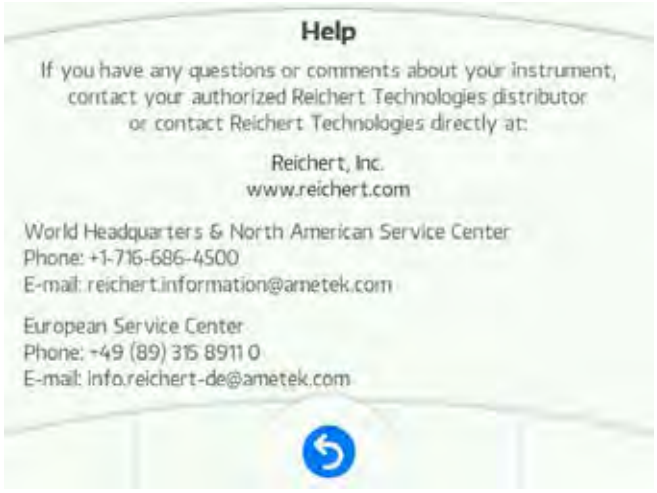
Figure CL-4. Install Forehead Rest Pad

Troubleshooting

Help Screen

To access the HELP menu, tap the MAIN MENU icon, then tap the HELP icon. This will display the contact information for Reichert.





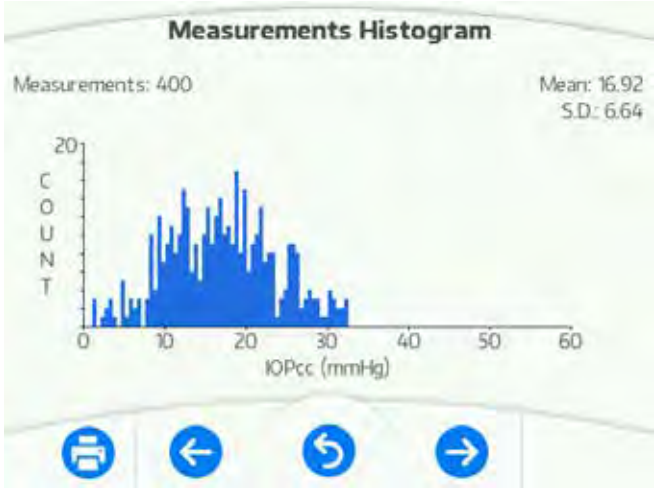
Troubleshooting (continued)

Service

To access the SERVICE screen, tap the MAIN MENU icon, then tap the SERVICE menu line. The following screen will appear.

Measurement Histogram

A graph displaying the last 400 measurements for either the IOPcc, IOPg, and CH can be seen by tapping the SERVICE HISTOGRAM icon. To scroll through the three different graphs (IOPcc,IOPg, and CH) tap the RIGHT and LEFT arrows. Any of these graphs can be printed by tapping the PRINT icon.



Troubleshooting (continued)

Print-Related Errors

If your printer runs out of paper during a print cycle, the following message will appear:

Note: If the printer paper runs out before printing all the measurement data, the data will be stored. Once the printer paper is replaced, a complete print out of all measurement data will start.

Time and Date Issues

Time and Date are maintained in memory by a long-life battery (CR 2032 Lithium Coin Cell Battery). This long-life battery lasts many years. If the Time and Date do not work, contact Reichert (Please refer to the Introduction section of this manual).

Troubleshooting (continued)

Chart of Common Errors

The following chart provides details of common problems and solutions for the Ocular Response Analyzer G3.

Definition	Probable Cause	Solution
Screen blank.	Unit is in Sleep Mode.	Touch the screen.
	ON/OFF Switch is set to OFF.	Press the "|" on the ON/OFF Switch.
	Fuse(s) are blown.	Replace the blown fuse(s) (Refer to Cleaning & Maintenance section). Press the ON/OFF Switch to OFF, wait two minutes, then press it to ON.
Screen is too dim.	Contrast is set too low.	Adjust brightness in General Setup Menu.
Instrument not responding to icon touch.	Touch screen needs recalibrating.	Re-boot unit while touching the screen to initiate calibration of the touch screen. Press the "blue dot" displayed on the screen at different locations to re-calibrate the touch screen.
"Unable to Locate Eye" message shown.	Patient not looking at the green fixation LED.	Instruct patient to look for the green LED, then move in toward headrest.
Does not find the eye (moves straight out, then goes straight back).	Dirty Positioning Windows or Applanation Windows.	Clean the Positioning and Applanation Windows (Refer to the Maintenance section of this manual).
	External light is confusing the positioning system.	Isolate sources of external light (e.g., incandescent or infrared light) and remove light source.
Finds one eye not the other. Infrared interference.	Light interference on measuring side.	Remove interference (e.g., infrared light source).
Will not take a reading.	Patient not holding still.	Encourage patient to remain still.
	Patient's eye too far from the Patient Window.	Ask patient to move toward the nosepiece.
	Patient not focusing on the target (eye moving around).	Ask patient to look only at target.
	Patient has dry eye.	Ask patient to blink their eyes.
	Dirty Positioning Windows.	Clean the Positioning Windows (Refer to the Maintenance section of this manual).
Low Waveform Scores or No Applanation readings shown.	Dirty Positioning Windows or Applanation Windows.	Clean the Positioning and Applanation Windows (Refer to the Maintenance section of this manual).
Printer is not printing.	Printer is out of paper.	Replace the paper with Reichert P/N 12430-887.
	Printer paper is installed backwards.	Reverse the printer paper.
	Not using Reichert thermal paper.	Replace the paper with Reichert P/N 12430-887.
Forehead Rest Pad fell off.	The Forehead Rest Pad has become loose and separated from the Headrest.	Replace the Forehead Rest Pad with P/N 16050-170. (Refer to the Maintenance section of this manual).

General Specifications

Model: 16170 - Ocular Response Analyzer G3

Physical Dimensions

Size:
Height: 50.2 cm (19.8 in.)
Width: 26.7 cm (10.5 in.)
Depth: 35.6 cm (14.0 in.)

Weight, unpacked: 10.4 Kg (23.0 lbs)

Electrical

Voltage: 100-240 VAC
Power: 60-85 VA
Frequency: 50/60 Hz
Fuses: Time-Lag (2.5A, 250V), 5 X 20mm, RoHS

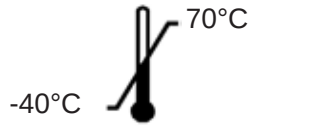
Measurement Range:
IOP: 7 – 60 mmHg CH: 0 to highest IOP measured
Measurement Accuracy:
Accuracy by NIST traceable pressure transducer (95% Confidence)

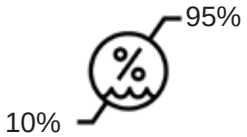
IOPg:	± 1.0 mmHg	(7 - 60 mmHg)
CH:	± 1.4 mmHg	(0 to highest IOP measured)
IOPcc:	± 1.0 mmHg	(7 - 60 mmHg)

Note: The accuracy complies with ISO 8612 Tonometer Standard

Operational Conditions

Environmental:
The environmental conditions are as follows:
Operating:
Temperature: 10° C (50° F) to 35° C (95° F)
Relative Humidity: 30% to 90%
Atmospheric Pressure: 80 kPa (23.6 in. Hg) to 106 kPa (31.3 in. Hg)
Transportation & Storage:
Temperature: -40° C (-40° F) to +70° C (158° F)
Relative Humidity: 10% to 95%
Atmospheric Pressure: 50 kPa (14.8 in. Hg) to 106 kPa (31.3 in. Hg)





Disposal

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

Software Revision

The software revision can be obtained by contacting Reichert Technologies or by accessing the Service screen via the Main Menu. The serial number identifies the manufacture date and will provide access to the software version.

Classifications

The Ocular Response Analyzer G3 is classified as Class I Equipment.

Class I 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 G3 is classified as Type B Equipment for patient contact per IEC 60601-1.

The Ocular Response Analyzer G3 is classified as IPX0 Equipment.

IPX0 Equipment is ordinary equipment enclosed without protection against ingress of water.

According to the mode of operation, the Ocular Response Analyzer G3 is a Continuous Operation instrument.

Guidance Tables

Table 201 – Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The ORA G3 is intended for use in the electromagnetic environment specified below. The customer or user of the ORA G3 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance -
Conducted and Radiated RF Emissions CISPR 11	Group 1	The ORA G3 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.
Conducted and Radiated RF Emissions CISPR 11	Class A	The ORA G3 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.*
Harmonic Distortion IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

Note: *The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance Tables (continued)

Table 202 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Medical Electrical Equipment and Medical Electrical Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ORA G3 is suitable for use in electromagnetic environment specified below. The customer or user of the ORA G3 should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment** - Guidance
Electrostatic Discharge IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
Electrical Fast Transients / Bursts IEC 61000-4-4	±2kV Mains Power Lines ±1kV I/O Lines 100kHz repetition frequency	±2kV Mains Power Lines ±1kV I/O Lines 100kHz repetition frequency	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surges IEC 61000-4-5	±0.5kV, ±1kV Line-to-line ±0.5kV, ±1kV, ±2kV Line-to-ground	±0.5kV, ±1kV Differential Mode ±0.5kV, ±1kV, ±2kV Common Mode	Mains power quality should be that of a typical residential, commercial or hospital environment.
Voltage Dips IEC 61000-4-11	0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0% Ut; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the ORA G3 requires continued operation during power mains interruptions, it is recommended that the ORA G3 be powered from an uninterruptible power supply or battery.
	0% Ut; 1.0 cycle and 70% Ut; 25/30 cycles Single phase: at 0°	0% Ut; 1.0 cycle and 70% Ut; 25/30 cycles Single phase: at 0°	
Voltage Interruptions IEC 61000-4-11	0% Ut, 250/300 cycles	0% Ut, 250/300 cycles	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30A/m 50 Hz or 60 Hz	30A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical residential, commercial or hospital environment.

Guidance Tables (continued)

Table 204 – Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Medical Electrical Equipment and Medical Electrical Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ORA G3 is intended for use in the electromagnetic environment specified below. The customer or user of the ORA G3 should ensure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment** - Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 KHz	(V1) = 3 Vrms 150 kHz to 80 MHz (V1) = 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 KHz	Portable and mobile RF communications equipment should be no closer to any part of the ORA G3, 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)(√P) d=(3.5/E1)(√P) 80 to 800 MHz d=(7/E1)(√P) 800 MHz to 2.7 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 Electromagnetic Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	(E1) = 3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	
	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	(E1) = 10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	

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.

* 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.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz, to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 206 – Recommended Separation Distances between Portable and Mobile RF Communications Equipment 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 ORA G3

The ORA G3 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ORA G3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the ORA G3 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 Outside ISM Bands d=(3.5/V1)(√P)	Separation (m) 150kHz to 80 MHz In ISM Bands d=(10/3)(3.5/V1)(√P)	Separation (m) 80 to 800 MHz d=(3.5/E1)(√P)	Separation (m) 800MHz to 2.7GHz d=(7/E1)(√P)
0.01	0.1166	0.1944	0.1166	0.2333
0.1	0.3689	0.6149	0.3689	0.7378
1	1.1666	1.9444	1.1666	2.3333
10	3.6893	6.1489	3.6893	7.3786
100	11.6666	19.4444	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.

Note 3: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

Table 9 – Guidance and Manufacturer's Declaration
Electromagnetic Immunity
Immunity to Proximity Fields from RF Wireless Communications Equipment

Guidance and Manufacturer's Declaration - Electronic Immunity

The ORA G3 is intended for use in the electromagnetic environment as specified below related to proximity fields from RF wireless communications equipment.

Immunity Test	**IEC 60601Test Level**							**Compliance Level**	**Electromagnetic Environment** -Guidance-
	Test Frequency (MHz)	Band (MHz)	Service (MHz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level	
Radiated RF IEC 61000-4-3	385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27	27 V/m at 0,3 m	$d = 6/E\sqrt{P}$ where d = Minimum separation distance in meters E = Immunity test level in V/m P = Maximum power in Watts (W)
	450	430-470	GMR 460, FRS 460	FM ±5 kHz deviation 1 kHs sine	2	0,3	28	28 V/m at 0,3 m	
	710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0,2	0,3	9	9 V/m at 0,3 m	
	745								
	780								
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 18 Hz	2	0,3	28	28 V/m at 0,3 m	
	870								
	930								
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28	28 V/m at 0,3 m	
	1845								
	1970								
	2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28	28 V/m at 0,3 m	
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9	9 V/m at 0,3 m	
	5500								
	5785								

Warranty

This product is warranted by Reichert Technologies (“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 that has 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 that has been sold, serviced, installed or repaired other than by a Reichert factory, Technical Service Center, or authorized Reichert Technologies Dealer.

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

All claims under this warranty must be in writing 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 should be filed within 30 days.

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.

Appendix A - Serial Data Description

I/O Connection

- RS-232 Serial DCE Port
- 9 Pin D-Subminiature female connector

Serial Port Configuration

- User selectable baud rates: 2400, 4800, 9600, 19200
- User selectable parity: None, Odd, Even
- User selectable data bits: 7, 8
- User selectable stop bits: 1, 2
- Flow control: none
- Default configuration is 19200, None, 8, 1

General Description of Data Format

- Data is output when the Print icon is touched
- Start with 2 <CR> characters
- Date and time the measurements were taken followed by a blank line
- Column headers for IOPcc, CH, IOPg and Waveform Score measurement data
- If measurement(s) were taken, right eye IOP measurement data includes the following:
    - right eye data tag - (R)
    - IOPcc (corneal compensated IOP) is a variable length, fixed point format value
    - CH (Corneal Hysteresis) is a variable length, fixed point format value
    - IOPg (Goldmann correlated IOP) is a variable length, fixed point format value
    - WS (Waveform Score) is a variable length, fixed point format value
- If measurement(s) were taken, left eye IOP measurement data includes the following:
    - left eye data tag - (L)
    - IOPcc (corneal compensated IOP) is a variable length, fixed point format value
    - CH (Corneal Hysteresis) is a variable length, fixed point format value
    - IOPg (Goldmann correlated IOP) is a variable length, fixed point format value
    - WS (Waveform Score) is a variable length, fixed point format value
- Blank line
- All lines end with <CR> character
- Message ends with an <EOT> character

-continued-

Appendix A - Serial Data Description (continued)

Possible Variations in Data

- The date format is set by the user (MDY, DMY or YMD)
- The time format is set by the user (24hr or AM/PM)
- The R and L eye data tags are different for each user selected language but the text length will always be the same
- Eye side text as follows:

English	R	L
French	D	
German	R	L
Spanish	D	I
Portuguese	D	E
Italian	D	S
OD/OS	OD	OS

- IOP measurement units are user selectable (mmHg or kPa). For mmHg, measurement precision is 0.1 mmHg. For kPa, measurement precision is 0.01 kPa.

Sample Data

06/05/2015 1:44 PM

	IOPcc	CH	IOPg	WS
(R)	19.8	11.7	21.6	8.1
(L)	19.7	11.8	21.5	7.3

<EOT>

Notes

Notes

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