Model 30™
Pneumatonometer

Instructions for Use

Reichert®
AMETEK®

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

Contents

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 manual.

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 MANUAL. 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 SO THAT CORRECT OPERATION OF THIS INSTRUMENT IS MAINTAINED 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 SO THAT CORRECT OPERATION IS MAINTAINED 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 THE 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 USE ANY OTHER PROBE WITH THIS INSTRUMENT THAN THOSE SUPPLIED BY REICHERT EXPRESSLY FOR USE WITH THIS INSTRUMENT. OTHER PROBES MAY CAUSE DAMAGE OR INJURY TO THE EYE.

WARNING: DO NOT USE THIS INSTRUMENT IF THE MEASUREMENT TIP IS CRACKED, CHIPPED OR SHOWS ANY IRREGULARITY OF THE SURFACE, TO PREVENT PATIENT INJURY AND OR INACCURATE READINGS.

WARNING: IN ORDER TO PREVENT PATIENT-TO-PATIENT TRANSFER OF INFECTION, AFTER EACH USE DISINFECT THE MEASUREMENT TIP FOLLOWING ACCEPTED LOCAL CLINICAL PROCEDURES REGARDING THE USE OF DISINFECTANTS. ANY CLINICALLY APPROVED CHEMICAL DISINFECTANT CAN BE USED.

Warnings & Cautions (continued)

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.

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 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 DISPLAY. SEE MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTION.

CAUTION: DO NOT AUTOCLAVE OR DISINFECT USING HIGH TEMPERATURES EXCEEDING THE RECOMMENDED TEMPERATURES INDICATED IN THE SPECIFICATIONS SECTION OF THIS MANUAL OR DAMAGE TO THE UNIT MAY OCCUR.

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: 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

Symbol Information

The following symbols appear on the instrument:


Caution


Type B Applied Part


Alternating Current Power


Protective Earth Connection

I O ON / OFF


Manufacturer


YYY-MM-DD Date of Manufacture

REF Catalog Number

S/N Serial Number


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


Accompanying Documents must be consulted


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


Important Instruction - remove Shipping Bracket

Introduction

Congratulations on your purchase of the Reichert® Model 30™ Pneumatonometer.

The Model 30 Pneumatonometer is a highly accurate instrument used to measure intraocular pressure (IOP) non-invasively through applanation tonometry and represents a significant advance in tonometry and tonography technology over its predecessors. The Model 30 Pneumatonometer system consists of the base unit, a probe, and the necessary accessories to accurately measure tonometry/tonography in one easy-to-use unit. This manual describes its operation and details.

These Instructions for Use are 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. Properly trained eye care professionals such as ophthalmologists, optometrists, opticians and eye care technicians should operate this instrument.

Please retain this guide for future reference and to share with other users. Additional copies can be obtained from your authorized Reichert Technologies dealer or contact our Customer Service department directly at:

Toll Free (US Only): 888-849-8955
Tel: 716-686-4500
Fax: 716-686-4555
Email: reichert.information@ametek.com

Please indicate the following when contacting Reichert to ensure that you receive the correct information:

- Model Number
- Serial Number
- Contact Phone Number or Email Address

Indications for use

The Model 30 Pneumatonometer is intended for the measurement of intraocular pressure. The Model 30 Pneumatonometer is indicated for use as a screening/monitoring tool for glaucoma or when increased intraocular pressure is suspected.

Contraindications

None.

Instrument Setup

Great care has been taken to deliver this instrument to you safely. The container and packaging was specially designed to transport this unit. Please retain the packaging if future transportation is required. Please remove the packaging material from the outer box and then remove the Model 30 Pneumatonometer and its accessories from the box. Refer to Figures 1-1 through 1-3.

Unpacking Instructions

Please remove the packaging material from the instrument in the following manner. Refer to Figures 1-1 through 1-3.

The instrument is packaged in a shipping container to protect the instrument from damage during shipment. Please read the Instructions for Use before operating the unit. The Model 30 Pneumatonometer includes the following accessories:

1. Instructions for Use (not shown)
   (P/N 16030-101)
2. Spare Tip and Membrane Assembly
   (P/N 230676)
3. Pneumatonometer Probe
   (P/N 232349)
4. Power Cord
   (P/N WCBL10018 for 16030 & 16032
   or P/N WCBL10027 for 16031)
5. Footswitch
   (P/N 232345 - only available with P/N 16033 kit)
6. Calibration Verifier
   (P/N 232373)
7. Yellow Shipping Bracket (not shown)
   (P/N 16030-009)
   (attached to the unit when shipped).
8. USB Cable (not shown)
   (P/N 15205-431)

Figure 1-1, Unpacking Unit

Figure 1-2, Unit with Foam

Figure 1-3, Accessories

Instrument Setup (continued)

Parts Identification

The Model 30 Pneumatonometer is housed in a single compact metal case that fits easily on most counters or an appropriate stand.

The front panel of the Model 30 Pneumatonometer includes: (Refer to the Figure 1-4.)

1. ON/ OFF switch
2. LCD readout
3. Connector for the pneumatic probe.

Figure 1-4, Pneumatonometer Parts (Front)

The rear panel of the Model 30 Pneumatonometer (Figure 1-5) includes:

1. Access door for changing filters and removing the yellow shipping bracket.
2. Receptacle for the optional footswitch, which allows the operator to select system functions while using his/her hands to restrain the patient's eyelid and position the probe.
3. Three-prong plug for the AC power cord that connects the Model 30 Pneumatonometer to an electrical outlet with an integral fuse holder.
4. USB connection for connecting to an external PC for data transfer.

Figure 1-5, Pneumatonometer Parts (Rear)

Instrument Setup (continued)

Parts Identification

Models and Options

The specifications for the different models of the Model 30 Pneumatonometer are found in the General Specifications section of this manual.

The Model 30 Pneumatonometer is a tonometer that provides the following tests: manual tonometry, pulsed tonometry, and tonography.

The Model 30 Pneumatonometer probe assembly (Figure 1-6) includes:

1. Tip and membrane assembly (Applied Part)
2. Probe assembly
3. Double lumen tubing
4. Quick-flow connector

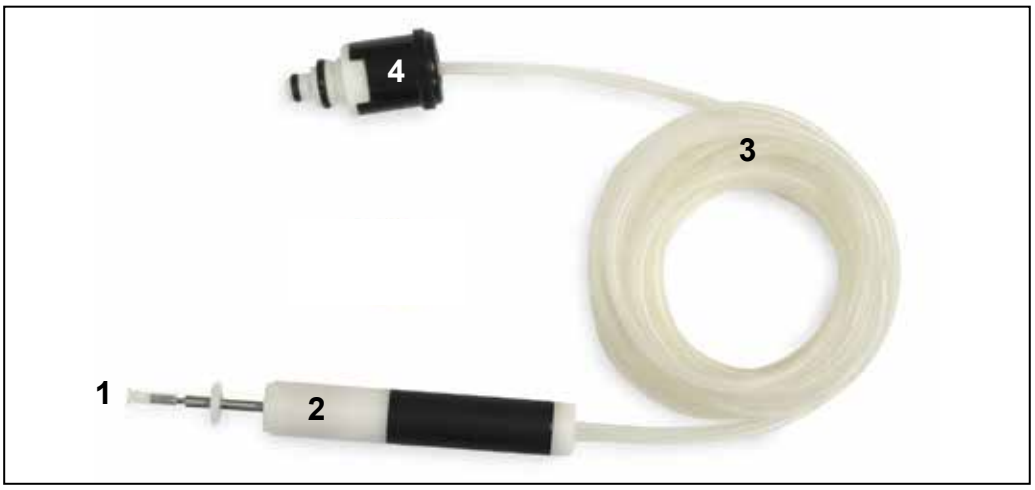


Figure 1-6, Pneumatonometer Probe

Optional Accessories

Part Number	Description
16033	Tonography Kit (includes Foot Pedal & 10 Gram Weight)
230677	Tip and Membrane Assembly, 3 pk
230678	Tip and Membrane Assembly, 10 pk
232346	Filter Kit

To order any of these accessories, contact your local authorized Reichert dealer, or purchase on the Reichert online store at store.reichert.com.

Instrument Setup (continued)

Icon Definition

The Model 30 Pneumatonometer incorporates a user-friendly icon/menu-based operating system that will increase the speed of measurements, training and use. Below are the Icons that are used during the operation of this instrument.

Icon	Icon Description	
	SETUP	Access the setup menu for changing default parameters.
	MEASURE	Initiates the measurement process.
	MANUAL MODE	Initiates the manual measurement mode process.
	PULSED MODE	Initiates the pulsed measurement mode process.
	TONOGRAPHY	Initiates the tonography mode.
	LEFT EYE	Left eye measurement.
	RIGHT EYE	Right eye measurement.
	2 MINUTE	Initiates the two minute tonography measurement mode.
	4 MINUTE	Initiates the four minute tonography measurement mode.
	ENTER DATA	Allows data to be entered manually.
	CALCULATE	Provides calculation of data.

Instrument Setup (continued)

Icon Definition (continued)

Icon	Icon Description	
	RETURN	Returns to preceding screen.
	RIGHT ARROW	Used in the setup menus to move right horizontally.
	LEFT ARROW	Used in the setup menus to move left horizontally.
	UP ARROW	Used in the setup menus to move up vertically.
	DOWN ARROW	Used in the setup menus to move down vertically.
	PLUS	Increases a numerical value displayed on the screen.
	MINUS	Decreases a numerical value displayed on the screen.
	SELECT	Used in the setup menus to activate the new parameter or setting.
	HOME	Returns to the main menu screen.

Instrument Setup (continued)

Default Settings

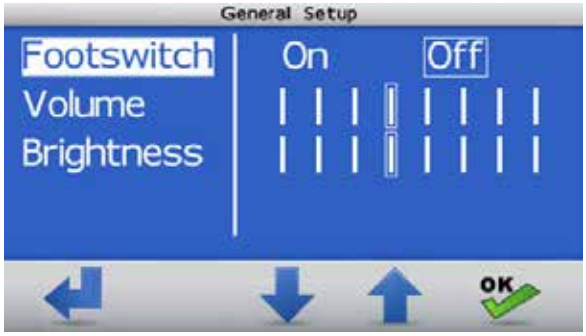
The instrument is configured at the factory with numerous default settings. These settings can be changed to the preferences of the operator/clinician. A summary of these settings is given below. The optional settings follow on subsequent pages.

General Setup:
- Footswitch: Off
- Volume: Middle
- Brightness: Middle

Date/Time:
- Date: (current date)
- Date Fmt: MDY
- Time: (current time)
- Time Fmt: AM/PM

Service:
- Service Screen with:
  - Software Version
  - Calibration Date
  - Customer Service Telephone Number

General Setup



Parameters:	Settings:
Footswitch:	Options are either On or Off.
Volume:	This option has a + or - to either decrease or increase the volume.
Brightness:	This option has a + or - to either decrease or increase the brightness.

Instrument Setup (continued)

Date/Time Setup

Parameters:	Settings:
Date:	When the unit is received, the date and time should be changed to the local time zone.
Date Fmt:	The options are: MDY, DMY, YMD (D=day, M=month, Y=year)
Time:	The correct time should be changed to agree with the local time zone.
Time Fmt:	The options are: AM/PM, 24HR

Service Screen

This sample screen provides the details of the Software Version, Calibration Date, and the customer service telephone number. If assistance is needed with this unit, consult the Troubleshooting section of this manual. If further assistance is needed, please contact the Technical Service Department at Reichert, Inc.

Instrument Setup (continued)

Installation

Consider the following factors as you find a location for the Model 30 Pneumatonometer:

- When taking tonometry measurements with the Model 30 Pneumatonometer, the patient can be either seated or supine. When conducting tonography tests, the patient must be supine.
- The console should be close enough to an electrical outlet so that the operator can connect the system with the power cord.
- The operator should be in a position to look directly at the contact between the probe and the surface of the eye.
- The operator should be able to see the instrument's LCD readout and optional Model 30 Pneumatonometer PC Software graph during a test.
- This medical device complies with IEC/EN 60601-1-2 Safety Standard for Electromagnetic Compatibility, Requirements and Test. However, if the equipment is operated in the presence of high levels of EMI or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the interference.

Pneumatonometer Installation

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. Set the ON/OFF switch on the front panel to the OFF position (the O is pushed in). Refer to Figure 1-7.
2. Remove the yellow shipping bracket according to the following steps. Refer to Figure 1-8.
   A. Remove the screw at the top of the air vent and remove the air vent.
   B. Loosen the screw that secures the yellow shipping bracket onto the back of the compressor.
   C. Remove the bracket and then tighten the screw.
   D. Replace the air vent and secure it using the screw that was removed.
   E. Leave the yellow shipping bracket off and store it in a safe place so that if it is needed for future shipping, it is available.
3. Plug the power cord into the back of the unit and the other end into an electrical outlet that has the correct input power parameters as indicated in the General Specifications section of this manual.

Figure 1-7, ON/OFF

Note: Leave the On/Off switch to the OFF position and do not apply power to the unit at this time.

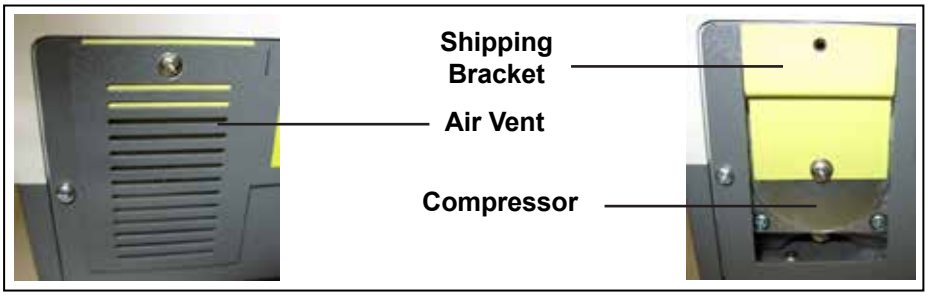


Figure 1-8, Shipping Bracket Removed

Instrument Setup (continued)

Pneumatonometer Installation (continued)

4. Remove the probe from its container and place the clean tip and membrane assembly that was sent with the unit onto the probe, if one is not already installed. If a tip is not installed, perform the following:
   A. Perform the steps of the Disinfection of the Tip and Membrane Assembly as indicated in the Reprocessing Guidelines section of this manual
   B. Install the tip and membrane onto the probe tip so that the tubing contacts the shoulder and approximately 1/8” of an air gap is visible between the end of the shaft and the tip, as shown in Figure 1-9.

Figure 1-9, Tip

5. Plug the other end of the probe tubing into the front panel connector as follows: (Refer to Figure 1-10)
   A. Push in the probe connector into its mating connector.
   B. Ensure the connection is tight and that there is no sound of leaking air from around the connector.
6. Loosely coil the probe tubing around the probe tray using the cutouts at either end of the tray and place the probe in the tray so that the tip is not in contact with any other item.
7. If the optional footswitch is being used, connect the footswitch cord into the receptacle on the back panel. Refer to Figure 1-5 for the location of the footswitch receptacle.
8. If the optional Model 30 Pneumatonometer PC Software is being used, or if unit will be connected to EMR, connect the USB cable to the rear panel of the instrument. Refer to the Model 30 Pneumatonometer PC Software section of this manual for further instructions on data transfer.

Figure 1-10, Probe Connection

Instrument Setup (continued)

Setup

This section describes the Model 30 Pneumatonometer initialization.

1. Turn the instrument ON by pressing down the “I” on the front panel ON /OFF switch. At start-up, the Model 30 Pneumatonometer LCD readout will display the initial screen for several seconds as the instrument conducts a self-check test. After initialization, the unit will display the Main Menu Screen. Refer to Figure 2-1.
2. Touch the SETUP icon to enter the setup mode.
3. Touch the OK icon to set the options in the General Setup mode. Refer to Figures 2-2 and 2-3.
   A. Footswitch - this option sets the footswitch ON or OFF. Default is OFF.
   B. Volume – sets the volume level for the audible prompts.
   C. Brightness – sets the brightness intensity level for the LCD Screen.
4. Touch the RETURN icon to return to the Main Menu screen.

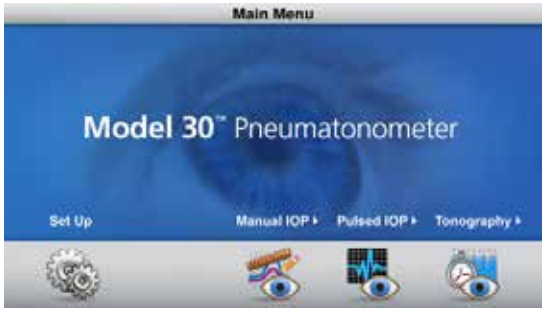


Figure 2-1, Main Menu Screen

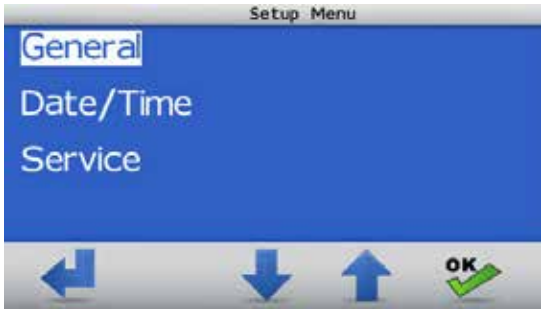


Figure 2-2, Setup Menu Screen

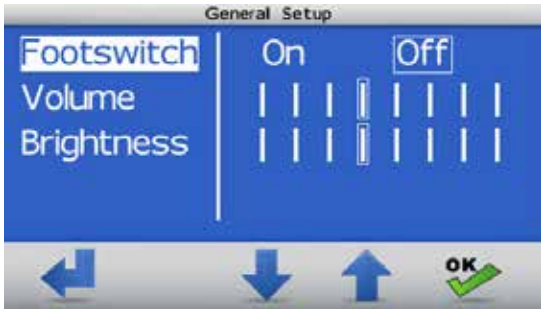


Figure 2-3, General Menu Option Screen

Instrument Setup (continued)

Setup (continued)

5. Touch the DOWN ARROW icon to highlight the Date/ Time Setup option.
6. Touch the OK icon to select the Date/Time Setup menu. Refer to Figure 2-4.
7. Touch the UP or DOWN icons to highlight the option that needs to be changed and touch the OK icon to select the option. Refer to Figure 2-5.
8. Touch the LEFT, RIGHT, "+" or "–" icons to change the option to the appropriate setting. Refer to Figure 2-6.
9. Touch the OK icon to activate the Date/Time Setup menu screen.
10. If all the options are set to the desired settings, touch the RETURN icon to display to the Setup Menu screen.
11. Touch the RETURN icon to return to the Main Menu screen.

Figure 2-4, Setup Menu Screen

Figure 2-5, Date/Time Menu Option Screen

Turning Off

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.

Figure 2-6, Changing Date/Time Options

Model 30 Pneumatonometer PC Software Setup

Software Installation

A computer with Windows 10* or higher is recommended for the Model 30 Pneumatonometer PC Software installation. The Model 30 Pneumatonometer PC Software is designed to receive data from the device via the included USB cable and will export data in CSV (comma-separated values) file format, along with a PDF report and a PNG image of the graph. The .csv file can be opened by any spreadsheet software.

1. Connect the included USB cable from the Model 30 Pneumatonometer to the computer.
2. Download and run the Model 30 Pneumatonometer PC Software installer.

Note: The Model 30 Pneumatonometer PC software can be downloaded at www.reichert.com/products/model-30, under the software tab.

Figure 2-7, Software Desktop Icon

3. Click Install to begin installation.
4. The program will install, and then open the Model 30 Pneumatonometer PC Software program once installation is complete.
5. After installation is complete, the Model 30 Pneumatonometer PC Software icon will be displayed on the computer desktop. Refer to Figure 2-7.

Software Setup

1. Click the Settings icon to switch to the settings panel.
2. Click the COM Port drop down and select the COM Port the Model 30 Pneumatonometer is connected to. Refer to Figure 2-9.
3. If the Model 30 Pneumatonometer device software version is displayed and the colored box next to the COM Port turns green, then the correct COM port was selected. Refer to Figure 2-10.

Note: If the Model 30 Pneumatonometer is powered off, the Device Version will display N/A.

Note: If the COM Port displays a green box but the Device Version displays N/A, the incorrect COM port was selected.

4. Once a COM Port is selected, the PC software will automatically re-connect to the device when it is powered on and connected to that COM Port.
5. Output Path displays the directory that output files will be written to. Click the Browse button to change this location.
6. Click the Settings icon again to return to the main panel.

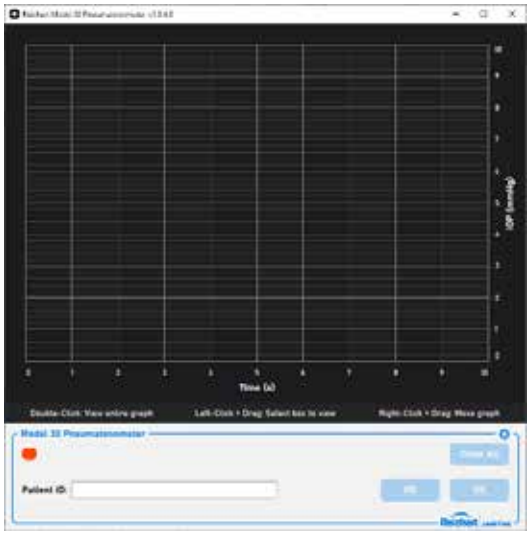


Figure 2-8, COM Port Selection

Figure 2-9, Settings Panel

Figure 2-10, Correct COM Port Selected

*The software has only been tested with Windows 10 since development of this Instruction for Use.

Instrument Setup (continued)

Quick Verification Check

Verify the operation of the probe and base unit using the calibration verifier in the Manual mode. Refer to Figure 2-11.

1. Fill the tube of the Calibration Verifier up to the line marked 15 mmHg with filtered water.
2. From the Main Menu, touch the Manual IOP icon. A menu screen will be displayed describing a summary of the Manual IOP measurement process. Touch the OK icon to continue to the Manual IOP screen.
3. The Model 30 Pneumatonometer will display the OD and OS menu. Select OD or OS to start the test. Place the tip of the probe against the calibration verifier test eye and apply force until the probe shaft compresses to the point where the black line is no longer visible, but the red line is still visible. When the probe is between the red and black lines, the Model 30 Pneumatonometer will be ready to display the average IOP readings and its standard deviation. Refer to Figure 2-12.

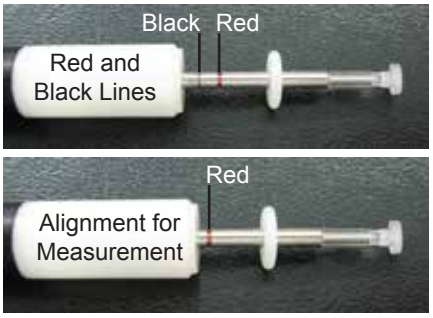


Figure 2-12, Probe Red and Black Lines

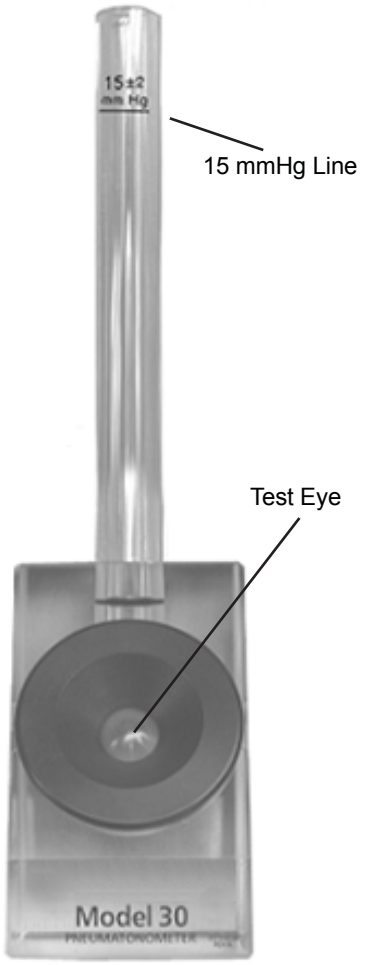


Figure 2-11, Calibration Verifier

Note: If the unit makes a loud vibration, stop the test immediately, turn off the unit, and remove the shipping bracket located on the back of the unit.

Note: The tone will settle to a lower tone when the probe is aligned properly. During an actual test, the tone will change to a noticeably lower pitch when the standard deviation is below 1.0 mmHg for at least three seconds. A lower tone change signifies that the instrument has acquired usable data.

After the reading is acquired, the probe can be removed from the Calibration Verifier.

Note: If the IOP is not 15 mmHg (± 2.0 mmHg), go to the Troubleshooting section of this manual for assistance. If the Troubleshooting section of the manual did not help, contact Reichert at the address or phone number in the Introduction section of this manual.

4. Touch the HOME icon to display the Main Menu.

Instrument Setup (continued)

Operating principle

The Model 30 Pneumatonometer measures intraocular pressure (IOP) non-invasively through applanation tonometry. The Model 30 Pneumatonometer probe contains a gentle, floating pneumatic sensor that touches the surface of the anesthetized cornea with the exact amount of applanating force required to take a tonometry or tonography measurement. Refer to Figure 3-1.

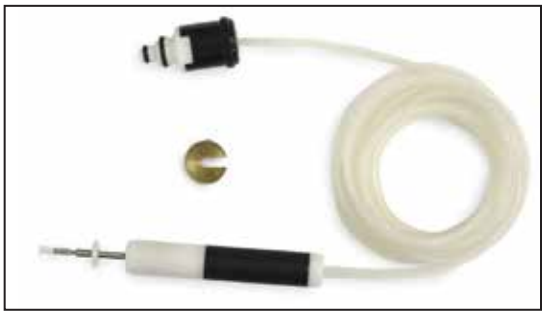


Figure 3-1, Pneumatonometer Probe

The sensing element is a lightweight plastic tip covered with a thin, highly elastic silicone membrane. The tip is mounted on a floating piston supported by a porous bearing.

A precisely regulated flow of filtered air enters the piston from the Model 30 Pneumatonometer and travels through the end of the sensor tip until it is blocked by the membrane. When nothing is touching the membrane, air flows to the periphery of the tip, where it escapes through venting ports. However, when the tip touches the eye, the pressure against the membrane causes it to seal the vents, blocking the escape of air and building up pressure in the system. The pressure increases until it matches the IOP and stops when the eye is applanated. At this point, the membrane can no longer maintain the seal. Any increased back pressure in the system is released through the venting ports. Applanation is then automatically maintained by the pneumatic feedback system. Refer to Figure 3-2.

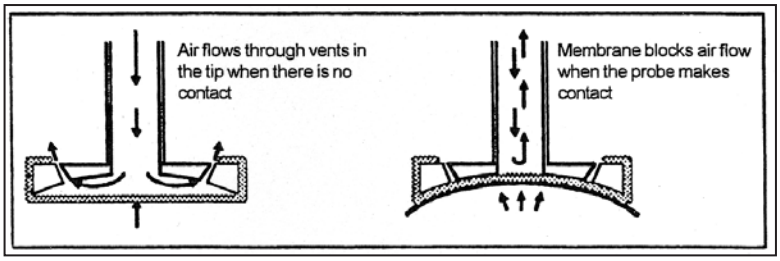


Figure 3-2, Probe Tip Open

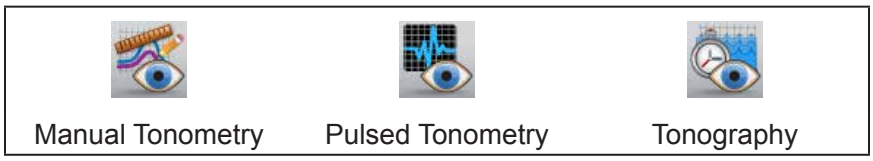
The Model 30 Pneumatonometer monitors the back pressure in the sensor and displays a real-time moving average of the IOP as well as its standard deviation. The Model 30 Pneumatonometer generates an audible tone to tell you when the most accurate reading is obtained. The tone will change to a noticeably lower pitch when the standard deviation among IOP readings remains below 1.0 mmHg for three seconds. The reading remains on the LCD readout when the probe is removed from the eye.

The Model 30 Pneumatonometer in the tonography mode calculates and displays the C value (aqueous outflow coefficient) using either a two-minute or a four-minute tonography examination.

The Model 30 Pneumatonometer can perform three different kinds of tests: manual tonometry, pulsed tonometry, and tonography. The manual tonometry test provides a single pressure value and ends the test when the operator touches OK on the device touchscreen. The pulsed tonometry test provides pressure output with pulse fluctuations and ends after it has read ten ocular pulses or when the operator touches OK on the device touchscreen. The tonography test records changes in IOP when a weighted probe is held on the cornea for a specified time. The tonography test enables the operator to conduct a two-minute or four-minute test for each eye.

Instructions for Use

This instrument is an easy to use instrument which provides fast and accurate tonometry and optional tonography functions. Utilizing a pneumatic pump and 5mm soft silicone contact area, the Model 30 Pneumatonometer records 40 readings per second and displays real time readings of intraocular pressure. In pulsed tonometry mode, the ocular pulse waveform is charted and recorded along with IOP using the optional Model 30 Pneumatonometer PC Software. There are three different tests that can be performed with the Model 30 Pneumatonometer. They are:



- Manual Tonometry: Displays real time readings of intraocular pressure.
- Pulsed Tonometry: Displays real time readings of the ocular pulse waveform.
- Tonography: Requires optional tonography kit (P/N 16033). Measurement of intraocular pressure over a two or four minute period, used to determine the rate of aqueous outflow.

Before taking measurements, there are certain conditions that should be analyzed. They are:

- Patient preparation.
- General Measurement Information.

Patient Preparation

For manual and pulsed tonometry, the patient can be either seated or supine. For tonography, the IOP must be measured first with the patient seated and then again with the patient supine. The actual tonography test is conducted with the patient in the supine position.

Use the following procedures to prepare the patient:

1. Depending on the test, have the patient seated straight in a chair, or supine.
2. Anesthetize the patient's eye(s) according to the physician's protocol.

Note: During the tests, it is best to have the patient concentrate on a fixation point to prevent the eye from wandering and causing erratic measurements.

3. Arrange the patient so that the operator is in a position to observe that the membrane of the probe tip is parallel and centered on the patient's cornea during measurements and that the probe is aligned between the red and black lines.
4. Describe the measurement procedure to the patient and what they should experience when a measurement is taken. Advise the patient to remain very still during the procedure.

Measurement Protocol

CAUTION: THE TIP AND MEMBRANE ASSEMBLY MUST ALWAYS BE CLEANED BEFORE AND AFTER MEASUREMENTS. REFER TO THE CLEANING AND MAINTENANCE SECTION OF THIS MANUAL FOR THE SUGGESTED CLEANING INSTRUCTIONS.

1. From the main menu screen, select the Manual, Pulsed, or Tonography test as necessary. Refer to Figure 4-1.
2. After selecting the test, the screen will display a message to apply the probe to the patient's cornea. When touching the cornea, perform the following steps: (Refer to Figure 4-2, Measurements)
   A. Hold the probe between the thumb and the index finger and rest the other three fingers on the patient's cheek.
   B. With your other hand, lift the patient's upper eyelid.

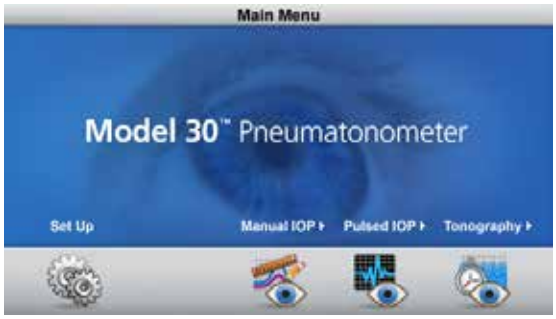


Figure 4-1, Main Menu Screen

Note: Hold the eyelid gently, excessive force applied to the eye will cause variability and inaccurate measurements.


Figure 4-2, Measurements

   C. Instruct the patient to focus on a fixation point.
   D. Move the probe into position along his/her line of sight such that the probe shaft extends directly toward the cornea.
   E. Gently move the sensor tip toward the eye, aligning it so that the center of the tip will make initial contact close to the corneal apex.

Note: Correct alignment is required during contact to obtain valid readings.

   F. As the membrane touches the cornea, continue to move the sensor handle toward the eye until the black line on the probe shaft is just hidden under the white housing. Refer to Figure 4-3.

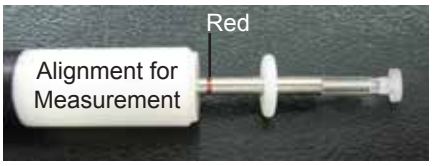


Figure 4-3, Probe Alignment

Note: Do not depress the probe so far that the red colored line on the shaft is hidden under the white housing.

3. The instrument provides a series of tones when acquiring measurements (provided the volume is set high enough in the Setup mode). When a low tone is audible, the measurement data is considered usable.

Note: The tone pitch will drop noticeably when the standard deviation of the readings is below 1.0 mmHg for three seconds.

Measurements

Manual Tonometry

To measure IOP using the manual tonometry mode, follow this procedure:

1. Touch the MANUAL IOP icon. Refer to Figures 5-1.
2. An information screen will pop up. Touch OK to close this screen.
3. Touch the OS or the OD icon. Refer to Figure 5-2.
4. Gently apply the sensor tip to the cornea using the procedures discussed in the Measurement Protocol section. Refer to Figure 5-3.

Note: The Model 30 Pneumatonometer will continue taking readings as long as the probe maintains proper contact with the cornea. When the standard deviation between readings goes below 1.0 mmHg for three seconds, the Model 30 Pneumatonometer will lower the tone pitch indicating that usable measurements have been attained.

5. If the device is connected to a PC running the Model 30 Pneumatonometer PC Software, the application will show a live graph of the exam. Refer to Figure 5-4.

Note: To reject all results, touch the Home icon on the device screen and the system will return to the Main Menu so the test can be repeated. Click Clear All on the Model 30 Pneumatonometer PC Software to clear the stored data for the rejected test.

6. When the test has completed, the results will be displayed in the main panel and all data will be exported as files in the specified Output Path.
7. To measure the other eye, touch the corresponding icon on the device screen for the other eye (OD or OS) and perform the test on the patient's other eye.

Note: Data for the first eye will not be deleted in the Model 30 Pneumatonometer PC Software when the other eye is selected and measured.

8. Touch the HOME icon on the device to display the Main Menu.

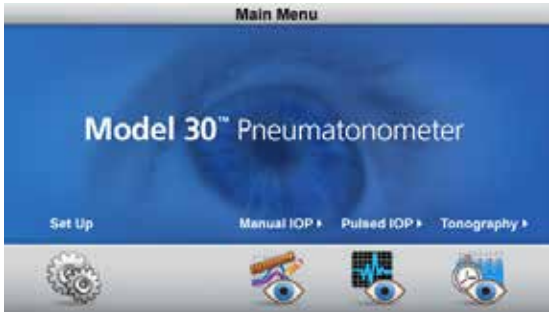


Figure 5-1, Main Menu Screen

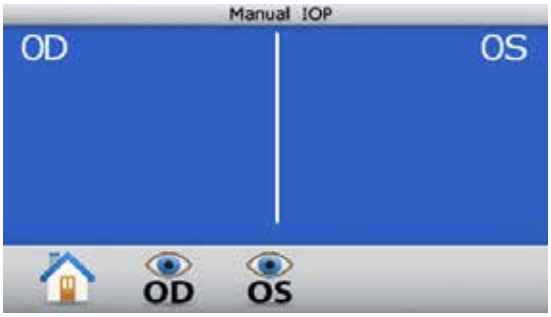


Figure 5-2, OS/OD

Figure 5-3, Measurements

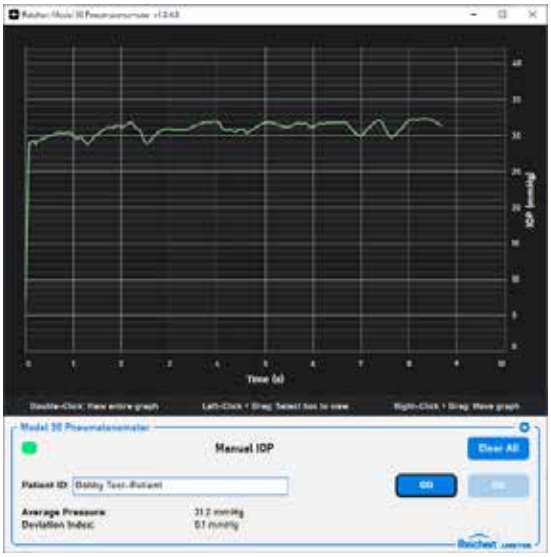


Figure 5-4, Software Graph

Measurements (continued)

Pulsed Tonometry

To measure IOP using the pulsed tonometry mode, follow this procedure:

1. Touch the PULSED IOP icon. Refer to Figures 6-1.
2. An information screen will pop up. Touch OK to close this screen.
3. Touch the OS or the OD icon. Refer to Figure 6-2.
4. Gently apply the sensor tip to the cornea using the procedures discussed in the Measurement Protocol paragraph in this section. Refer to Figure 6-3.

Note: The tone will change when the Model 30 Pneumatonometer has sensed five ocular pulses indicating that the instrument has enough samples to compute an average. The instrument will end the test after it has sensed ten ocular pulses. The reading displayed is the average of all detected pulses.

5. If the device is connected to a PC running the Model 30 Pneumatonometer PC Software, the application will show a live graph of the exam. Refer to Figure 6-4.

Note: To reject all results, touch the Home icon on the device screen and the system will return to the Main Menu so the test can be repeated. Click Clear All on the Model 30 Pneumatonometer PC Software to clear the stored data for the rejected test.

6. When the test has completed, the results will be displayed in the main panel and all data will be exported as files in the specified Output Path.
7. To measure the other eye, touch the corresponding icon on the device screen for the other eye (OD or OS) and perform the test on the patient's other eye.

Note: Data for the first eye will not be deleted in the Model 30 Pneumatonometer PC Software when the other eye is selected and measured.

8. Touch the HOME icon on the device to display the Main Menu.

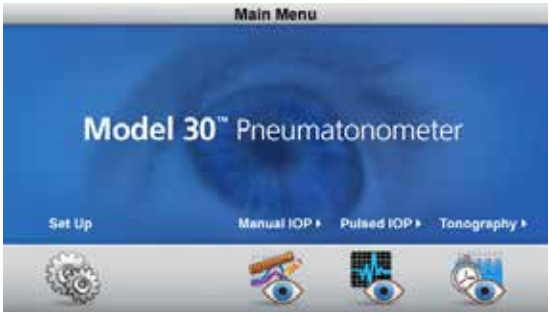


Figure 6-1, Main Menu Screen

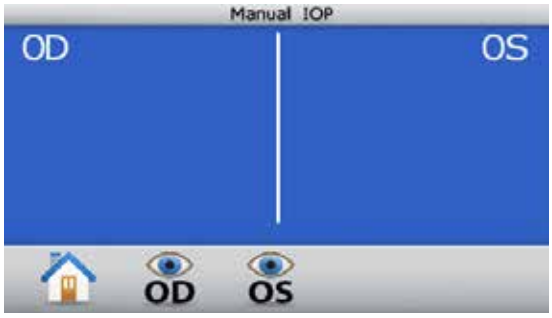


Figure 6-2, OS/OD

Figure 6-3, Measurements

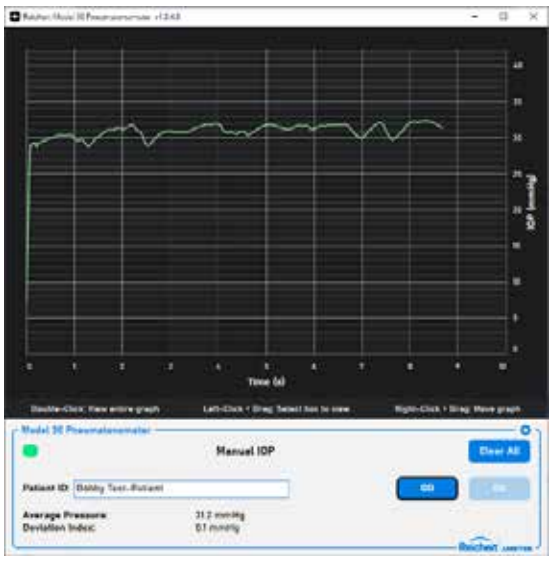


Figure 6-4, Software Graph

Measurements (continued)

Tonography

The tonography test measures aqueous humor outflow. In this test, the Model 30 Pneumatonometer records changes in IOP when a weighted probe is held on the cornea for a specified time. The Model 30 Pneumatonometer enables the operator to conduct a two-minute or four-minute test for each eye. To measure IOP using the tonography mode, follow this procedure:

- Measure IOP with patient seated, or enter the results from a previous measurement.
- Measure IOP with the patient supine, or enter the results from a previous reading.
- Measure aqueous outflow with the patient supine using the weighted probe.
- Edit the data if necessary (Adjust Endpoints).

Note: The tonography option requires the Tonography Kit, P/N 16033.

CAUTION: THE TIP AND MEMBRANE ASSEMBLY MUST ALWAYS BE CLEANED BEFORE AND AFTER MEASUREMENTS. REFER TO THE CLEANING & MAINTENANCE SECTION OF THIS MANUAL FOR THE SUGGESTED CLEANING INSTRUCTIONS.

1. With the main menu displayed, touch the TONOGRAPHY icon. Refer to Figure 7-1.
2. An information screen will pop up. Touch OK to close this screen.
3. Touch the 2-MIN or 4-MIN icon to select the test time. Refer to Figure 7-2.
4. Touch the OD or the OS icon to select either the right eye or left eye, respectively. Refer to Figure 7-3.

Note: After the OD or the OS icon is selected, the Seated data screen is active.

Note: The tone will settle to a lower tone when the probe is aligned properly. During an actual test, the tone will change to a noticeably lower pitch when the standard deviation is below 1.0 mmHg for at least three seconds. This tone change signifies that the instrument has acquired usable data.

Figure 7-1, Main Menu Screen

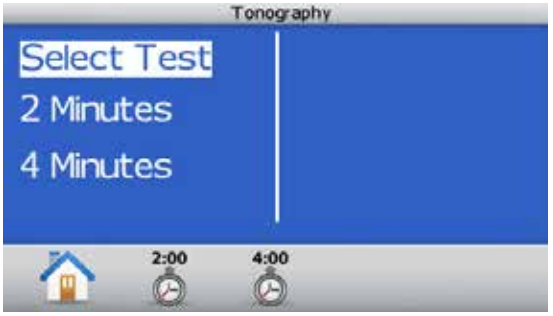


Figure 7-2, 2-Min/4-Min

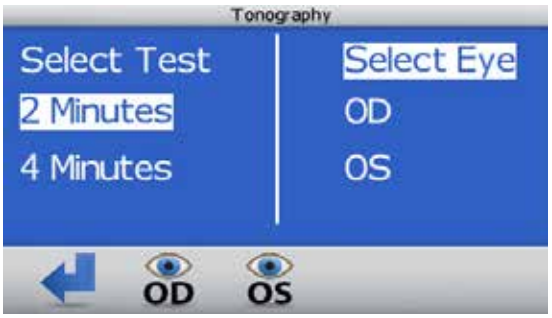


Figure 7-3, OS/OD

Measurements (continued)

Tonography (continued)

Seated IOP

1. Either touch the MEASURE or the ENTER DATA icon to acquire the Seated IOP data. Refer to Figure 7-4.
   - If the MEASURE icon is selected, then gently apply the probe to the patient's cornea as indicated in the Measurement Protocol paragraph in this section to acquire the data.
   - If the ENTER DATA icon is selected, then touch the "+" or "-" icons as needed to enter the IOP data. Refer to Figure 7-5.
2. Touch the OK icon to use the displayed Seated IOP value.
3. If the device is connected to a PC running the Model 30 Pneumatonometer PC Software, the application will show a live graph of the exam. When the test has completed, the results will be displayed in the main panel and all data will be exported as files in the specified Output Path. Refer to Figure 7-6.

Note: After the Seated IOP data is entered, the Supine data screen is active.

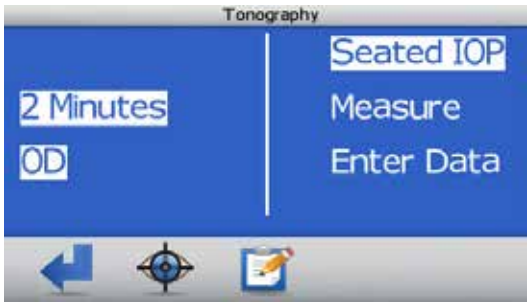


Figure 7-4, Seated IOP

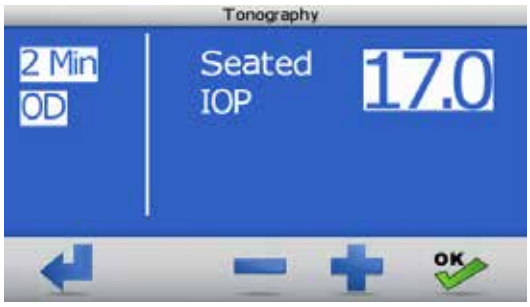


Figure 7-5, Changing Data

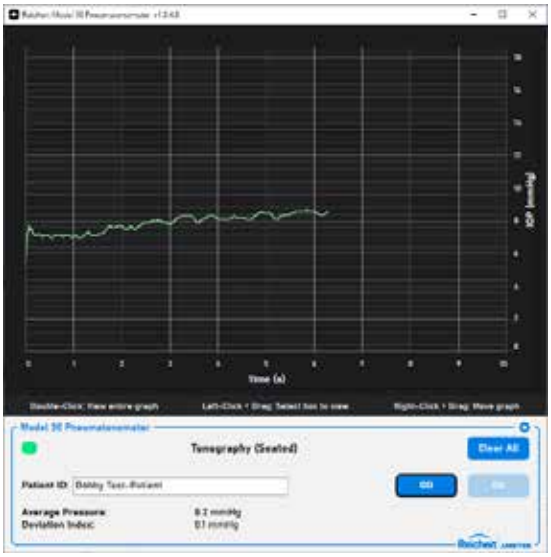


Figure 7-6, Software Graph

Measurements (continued)

Tonography (continued)

Supine IOP

1. Either touch the MEASURE or the ENTER DATA icon to acquire the Supine IOP data. Refer to Figure 7-7.
   - If the ENTER DATA icon is selected, touch the "+" or "-" icons as needed to enter the IOP data. Refer to Figure 7-8.
   - If the MEASURE icon is selected, then gently apply the probe to the patient's cornea as indicated in the Measurement Protocol paragraph in this section to acquire the data.
2. Touch the OK icon to use the displayed Supine IOP data.
3. If the device is connected to a PC running the Model 30 Pneumatonometer PC Software, the application will show a live graph of the exam. When the test has completed, the results will be displayed in the main panel, and all data will be exported as files in the specified Output Path. Refer to Figure 7-9.

Note: After the Supine IOP data is entered, the Tonography screen is active.

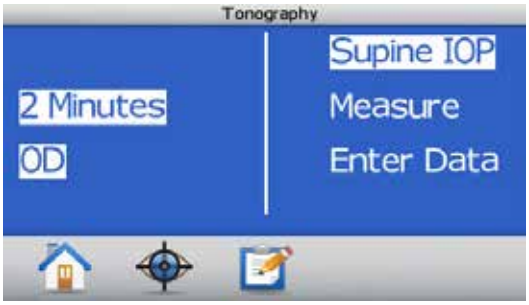


Figure 7-7, Supine IOP

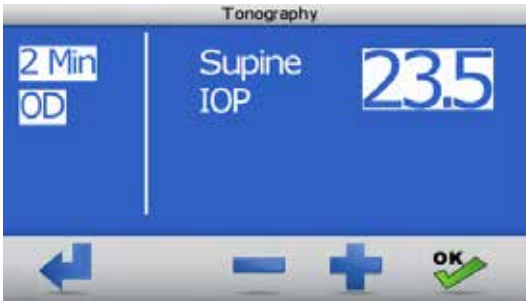


Figure 7-8, Changing IOP

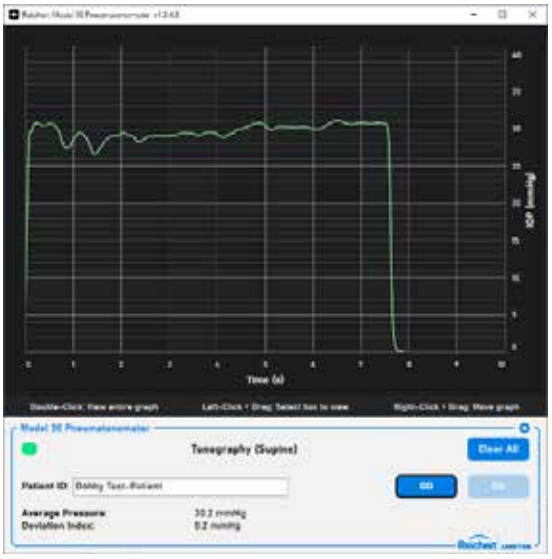


Figure 7-9, Software Graph

Measurements (continued)

Tonography (continued)

Tonography Exam

1. Touch the Tonography icon to acquire tonography data. Refer to Figure 7-10.
2. Gently apply the probe with the 10-gram weight to the patient's cornea and acquire data until the tonography test ends. Maintain the probe alignment between the red and black lines during this test. Refer to Figure 7-11.
3. If the device is connected to a PC running the Model 30 Pneumatonometer PC Software, the application will show a live graph of the exam. When the test has completed, the results will be displayed in the main panel, and all data will be exported as files in the specified Output Path. Refer to Figure 7-12.
4. Touch the OK icon to exit the Statistics screen.
5. Select the "End Test" option and touch the OK icon to finish the test. Refer to Figure 7-13.

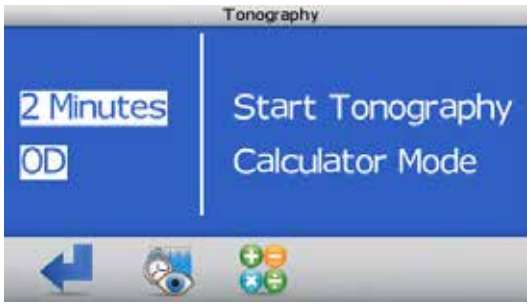


Figure 7-10, Tonography

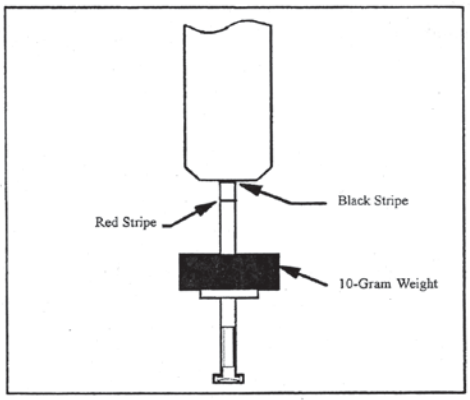


Figure 7-11, Tonography 10g. Weight

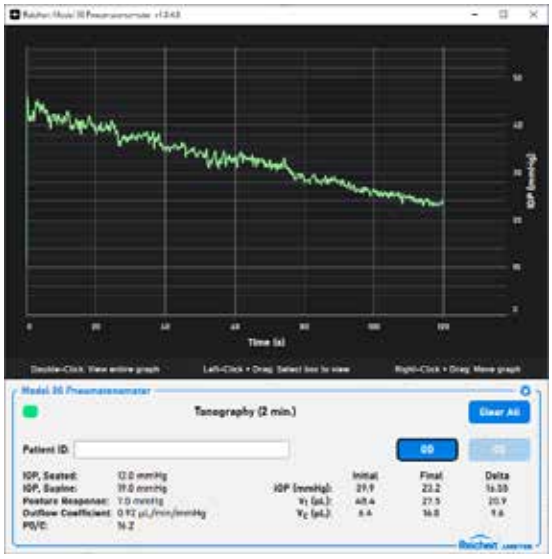


Figure 7-12, Software Graph

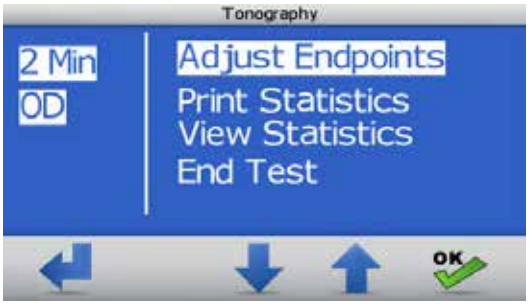


Figure 7-13, Results

Measurements (continued)

Tonography (continued)

Tonography Calculation

Calculator Mode can be used to calculate test results based on manually entered IOP values.

1. Touch the Calculator Mode icon to skip the Tonography data acquisition.
2. Select “Adjust Endpoints” and touch the OK icon. Refer to Figure 7-13.
3. Enter the Initial IOP value and press OK.
4. Enter the Final IOP value and press OK.
5. Select “View Statistics” and press OK to view the results on the Model 30 screen.
6. Select “Print Statistics” and press OK to send the results to the Model 30 Pneumatonometer PC Software.
7. Select “End Test” and press OK to finish the test.

Note: C is the aqueous humor outflow coefficient. C is derived from the supine tonometry reading, the change in pressure from initial to final IOP, the change in volume due to pressure and the change in volume due to deformation of the cornea.

Note: P0/C is the pressure in an undisturbed eye divided by the outflow coefficient.

Note: If the operator ends the test before it is complete by touching the OK icon, the device will show “Invalid Test”. Touch OK. Touch the return arrow.

Model 30 Pneumatonometer PC Software

Install the Model 30 Pneumatonometer PC Software on your PC. Refer to the Model 30 Pneumatonometer PC Software Setup section of this manual for installation instructions.

Graph Display

When a test is running on the device, the readings will appear on the software graph in real time. Refer to Figure 8-1. The following shortcuts can be used to alter the appearance of the graph:

- **Hovering:** Hovering the cursor over any spot on the graph will display the value for that specific point.
- **Double Click:** Double click on the graph to display the entire graph in the window.
- **Left-Click + Drag:** To zoom in to a particular section of the graph, left-click and drag a selection box over the desired graph section to view.
- **Right-Click + Drag:** Slide the graph to display a different section by right-clicking and dragging the graph to the desired position.
- **Mouse Scroll Wheel:** Adjusting the mouse scroll wheel will zoom in and out of the graph.

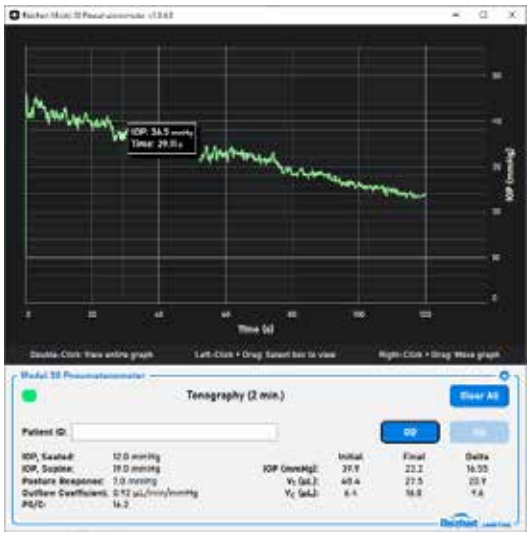


Figure 8-1, Software Graph

Software Controls

- **Patient ID:** Before beginning an exam, enter a Patient ID in this field. The Patient ID is used in naming the exported data files for easy identification.
- **OD/OS:** The OD and OS buttons are enabled when test data has been received for that eye. Click the OD or OS button to select the data you wish to view.
- **Clear All:** Press the Clear All button to clear all current test data from the software. Always Clear All before starting a new exam.

Note: Once the data is cleared, there is no way to retrieve it.

Model 30 Pneumatonometer PC Software (continued)

Sample File

OD Time (s)	OD IOP (mmHg)	Reports (OD then OS)
0	10.3	Model 30 Pneumatonometer
0.006	14.9	Patient Name: _____
0.012	19.1	Test Date: 21/09/22
0.017	23.2	Test Time: 02:09PM
0.023	27.1	Average Pressure = 47.7 mmHg
0.029	30.8	Deviation Index = 0.0 mmHg
0.035	34.1	
0.04	37	
0.046	39.3	
0.052	41.1	
0.057	42.4	
0.063	43.5	
0.069	44.2	
0.075	44.8	
0.08	45.2	
0.086	45.6	
0.092	45.9	
0.097	46.1	
0.103	46.3	
0.109	46.4	
0.115	46.6	
0.12	46.7	
0.126	46.8	
0.132	47	

Cleaning & Maintenance

Tip and Membrane Assembly

The tip and membrane assembly contacts the surface of the patient's eye and must be cleaned to a high level of disinfection after each use to prevent cross contamination between patients. It is recommended by the manufacturer of the Model 30 Pneumatonometer to utilize the following process to achieve a high level of disinfection on the tip and membrane assembly.

WARNING: THE TIP AND MEMBRANE ASSEMBLY MUST BE CLEANED BEFORE AND AFTER MEASUREMENTS WITH 70% ISOPROPYL ALCOHOL FOLLOWED BY 3% HYDROGEN PEROXIDE. TO PREVENT DAMAGE TO THE EYE, THE ALCOHOL AND HYDROGEN PEROXIDE MUST BE COMPLETELY RINSED AND DRY PRIOR TO USE.

WARNING: DO NOT FLASH AUTOCLAVE THE TIP AND MEMBRANE ASSEMBLY. FLASH AUTOCLAVING CAN MELT THIS DEVICE.

WARNING: DO NOT PLACE THE PROBE, WITH A HIGH LEVEL DISINFECTED TIP, ON THE FRONT TRAY OF THE MODEL 30 PNEUMATONOMETER CONSOLE SINCE IT MAY COMPROMISE THE INTEGRITY OF THE DISINFECTION. THE TRAY SHOULD ONLY BE USED AS A STORAGE LOCATION FOR THE PROBE WHEN IT IS NOT IN USE AND PRIOR TO DISINFECTION.

CAUTION: DO NOT USE A WIRE BRUSH ON THE TIP AND MEMBRANE ASSEMBLY AS IT MAY DAMAGE THE MEMBRANE.

Cleaning & Disinfecting the Tip and Membrane Assembly

1. Remove the tip and membrane assembly from the probe.
2. Separate the silicone membrane from the tip.
3. **Cleaning** - Soak tip and membrane separately in 50-100 ml of 70% isopropyl alcohol for 5 minutes. To dislodge organic matter, either swirl the tip and membrane in the alcohol solution or place the alcohol container with tip and membrane into an ultrasonic cleaner.
4. Make sure there is no dust or lint in the tip air vents prior to continuing with the disinfecting process. If debris is apparent, repeat step 3.
5. **Disinfecting** - Soak the tip separately from the membrane for two 15 minute cycles in a minimum of 150-200 ml fresh 3% Hydrogen Peroxide.
6. Thoroughly rinse both tip and membrane with sterile water.
7. Allow tip and membrane to completely air dry (25-30 minutes) prior to use.
8. Replace the membrane onto the tip. The membrane should float freely on the tip. To test this, gently turn the membrane while holding the tip stem. If the membrane will not move freely on the tip, additional drying time may be necessary. If dry, inspect the tip and membrane for damage.

Inspection of the Tip and Membrane Assembly

Before and/or after reprocessing, inspect the tip and membrane for damage and wear. A slit lamp or low powered microscope can be used, as necessary. The opening in the center of the tip should be a distinct edge with no nicks or distortions. Discard the tip and membrane assembly if you see drying, cracking, deformation, or deterioration of the components.

Cleaning & Maintenance (continued)

Fuses

Fuses are located next to the power inlet. Replace fuses with only a rating as indicated on the power inlet panel. Refer to the General Specifications section in this manual. Refer to Figure 8-1.

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 and press down on the tab in the middle of the Power Input Module to release the Fuse Holder. Refer to Figure 9-1.
2. Pull the fuse holder out of the input module.
3. Install new fuses that are indicated in the Specification section of this manual into the Fuse Holder.
4. Push the Fuse Holder into the Power Input Module until it snaps into place.

Note: Replacement of this fuse must be performed by qualified service personnel only.

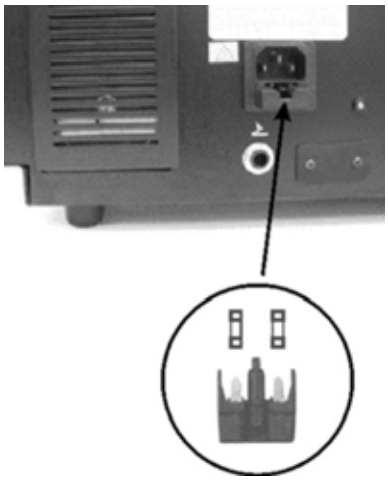


Figure 9-1, Fuse Locations

Calibration Verifier Cornea Replacement

The artificial cornea for the Calibration Verifier can be replaced if it is damaged by replacing the cornea assembly. The cornea assembly is held in place by a o-ring. To replace the cornea assembly, perform the following steps. Refer to Figure 9-2.

1. Remove any water from the calibration verifier by pouring it out from the top of the tube until all the water is removed.
2. Place a medium flat-blade screwdriver into the slot on one side of the cornea assembly as indicated in Figure 9-2 and push one side of the cornea assembly away from the acrylic base.
3. Repeat the above step for the slot on the opposite side to remove the assembly from the acrylic base.
4. Replace with a new cornea assembly by pressing the cornea assembly into the acrylic base until it is firmly in place.

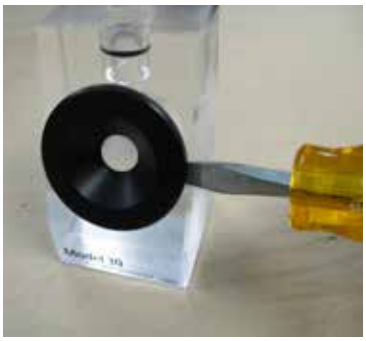


Figure 9-2, Cornea Replacement

External Cleaning

Clean the external surfaces of this instrument at least 3 times per year using a clean, soft cloth moistened with an approved cleaning solution. Wring excess solution from cloth prior to cleaning. Moisture inside the unit could cause damage. After cleaning, thoroughly dry with a clean, non-abrasive cloth. Approved cleaning solutions for the exterior surfaces, display, and the probe handle are:

- Soap and Water
- 70% Isopropyl Alcohol
- 5.25% Bleach and Water Solution
- 7.5% Hydrogen Peroxide and Water Solution
- Sani-cloth* Prime Germicidal Wipes (Didecyl Dimethyl Ammonium Chloride, isopropyl alcohol and ethyl alcohol.)

* Sani-Cloth is a registered trademark of PDI, Inc., Woodcliff Lake, NJ.

Cleaning & Maintenance (continued)

Filter Replacement

There are two filters (order Product No. 232346) in the Model 30 Pneumatonometer which should be changed semi-annually using the following procedure for each:

Compressor Filter Replacement

1. Remove the filter Access Door in the rear panel by removing the screw at the top of the door. Refer to Figure 9-3.
2. Remove the screw and filter cover from the end of the pump. Refer to Figure 9-4.
3. Remove the foam Pump Filter and replace it with the new filter from the Reichert Filter Kit (refer to the Accessories section of this manual for the part number). Refer to Figure 9-4.
4. Install the removed filter cover and screw and then tighten the screw.
5. Install the removed Access Door and screw and then tighten the screw. Refer to Figure 9-3.

Figure 9-3, Access Door Removal

Inline Filter Replacement

CAUTION: DO NOT USE EXCESSIVE FORCE WHEN REMOVING THE FILTER. IF THE INTERNAL TUBING DISCONNECTS FROM THE INLINE FILTER, THE UNIT WILL MALFUNCTION.

1. Remove the filter Access Door in the rear panel by removing the screw at the top of the door. Refer to Figure 9-3.
2. Remove the Inline Filter from by turning the connectors a quarter turn counterclockwise.

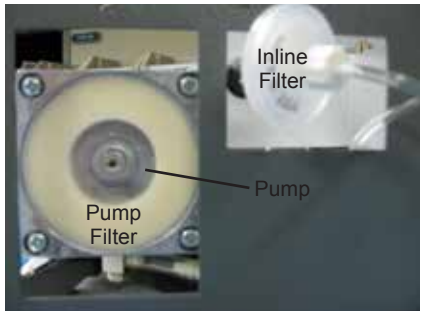


Figure 9-4, Pump Filters

CAUTION: TAKE CARE TO AVOID KINKING THE TUBING WHEN INSTALLING THE NEW FILTER INTO THE ACCESS CAVITY.

3. Replace the filter with the new filter from the Reichert Filter Kit (P/N 232346). Refer to Figure 9-4.
4. Install the removed Access Door and screw and then tighten the screw. Refer to Figure 9-3.

Troubleshooting

The following chart provides details of common problems and solutions for the Model 30 Pneumatonometer.

Definition	Probable Cause	Solution
Screen is blank.	ON/OFF Switch set to OFF.	Press the "—" on the ON/OFF Switch.
	Fuse(s) Blown.	Replace blown fuse(s).
Instrument not responding to icon touch.	Instrument is "locked up."	Press the ON/OFF button to OFF, wait ten seconds then push it to ON.
Instrument making a loud vibrating noise.	Shipping bracket still attached to the unit.	Remove the shipping bracket as indicated in the Instrument Setup section of this manual.
Will not take a reading.	Patient not holding still.	Encourage patient to remain still.
	Operator not positioning probe between the red and black lines.	Have operator refer to the Instrument Operation section of this manual.
	Operator not holding probe perpendicular to the cornea.	Have operator refer to the Instrument Operation section of this manual.
	Patient has dry eye.	Have patient blink eyes.
	Unit needs reboot of hardware.	Unplug unit, wait 2 minutes then apply input power.
Readings are low.	Air leak in the system.	Check hoses for air leaks.
	Probe connector not fully engaged on unit.	Check probe connection on unit.
	Filter is becoming clogged.	Change Filter - Refer to Filter Kit P/N in the Accessory section.
Readings are high.	Dirt/Contamination in the system.	Check hoses for dirt or contamination.
Erratic readings.	Dirt/Contamination under the membrane.	Refer to Reprocessing Guidelines in this manual.
	Tip and membrane not installed properly.	Refer to the Tip Installation Procedure in this manual.
	Filter is becoming clogged.	Change Filter - Refer to Filter Kit P/N in the Accessory section.
Screen difficult to see.	Contrast is set too low.	Adjust contrast in Setup menu.
Calibration verifier cornea damaged	Replace the Cornea Assembly.	Replace to the Maintenance Section of this manual.

Specifications

This section contains the specifications for the Model 30 Pneumatonometer.

Physical Dimensions
Instrument Console

Size:
Height: 5.25 in. (13.3 cm)
Width: 14.0 in. (35.6 cm)
Depth: 10.5 in. (26.7 cm)

Weight, unpacked: 8.5 lbs. (3.83 Kg)

Instrument Probe

Size:
Outside Diameter: 0.5 in. (1.3 cm)
Length: 4.25 in. (10.8 cm)

Weight, unpacked: 2.0 ounces (57 grams)

Tonometry

IOP Range: 5-80 millimeters of mercury (mmHg)
Measurement Accuracy (at 95% confidence)
0 - 40 mmHg ± 1.5 mmHg
40 - 80 mmHg ± 3.5 mmHg

Tonography

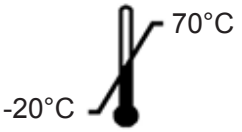
Effective Sample Rate: 40 hertz
Chart Scale: 0 to 80 millimeters of mercury (mmHg)
Test Duration: 2 or 4 minutes

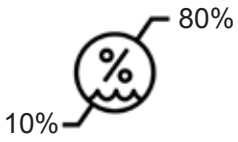
Electrical

Part Number (P/N):	P/N 16030	P/N 16031	P/N 16032
Voltage:	120 volts AC 50/60 Hz	230 volts AC 50/60 Hz	100 volts AC 50/60 Hz
Current:	2.0 A	1.6 A	2.0 A
Watts:	43 VA	50 VA	57 VA
Fuses:	Time-Lag (T 2.0 A L 250V), 5 x 20mm, RoHS	Time-Lag (T 1.6 A L 250V), 5 x 20mm, RoHS	Time-Lag (T 2.0 A L 250V), 5 x 20mm, RoHS

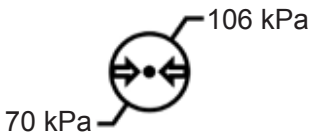
Operational Conditions

Environmental:
The environmental conditions are as follows:
Operating:
Temperature 10° C (50° F) to 35° C (95° F)
Relative Humidity: 30% to 75% (non-condensing)
Atmospheric Pressure: 80 (23.6 in. Hg) to 106 kPa (31.3 in. Hg)





Transportation & Storage:
Temperature -20° C (-4° F) to +70° C (158° F).
Relative Humidity: 10% to 80% (non-condensing)
Atmospheric Pressure: 70 (20.7 in. Hg) to 106 kPa (31.3 in. Hg)



Exposure to extreme temperature conditions indicated above must not exceed 15 weeks.

Specifications (continued)

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 device software revision can be obtained by contacting Reichert, Inc.
The serial number identifies the manufacture date and will provide access to the software version.
The Model 30 Pneumatonometer PC Software revision can be found in the title bar of the software.

Classifications

The Model 30 Pneumatonometer 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 Model 30 Pneumatonometer 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 Model 30 Pneumatonometer is classified as IPX0 Equipment.

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

According to the mode of operation, the Model 30 Pneumatonometer is a Continuous Operation instrument.

Guidance & Manufacturer's Declarations

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 Model 30 Pneumatonometer is intended for use in the electromagnetic environment specified below. The customer or user of the Model 30 Pneumatonometer 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 Model 30 Pneumatonometer 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 B	The Model 30 Pneumatonometer 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	

Guidance & Manufacturer's Declarations (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 Model 30 Pneumatonometer is suitable for use in electromagnetic environment specified below. The customer or user of the Model 30 Pneumatonometer 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 Model 30 Pneumatonometer requires continued operation during power mains interruptions, it is recommended that the Model 30 Pneumatonometer 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.

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 Model 30 Pneumatonometer is intended for use in the electromagnetic environment specified below. The customer or user of the Model 30 Pneumatonometer 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 Model 30 Pneumatonometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d=(3.5/V1)(\sqrt{P})$ $d=(3.5/E1)(\sqrt{P})$ 80 to 800 MHz $d=(7/E1)(\sqrt{P})$ 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	N/A	

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 Model 30 Pneumatonometer

The Model 30 Pneumatonometer is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Model 30 Pneumatonometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Model 30 Pneumatonometer 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 $d=(3.5/V1)(\sqrt{P})$	Separation (m) 150kHz to 80 MHz In ISM Bands $d=(10/3)(3.5/V1)(\sqrt{P})$	Separation (m) 80 to 800 MHz $d=(3.5/E1)(\sqrt{P})$	Separation (m) 800MHz to 2.7GHz $d=(7/E1)(\sqrt{P})$
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 Model 30 Pneumatonometer 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 √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.

Notes

Notes

Notes

Manufactured By
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ISO 13485 Certified

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