Tono-Pen® XL
Tonometer

User's Guide



AMETEK®
ULTRA PRECISION TECHNOLOGIES

Reichert®
TECHNOLOGIES

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

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Warnings & Cautions

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

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

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

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

WARNING: 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: 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: 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: DO NOT USE THE TONO-PEN XL TONOMETER ON A PATIENT WITHOUT AN OCU-FILM + TIP COVER OR INACCURATE READINGS MAY BE OBTAINED.

WARNING: DO NOT USE AN OCU-FILM + TIP COVER ON MORE THAN ONE PATIENT TO HELP PREVENT CROSS CONTAMINATION.

WARNING: IT IS IMPERATIVE THAT A FRESH OCU-FILM + TIP COVER BE USED FOR EACH PATIENT FOR THE PROTECTION OF THE EYE AND THE TRANSDUCER ASSEMBLY. THE TRANSFER OF INFECTION IS THUS PREVENTED. REPLACE OCU-FILM + TIP COVERS AFTER EXAMINATION OF EACH PATIENT.

Warnings & Cautions (continued)

WARNING: DO NOT USE THE TONO-PEN XL TONOMETER IF THE TRANSDUCER ASSEMBLY IS CRACKED, CHIPPED OR SHOWS ANY IRREGULARITY OF THE SURFACE, TO PREVENT PATIENT INJURY, AND/OR INACCURATE READINGS.

WARNING: DO NOT USE EXCESSIVE PRESSURE DURING APPLANATION OR EYE INJURY MAY OCCUR.

WARNING: THE CORNEAL SURFACE NEEDS ONLY TO BE MOMENTARILY TAPPED, INDENTATION OR ADDITIONAL PRESSURE AFTER THE AUDIO "CHIRP" TONE IS HEARD IS NOT REQUIRED AND MAY LEAD TO DAMAGE TO THE EYE. IF MEASUREMENT PROCESS CAUSES PATIENT DISCOMFORT, DEVICE DOES NOT SHOW A MEASUREMENT, OR IF DEVICE REQUIRES MULTIPLE ATTEMPTS TO OBTAIN A MEASUREMENT, STOP THE EXAMINATION AND REFER TO THE TROUBLESHOOTING SECTION OF THIS MANUAL.

WARNING: OCU-FILM + TIP COVERS CONTAIN NATURAL LATEX WHICH MAY CAUSE ALLERGIC REACTIONS. QUESTION PATIENTS ABOUT ALLERGIES TO LATEX BEFORE MEASURING THEM WITH THE TONO-PEN XL TONOMETER.

WARNING: DO NOT CARRY THE TONO-PEN XL OCU-CEL BATTERIES IN A POCKET, OR CLOSE TO YOUR PERSON, AS A BURN INJURY MAY RESULT.

WARNING: THE BATTERY SHOULD ONLY BE REPLACED WITH THE BATTERY SPECIFIED IN THIS MANUAL. USE OF ANOTHER BATTERY MAY CAUSE FIRE OR AN EXPLOSION.

WARNING: DO NOT PLACE A SHORTING DEVICE BETWEEN THE BATTERY TERMINALS, OR ALLOW THE BATTERY TO BECOME WET. MISUSE OR IMPROPER DISPOSAL OF THIS BATTERY MAY CAUSE IT TO BECOME VERY HOT, IGNITE OR EXPLODE. DAMAGE TO THIS UNIT AND/OR SERIOUS PERSONAL INJURY MAY RESULT.

WARNING: DO NOT RECHARGE THE BATTERY. THE BATTERY IS NOT DESIGNED TO BE CHARGED BY ANY ELECTRICAL SOURCE. CHARGING COULD GENERATE GAS AND INTERNAL SHORT-CIRCUITING, LEADING TO DISTORTION, LEAKAGE, OVERHEATING, EXPLOSION OR FIRE.

WARNING: DO NOT EXPOSE THE BATTERY TO TEMPERATURES ABOVE 140ºF, DISASSEMBLE THE BATTERIES, OR DAMAGE TO THIS UNIT AND/OR SERIOUS PERSONAL INJURY MAY RESULT.

WARNING: NEVER ALLOW LIQUID LEAKING FROM THE BATTERY TO GET IN YOUR EYES OR MOUTH AS THIS LIQUID COULD CAUSE SERIOUS PERSONAL INJURY. IF IT COMES IN CONTACT WITH YOUR EYES OR MOUTH, FLUSH THEM IMMEDIATELY WITH PLENTY OF WATER AND CONSULT A PHYSICIAN.

Warnings & Cautions (continued)

WARNING: ALWAYS KEEP BATTERIES OUT OF THE REACH OF INFANTS AND YOUNG CHILDREN TO PREVENT THEM FROM BEING SWALLOWED. IF SWALLOWED, CONSULT A PHYSICIAN IMMEDIATELY.

WARNING: USE OF BATTERIES OTHER THAN THOSE SPECIFIED OR PROVIDED BY REICHERT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS INSTRUMENT AND RESULT IN IMPROPER OPERATION. THERE ARE NO TRANSDUCERS, CABLES, OR OTHER ACCESSORIES ASSOCIATED WITH THIS INSTRUMENT,

WARNING: USE OF THIS INSTRUMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS INSTRUMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

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

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

CAUTION: DO NOT USE THE TONO-PEN XL TONOMETER WITHOUT AN OCU-FILM + TIP COVER TO PREVENT DAMAGE TO THE TRANSDUCER ASSEMBLY.

CAUTION: DO NOT TOUCH THE TRANSDUCER ASSEMBLY WITHOUT AN OCU-FILM + TIP COVER APPLIED OR DAMAGE TO THE TRANSDUCER ASSEMBLY MAY RESULT.

CAUTION: DO NOT BUMP, JAR OR DROP THE DEVICE, OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

CAUTION: DO NOT IMMERSE THE TONO-PEN XL TONOMETER IN FLUIDS OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

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.

Warnings & Cautions (continued)

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: DO NOT ATTEMPT TO STERILIZE THE TONO-PEN XL TONOMETER OR DAMAGE TO THE ELECTRONICS MAY OCCUR.

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: DO NOT ATTEMPT TO MODIFY THE TONO-PEN XL TONOMETER OR THE TONO-PEN XL OCU-CEL BATTERIES OR DAMAGE TO THE DEVICE MAY OCCUR.

CAUTION: DO NOT STORE THE TONO-PEN XL TONOMETER WITHOUT AN OCU-FILM + TIP COVER OR DEBRIS MAY ENTER THE TRANSDUCER ASSEMBLY AND CAUSE MALFUNCTIONS.

CAUTION: MEDICAL ELECTRICAL EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THIS GUIDE. PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT MEDICAL ELECTRICAL EQUIPMENT.

CAUTION: ELECTROMAGNETIC INTERFERENCE FROM OTHER DEVICES MAY AFFECT THIS INSTRUMENT. IF INTERFERENCE IS PRESENT, TURN OFF OTHER ELECTRONIC DEVICES, OR REMOVE THEM FROM THE IMMEDIATE AREA WHILE OPERATING THIS INSTRUMENT.

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

CAUTION: OCU-FILM + TIP COVERS SHOULD BE STORED BETWEEN 35° AND 80° FAHRENHEIT (2°-27° CELSIUS).

CAUTION: EACH BOX OF HIGH QUALITY OCU-FILM + TIP COVERS HAS A "USE BEFORE" DATE STAMPED ON THE BOX. WE SUGGEST USE OF OUR OCU-FILM + BEFORE THIS DATE TO GUARD AGAINST THE POSSIBILITY OF SHELF WEAR. THE LATEX MATERIAL USED IN THE OCU-FILM + TIP COVERS CAN DEGRADE. A DEGRADED FILM MAY RESULT IN LEAKAGE OF WETTING SOLUTION AND INSTRUMENT DAMAGE. EXAMINE EACH OCU-FILM + TIP COVER FOR YELLOWING, CRACKS, OR A STICKY TEXTURE PRIOR TO USE.

Symbols


Caution

REF Catalog Number

SN Serial Number



Date of Manufacture


Manufacturer


Waste of Electrical and Electronic Equipment



Compliance to Medical Device Directive 93/42/EEC


Consult Instructions for Use



Authorized Representative in European Community


Fragile Contents in Shipping Container - handle with care


Do not get Shipping Container wet


Type BF Applied Part

SYMBOLS FOR OCU-FILM + TIP COVERS ONLY


Do not reuse. Single Use


Use By

LOT Lot Number



Contains natural rubber latex

Introduction

Congratulations on your purchase of the Reichert® Tono-Pen® XL tonometer.

The Tono-Pen XL tonometer is a prescription only device intended for measuring intraocular pressure (IOP) during routine eye examinations or when increased intraocular pressure is suspected by properly trained eyecare professionals such as ophthalmologists, optometrists, opticians and eye care technicians.

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 Tono-Pen XL tonometer 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.

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

Tel: 716-686-4500
Toll Free: 888-849-8955
Fax: 716-686-4555
E-mail: reichert.information@ametek.com

Indications for Use

The indications for use include measuring intraocular pressure (IOP) for suspected glaucoma, or when increased intraocular pressure is suspected.

Contraindications

None.

Device Description

The Reichert Tono-Pen XL is a precision electronic tonometer which measures intraocular pressure (IOP). The body of the instrument is specially designed to fit comfortably in the user's hand, facilitating fast and accurate measurements. The stainless steel probe on the Tono-Pen XL contains a solid state strain gauge which converts intraocular pressure (IOP) to an electrical signal. The probe tip must be covered by a protective membrane. Reichert Ocu-Film® Tip Covers are recommended.

Utilizing a sophisticated "single chip" microprocessor and electronics housed in the body of the instrument, the waveform produced by each touch to the anesthetized corneal surface is analyzed and stored for a statistical comparison process. Each single valid IOP reading is digitally displayed on the liquid crystal display (LCD). When four valid readings are obtained, the mean IOP and the standard deviation for those readings (an indication of reliability) are shown on the LCD.

Features

The Tono-Pen XL tonometer has the following features:

- Easy to use - IOP can be measured reliably by medical professionals.
- Portable - The Tono-Pen XL tonometer weighs just 59.4 g (2.1 oz) and is battery operated.
- Accurate - The measurements from the Tono-Pen XL tonometer correlate strongly with Goldmann applanation tonometry and direct measurements of IOP.
- Versatile - The Tono-Pen XL tonometer may be used easily with the patient in any position, making the instrument suitable for the office, in glaucoma clinics, at the hospital bedside, and in remote locations.

Parts Identification

A. Tip – location of sensor.
B. Transducer Assembly - housing for sensor.
C. Activation Button - Applanation Mode select button.
D. LCD - displays the IOP in mmHg, statistical confidence indicator, and battery life status.
E. Battery Compartment- Where the batteries are located.



Figure 1 Parts Identification

Accessories

230570	Tono-Pen OCU-CEL™ Battery
230651	Ocu-Film® + Tip Covers (150 per box)
23065070	Carrying Case
23050140	Stylus (opening case and battery removal)
68E3441	User's Guide
980041	Quick Reference Guide

Optional Accessories

23050060	Replacement Battery Compartment Door

Battery Installation

The Tono-Pen XL tonometer is shipped without the batteries installed. The batteries need to be installed prior to using the instrument. The Tono-Pen XL is supplied with four OCU-CEL 3.0 volt lithium manganese dioxide batteries.

Note: The Tono-Pen XL unit will not function properly with mercury batteries.

Note: It is recommended that Reichert OCU-CEL XL Batteries be used when the batteries need replacement.

1. Open the battery compartment by gently inserting the stylus blade in the end slot. After insertion, slowly push the stylus forward and pry the cover up to remove. Refer to Figure 2.

CAUTION: CHECK TO BE SURE THAT THE BATTERIES ARE INSTALLED CORRECTLY. INCORRECT INSTALLATION COULD CAUSE SEVERE DAMAGE TO THE ELECTRONICS AND VOID THE WARRANTY.

2. Install two batteries. Refer to Figure 3.

Note: Check to be sure that the plus side of the battery is installed facing the plus side, and the minus is installed facing the minus side. The positive and negative ends are marked on the battery. The flat side is the positive end.

3. Replace the battery cover.



Figure 2 Open Battery Compartment

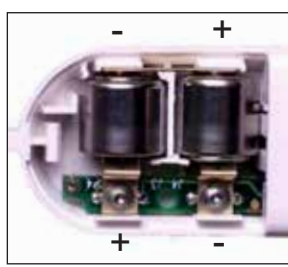


Figure 3 Battery Installation

Tono-Pen XL Tonometer Preparation

1. Allow the instrument to thermally stabilize to room temperature for approximately 30 minutes prior to use.
2. Remove the storage Ocu-Film + tip cover from the Transducer Assembly.
3. Visually inspect the Transducer Assembly for cracks, chips or other irregularities. Do not use if these conditions are present.
4. Slide an Ocu-Film + Tip Cover onto the Transducer Assembly until the ridge is seated, taking care not to apply the tip cover too tightly or too loosely. Make certain that the rubber is flat across the tip, but not taut. Refer to Figure 4.



OCU-FILM Tip Cover - CORRECT



OCU-FILM Tip Cover - Too Loose



OCU-FILM Tip Cover - Too Tight

Figure 4 Ocu-Film Tip Cover Placement

5. Perform the Calibration procedure.

Note: Calibration should only be performed on the Tono-Pen once daily, unless otherwise indicated by the instrument. The Tono-Pen does not require calibration after every patient examination.

Note: Use of the Ocu-Film + Tip Cover is required under original Tono-Pen instrument warranty and service contract terms.

Note: Corneal topical anesthetic is required with tonometry.

Calibration Procedure

The Tono-Pen XL unit is internally calibrated, thus the instrument calibration should be checked only before the first use each day or in the event of unanticipated readings. Calibration must be routinely and successfully performed once daily prior to instrument use. Calibration should also be performed whenever it is indicated by the LCD display, when batteries are replaced, or after an unsuccessful calibration. It is not necessary to check calibration prior to each use.

1. Point the transducer end of the Tono-Pen straight down towards the floor. Refer to Figure 5.
2. Depress the Operator's Button two times rapidly. The time between the first and second button press must be between 0.5 and 1.5 seconds. The Tono-Pen will "beep" and display **[CAL]**.
3. Wait approximately 15 seconds for the Tono-Pen to "beep". The display will change from **[CAL]** to **[UP]**.
4. Immediately (within 1 second) invert the Tono-Pen smoothly, pointing the transducer end straight up. Refer to Figure 5.
5. A properly functioning Tono-Pen will display **[Good]** followed by a "beep".
6. Repeat this Calibration Procedure if **[bAd]** is displayed.
7. After **[Good]** is displayed, depress the Operator's Button one time and the Tono-Pen will display **[8888]**, followed by a single row of dashes, **[- - - -]**, and then by a double row of dashes **[====]** followed by a "beep" tone, indicating the instrument is ready to measure IOP (Depressing the activation button a second time will interrupt this process and send the unit to calibration mode).

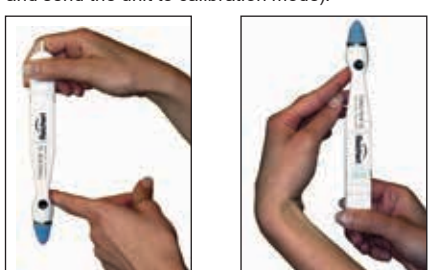


Figure 5 Calibration Procedure - Up - Down

Calibration Procedure (continued)

If several consecutive attempts at checking the calibration are unsuccessful:

- Loosen or remove the Ocu-Film Tip Cover from the Tono-Pen XL probe tip and repeat the calibration check.
- Spray the probe tip with compressed gas, and repeat the calibration check.
- Replace the batteries and repeat the calibration check.

Note: If **[CAL]** appears followed by a row of four dashes **[- - - -]**, the unit did not go into calibration mode. To correct this, depress the button quicker two times or slower two times.

Note: Do not take measurements with the instrument if two consecutive **[Good]** calibration checks cannot be obtained. The instrument will not take a measurement when the prior calibration check was **[bAd]**.

Note: If the Tono-Pen XL fails to yield a **[Good]** calibration, call Reichert Technical Service.

Instructions for Use

Performing IOP Measurements

WARNING: OCU-FILM CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS. QUESTION PATIENTS ABOUT ALLERGIES TO LATEX BEFORE EXAMINING THEM WITH THE TONO-PEN XL.

WARNING: DO NOT USE AN OCU-FILM + TIP COVER ON MORE THAN ONE PATIENT TO HELP PREVENT CROSS CONTAMINATION.

Note: Refer to the Reichert website for instructional videos.

1. Instill a drop of topical anesthetic onto the eye to be examined.
2. Position the patient, seated or supine, in front of a fixation target; or have the patient fixate on a point of reference (i.e. ear, nose, distant object) to minimize eye movement.

Note: The Tono-Pen XL unit will function in any stable position.

3. Instruct the patient to look straight ahead at the fixation target (i.e. ear, nose, distant object) to minimize eye movement, with eyes fully open.
4. Hold the Tono-Pen XL unit as you would a pencil and position yourself to facilitate viewing of the probe tip and patient's cornea where contact will be made. For normal corneas, central corneal contact is recommended.
5. The corneal surface needs only to be momentarily contacted. **Indentation or excessive pressure is not required and may lead to injury to the eye.** Refer to Figure 6.



Figure 6 Corneal Applanation

6. Brace the heel of your hand on the patient's cheek for stability while holding the Tono-Pen XL unit perpendicular to and within 1/2 inch of the patient's cornea. Refer to Figure 6 for correct positioning.
7. To initiate an IOP measurement, depress the Operator's Button once, and only once.
8. Initially you will see a brief display of **[8888]**. This is a self-test of the LCD (Liquid Crystal Display).

Note: If any of the LCD segments are not displayed, the Tono-Pen requires service.

Performing IOP Measurements (continued)

Note: If a momentary display of **[CAL]** is seen, followed immediately by a single row of dashes **[- - - -]**, it indicates that the Tono-Pen requires calibration before it will measure.

9. If a double row of dashes **[====]** is seen and a "beep" tone is heard, it indicates that the Tono-Pen is ready to measure IOP. Proceed with applanation within 15 seconds.

Note: After acquiring the double row of dashes **[====]**, if more than 15 seconds elapses prior to applanation, the Tono-Pen will not measure. The software will have initiated a battery-saving function, indicated initially by the display of a single row of dashes **[- - - -]**, then followed in sequence by a blank display **[ ]**. A new IOP measurement can be initiated by depressing the operator's button once.

Note: Anytime the operator's button is depressed twice within 1.5 seconds, (which may be caused by operator's inadvertent pressure on the button) the software will interpret this as a demand for calibration. Then a sustained display of **[CAL]** will be seen which initiates the calibration sequence. The calibration sequence must be successfully completed before further measurements can be accomplished.

10. Once activated, after **[====]** is displayed and a "beep" tone is heard, gently apply the Tono-Pen XL tip to the cornea in a brief tapping motion, then withdraw. Repeat several times. The corneal surface needs only to be momentarily contacted; **indentation or excessive force is not required and may lead to inaccurate readings or patient injury.**
11. A chirp will sound and a digital IOP measurement will be displayed each time a valid reading is obtained. The single horizontal bar at the bottom of the LCD, indicating statistical reliability, will not be displayed with each single IOP measurement.
12. After four (4) valid readings are obtained, a final beep will sound and the averaged measurement will appear on the LCD along with the single bar denoting statistical reliability.

Note: If a single row of dashes **[- - - -]** appears on the LCD after the final beep, an insufficient number of valid readings was collected. If this occurs, repeat the patient examination procedure, starting at step 1.

-continued-

Performing IOP Measurements (continued)

To take another measurement, reactivate the Tono-Pen XL unit by pressing and releasing the activation switch as described in step 5.

Note: If not reactivated within 25 seconds, the Tono-Pen XL unit will automatically turn off and the LCD will clear, placing the device in sleep mode, to conserve battery life. If this occurs, activate the TONO-PEN XL by pressing the Operator's Button once.

13. Replace the Ocu-Film Tip Cover before using the Tono-Pen XL unit on another patient and before storage.

Note: Failure to replace the Ocu-Film Tip Cover between patients may result in unreliable readings of IOP by allowing debris to enter the transducer assembly.

Note: A reused Ocu-Film Tip Cover may leak. This may cause damage to the strain gauge and void the Warranty.

Interpreting the LCD Screen

The number display represents IOP in millimeters of mercury (mmHg.) A number with a single horizontal bar displayed at the bottom of the LCD is an average of the valid measurements. A number without the single bar is a single measurement of IOP. Refer to Figure 7.

The display of one of four horizontal bars located along the lower border of the LCD block indicates the statistical reliability of the averaged measurement. For example, if the 5% bar is displayed, the standard deviation of the valid measurements is 5% or less of the number shown.

If the reliability measure is 20% or > 20%, a repeat measurement is recommended.

A single row of dashes **[- - - -]** indicates that the instrument is activated.

Two rows of dashes **[====]** followed by a “beep” indicates that the instrument is ready to take measurements.

- **[CAL]** indicates that the instrument is in the process of calibration check or the instrument needs to undergo calibration check procedure. If **[CAL]** is displayed following a long beep and **[- - - -]**, the latter is the case. A **[Good]** calibration check must be obtained.
- **[Lob]** indicates the need to replace both batteries prior to using the instrument.
- **[UP]** indicates that the instrument is being calibrated and the probe tip should be turned from pointing down to pointing up.
- **[Good]** indicates the calibration check procedure was successful. After two **[Good]** calibration checks, the Tono-Pen XL unit is ready for use in patient examinations.
- **[bAd]** indicates the calibration check procedure was unsuccessful and must be repeated.

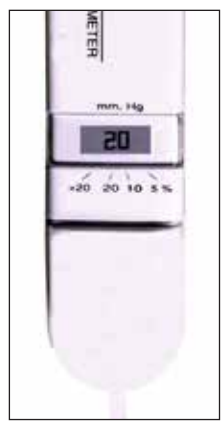


Figure 7
LCD Showing A Single IOP Measurement Of 20

Cleaning Instructions

The Tono-Pen XL tonometer may have difficulty taking measurements or display **[bAd]** after a calibration when its tip is dirty and requires cleaning. When the Transducer Assembly of the tonometer has dirt and contaminants in the tip, cleaning of the tip is necessary. When the tip contains contaminants, it cannot move freely and the Tono-Pen XL may have erratic readings and then show a **[bAd]** calibration.



Figure 8
Cleaning the Tip

1. Remove Ocu-Film + tip cover from the tonometer, if one is installed.
2. Using canned air, place the outlet of the canned air firmly against the Transducer Tip of the Tono-Pen XL to inject air into the tip as shown in Figure 8.
3. Blow canned air directly into the tip of the tonometer for approximately 3 seconds to push out any contaminants embedded in the tip of the Tono-Pen XL.

Note: Try to get a good seal between the canned air and the Tono-Pen XL tip to blow any contaminants stuck in the tip of the Tono-Pen XL safely into the internal cavity of the Tono-Pen XL.

4. After cleaning the tip with compressed air, the Transducer Assembly will be cold. Allow the Transducer Assembly to warm to room temperature.
5. Wipe the outside of the Tono-Pen XL with a clean, dust-free, cotton cloth dampened with an approved cleaning solution* and distilled water, or an approved cleaning wipe**. Refer to Figure 9.
6. Perform the tonometer calibration as indicated in the Calibration Procedure section of this manual.

Note: If the tonometer does not calibrate **[Good]**, then repeat the above cleaning instructions as needed. If the Tono-Pen XL has been cleaned 3 times in a row and it still does not pass the calibration, request an RMA (http://www.reichert.com/service.cfm) to return of the Tono-Pen XL for repair.



Figure 9
Wiping Down the Tip

Cleaning Instructions (continued)

7. Install a new Ocu-Film tip cover as indicated in the User Guide.

Note: DO NOT use the Tono-Pen XL tonometer on a patient without a new Ocu-Film tip cover installed.

Note: ALWAYS store the Tono-Pen XL tonometer in its case with a new Ocu-Film tip cover installed to protect the tonometer tip from dirt and contaminants.

Note: Ocu-Film + tip covers are the only manufacturer approved covers for use with the Tono-Pen XL tonometer. Use of any other type of branded tip cover may affect readings or may void your warranty.

Suggested Cleaning Schedule

Number of Patients per Week	Number of Days Between Cleaning
10	30
100	15
300	7
600	1

Tono-Pen XL Body

CAUTION: DO NOT USE EXCESS ALCOHOL ON OR AROUND THE LCD SCREEN AS THIS MAY DAMAGE IT.

CAUTION: DO NOT IMMERSE TONO-PEN XL BODY IN FLUIDS. THIS WILL CAUSE DAMAGE TO THE ELECTRONICS AND VOID THE WARRANTY.



Figure 10 Wiping Down the Body

Avoid any shock or excessive vibration which will damage the unit. Clean with a non-abrasive, dry cloth. When cleaning between patients is required, the body may be wiped down with a paper towel or soft cloth lightly moistened with an approved cleaning solution*, or an approved cleaning wipe**. Refer to Figure 10.

* 70% isopropyl alcohol, 7.5% Hydrogen Peroxide solution, 5.25% Bleach solution.
** Clorox[1] Bleach Germicidal Wipes (0.55% sodium hypochlorite), Sani-Cloth[2] Prime Germicidal wipes (Didecyl Dimethyl Ammonium Chloride, isopropyl alcohol and ethyl alcohol)

[1] Clorox is a registerd trademark of the Clorox Company, Oakland, CA.
[2] Sani-Cloth is a registered trademark of PDI, Inc., Woodcliff Lake, NJ.

Battery Replacement

The batteries need replacing when multiple beeps sound and “Lob” appears on the LCD upon depressing the activation switch. Occasionally, a noticeable slowing in the calibration check process or in activating the instrument for taking measurements may suggest that the batteries need replacing.



Figure 11 Remove Batteries

Note: Replace the battery with P/N 230570.

Note: Always replace both batteries. Do not mix used and new batteries in the instrument. Reichert OCU-CEL XL batteries are recommended.

Note: The instrument will not function properly when mercury batteries are used.

Replace the batteries using the procedure described in the Battery Installation section. Remove the battery cover and then remove the batteries using the Stylus. Refer to Figure 11.

Note: One end of the Stylus has a thin pointed end. Insert this end into the holes on the back of the pen to remove the batteries.

If the instrument is not to be operated for an extended period of time, remove both batteries. This will avoid possible damage to the instrument due to battery leakage.

Storage

- Cover the tip with an Ocu-Film + tip cover for protection.
- If the Tono-Pen XL tonometer is not to be used until a subsequent day, the instrument and accessories should be placed in the storage case provided.
- If the instrument is to be stored for an extended period, remove the Tono-Pen XL OCU-CEL Batteries to avoid possible damage to the instrument due to battery leakage.

Disposal

The Tono-Pen XL, Ocu-Film, and Tono-Pen XL OCU-CEL do 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.

Troubleshooting

The table below provides a guide for troubleshooting some basic Tono-Pen XL tonometer operational problems. If a problem persists after using this guide contact Reichert technical services.

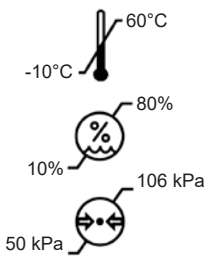
SYMPTOM	PROBABLE CAUSE	CORRECTION
[Lob] displayed on LCD Screen	Low Tono-Pen XL OCU-CEL Battery capacity	Replace Tono-Pen XL OCU-CEL Batteries
Noticeable slowing in the calibration check process, in activating instrument	Low Tono-Pen XL OCU-CEL Battery capacity	Replace Tono-Pen XL OCU-CEL Batteries
	Compressed air cleaning has lowered the temperature of the instrument	Allow Tono-Pen XL unit to warm to room temperature
Multiple inaccurate readings	Improper technique (Example: too much or too little force used, taps too long, device not held perpendicular to the patient's eye)	Review "INSTRUCTIONS FOR USE" Section of this manual
	Old or improperly applied Ocu-Film + tip cover being used, or non-Reichert tip cover being used	Replace Ocu-Film tip cover
	Low Tono-Pen XL OCU-CEL Battery capacity	Replace Tono-Pen XL OCU-CEL Batteries
	Need to check calibration	Perform calibration check procedure.
	Debris in tip	Clean tip
	Mechanical or electronic damage	Arrange for service through Reichert Technical Service Group
No beeps and/or no dashes upon activation	Activation button not properly pressed	Press Activation button
	Activation switch not depressed long enough	Depress activation switch longer
	Low Tono-Pen XL OCU-CEL Battery capacity	Replace Tono-Pen XL OCU-CEL Batteries
	Mechanical or electronic damage	Arrange for service through Reichert Technical Service Group
Unable to obtain **[Good]** calibration check	Debris in tip	Clean tip
	Compressed air cleaning has lowered the temperature of the instrument	Allow Tono-Pen XL tonometer unit to warm to room temperature
Unit displays **[CAL]** then single dashed line then turns off.	Button pressed too quickly or too slowly	Press the button twice, a little slower or faster until the word **[CAL]** appears on the screen and stays on the screen. If the single row of dashed lines appears, repeat the double press.

Specifications

PHYSICAL DIMENSIONS

Size: 7 1/4" x 1" x 7/8" (18.42 x 2.54 x 2.22 cm)

Weight: 2.1 oz. (59.4 g)



ENVIRONMENTAL REQUIREMENTS

Operational Environment

Ambient Temperature range: 15° to 35°C (59° to 95°F)

Relative Humidity range: 30 to 75%

Atmospheric Pressure range: 80 kPa to 106 kPa (23.6 to 31.3 in.Hg)

Transport and Storage Environment

Ambient Temperature range: -10° to 60°C (14° to 140°F)

Relative Humidity range: 10 to 80% (non-condensing)

Atmospheric Pressure range: 50 kPa to 106 kPa (14.8 to 31.3 in.Hg)

ELECTRICAL

Input Voltage (Tono-Pen OCU-CEL Batteries)

2 x 3V Lithium Manganese Dioxide batteries

RANGE OF IOP MEASUREMENTS

Accuracy by manometric measurements (95% Confidence)

Measurement (mmHg)	Accuracy (mmHg)
5-27	± 2.0
28-80	± 5.0

OCU-FILM + TIP COVER

Contains natural rubber latex

SOFTWARE REVISION

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

Tono-Pen XL Regulatory Classification

- Insulation Protection: internally powered, 6V battery
- Ingress Protection: IPX0
- Applied Part Type: BF
- Mode of Operation: Continuous

Guidance & Manufacturer's Declaration

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 Tono-Pen XL is intended for use in the electromagnetic environment specified below. The customer or user of the Tono-Pen XL should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance -
Radiated RF Emissions CISPR 11	Group 1	The Tono-Pen XL 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.
Radiated RF Emissions CISPR 11	Class B	The Tono-Pen XL 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	N/A	
Voltage Fluctuations and Flicker IEC 61000-3-3	N/A	

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 Tono-Pen XL is suitable for use in electromagnetic environment specified below. The customer or user of the Tono-Pen XL 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	N/A	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	N/A	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°	N/A	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the Tono-Pen XL requires continued operation during power mains interruptions, it is recommended that the Tono-Pen XL be powered from an uninterruptible power supply or battery.
	0% Ut; 1.0 cycle and 70% Ut; 25/30 cycles Single phase: at 0°	N/A	
Voltage Interruptions IEC 61000-4-11	0% Ut, 250/300 cycles	N/A	
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 Tono-Pen XL is intended for use in the electromagnetic environment specified below. The customer or user of the Tono-Pen XL 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	N/A	Portable and mobile RF communications equipment should be no closer to any part of the Tono-Pen XL, 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 frequence 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 Tono-Pen XL.

The Tono-Pen XL is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Tono-Pen XL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Tono-Pen XL 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 – Electromagnetic Immunity

The Tono-Pen XL is intended for use in the electromagnetic environment as specified below related to proximity fields from RF wireless communications equipment.

Immunity Test	IEC 60601 Test Level							Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	Test Frequency (MHz)	Band (MHz)	Service (MHz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level	d = 6/E √P where d = Minimum separation distance in meters E = Immunity test level in V/m P = Maximum power in Watts (W)
	385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27	27 V/m at 0,3 m	
	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, Inc. against defective material and workmanship under normal use for a period of one year from the date of invoice to the original purchaser. (An authorized dealer shall not be considered an original purchaser.) Under this warranty, Reichert's sole obligation is to repair or replace the defective part or product at Reichert's discretion.

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

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

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

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

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

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

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