

**5.6**

**Tonopen**

## I. GENERAL DESCRIPTION

The MENTOR<sup>®</sup> Tono-Pen<sup>™</sup> XL unit 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 Tono-Pen XL Tonometer contains a solid state strain gauge which converts intraocular pressure to an electrical signal. The probe tip must be covered by a latex protective membrane. MENTOR Ocu-Film<sup>™</sup> 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 (4) valid readings are obtained, the mean IOP and an indication of reliability are shown on the LCD.

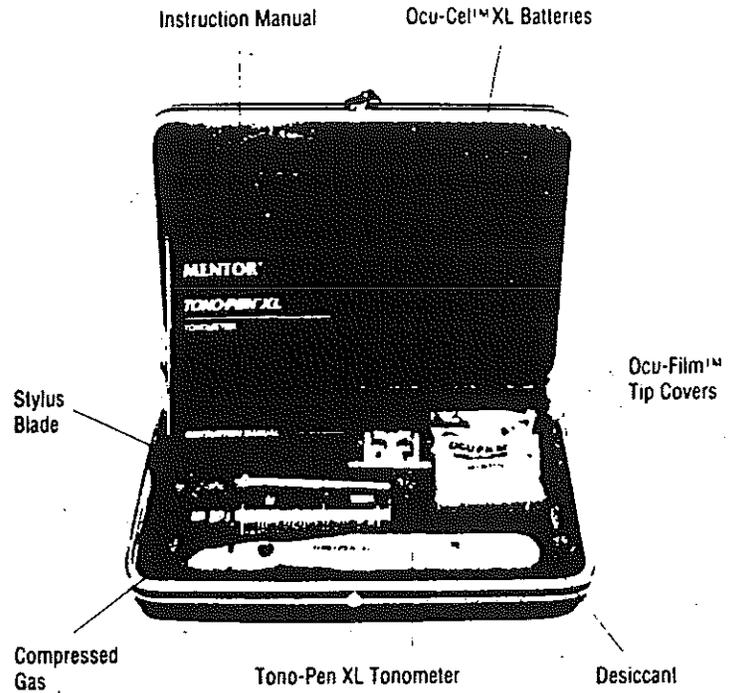


Figure 1 - Storage Case Layout

The Tono-Pen XL unit has the following features:

1. **Easy to use.** IOP can be measured reliably by ophthalmologists, optometrists, technicians and other medical professionals.
2. **Portable.** The Tono-Pen XL unit weighs just 2.6 ounces and is battery operated.
3. **Accuracy.** The accuracy of the Tono-Pen XL unit equals or exceeds that of other electronic applanation tonometers. It is highly correlated with Goldmann applanation tonometry and direct measurements of intraocular pressure.
4. **Versatile.** The Tono-Pen XL unit can be used in cases of irregular or high corneal astigmatism. It may be used easily with the patient in any position, making the instrument suitable for the office, during surgery, in glaucoma clinics, at the hospital bedside and in remote locations.

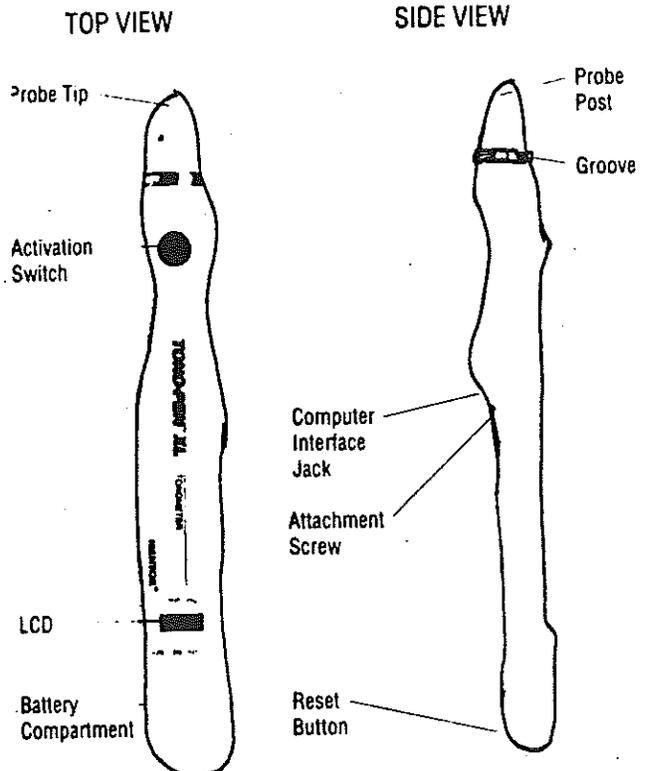


Figure 2 - Instrument diagram

## II. UNPACKING INSTRUCTIONS

- A. Remove all protective packaging materials. Remove and discard the desiccant. Carefully remove the tonometer and accessories from the carton.
- B. Check for missing items (see Figure 1).
- C. Visually check the instrument and accessories for damage.
- D. NOTIFY MENTOR CUSTOMER SERVICE (SHOWN IN SECTION XI) IMMEDIATELY IF ANY COMPONENTS ARE MISSING OR DAMAGED.
- E. Slide a new Ocu-Film Tip Cover over the Tono-Pen XL unit's stainless steel probe until the Ocu-Film ridge is seated in the groove (see Figure 2). The Ocu-Film Tip Cover should fit snugly over the probe tip (see Figure 3).

## III. BATTERY SPECIFICATION AND INSTALLATION

### A. Battery Specification:

1. Two (2) each 3.0 volt lithium manganese dioxide batteries. MENTOR Ocu-Cel™ XL Batteries are recommended.

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

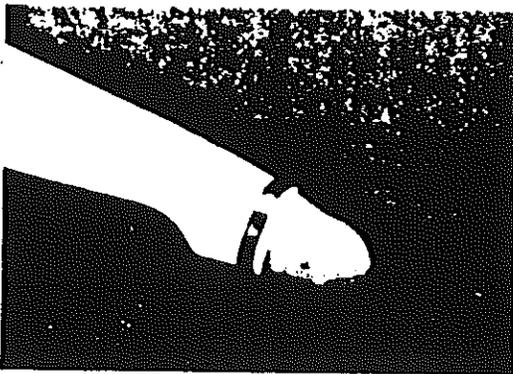
### B. Battery Installation:

1. Locate the battery compartment (see Figure 2). Open the battery compartment by inserting the stylus blade (see Figure 1) in the end slot. Push gently and remove the loosened battery cover (see Figure 4).
2. Insert two (2) batteries as shown in Figure 5 (also diagrammed on the floor of the battery compartment).

### CAUTION

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

3. Replace the battery cover.
4. Immediately perform the Reset procedure as described in the next section (Section IV), followed by the Calibration Check procedure as described in Section V, B.



*Ocu-Film Tip Cover correct.*



*Ocu-Film Tip Cover too loose.*



*Ocu-Film Tip Cover too tight.*

*Figure 3 - Instrument diagram*

## IV. RESET PROCEDURE

- A. Gently depress and then release the reset button (see Figure 2) located inside the opening labeled "RESET" on the underside rear of the Tono-Pen XL body. To press the RESET button, use the stylus blade (see Figure 1) or any pointed, unbreakable object such as a ball point pen. **DO NOT USE ANY EASILY BROKEN OBJECT SUCH AS A MECHANICAL PENCIL.**
- B. The LCD will display "----" and a beep will sound.

NOTE: IMMEDIATELY PERFORM A CALIBRATION CHECK (SEE SECTION V, B) AFTER PERFORMING THE RESET PROCEDURE.



Figure 4 - Battery cover removal procedure

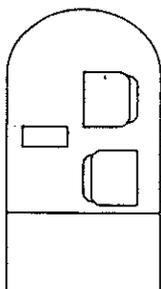


Figure 5 - Battery compartment

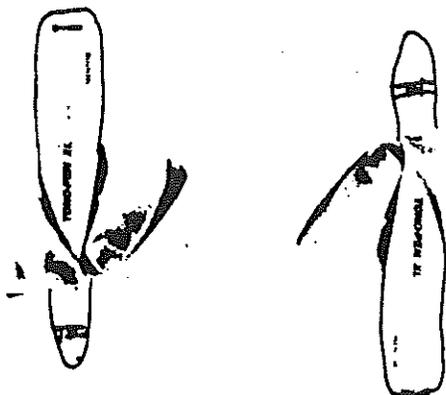


Figure 6—Calibration check procedure

## V. INSTRUCTIONS FOR USE

### A. Instrument Preparation:

1. Allow the instrument to thermally stabilize at room temperature (22 - 28 degrees Celsius) for approximately 30 minutes prior to use.
2. Remove the Ocu-Film Tip Cover from the probe. Visually inspect the tonometer's probe tip for cracks, chips or other irregularities. If irregularities are present, contact MENTOR (see Section XI). Do not use the instrument.
3. If the probe tip passes a visual inspection, proceed.
4. To help prevent build-up of debris around the probe post (see Figure 2), spray the probe tip with compressed gas (see Figure 1) before the first use of the day (see Section VIII, A, 2 for procedure).
5. Cover the Tono-Pen XL probe tip with a new Ocu-Film Tip Cover.

MENTOR Ocu-Film Tip Covers are:

- (a) Individually wrapped and sanitized but non-sterile.
- (b) FOR SINGLE USE ONLY.
- (c) May be gas sterilized for intraoperative use.

**DO NOT USE INSTRUMENT WITHOUT  
OCU-FILM TIP COVER**  
USE WITHOUT AN OCU-FILM TIP COVER WILL DAMAGE  
THE INSTRUMENT AND INVALIDATE THE WARRANTY.

### B. Calibration Check:

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. The calibration **must** be checked after changing the batteries or depressing the RESET button. It is **not necessary** to check calibration prior to each use.

1. Depress the activation switch momentarily, then release.
  - a. If the previous calibration check was "Good", the LCD will briefly display "----" followed by "====", accompanied by a beep. A calibration check can only be performed when "----" is displayed. If "====" is displayed, depress the activation switch once to change the display to "----".
  - b. If the previous calibration was "bAd" or the memory of that calibration has been lost due to battery change or depressing the RESET button, then a long beep sounds. Following this, "CAL" appears and a short beep will

sound. The display will then change to "----" and another short beep will sound.

- c. If the activation switch is not depressed for a long enough period, "----" will be displayed momentarily, followed by a blank LCD. Repeat step 1 and hold the activation switch in the depressed position for a longer period of time.
2. Hold the tonometer vertically with the probe tip pointing straight down (see Figure 6).
3. Press and release the activation switch twice in rapid succession. Two beeps will sound and "CAL" will appear on the LCD.
4. Wait (up to 20 seconds) until a beep sounds and "- UP -" appears on the LCD.
5. Quickly turn the Tono-Pen XL unit so that the probe tip is pointing straight up (see Figure 6).
6. Wait a few seconds. A second beep will sound indicating the end of the calibration check.
7. Read the output on the LCD.

If "Good", the calibration check was successful.  
If "bAd", the calibration check was unsuccessful:

NOTE: If the instrument is not stable with the probe tip pointing up prior to the second beep, a "bAd" reading may result.

8. Repeat steps 2 through 7 until two consecutive "Good" calibration checks are obtained.  
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.  
If still unsuccessful:  
Press the RESET button (see Section IV for the reset procedure) and repeat the calibration check.  
If still unsuccessful:  
Spray the probe tip with compressed gas (see Section VIII, A, 2 for details of this procedure), press the reset button (see Section IV for the reset procedure) and repeat the calibration check.  
If still unsuccessful:  
Replace the batteries, press the RESET button (see Section IV for the procedure) and repeat the calibration check.

Call MENTOR Technical Service Group (shown in Section XI) if the instrument still fails to yield a "Good" calibration check.

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".

#### C. Patient Preparation:

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.

#### D. Patient Examination:

1. Instruct the patient to look straight ahead at the fixation target with his/her eyes fully open.
2. Hold the Tono-Pen XL unit as you would a pencil.
3. 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.
4. 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.
5. Activate the Tono-Pen XL unit for taking a measurement by depressing the activation switch momentarily, then release.
  - a. If the activation switch is not depressed for a long enough period, "----" will be displayed followed by a blank LCD. Repeat step 1 and hold the activation switch in the depressed position for a longer period of time.
  - b. If the activation switch is depressed continuously, a series of beeps will sound and the LCD will alternate "----" and "===".
  - c. If you press the activation switch twice by accident and "CAL" is displayed on the LCD, depress the activation switch momentarily to

take a measurement. The prior calibration check display ("Good") will briefly appear on the LCD. (If "bAd" is displayed, repeat the calibration check procedure as described in Section V, B).

6. The LCD will change to " = = = " and a beep will sound when the Tono-Pen XL unit is ready to take a measurement.
7. Once activated, (" = = = " is displayed) touch the Tono-Pen XL unit to the cornea lightly and briefly, then withdraw (see Figure 7). Repeat several times. The corneal surface needs only to be momentarily contacted; indentation is not required and may lead to inaccurate readings.
8. A click 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.
9. 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 (see Section VI, B).

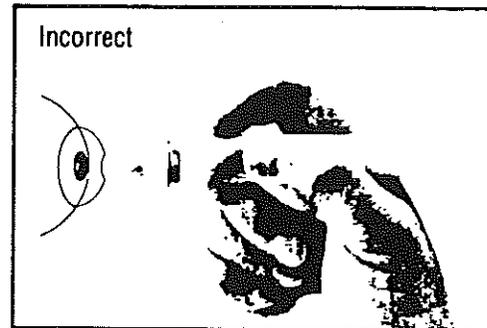
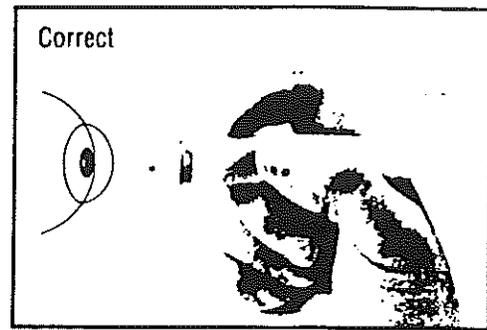


Figure 7 - Corneal Applanation

NOTE: If four dashes (- - -) appear 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.

10. 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 20 seconds, the Tono-Pen XL unit will automatically turn off and the LCD will clear. If this occurs, activate the Tono Pen XL as described in step 5.

11. 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.

A REUSED OCU-FILM TIP COVER MAY LEAK. THIS MAY CAUSE DAMAGE TO THE STRAIN GAUGE AND INVALIDATE THE WARRANTY.

## VI. INTERPRETING THE LCD

- A. The number display represents IOP in millimeters of mercury (mm. Hg.) A number with a single horizontal bar displayed at the bottom of the LCD (see Section VI, B), is an **average** of the valid measurements. A number without the single bar is a **single** measurement of IOP.
- B. 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 (see Figure 8). 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.
- C. Four dashes (- - -) indicate that the instrument is activated.
- D. Two rows of dashes (= = =) indicate that the instrument is ready to take measurements.

- E. "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. (see Section V, B).

Note: If the activation switch is inadvertently pushed twice causing "CAL" to appear, simply press the activation switch once more.

- F. "Lo b" indicates the need to replace both batteries prior to using the instrument (see Section VIII, C).
- G. "UP" indicates that the instrument is being calibrated and the probe tip should be turned from pointing down to pointing up (see Section V, B).
- H. "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.
- I. "bAd" indicates the calibration check procedure was unsuccessful and must be repeated (see Section V, B).

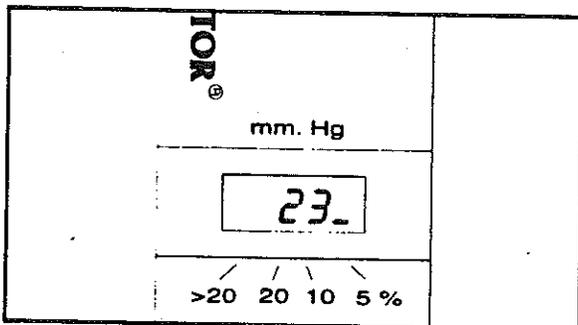


Figure 8 - LCD

## VII. INSTRUMENT STORAGE

- A. Cover the probe tip with an Ocu-Film Tip Cover for protection.
- B. If the Tono-Pen XL unit is not to be used until a subsequent day, the instrument and accessories should be replaced in the storage case provided.
- C. If the Tono-Pen XL unit is not to be used for an extended period of time, remove the batteries from the instrument.

## VIII. MAINTENANCE

### A. Probe:

1. Keep the probe tip protected with an Ocu-Film Tip Cover when in use or in storage. Avoid any contact with the probe tip when not protected by an Ocu-Film Tip Cover.

USE OR STORAGE OF THE TONO-PEN XL UNIT WITHOUT AN OCU-FILM TIP COVER CAN CAUSE SEVERE DAMAGE TO THE INSTRUMENT AND INVALIDATE THE WARRANTY.

2. The probe post (see Figure 2) must be cleaned only with optical quality compressed gas (see Figure 1) before the first use each day, before instrument storage, in the event of unanticipated readings or if a "Good" calibration check cannot be obtained.
  - a. Remove the Ocu-Film Tip Cover.
  - b. Insert the probe tip into compressed gas nozzle and spray for approximately 2 seconds.
  - c. Wait 3 minutes to allow the instrument to thermally stabilize.
  - d. Cover the Tono-Pen XL unit's probe tip with a new Ocu-Film Tip Cover.

- e. Press the RESET button (see Section IV for the reset procedure) and perform the calibration check procedure (see Section V, B) before taking any measurements.

DO NOT IMMERSE PROBE IN FLUIDS  
THIS WILL CAUSE DAMAGE TO THE ELECTRONICS AND  
INVALIDATE THE WARRANTY.

### B. Tono-Pen XL Body:

1. Avoid any shock or excessive vibration which will damage the unit.
2. Clean with a non-abrasive, dry cloth.

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

### C. Battery Replacement:

1. The batteries need replacing when multiple beeps sound and "Lo b" 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.

2. Always replace both batteries. Do not mix used and new batteries in the instrument. MENTOR Ocu-Cel XL Batteries are recommended.

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

3. Replace the batteries using the procedure described in Section III, B.
4. 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.

#### D. Computer Interface Jack:

1. The computer interface jack is located on the underside of the Tono-Pen XL unit (see Figure 2). This jack is to be used only with the MENTOR connector cable (Part No. 23-0255).

#### DANGER

DO NOT INSERT ANY OTHER CONNECTORS OR MATERIALS INTO THE COMPUTER INTERFACE JACK.

THIS COULD LEAD TO ELECTRIC SHOCK AND/OR DAMAGE TO THE INTERNAL ELECTRONICS AND INVALIDATE THE WARRANTY.

#### E. Attachment Screw:

1. The attachment screw, located on the underside of the instrument (see Figure 2), is used to protect the sensitive electronics against intrusion and should be removed only by the manufacturer.

#### WARNING

UNAUTHORIZED REMOVAL OF THE ATTACHMENT SCREW WILL INVALIDATE THE WARRANTY.

## IX. TROUBLE SHOOTING

Symptom	Probable Cause	Correction
1. "Lo b" displayed	Batteries are low	Replace batteries (See Section III, B)
2. Noticeable slowing in the calibration check process, or in activating instrument	1) Batteries are low	1) Replace batteries
	2) Compressed air cleaning has lowered the temperature of the instrument	2) Allow Tono-Pen XL unit to warm to room temperature
3. Multiple inaccurate readings	1) Improper technique	1) Review Section V or watch Instructional Video
	2) Old or improperly applied Ocu-Film Tip Cover	2) Replace Ocu-FilmTip Cover (see Figure 3)
	3) Debris around probe post	3) Clean with compressed gas (see Section VIII, A, 2 for procedure)
	4) Need to check calibration	4) Perform calibration check procedure (see Section V, B)
	5) Batteries are low	5) Replace batteries
	6) Mechanical or electronic damage	6) Arrange for repair through MENTOR Technical Service Group

- |  |  |   |
|--|--|---|
| 4. No beeps and/or no dashes upon activation | 1) Activation switch not depressed long enough | 1) Depress activation switch longer                                       |
|  | 2) Incorrect battery installation              | 2) Check batteries  |
|  | 3) Batteries are low                           | 3) Replace batteries  |
|  | 4) Microprocessor not initialized              | 4) Press RESET button (see Section IV)                                    |
|  | 5) Mechanical or electronic damage             | 5) Arrange repair through MENTOR Technical Service Group (See Section XI) |
| 5. Unable to obtain "Good" calibration check | See Section V, B                               | See Section V, B  |

If the symptom is not corrected, press the RESET button (see Section IV for reset procedure). If this procedure does not solve the problem, call MENTOR Technical Service Group (shown in Section XI).

## X. WARRANTY

Mentor O & O, Inc. warrants its new equipment to be free from defects in workmanship or materials. Any product which is proven to be defective in workmanship or materials will be repaired or replaced at our discretion, free of charge, up to one year from date of purchase. This warranty covers all repairs and service of parts that have proved defective by manufacture and not by use or mishandling. This type of service will be handled by our trained sales force or, if necessary, in our home office. Shipping charges for returns for repair of non-warranted items will be the responsibility of the customer. Alteration, repair or modification of any product which is performed by persons not authorized by Mentor O & O, Inc. will result in immediate loss of warranty.

## XI. SERVICE AND REPAIR

Technical information and operational instruction may be obtained for your MENTOR product by calling the MENTOR Technical Service Group at 1-800-992-7557 or (617) 871-6950.

When it be deemed necessary to return your MENTOR product for factory service, you must obtain a Return Goods Authorization (RGA) number.

Items sent to MENTOR for repair are to have the issued RGA number **printed on the outside of the package**. The package needs to be addressed as follows:

**Mentor O & O, Inc.  
3000 Longwater Drive  
Norwell, MA 02061-1672**

## XII. PATENT STATUS

The Tono-Pen XL Tonometer is manufactured under one or more U.S. and International patents. It is also protected by applicable copyright laws and the Semi-conductor Chip Protection Act of 1984 (P.L. 98-620).



# Calibration At A Glance

**STEPS:**

1. Point the transducer end of the pen towards the floor.

2. Depress the operator's button for one second.

3. The pen will BEEP and display a double line. (see Fig. 1)

If a single line appears, depress the operator's button once more.

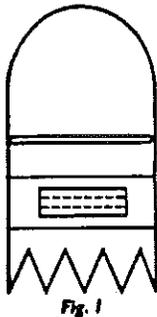


Fig. 1

4. Immediately depress the operator's button three times in rapid succession.

(TAP TAP TAP)

The pen will BEEP and display CAL (see Fig. 2)

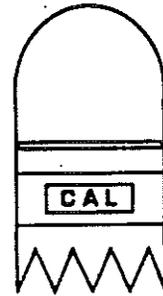


Fig. 2

5. Within 20 seconds the pen will BEEP and display UP. (see Fig. 3)

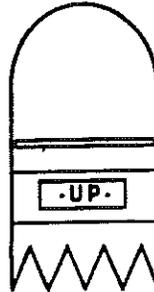


Fig. 3

6. Immediately (within 1/2 second) invert the transducer end of the pen to point toward the sky. (see Fig. 4)

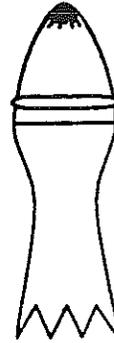


Fig. 4

7. A properly functioning pen will display GOOD. (see Fig. 5)

**NOTE:** If the pen goes from CAL to a single line "—" or directly to either GOOD or BAD the operator's button was not pressed fast enough.



Fig. 5



# Reset At A Glance\*

**STEPS:**

1. Point the transducer end of the pen towards the floor.

2. Using the stylus, hold the RESET button down and count ONE THOUSAND ONE Release (see Fig. 1)

3. The pen will BEEP and display a single line.

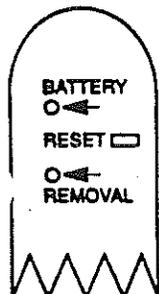


Fig. 1

4. Immediately depress the operator's button two times within one second.

(TAP TAP)

The pen will BEEP and display CAL (see Fig. 2)

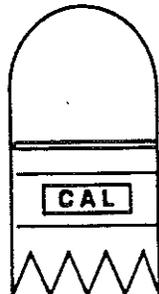


Fig. 2

5. Within 60 seconds the pen will BEEP and display UP. (see Fig. 3)

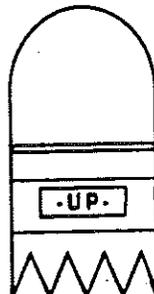


Fig. 3

6. Immediately (within 1/2 second) invert the transducer end of the pen to point toward the sky. (see Fig. 4)



Fig. 4

7. A properly functioning pen will display GOOD. (see Fig. 5)

**NOTE:** If the pen goes from CAL to a single line "—" or directly to either GOOD or BAD the operator's button was not pressed fast enough.

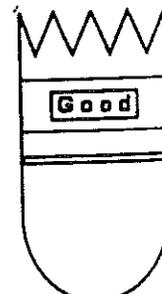


Fig. 5

