

Medtronic Solan
6743 Southpoint Drive North
Jacksonville, FL 32216-0980 U.S.A.
1-800-535-4646 or 1-904-296-9600
www.medtronicsolan.com

Copyright © 2000 Medtronic Solan
Fabricado en EE.UU.

Tono-Pen[®] XL

Instruction Manual

8 CAUTION

Do not use the instrument without an Ocu-Film Tip Cover. Use without an Ocu-Film Tip Cover will damage the instrument and void the Warranty.

4.2 Calibration

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.

**Note: If during operation the Operator's Button is pushed only once and the Tono-Pen displays CAL, the Tono-Pen needs to be calibrated.*

The calibration procedure is as follows:

1. Point the transducer end of the Tono-Pen straight **down** towards the floor.
2. Depress the Operator's Button two times rapidly, (within 1.5 seconds). The Tono-Pen will "beep" and display CAL.
3. Wait approximately 15 seconds for the Tono-Pen to "beep" and display UP.
4. Immediately (within 1 second) invert the Tono-Pen smoothly, pointing the transducer end straight **up**.
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 **18.8.8.8**, followed by a single row of dashes, **1- - -1**, 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).

4.2.1 Unsuccessful Calibration

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:

- Spray the probe tip with compressed gas (see Section 5 for details of this procedure), and repeat the calibration check.

If still unsuccessful:

- Replace the batteries (see Section 3 for the procedure) and repeat the 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".*

**Note: If the Tono-Pen XL fails to yield a "Good" calibration, call Medtronic Solam Technical Service.*

4.3 Performing IOP Measurements

After the Tono-Pen XL has been prepared for operation, the patient must be prepared and then IOP measurements can be performed.

4.3.1 Patient Preparation

CAUTION

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.

To prepare a patient for an IOP measurement:

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.*

4.3.2 Patient Examination

To perform an IOP measurement:

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. (See Figure 4-1 for correct positioning.)

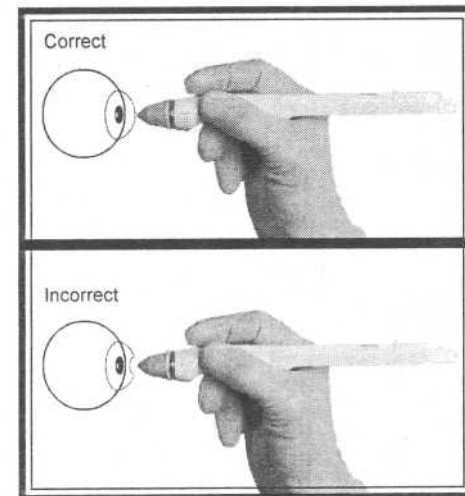


Figure 4-1 Corneal Applanation

5. To initiate an IOP measurement, depress the Operator's Button **once**, and only **once**.
- Initially you will see a brief display of **18.8.8.81**. This is a self-test of the LCD (Liquid Crystal Display). If any of the LCD segments are not displayed, the Tono-Pen requires service.
 - If a momentary display of ICALI is seen, followed immediately by a single row of dashes [- - -], it indicates that the Tono-Pen requires calibration before it will measure.
 - If a double row of dashes [_ _] is seen and a "beep" tone is heard, it indicates that the Tono-Pen is ready to measure [OP]. Proceed with applanation within 15 seconds.

***Note:** After acquiring the double row of dashes [---]J, if more than 15 seconds elapses prior to application, 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 [J. A new IOP measurement can be initiated by depressing the operators 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.

6. Once activated, after [---]J is displayed and a "beep" tone is heard, touch the Tono-Pen XL unit to the cornea lightly and briefly, then withdraw. Repeat several times. The corneal surface needs only to be momentarily contacted: indentation is not required and may lead to inaccurate readings.
7. 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.
8. 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,

9. 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 Operators Button once.

10. 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.