

Instructions for Use



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I-PEN®

Instructions for Use

REMOVE THE SINGLE USE SENSOR FROM PACKAGE

- Tear along the dotted line to separate the attached (1), wrapped Single Use Sensors.
- Grasping the bottom firmly with one hand ②, with the other tear in the direction of the pre-cut section to expose the end of the Single Use Sensor ③ to be inserted into the i-Pen® device.







INSERT THE SINGLE USE SENSOR

First 1 remove the unit cover, then 2 insert the disposable Single Use Sensor and DO NOT TOUCH THE GOLD NODES or the tip - sterile





TAKING A READING



- Ask the patient to gently squeeze their eyelids shut for 30-60 seconds prior to taking a reading.
- Position the tip of the disposable Single Use Sensor just above the lower eyelid with the LCD screen facing upwards.
- Turn on the i-Pen® as indicated by pressing the main button.

- Approach at a 30-45 degree angle from horizontal and gently lower the end of the Single User Sensor on to the conjunctiva on the inside of the lower eyelid.
- When correctly placed, the tip of the Single Use Sensor should be depressing the surface slightly so that both gold nodes are in good contact with the conjunctiva.
- The i-Pen® will make an audible beep after several seconds and display the reading on the LCD screen.

EJECT THE SINGLE USE SENSOR



1 Push the Ejector button and the Single Use Sensor will be ejected.

You may now discard the Single Use Sensor.



The LCD will display a test result.

EXPECTED RESULTS

i-Pen® test results are displayed on the LCD in units of mOsms/L. No calculations are required. The illustration below shows some typical test results and their possible interpretation. All such interpretation is subject to the review of the physician or other medical professional.

DRY EYE SEVERITY SCALE

Normal		Mild	Moderate		Severe				
275	290	305	320	335	350	365	380	400	

REFERENCE TEAR OSMOLARITY VALUES

	Range of Values	Mean Value
Normal Patients	275-316 mOsms/Lw	300 mOsms/L
Dry Eye Disease Patients	>300 mOsms/L	327 mOsms/L

QUESTIONS? COMMENTS?

Customer satisfaction is an I-MED Pharma Inc. priority. To help us in providing you with the best possible product and support, please send us your comments and suggestions.



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Marking by the CE symbol indicates compliance of this device as a Class 1 medical device with a measuring function, with the Medical Device Directives 93/42/ EEC as amended by 2007/47/CE.