

THE NEW STANDARD FOR DIAGNOSING DRY EYE DISEASE

RAPID – RELIABLE - REPRODUCIBLE

I-PEN[®], the world's first, point-of-care, electronic diagnostic testing device to detect and indirectly measure the tear film osmolarity levels associated with marginal, mild, moderate and severe Dry Eye Disease.



- Quantitative Measurement of Osmolarity ✓
- Simple to Use & No Calculations Required ✓
- Accurate & Reliable Results ✓
- Quick to Administer (2 seconds per eye) ✓
- Minimally Invasive ✓
- Affordable ✓

Uses Single-Use-Sensors

I-PEN[®] MEASURES TEAR OSMOLARITY IN SECONDS

The I-PEN[®] Osmolarity System, used in conjunction with the I-PEN[®] Osmolarity Single-Use-Sensors (SUS), provides a quick and simple method for determining tear osmolarity from the tear soaked papabral conjunctiva.

After approximately 2 seconds of contact with the eyelid tissue, the I-PEN[®] will display a quantitative tear osmolarity test result on the liquid crystal display (LCD) in units of mOsm/L. **No calculations required!** The I-PEN[®]

osmolarity test utilizes an impedance measurement to provide an indirect assessment of osmolarity of the tear film of the eye.

The I-PEN[®] is designed for use as an in-practice screening device both for patients presenting with dry eye symptoms and for all pre- and post-surgical patients. In addition, the I-PEN[®] is an invaluable asset for monitoring the progress of dry eye treatment therapies.

THE I-PEN[®] IS FOR PROFESSIONAL IN-VIVO DIAGNOSTIC USE ONLY.

To arrange an in-office demonstration, please contact your local I-MED Pharma Sales Representative.

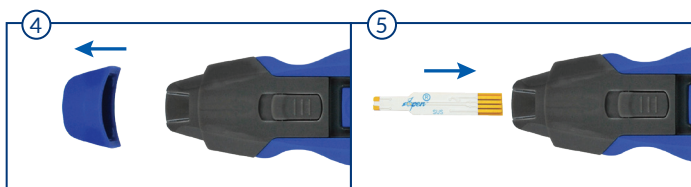
REMOVE THE SINGLE-USE-SENSOR FROM PACKAGE

1. Tear along the dotted line to separate the attached ①, wrapped Single-Use-Sensor.
2. Grasping the bottom firmly with one hand ②, with the other hand, 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 ④ remove the unit cover, then ⑤ insert the disposable Single-Use-Sensor and **DO NOT TOUCH THE GOLD NODES** or the sterile tip.



TAKING A READING

1. Ask the patient to close their eyes for 30-60 seconds prior to taking a reading.
2. Position the tip of the disposable Single-Use-Sensor just above the lower eyelid with the LCD screen facing upwards.
3. Turn on the I-PEN **only when you are ready to take the reading** by pushing the on/off switch to the on position.
4. Approach at a 30-45 degree angle from horizontal and gently lower the end of the Single-Use-Sensor on to the conjunctiva on the inside of the lower eyelid.
5. 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.
6. The I-PEN[®] will make an audible beep after a couple of seconds and display the reading on the LCD screen.

Please note: In order to conserve battery life, the I-PEN is programmed to enter Sleep Mode automatically thirty seconds after it powers up. In doing so, this can invalidate the SUS and a new SUS should be inserted.

WATCH THE I-PEN[®] IN ACTION

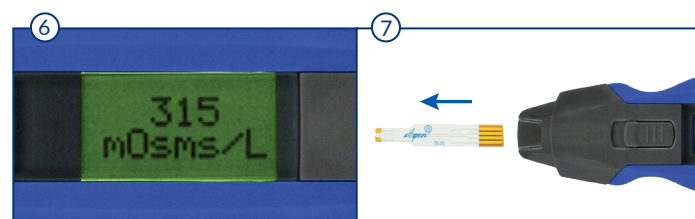
imedpharma.com/diagnostic-tools/tear-osmolarity

THE LCD WILL DISPLAY THE TEST RESULT

⑥ I-PEN[®] test results are displayed on the LCD in units of mOsm/L. No calculations are required. The chart below shows some typical test results and their possible interpretations. All such interpretations are subject to the review of the physician/medical professional.

EJECT THE SINGLE-USE-SENSOR

⑦ Push the Ejector button and the Single-Use-Sensor will be ejected. **You may now discard the Single-Use-Sensor and insert a new one for the second eye.**



DRY EYE SEVERITY SCALE

275	290	305	320	335	350	365	380
Normal < 290	Marginal 290-310	Mild 310-330	Moderate 330-350	Severe > 350			

REFERENCE TEAR OSMOLARITY VALUES

Reading in mOsm/L (Use result from eye with highest reading)	Variance Between Right & Left Eye	Interpretation
<290		Normal Patient
290-310	≤7	Normal Patient
290-310	≥8	Dry Eye Disease Patient
>310		Dry Eye Disease Patient

QUESTIONS OR 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 to info@imedpharma.com.

CE
0086

Rx Only

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.