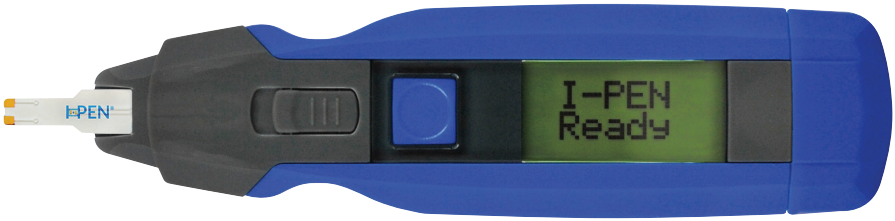
I-MED PHARMA

SEE THE DIFFERENCE

I-PEN®

FREQUENTLY ASKED QUESTIONS

FOR EYE CARE PROFESSIONALS



www.imedpharma.com
www.osdcare.com

I-MED PHARMA

THE I-PEN® OSMOLARITY SYSTEM IS 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 (DED).

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 of the tissues bathed in the tear film of the orbital tissues, such as the palpebral 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 mOsms/L. **No calculations required.**

The I-PEN® Osmolarity Test utilizes an impedance measurement to provide an 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 learn more about the I-PEN® click **here** or visit **https://youtu.be/JAcSzGSCZ64**

This document is intended as a resource for **eye care professionals** to help answer frequently asked questions regarding the I-PEN® Osmolarity System.

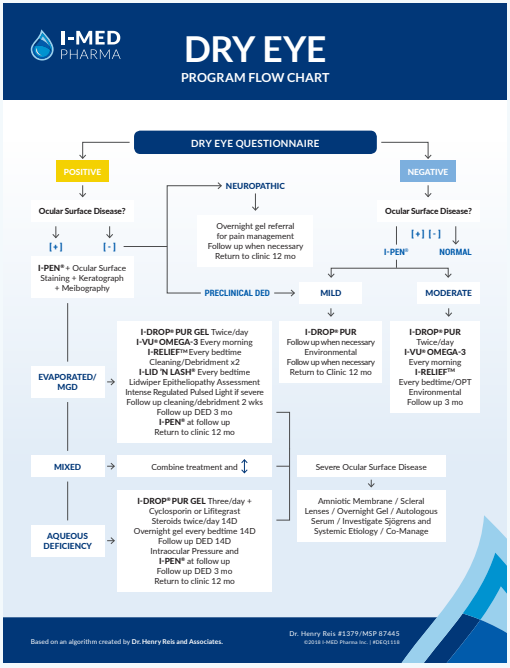
WHY IS OSMOLARITY SO IMPORTANT?

Osmolarity is important because it provides an objective number, which can then be monitored and measured against. It provides you with a means to classify the severity of a patient's DED. The I-PEN® produces a **specific number** that represents the patient's osmolarity result and **the band it falls in** (i.e.: 310-330) gives it context. A high osmolarity reading indicates an increasing severity of evaporative dry eye (EDDE).

HOW WILL THE I-PEN® CHANGE MY SCOPE OF PRACTICE?

The I-PEN® is most useful as a screening and communication tool. Approximately 50% of patients who enter a clinic have DED, however, many go undiagnosed. We recommend that every eye care professional conducts a validated questionnaire such as the **OSDI** or **DEQ-5.** Any patient whose result comes back positive for symptoms should be screened with the I-PEN®. The I-PEN® gives an objective measure of the severity of the DED and helps determine the correct treatment pathway to pursue. It allows for patients to clearly understand their treatment strategy, as you can point out their osmolarity result on the dry eye severity scale poster. This will pinpoint which products will be the most beneficial for them to use based on their osmolarity result.

The I-PEN® is also a great tool to help monitor the progress of the treatment and adjust accordingly. For example, patients can be re-tested after 3 months of using the products to see if their osmolarity result has improved.



Please refer to **Dr. Reis' Algorithm** on the left for further clarification on how to conduct the questionnaire.

HOW DO I PRESCRIBE YOUR PRODUCTS BASED ON OSMOLARITY READINGS?

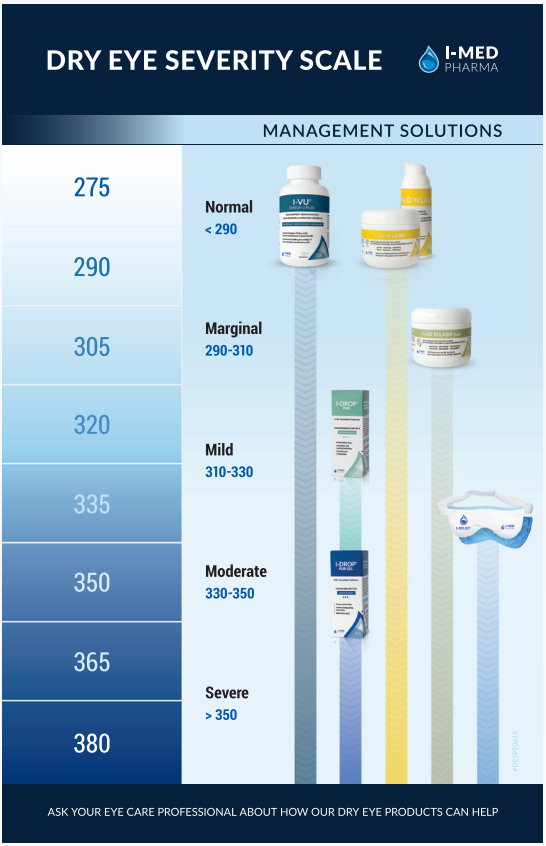
Please refer to our **Dry Eye Severity Scale** chart below to see which products should be used based on patients' osmolarity readings.

For results below 330, we recommend using:

- ✓ I-DROP® PUR
- ✓ I-LID 'N LASH® Wipes
- ✓ I-VU® OMEGA-3 PLUS

For results above 330, we recommend using:

- ✓ I-DROP® PUR GEL
- ✓ I-LID 'N LASH® PLUS
- ✓ I-VU® OMEGA-3 PLUS
- ✓ I-RELIEF™ Therapeutic Mask



IS THE I-PEN®'S RESULT REPRODUCIBLE? WHY ARE THE RESULTS SO VARIED WHEN I TAKE MULTIPLE, CONSECUTIVE READINGS?

Yes, the I-PEN®'s result is reproducible. With each test that is done, the I-PEN® takes a minimum of 192 readings in less than 2 seconds. The average of these readings is then displayed on the LCD screen.

The results can vary when multiple, consecutive readings are taken, because each test introduces reflex tearing, which will have an impact on the next reading. It is not necessary to perform consecutive readings in a clinical setting.

It is important that the I-PEN® test be the first test performed on the patient prior to any other test, to ensure an accurate reading.

To learn more about the I-PEN®, please visit **www.imedpharma.com/resources** or click on the following link: **Validity and Reliability of a Novel Handheld Osmolarity System for Measurement of a National Institute of Standards Traceable Solution** Clara C. Chan, MD, FRCSC, FACS,* Armand Borovik, MBBS, FRANZCO,† Ilan Hofmann, PhD,‡ Eric Gulliver, BSc (Hons),§ and Guillermo Rocha, MD, FRCSC, FACS

HOW CAN THE I-PEN® BE RELIABLE WITH SO MANY EXTERNAL FACTORS COMING IN TO PLAY?

Ideally, we would prefer that all external factors be minimized in order to get an accurate reading. External factors include, but are not limited to:

- ✓ **Airflow in the room**
- ✓ **The patient wearing make-up**
- ✓ **The patient applying drops prior to visit**
- ✓ **The office staff forgetting to ask the patient to close their eyes prior to taking the reading.**

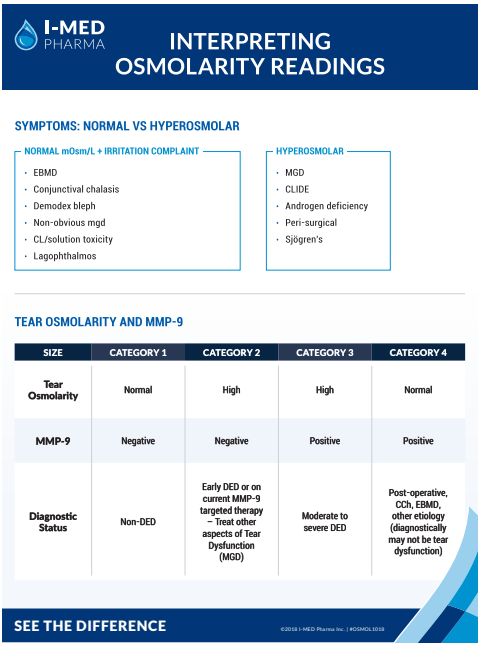
It is very difficult to control all external factors, which is why we look at the results in **bands** (i.e. 310-330), in addition to **specific numbers.** After steps are taken to reduce the external factors, the results should be accurate. We are also looking for trends over time. It is always recommended to perform the I-PEN® test before any other tests are conducted. In addition, a DED work-up should always be performed on a separate appointment date.

WHY DOES THE I-PEN® GIVE "NORMAL-RANGE" READINGS IN PATIENTS COMPLAINING OF VERY DRY EYES?

(WHY DOESN'T THE READING I GET MATCH THE PATIENT'S SYMPTOMS?)

It depends on the patient, case by case. DED is a very varied pathology. A normal osmolarity reading in patients with symptoms can help the eye care professional pinpoint the source of the issue. All results from the I-PEN® allow the eye care professional to narrow down the possible causes of DED and help provide tailored treatment plans.

Please refer to our document on **"Interpreting Osmolarity Readings"** on the right.



Source:
Dr. R. Maharaj, OD, FAAO

IF A PATIENT IS COMPLIANT WITH THEIR TREATMENT PLAN (USES I-DROP®, I-LID 'N LASH®, ETC.) SHOULDN'T THEIR FOLLOW-UP TEST COME BACK WITH A LOWER READING AS OPPOSED TO EITHER STAYING THE SAME OR GOING UP?

If both the preliminary test and follow-up test were done properly, considering the external variables mentioned previously, the patient's number should go down assuming they were compliant. If they are compliant and their number continues to climb or doesn't improve, we can assume that it may not simply be dry eye, but another problem which mimics these same symptoms. Therefore, further testing should be done to eliminate any other diagnoses.

Please refer to our document on **"Interpreting Osmolarity Readings"** above.

WHICH IS THE BEST WAY TO HOLD THE I-PEN®?

See image on the right. (For proper placement on the patient's conjunctiva, refer to the image from question below.)

WHAT IS THE CORRECT WAY TO TAKE A READING?

1. Ask the patient to gently squeeze their eyelids shut for 30-60 seconds prior to taking a reading.
2. After inserting the single-use-sensor (SUS), position the tip of the disposable SUS just above the lower eyelid with the LCD screen facing upwards.

3. Turn on the I-PEN® 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 SUS on to the conjunctiva on the inside of the lower eyelid.
5. When correctly placed, the tip of the SUS 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 several seconds and display the reading on the LCD screen.

Please refer to the **I-PEN® User Manual** for specific instructions.

DOES THE I-PEN® NEED TO BE TURNED ON BEFORE INSERTING THE SENSOR?

No, it can be turned on **before** or **after** inserting the sensor. However, you only have a certain amount of time to take the reading once the I-PEN® has been turned on and indicates "I-PEN® READY". The advantage to inserting the SUS prior to turning on the device is that you reduce the risk of the I-PEN® turning off and invalidating the SUS because too much time has passed.

WHAT HAPPENS IF THE I-PEN® TURNS OFF BEFORE I'VE DONE THE TEST?

If the I-PEN® is not used as soon as it indicates "I-PEN® READY", the SUS is considered "used" and a new SUS must be inserted. (The SUS is not reusable)

DO I NEED TO TURN OFF THE I-PEN® AFTER I USE IT?

No, it turns off automatically to maintain the battery life.

HOW OFTEN DO I NEED TO REPLACE THE BATTERY?

It should be replaced once per year, or as needed and can be bought at any dollar store or hardware store.

IS THE I-PEN® OSMOLARITY TEST PAINFUL?

No, the patient won't feel any pain if the I-PEN® is used properly. The patient will only feel a slight pressure of the SUS on the eyelid.

ONCE THE PATIENT HAS ARRIVED AT THE CLINIC, HOW LONG SHOULD HE/SHE WAIT BEFORE TAKING THE I-PEN® TEST?

5-10 minutes is plenty of time to allow the ocular surface to settle before taking an osmolarity test. Patients should be encouraged to complete the recommended questionnaire (OSDI or DEQ-5) prior to I-PEN® testing.

FREQUENTLY ASKED QUESTIONS

HOW CAN I EASILY TEST THE PATIENT WHEN THEY HAVE A TIGHTER LID?

Use a tongue depressor or a Q-tip to gently apply pressure to the lower third of the inferior eyelid. This causes it to evert, allowing you to perform the test.

WHAT CAN I DO IF I AM UNABLE TO TAKE THE READING DUE TO THE PATIENT BLINKING TOO MUCH?

Excessive blinking leads to osmolarity underestimation. Those patients can close their eyes and "look up with their eyes closed". Then you can evert the inferior eyelid using the technique above.

HOW OFTEN SHOULD I DO THE I-PEN® OSMOLARITY TEST?

An osmolarity test should be done at least once per year or each time the patient returns to the clinic for a DED workup. It is also recommended to re-test after a patient has been using OSD products for approximately 3 months to see if their osmolarity result has improved, stayed the same or gone up.

HOW MUCH DOES THE I-PEN® COST THE CLINIC PER PATIENT AND HOW MUCH SHOULD I CHARGE THE PATIENT FOR THE TREATMENT?

The treatment will cost the clinic $15.90 per patient, not including the price of the I-PEN®. Stand-alone tests would cost the patient approximately $35.00 to $60.00 per test, depending on the market.

CAN I GET A DISCOUNT ON THE SENSORS?

We offer the following promotion on the sensors:
Buy 5 boxes of Single-Use-Sensors and get the 6th box free.

HOW DOES THE I-PEN® COMPARE TO TearLab® IN TERMS OF PRECISION AND RELIABILITY?

Studies have been conducted that show that the I-PEN® is more precise and reliable than TearLab® and that it is "nearly perfect" when measuring a standard solution. Studies have shown that the I-PEN® represents a rapid and accurate instrument for measurement of tear osmolarity in a simulated testing setting.

To learn more about the studies conducted on the I-PEN®, please click on the links on the right, or visit: **www.imedpharma.com/resources**

- **A Comparison of *In Vivo* and *In Vitro* Osmometers for the Assessment of Dry Eye Disease**
  Henry Reis, MD; Stefanie Grenier, BSc; Daniela Albuquerque, MD

- **Validity and Reliability of a Novel Handheld Osmolarity System for Measurement of a National Institute of Standards Traceable Solution**
  Clara C. Chan, MD, FRCSC, FACS,* Armand Borovik, MBBS, FRANZCO,† Ilan Hofmann, PhD,‡ Eric Gulliver, BSc (Hons),§ and Guillermo Rocha, MD, FRCSC, FACS

I-MED Pharma Inc.
1601 St-Regis Blvd.
Dollard-des-Ormeaux, QC
CANADA H9B 3H7

Tel.: (514) 685-8118
Toll free: (800) 463-1008
Fax: (514) 685-8998

www.imedpharma.com
info@imedpharma.com

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