I-PEN®

Osmolarity System

FOR QUANTITATIVE MEASUREMENT
OF OSMOLARITY OF OCULAR TISSUES

USER MANUAL

osdcare.com
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CONTACT INFORMATION
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.
1. ABOUT THIS MANUAL

This manual provides the information necessary to operate the I-PEN® system in a safe and efficient manner. Please read and thoroughly understand this manual before operating the system. If any part of this manual is not clear, contact customer support for clarification.

1.1. WARNINGS AND PRECAUTIONS

Three types of special messages appear in this User Manual:

- **A WARNING** indicates the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.

- **A CAUTION** indicates the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions, device failure, damage to the device or damage to other property.

- **A NOTE** provides other important information.

2. ESSENTIAL PRESCRIBING INFORMATION

2.1. DEVICE DESCRIPTION

The I-PEN® Osmolarity System is a diagnostic testing device for the quantitative measurement of osmolarity (concentration of dissolved, active particles in solution) of ocular tissues in normal and Dry Eye Disease patients. The I-PEN® is for professional in vivo diagnostic use only.

When either the quantity or quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), increased rates of evaporation lead to a concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

The I-PEN® Osmolarity Single-Use-Sensor, in conjunction with the I-PEN® Osmolarity System, provides a quick and simple method for determining tear osmolarity using impedance measurements of the saline concentration of the extracellular fluid contained in the eyelid tissue. To perform a test, attach a new Single-Use-Sensor onto the System Reader and touch the tip of the Single-Use-Sensor to the inner tissue of the lower eyelid.

After several seconds of contact with the eyelid tissue, the I-PEN® will display a quantitative tear osmolarity test result on the liquid crystal display (LCD). The I-PEN® Osmolarity System simplifies the osmolarity determination process by eliminating the need to transfer tear fluid samples and reducing the risk of evaporation.

The I-PEN® Osmolarity Test utilizes an impedance measurement to provide an assessment of osmolarity of the conjunctival tissues surrounding the eye.

2.2. INTENDED USE

The I-PEN® Osmolarity System is a device for the quantitative measurement of osmolarity (concentration of dissolved, active particles in tissue immersed in solution) of human tears in normal and Dry Eye Disease patients.

The I-PEN® Osmolarity System should be used only by a trained clinician or under the supervision of a trained clinician.

2.3. INDICATIONS

The I-PEN® Osmolarity Device is indicated for use in the diagnosis of certain ocular surface disorders which affect the osmolarity of the tear film on the surface of the eye.

2.4. CONTRAINDICATIONS

There are no contraindications known at this time.
2.5. GENERAL SAFETY INSTRUCTIONS

⚠️ **WARNING:** Changes or modifications not expressly approved by I-MED Pharma Inc. can affect the safety and effectiveness of the system and will void the system's warranty.

⚠️ **WARNING:** Use only indoors, in a clean, dry environment.

⚠️ **WARNING:** Do not use a Single-Use-Sensor that is physically damaged.

⚠️ **WARNING:** The system contains no user-serviceable components.

⚠️ **WARNING:** Medical device regulations restrict the operation of the application to trained and qualified personnel.

⚠️ **WARNING:** Do not test patients who have used eye drops within two hours prior to testing.

⚠️ **WARNING:** Do not test patients wearing makeup on eyelids.

⚠️ **WARNING:** Do not test patients within 10 minutes after removal of eye makeup.

⚠️ **WARNING:** Do not test patients after ocular surface staining.

⚠️ **WARNING:** Do not test patients after invasive ocular diagnostic testing.

⚠️ **WARNING:** Do not test patients within 10 minutes after a slit lamp examination.

⚠️ **WARNING:** Do not test a patient who has been crying.

⚠️ **CAUTION:** The information contained in this Manual is intended for the sole and exclusive use of the Company's customers. Any other unauthorized use of this Manual or any of the information it contains is prohibited.

⚠️ **CAUTION:** Refer all service problems to a qualified I-MED Pharma Inc. representative only.

⚠️ **CAUTION:** Replace the device if the LCD is cracked, unreadable, has missing pixels, or is otherwise damaged.

⚠️ **CAUTION:** Replace the device if a “beep” is not heard after turning it on.

⚠️ **CAUTION:** Check the operation of the device prior to use. Replace if damaged.

⚠️ **CAUTION:** Replace the device if the casing or battery cover is lost or damaged.

⚠️ **CAUTION:** Single-Use-Sensors are for single use only.

⚠️ **CAUTION:** Do not use the Single-Use-Sensors past the expiration date.

⚠️ **CAUTION:** The device is to be used within a clinical facility environment only.

⚠️ **CAUTION:** The device is for professional in vivo diagnostic use only.

3. DESCRIPTION OF COMPONENTS

3.1. IDENTIFYING SYSTEM COMPONENTS

The figures which follow illustrate the components of the I-PEN® System.

3.2. I-PEN® OSMOLARITY SYSTEM

The I-PEN® is a portable hand held battery-operated unit that calculates and displays the osmolarity test result. The unit includes a small display screen that shows the osmolarity test result.

3.3. I-PEN® OSMOLARITY TEST SENSOR

Each Single-Use-Sensor is a single-use, individually packaged unit, designed to work in conjunction with the I-PEN®. The Single-Use-Sensor does not contain chemicals or reagents.

⚠️ **WARNING:** Do not use a Single-Use-Sensor that is physically damaged.

⚠️ **CAUTION:** Do not use the Single-Use-Sensors past the expiration date.

⚠️ **CAUTION:** Single-Use-Sensors are for single use only.
4. PERFORMING AN OSMOLARITY MEASUREMENT

**WARNING:** Do not test patients who have used eye drops within two hours prior to testing.

**WARNING:** Do not test patients wearing makeup on eyelids.

**WARNING:** Do not test patients within 10 minutes after removal of eye makeup.

**WARNING:** Do not test patients after ocular surface staining.

**WARNING:** Do not test patients after invasive ocular diagnostic testing.

**WARNING:** Do not test patients within 10 minutes after a slit lamp examination.

**WARNING:** Do not test a patient who has been crying.

4.1. PREPARE THE I-PEN® FOR USE

**WARNING:** Use only indoors, in a clean, dry environment.

In order to prepare for a test, place the battery in the System Reader, and insert a Single-Use-Sensor.

**WARNING:** Do not use a Single-Use-Sensor that is physically damaged.

4.1.1. INSERT THE BATTERY

1. **CAUTION:** This device uses a battery type CR2032 only.

The battery compartment can be accessed by removing the battery cover, as shown below.

2. **CAUTION:** Replace the device if the casing or battery cover is lost or damaged.

4.2. REMOVE THE SINGLE-USE-SENSOR FROM PACKAGE

1. Tear along the dotted line to separate the attached ①, wrapped Single-Use-Sensors.

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.

4.3. INSERT THE SINGLE-USE-SENSOR

1. **CAUTION:** Replace the device if a "beep" is not heard after turning it on.

2. **CAUTION:** It is important to visually inspect the Single-Use-Sensor before use. In the case of suspected contamination, or if the expiration date is expired, replace the Test Sensor.

3. **CAUTION:** Do not touch the gold nodes while inserting the Single-Use-Sensor.

First ④ remove the unit cover, then ⑤ insert the disposable Single-Use-Sensor.

**WARNING:** Do not use a Single-Use-Sensor that is physically damaged.
4.4. TURN ON THE DEVICE

Push the On/Off switch. You should hear a “beep” and the LCD display should display the “I-PEN Ready” message.

- **CAUTION:** Replace the device if a “beep” is not heard after turning it on.
- **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.
- **CAUTION:** Do not use the unit if the Reader does not display “I-PEN Ready”.

4.5. TAKING A READING

1. Ask the patient to gently squeeze their eyelids shut 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® as indicated in section 4.4 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 take make an audible beep after several seconds and display the reading on the LCD screen.

4.5.1. TIPS FOR USE

1. Do not immerse the tip of the Single-Use-Sensor in the lower tear meniscus.
2. If the reading on the LCD screen shows an “Error”, you may attempt another reading in the same eye by pressing the Ready button.

4.6. EJECT THE SINGLE-USE-SENSOR

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.

See the next Section for a discussion of how to interpret the measurement results.

5. EXPECTED RESULTS

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

**DRY EYE SEVERITY SCALE**

<table>
<thead>
<tr>
<th>Reading in mOsms/L (Use result from eye with highest reading)</th>
<th>Variance Between Right &amp; Left Eye</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;290</td>
<td>≤7</td>
<td>Normal Patient</td>
</tr>
<tr>
<td>290–310</td>
<td></td>
<td>Normal Patient</td>
</tr>
<tr>
<td>290–310</td>
<td>≥8</td>
<td>Dry Eye Disease Patient</td>
</tr>
<tr>
<td>&gt;310</td>
<td></td>
<td>Dry Eye Disease Patient</td>
</tr>
</tbody>
</table>
6. CLEANING AND MAINTENANCE

6.1. CLEANING

WARNING: Cleaning fluids should never be used on the Single-Use-Sensor.

6.1.1. I-PEN® DEVICE

The I-PEN® can be cleaned with a damp cloth or alcohol wipe as required. When cleaning, it is important to keep the electronic contacts of the control unit and Reader dry. The electronic contacts and docking port should also be kept free of dust and dirt.

6.1.2. SINGLE-USE-SENSORS

Single-Use-Sensors are for use on a single eye. Never reuse or try to clean a Single-Use-Sensor.

Single-Use-Sensors may be ordered on line at www.imedpharma.com or by calling your representative at I-MED Pharma Inc. Tel. Number: (800) 463-1008 or (514) 685-8118.

6.2. MAINTENANCE

The I-PEN® Osmolarity System is designed to work without direct service or preventive maintenance. If quality checks fail, contact I-PEN® Customer Support.

Battery should be replaced when “Low Bat” indication appears on the screen.

6.2.1. TROUBLESHOOTING

Single-Use-Sensors are for single use only. Never reuse or try to clean a Single-Use-Sensor.

NOTE: If the Recommended Action does not solve the problem, contact I-MED Pharma Inc. Customer Support.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Possible Cause</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “I-PEN Ready” message does not display</td>
<td>Battery not installed. Device malfunction.</td>
<td>Verify that the correct type of battery is installed, and that the battery is fresh. Contact I-PEN® customer support.</td>
</tr>
<tr>
<td>A “beep” is not heard when the device is turned on</td>
<td>Device malfunction.</td>
<td>Contact I-PEN® customer support.</td>
</tr>
<tr>
<td>“Low Bat” indication appears on screen</td>
<td>Battery close to end-of-life.</td>
<td>Replace battery.</td>
</tr>
<tr>
<td>Screen goes dim</td>
<td>Battery close to end-of-life.</td>
<td>Replace battery.</td>
</tr>
</tbody>
</table>

7. OPERATING AND STORAGE CONDITIONS

To ensure warranty coverage and reliable system operation, defective system components should be serviced and/or replaced exclusively by I-MED Pharma Inc. authorized personnel, and replacement parts should be those specified by the manufacturer. It is important to use and store the device within the environmental conditions shown in the table below.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport and Storage Temperature</td>
<td>2°–35°C/36°–95°F</td>
</tr>
<tr>
<td>Transport and Storage Relative Humidity</td>
<td>10–85% non-condensing</td>
</tr>
<tr>
<td>Transport and Storage Altitude</td>
<td>0–2,000 meters</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>15°–30°C/59–86°F</td>
</tr>
<tr>
<td>Operating Altitude</td>
<td>0–2,000 meters</td>
</tr>
<tr>
<td>Operating Relative Humidity</td>
<td>10–85% non-condensing</td>
</tr>
</tbody>
</table>

8. TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration</td>
<td>No calibration required</td>
</tr>
<tr>
<td>Degree of Protection Against Electric Shock</td>
<td>BF Type applied part</td>
</tr>
<tr>
<td>Size (not including probe holder)</td>
<td>W 140mm L 223mm H 140mm</td>
</tr>
<tr>
<td>Weight</td>
<td>50 gm</td>
</tr>
<tr>
<td>Battery</td>
<td>CR2032</td>
</tr>
<tr>
<td>Frequency</td>
<td>80 Hz</td>
</tr>
<tr>
<td>Peak Voltage</td>
<td>± 1.5V</td>
</tr>
<tr>
<td>Current Source</td>
<td>Max100 µA AC</td>
</tr>
<tr>
<td>Sinus Distortions</td>
<td>5%</td>
</tr>
</tbody>
</table>
9. ELECTROMAGNETIC EMISSIONS

NOTES

• The I-PEN® requires special precautions with regard to electromagnetic compatibility.
• It must be installed and prepared for use as described in Section 4. Performing an Osmolarity Measurement.
• Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the I-PEN®.
• The recommended separation distances in this paragraph must therefore be complied with.
• The I-PEN® must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.
• The use of accessories other than those specified or sold by I-MED Pharma Inc. as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the unit.
• I-PEN® is intended for use in the electromagnetic environment specified in the following tables. This is not a life-sustaining device.
• The user and/or installer of the unit must ensure that it is used in such an environment.

Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

The I-PEN® is intended for use in the electromagnetic environment specified below. The customer or the user of the I-PEN® device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions Test: CISPR 11</td>
<td>Group 1</td>
<td>The I-PEN® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

10. ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The I-PEN® is intended for use in the electromagnetic environment specified below. The customer or the user of the I-PEN® device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact</td>
<td>±8 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±1 kV for input/Output lines</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode</td>
<td>±2 kV common mode</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>&lt;5 %UT (&lt;95 %dip in UT) for 0.5 cycle</td>
<td>40 %UT (60 %dip in UT) for 5 cycles &lt;5 %UT</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.</td>
</tr>
</tbody>
</table>
Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The I-PEN® is intended for use in the electromagnetic environment specified below. The customer or the user of the I-PEN® device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment-Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150kHz to 80MHz</td>
<td>Not applicable</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the I-PEN®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance ( d = 1.17\sqrt{P} ) for 80 MHz to 2.5 GHz. Where ( P ) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ( d ) is the recommended separation Distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80MHz to 2.5GHz</td>
<td>3 V/m</td>
<td></td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10.1. RECOMMENDED SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the I-PEN®

The I-PEN® is intended for use in an electromagnetic environment in which radiated radio frequency disturbances are controlled. The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (emitters) and the I-PEN®, according to the maximum output power of the equipment, as recommended in the table below.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>80MHz to 800MHz</th>
<th>800MHz to 2.5GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Separation distance according to the frequency of transmitter (m)</td>
<td>( d = 1.17\sqrt{P} )</td>
<td>( d = 2.3\sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>11.7</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10.1.1. APPLICABLE STANDARDS

The following list of standards applies to the I-PEN® Osmolarity Device:

- ISO 15223: 2012, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.
11. LABELS AND SYMBOLS

11.1. LABELS

![OSMOLARITY SYSTEM](image)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Symbol meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Attention: Consult Accompanying Document" /></td>
<td>Attention: Consult Accompanying Document</td>
</tr>
<tr>
<td><img src="image" alt="BF type applied part" /></td>
<td>BF type applied part</td>
</tr>
<tr>
<td><img src="image" alt="Month/Year of Manufacture" /></td>
<td>Month/Year of Manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Manufactured by" /></td>
<td>Manufactured by</td>
</tr>
<tr>
<td><img src="image" alt="Special Requirements for Waste of Electrical and Electronic Equipment (WEEE Directive)" /></td>
<td>Special Requirements for Waste of Electrical and Electronic Equipment (WEEE Directive)</td>
</tr>
<tr>
<td><img src="image" alt="CE Compliance (Medical Device Directive)" /></td>
<td>CE Compliance (Medical Device Directive)</td>
</tr>
</tbody>
</table>

**CAUTION:** At the end of its useful life, the system must be disposed of in accordance with local law and/or code concerning electrical and electronic equipment.