I-MED PHARMA

I-PEN®

Tear Osmolarity System

FOR QUANTITATIVE MEASUREMENT OF OSMOLARITY OF OCULAR TISSUES

USER MANUAL

www.imedpharma.com

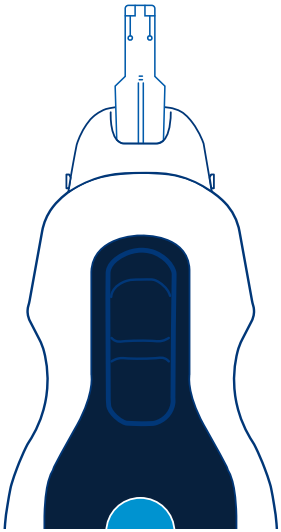
I-PEN® TEAR OSMOLARITY SYSTEM

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 your comments or questions to info@imedpharma.com

I-MED PHARMA

I-MED Pharma Inc.
7190 Frederick Banting Rd.
St. Laurent, QC
Canada H4S 2A1



1. ABOUT THIS MANUAL

This manual provides the information necessary to operate the I-PEN® Tear Osmolarity 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® Tear Osmolarity System is a 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® Tear Osmolarity System is for professional in vivo **testing** 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® Single-Use-Sensor, in conjunction with the I-PEN®, 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® Tear 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® Tear Osmolarity System utilizes an impedance measurement to provide an assessment of osmolarity of the conjunctival tissues surrounding the eye.

2.2. INTENDED USE

The I-PEN® Tear Osmolarity System is used for the quantitative measurement of osmolarity (concentration of dissolved salts in solution in the tear film) of human tears in normal and Dry Eye Disease patients.

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

2.3. INDICATIONS

The I-PEN® Tear Osmolarity System is indicated for use in the quantitative measurement of 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

- **CAUTION:** 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.
- **CAUTION:** Use only indoors, in a clean, dry environment.
- **CAUTION:** Single-Use-Sensors that are physically damaged should not be used.
- **CAUTION:** The system contains no user-serviceable components.
- **CAUTION:** Medical device regulations restrict the operation of the application to trained and qualified personnel.
- **CAUTION:** Patients who have applied eye drops within the last 2 hours should not be tested.
- **CAUTION:** Patients should not be tested while wearing eye make-up.
- **CAUTION:** Patients should not be tested within 10 minutes of removing their eye make-up.
- **CAUTION:** Patients should not be tested after ocular surface staining.
- **CAUTION:** Patients should not be tested after invasive ocular diagnostic testing.
- **CAUTION:** Patients should not be tested within 10 minutes of a slit lamp examination.
- **CAUTION:** Patients who have been crying should not be tested.
- **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:** The Single-Use-Sensors should not be used past their expiration date.
- **CAUTION:** The device is to be used within a clinical facility environment only.
- **CAUTION:** The device is for professional in vivo use only.
- **CAUTION:** Serious incidents should be reported to the manufacturer and local competent authority.
- **CAUTION:** Used and/or depleted I-PEN® batteries are to be disposed of in battery specific recycling bins.
- **CAUTION:** Return used and/or defective I-PEN® devices to I-MED Pharma Inc., address: 7190 Frederick Banting Rd., St. Laurent, QC Canada H4S 2A1.

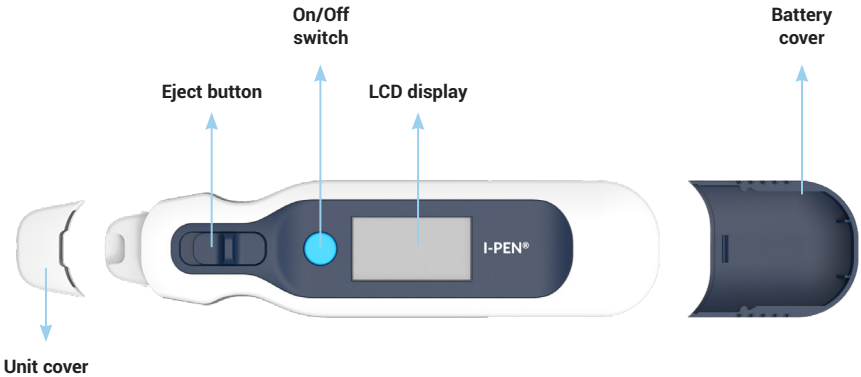
3. DESCRIPTION OF COMPONENTS

3.1. IDENTIFYING SYSTEM COMPONENTS

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

3.2. I-PEN®

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® SINGLE-USE-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.

- **CAUTION:** Single-Use-Sensors that are physically damaged should not be used.
- **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

- **CAUTION:** Patients who have applied eye drops within the last 2 hours should not be tested.
- **CAUTION:** Patients should not be tested while wearing eye make-up.
- **CAUTION:** Patients should not be tested within 10 minutes of removing their eye make-up.
- **CAUTION:** Patient testing should not be performed after ocular surface staining.
- **CAUTION:** Patients should not be tested after invasive ocular diagnostic testing.
- **CAUTION:** Patients should not be tested within 10 minutes of a slit lamp examination.
- **CAUTION:** Patients who have been crying should not be tested.

List of messages and text displayed by the I-PEN® device:			
I-PEN V*.*	Software version	**Low Battery**	Indicates low battery in I-PEN®
INSERT SUS	I-PEN® ready for user to insert SUS	**Previous *value***	Displays the value of the previous measurement in mOsmol/L
I-PEN Ready	I-PEN® ready to refer measurement	***value* mOsmol/L**	Current measurement of osmolarity of tear film
ERROR!!	Error in measurement during operation		

- **CAUTION:** If the I-PEN® indicates a **Low Battery** message, it is required to wait for a minimum of two minutes without using the device. After the waiting period, try using the device again. If the **Low Battery** message persists, it is advised to replace the battery.

STEP 1. PREPARE THE I-PEN® TEAR OSMOLARITY SYSTEM FOR USE

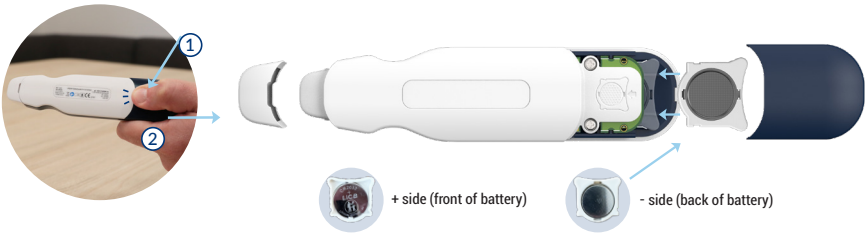
- **CAUTION:** Use only indoors, in a clean, dry environment.

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

1.1. INSERT THE BATTERY

NOTE: This device uses a battery type CR2032 only.

The battery compartment can be accessed by removing the battery cover, as shown below. To remove the battery cover, apply downward pressure (1) on the dark blue area and smoothly slide the cover off (2).



- **CAUTION:** Replace the battery case if lost and replace the device if the casing is damaged.

STEP 2. REMOVE THE SINGLE-USE-SENSOR FROM PACKAGE

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

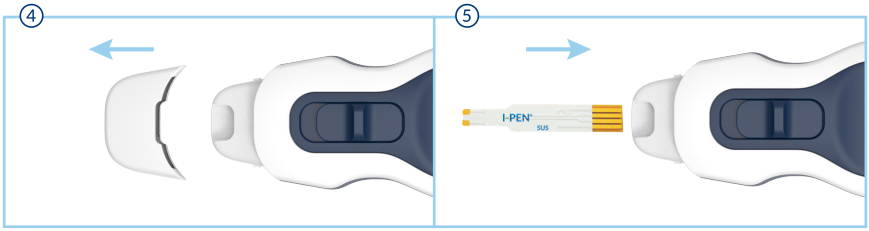
2. Grasping the bottom firmly with one hand ②, with the other hand tear in the direction of the pre-cut section to expose the end of the Single-Use-Sensor ③ to be inserted into the I-PEN® device .

STEP 3. INSERT THE SINGLE-USE-SENSOR

- Replace the device if a "beep" is not heard after turning it on.
- 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 Single-Use-Sensor.

CAUTION: Insert the Single-Use-Sensor without touching the gold nodes.

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



CAUTION: Single-Use-Sensors that are physically damaged should not be used.

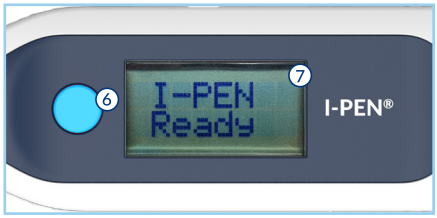
STEP 4. TAKING A READING

CAUTION: Do not use the unit if the Reader does not display "I-PEN Ready".

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 above **only when you are ready to take the reading** by pushing the on/off switch to the on position.



Push the On/Off switch ⑥. You should hear a "beep" and the LCD display ⑦ should display the "I-PEN Ready" message.

4. Approach at a 30-45 degree angle from horizontal and gently lower the end of the Single-Use-Sensor on to the **middle of** conjunctiva on the inside of the lower eyelid.

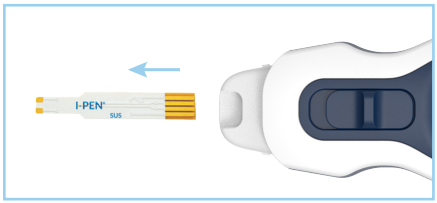
5. When correctly placed, the tip of the Single-Use-Sensor should be depressing the surface slightly so that both gold nodes are in good contact with the conjunctiva.

6. The I-PEN® will make an audible beep after several seconds and display the reading on the LCD screen.

4.1. RECOMMENDATION FOR USE

Do not immerse the tip of the Single-Use-Sensor in the lower tear meniscus.

STEP 5. 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.

5. RESULTS

I-PEN® test results are displayed on the LCD in units of mOsmol/L. No calculations are required.

In the case of a reading error, replace the SUS, as a second reading cannot be made. Please be aware that a second reading may also produce reflex tearing which may affect the osmolarity of the tear film.

6. CLEANING AND MAINTENANCE

6.1. CLEANING

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.

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

6.1.2. SINGLE-USE-SENSORS

Single-Use-Sensors are for use on a single eye. Do not re-use 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® Tear Osmolarity System is designed to work without direct service or preventive maintenance. If troubleshooting fails, contact customer service at 1-800-463-1008.

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

6.2.1. TROUBLESHOOTING

Single-Use-Sensors are for single use only. Do not re-use or try to clean a Single-Use-Sensor.

NOTE: If the Recommended Action does not solve the problem, contact customer service at 1-800-463-1008.

Condition	Possible Cause	Recommended Action
The "I-PEN Ready" message does not display	Battery not installed. Device malfunction.	Verify that the correct type of battery is installed, and that the battery is fresh. CR2032 / Refer to section 1.1 for details on battery installation Contact customer service.
A "beep" is not heard when the device is turned on	Device malfunction.	Contact customer service.
"Low Bat" indication appears on screen	Battery close to end-of-life.	Replace battery.

7. OPERATING AND STORAGE CONDITIONS

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

Transport and Storage Temperature	2°–35°C/36°–95°F
Transport and Storage Relative Humidity	10–85% non-condensing
Transport and Storage Altitude	0–10,000 meters
Operating Temperature	15°– 30°C / 59–86°F
Operating Altitude	0–2,000 meters
Operating Relative Humidity	10–85% non-condensing

8. TECHNICAL SPECIFICATIONS

Calibration	No calibration required
Degree of Protection Against Electric Shock	BF Type applied part
Size (not including probe holder)	W 34.5mm L 142.5mm H 18mm
Weight	50 gm
Battery	CR2032 - The I-PEN® battery complies with IEC 60086-4
Frequency	80 Hz
Peak Voltage	± 1.5V
Current Source	Max100 µA AC
Sinus Distortions	5%

9. ELECTROMAGNETIC EMISSIONS

- The I-PEN® Tear Osmolarity System requires special precautions with regard to electromagnetic compatibility.
- It must be installed and prepared for use as described in Section 4. Performing a Tear Osmolarity Measurement.
- Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the I-PEN® Tear Osmolarity System.
- The recommended separation distances in this paragraph must therefore be complied with. Refer to section 10.1.
- The I-PEN® Tear Osmolarity System 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.
- The I-PEN® Tear Osmolarity System user must ensure that it is used in such an environment.

10. ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The I-PEN® Tear Osmolarity System is intended for use in the electromagnetic environment specified below. The customer or the user of the I-PEN® Tear Osmolarity System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ Output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	
RF Emissions CISPR 11	Class A	Compliant	I-PEN® is designed to be used in clinical environments. Test results should not interfere with other electronic devices. Refer to Note below.
Voltage fluctuations/flicker emissions IEC 61000-3-3	<5 %UT (>95 %dip in UT) for 0.5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Not applicable	I-PEN® is a battery operated device that does not connect to AC mains.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Compliant	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.
IEC 61000-4-39, Proximity Magnetic Fields Immunity	30kHz, CW at 8A/m 134.2kHz, 2.1kHz Pulse Modulation at 65A/m 13.56MHz, 50kHz Pulse Modulation at 7.5A/m	Compliant	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment- Guidance
Conducted RF IEC 61000-4-6		Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the I-PEN® Tear Osmolarity System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80MHz – 2.7GHz 27V/m, 385MHz 28 V/m, 450 MHz 9 V/m, 710/745/780 MHz 28 V/m, 810/870/930 MHz 28 V/m, 1720/1845/ 1970 MHz 28V/m, 2450 MHz 9 V/m, 5240/5500/5785 MHz	Compliant	Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.3\sqrt{P}$ 800 MHz t o 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 R F transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:

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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the I-PEN® Tear Osmolarity System is used exceeds the applicable RF compliance level above, the I-PEN® Tear Osmolarity System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the I-PEN® Tear Osmolarity System.

10.1. RECOMMENDED SEPARATION DISTANCES

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

The I-PEN® Tear Osmolarity System 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® Tear Osmolarity System, according to the maximum output power of the equipment, as recommended in the table below.

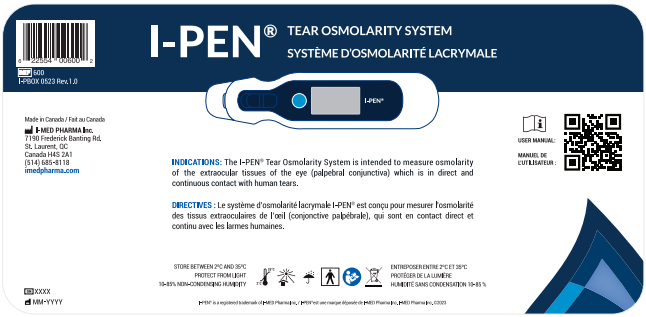
	Separation distance according to the frequency of transmitter (m)	
Rated maximum output power of transmitter (W)	**80MHz to 800MHz $d = 1.17 \sqrt{P}$**	**800MHz to 2.5GHz $d = 2.3 \sqrt{P}$**
0.01	0.12	0.23
0.1	0.37	0.73
1	1.17	2.3
10	3.7	7.3
100	11.7	23

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.

11. LABELS AND SYMBOLS

11.1. LABELS



11.2. SYMBOLS

A number of internationally recognized symbols are found on the I-PEN® unit.
These relate to safety requirements and standards and are briefly reviewed below.

Symbol	Symbol meaning
	Attention: Consult Accompanying Document
	BF type applied part
	Month/Year of Manufacture
	Manufactured by
	Special Requirements for Waste of Electrical and Electronic Equipment (WEEE Directive)
	Keep dry

Symbol	Symbol meaning
35°C 2°C	Store between 2°C and 35°C
	Protect from light
85% % 10%	10-85% non-condensing humidity
SN	Serial number
REF	Reference / catalog number
UDI	Unique Device Identifier

CAUTION: At the end of its useful life, the I-PEN® Tear Osmolarity System must be disposed of in accordance with local law and/or code concerning electrical and electronic equipment.

Manufactured by:

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