

ScoutPro

ScoutPro Quick Reference Guide





ScoutPro Charging Base

Plug the power cord provided into a normal wall outlet. Then plug the cord into the Charging Base. There is no power switch.

ScoutPro Pen

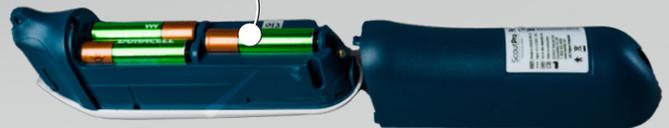
Use the screwdriver included with the system to unscrew the back cover of the Pen and slide off to access the battery compartment. Insert three RECHARGEABLE AAA batteries. Replace the back cover. Place the Pen in the Charging Base. A charging icon on the LCD indicates the battery is charging, when Pen is docked in the Charging Base.

Note: Use of non-rechargeable batteries may damage the Pen and void the warranty.

Using ScoutPro Buttons

When a new Test Card is first inserted, a calibration code will appear on the display. Use the right (>) button to increase, or left (<) button to decrease to match the code on top of the Test Card. If a result is displayed, or the screen is dark, pressing either button will recall previous test results. The Pen stores the last three test results: the current result and the previous 2 results

Rechargeable AAA batteries

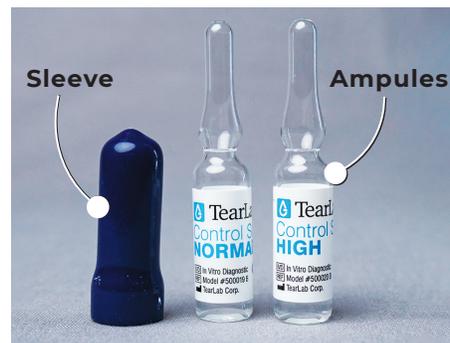


Test Cards



Each Test Card can be used only once. The number code printed on top of the Test Card should be entered on the Pen prior to the test. Test Cards should be stored at room temperature.

Control Solutions



Control Solutions confirm that the Test Cards are working correctly. The glass bottles (ampules) should be kept at room temperature. Do NOT refrigerate or keep in a hot place.

Electronic Check Cards



Electronic Check Cards are blue. Two identical cards come in each box. They can be reused to check the performance of the Pen. Test the blue Electronic Check Card once a day before testing a patient or if a Pen has been dropped or mishandled.

QUALITY CONTROL TESTING

When testing the control solution or the Electronic Check Cards, make sure the results match the expected values shown in the instruction sheets. If they do not match, the quality tests have FAILED. Stop testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006**.

Electronic Check Card

Read the Electronic Check Card instruction sheet for expected values. Be sure to test the blue Electronic Check Cards on the Pen once a day before patient testing. Do NOT collect tears or control solutions with the Electronic Check Cards.

Procedure

- Attach Electronic Check Card onto the Pen.
- The Pen will beep and a green light will turn on.
- A test result will appear on the display.
- If results FAIL, stop testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006**.



Control Solutions

Test both levels of Control Solutions with each new shipment of Test Cards (even if the lot number is the same), with each new lot number, and monthly to check storage. Read the Control Solution instructions sheet for expected values.

Procedure

- Allow Test Cards and Control Solution to equilibrate at room temperature in the testing room for 30-minutes prior to testing.
- Attach a Test Card to the Pen (refer to this guide), enter the code.
- Do NOT collect tears.
- Instead of collecting tears, use a Control Solution.
- Use the blue sleeve to snap off the top of an ampule.
- Turn the ampule upside down (the fluid will not spill out).
- Touch the tip of the Pen to the Control Solution.
- Compare Control Solution results to the expected value.
- If test results are within the expected range, patient testing may proceed.
- If test results are not within the expected range, you should not perform patient testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006**.



SERIOUS ADVERSE EVENT

Report a serious adverse event, product quality problem, product use error, or therapeutic inequivalence /failure that you suspect is associated with the use of the ScoutPro Osmolarity System to Trukera Customer Support (Tel: (858) 455-6006) and/or to FDA MedWatch (Tel: (800) FDA-1088, Fax: (800) FDA-0178, or www.fda.gov/medwatch).

For outside the US, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

SCOUTPRO TESTING PROCEDURE

Use good hygiene when collecting tears. Throw away used Test Cards in an appropriate container.



Attach Test Card. Enter the code on the top of the card by pressing right (>) or left (<) buttons on the Pen.

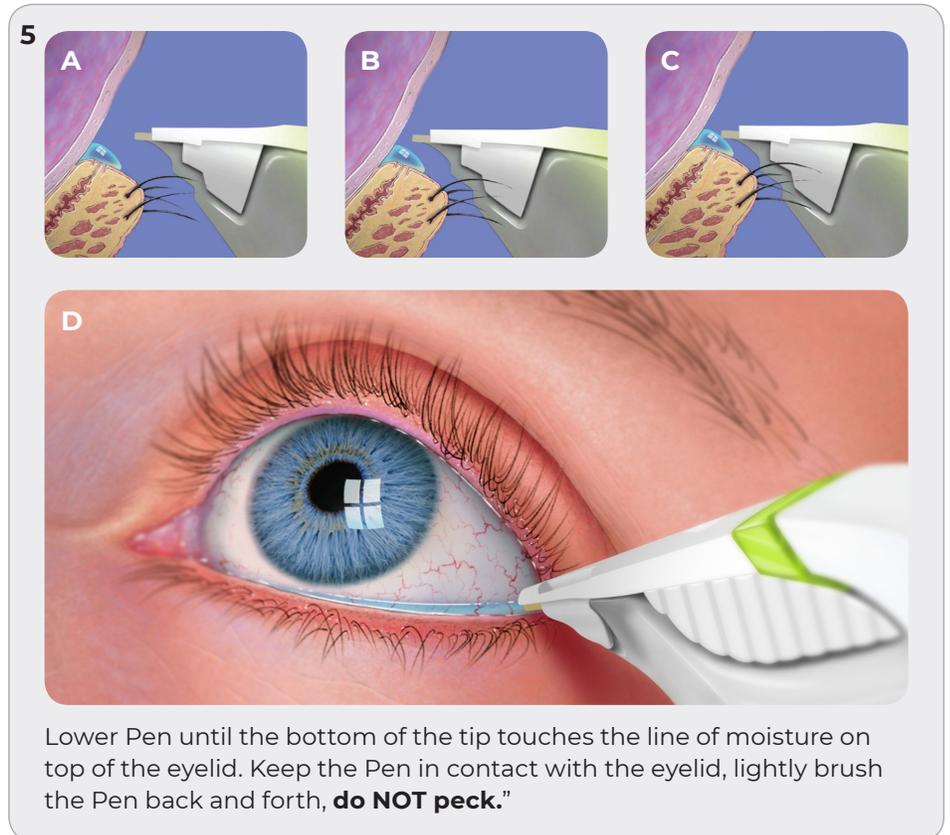


Hold wings, remove cover.



Seat patient with head back and eyes looking up and towards ceiling.

- **Do NOT pull the eyelid away from the eye.**
- When tears are collected, the Pen will beep.
- Remove the Pen from the eyelid immediately after the beep to avoid an ER error.



A test result will appear on the display. DO NOT DOCK the Pen while waiting for results. Record the test result in the patient's chart.

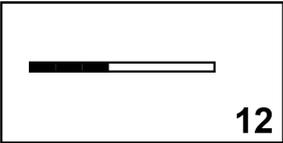


Remove the test card by sliding forward with your index finger and discard. Do NOT reuse Test Cards.



To view previous test results, press either the right (>) or left (<) buttons on the Pen.

DISPLAY SCREEN EXPLANATION

THE DISPLAY	YOU WILL SEE THIS WHEN...	EXPLANATION
	<p>A new Test Card is inserted</p>	<p>The Test Card code for the previous test is shown in the center of the display.</p>
	<p>A new Test Card code is entered</p>	<p>Before testing a patient, press the right (>) or left (<) buttons on the Pen until the number on the display matches the code printed on top of the new Test Card.</p>
	<p>A tear sample has been collected</p>	<p>When a tear sample has been collected, a progress bar will be shown on the display while the sample is analyzed. The numeric code for this test is shown in bold in the lower right corner.</p>
	<p>The test is complete</p>	<p>The current test result will be displayed in black text on a white background. Removing the Test Card will push this result into memory and turn the screen off. The numeric code for the test is shown in bold in the lower right corner.</p>
	<p>A previous test result is recalled</p>	<p>Previous test results will be displayed in white text on a black background, and include the previous result (296), the code used for that test (5), and the minutes elapsed since it was performed (e.g., :07).</p>
	<p>Battery Charge is low</p>	<p>If an LO temporarily appears on the LCD when a Test Card is attached to the Pen, recharge the Pen in the Charging Base. If the LCD goes black, the batteries are too low to continue testing.</p>

FREQUENTLY ASKED QUESTIONS

1. WHAT IS A NUMERIC CODE?

There is a numeric code printed on the top of each Test Card. The code needs to match the number on the Pen display for the test to be accurate. Within 5 seconds of a new Test Card being placed onto the Pen, immediately change the code on the Pen (using the < and > buttons) to match the numeric code on the Test Card.

2. WHAT DOES IT MEAN IF THE GREEN LIGHT ON THE PEN DOES NOT TURN ON?

If the green light does not turn on, then do NOT test a patient. The green light tells you the Pen is ready for you to perform a test.

3. HOW DO I KNOW IF I HAVE SUCCESSFULLY COLLECTED A TEAR SAMPLE?

The green light will turn off and the Pen will beep.

4. HOW CAN I DETERMINE IF A TEST CARD HAS BEEN USED?

A Test Card without a protective cover should always be considered a used Test Card. All Test Cards should be discarded after use. Do NOT reuse Test Cards.

5. WHAT IS PROPER HYGIENE FOR TESTING?

Always disinfect your hands and keep the ScoutPro Pen clean. Read the Osmolarity Test Card insert for more information.

6. HOW OFTEN SHOULD I TEST THE BLUE ELECTRONIC CHECK CARD?

Test the blue Electronic Check Card once a day before testing a patient or if a Pen has been dropped or mishandled.

7. HOW OFTEN SHOULD I TEST THE CONTROL SOLUTIONS?

Test both levels of Control Solution with each new shipment of Test Cards (even if the lot number is the same as the previous shipment), with each new lot of Test Cards, and monthly to check storage.

8. HOW SHOULD I STORE THE TEST CARDS?

Test Cards should be stored at room temperature. Pay attention to the expiration date printed on the box and on each package. Never use a Test Card after the expiration date.

9. WHAT IF THE QUALITY CONTROL TESTING FAILS?

Stop testing. Contact Trukera Technical Support in your area or call Trukera at (858) 455-6006. Refer to the User Manual for information on troubleshooting and maintenance.

10. HOW CAN I RESET THE PEN IF NECESSARY?

Press the left arrow key for 5 seconds to reset the Pen or unscrew the battery cover on the back of the Pen and remove the batteries. Reinsert the batteries, replace the cover and screw into place.

CLIA CONSIDERATIONS – FOR U.S. CUSTOMERS ONLY

The ScoutPro Osmolarity System is a CLIA-waived test system for human tears. Each laboratory or testing site using the ScoutPro Osmolarity System must have a CLIA Certificate of Waiver before starting testing. To obtain a Certificate of Waiver, call your state department of health or Trukera Customer Support at (858) 455-6006 for an application (Form CMS-116). Trukera can provide the phone number of your state department of health and assist you in filling out the application. The ScoutPro Osmolarity System is a waived test so long as it is used according to the instructions set in the Package Insert. Refer to the package insert for more complete information. User should read the complete test procedure, including recommended quality control procedures, before performing the ScoutPro osmolarity test. Any modification by the laboratory to the test system or the test system instructions will result in this test no longer meeting the requirements for waived categorization. A modified test is considered to be high complexity and is subject to all applicable CLIA requirements.

Manufactured by: Trukera Medical
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Temecula, CA 92590 USA
1-858-455-6006, www.trukera.com

For more information, refer to the ScoutPro User Manual.

Authorized Representative for the
European Union: Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

One or more of the following patents
may apply: U.S. Patents 7,017,394;
7,051,569; 7,111,502; 7,129,717;
7,204,122; 8,020,433; 7,987,702;
7,905,134; 7,810,380; 7,574,902