ScoutPro

ScoutPro Osmolarity System - USER MANUAL

Trukera™
MEDICAL

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TABLE OF CONTENTS

INCLUDED CONTENTS:

- ScoutPro
- Charging Base
- AAA Batteries
- Power Supply
- Power Cord(s)
- Set of (2) Electronic Check Cards with Instructions for Use

SOLD SEPARATELY:

- Osmolarity Test Cards
- Osmolarity Control Solutions

PRODUCT OVERVIEW

Intended Use Statement: The ScoutPro Osmolarity System is an automated device intended to quantitatively measure the osmolarity of human tears to aid in the diagnosis of dry eye disease, in patients suspected of having dry eye disease in conjunction with other methods of clinical evaluation. For professional use only.

Tears fulfill an essential role in maintaining ocular surface integrity, protecting against microbial challenge, and preserving visual acuity. These functions, in turn, are critically dependent upon the composition and stability of the tear film structure.[1]

Osmolarity is a basic and essential aspect of physiologic homeostasis in body fluids. Small deviations in homeostasis, such as variations in pH, temperature, glucose and oxygen concentrations, and osmotic pressure, activate physiological mechanisms to return that variable to its set point. The body is able to regulate osmolarity of body fluids within very narrow limits through various mechanisms of osmoregulation, such as the compensation and correction of fluid volume and salt concentration. Hyperosmolarity of any body fluid, including tear fluid, indicates a disorder in the body's ability to regulate homeostasis and is a basic indication of a physiological disorder. The higher the osmolarity, the more concentrated the tear film.[2]

Hyperosmolarity has been described in the literature as a primary marker of tear film integrity.[3] When either the quantity or the quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), an increased evaporation rate leads to a concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

The Osmolarity Test Card, in conjunction with the ScoutPro, provides a quick and simple method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the eyelid margin. To perform a test, attach a new Test Card onto the Pen and touch the tip of the Pen to the tear fluid meniscus, located above the lower eyelid. After a successful collection, the ScoutPro Pen will display a quantitative tear osmolarity test result on the liquid crystal display (LCD). The ScoutPro simplifies the tear-collection process by eliminating the need to transfer tear fluid samples and reducing the risk of evaporation.

PRINCIPLES OF THE PROCEDURE

The ScoutPro Test utilizes a temperature-corrected impedance measurement to provide an indirect assessment of osmolarity.[4] After application of a calibration curve to the steady-state electrical impedance of the tear fluid, osmolarity is calculated and displayed as a quantitative numerical value.

SYSTEM COMPONENTS

SCOUTPRO PEN

The ScoutPro Pen is a portable unit that is designed to hold the Test Card and facilitate safe, simple tear fluid collection. The Pen electronics confirm the proper attachment of the Test Card onto the Pen, detect the presence of tear fluid in the Test Card, and signal when a tear fluid sample has been successfully collected. The Pen then measures the electrical impedance of the tear fluid, calculates and displays the osmolarity test result. The Pen is powered by three (3) AAA rechargeable batteries.

Three (3) Rechargeable AAA Batteries

NOTE: *Use Rechargeable AAA Battery only - Duracell AAA90HP1118 or equivalent. Use of non-rechargeable batteries may damage the Pen and void the warranty.*

SCOUTPRO CHARGING BASE

The ScoutPro Charging Base holds the Pen when not in use and charges the Pen batteries. The Charging Base can be set on a flat countertop or mounted flush against a wall. The Charging Base needs to be plugged into a wall outlet with the supplied power cords.

OSMOLARITY TEST CARD

Each Test Card is a single-use, individually packaged, non sterile, polycarbonate microchip containing (a) microfluidic channel to collect 50 nanoliters (nL) of tear fluid by passive capillary action, and (b) gold electrodes embedded in the polycarbonate microfluidic channel to enable on-board measurement of tear osmolarity. Test Cards are clinically hygienic and have a protective cover that should be removed only after the Test Card has been successfully attached onto the Pen and immediately prior to tear collection. Each Test Card is imprinted with a code that must be entered into the Pen at the time of testing. Designed to work in conjunction with the ScoutPro Pen, the Test Card does not contain chemicals or reagents, and collects tear fluid in less than one second. Please note that Test Cards are not included with the ScoutPro and must be purchased separately.

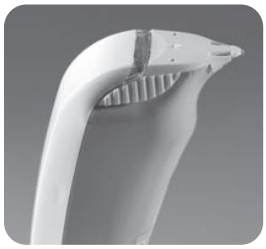
ELECTRONIC CHECK CARDS

Two identical, blue, reusable Electronic Check Cards are provided as a procedural quality control to confirm the function and calibration of the ScoutPro is within manufacturer specifications. The Electronic Check Cards can be used to verify the function of the ScoutPro if it is mishandled or dropped. Tear fluid samples cannot be collected with the Electronic Check Cards.

INSTALLATION

A ScoutPro, charging base, power cord(s), Electronic Check Cards, and rechargeable AAA batteries are delivered together. Open the carton on a stable surface, remove the components, and set them on a flat surface. Use the power cord that corresponds to your local electrical outlet configuration. Connect the power cord to the power supply, plug the power cord into an electrical outlet, and connect the power supply to the back of the ScoutPro Charging Base. Use the screwdriver included with the System to unscrew the back cover of the Pen and slide off to access the battery compartment. Install the three rechargeable AAA batteries, and replace the cover. Use of non-rechargeable batteries may damage the Pen and void the warranty. Dock the Pen in the Charging Base and allow to charge for 1 hour before initial use. Always dock the Pen in the Charging Base after testing to ensure the Pen batteries maintain a charge.

WARNING: *Modification of this equipment is not recommended. This may cause a safety hazard and will nullify the manufacturer's warranty. Do not locate the ScoutPro Charging Base directly in front of the power outlet. The power cord and plug must be accessible for removal from the power outlet.*



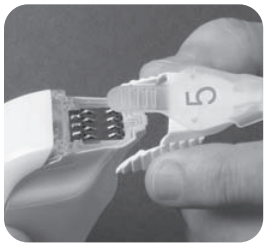
SCOUTPRO PEN

The ScoutPro Pen should be docked in the Charging Base and allowed to charge for 1 hour before initial use. The Pen batteries automatically recharge when the Pen is docked in the Charging Base and the Base is plugged in. A battery icon is located in the top right of the ScoutPro Display. A battery icon displaying a lightning bolt inside indicates that the battery is charging. Pen batteries will not overcharge.

LOW BATTERY WARNING

When a Test Card is docked to a Pen with low battery power, the ScoutPro Pen will display a low battery icon. If this occurs, dock the ScoutPro into the Charging Base to charge the batteries or replace the rechargeable AAA batteries with new batteries.

WAKE AND SLEEP MODES



The Pen will enter Sleep Mode when not in use or when a Test Card is removed, and will automatically awaken when a new Test Card is attached, as indicated by the green light and the beep. The Pen will remain in Wake Mode for two minutes. If two minutes pass without tear collection, the Pen will return to Sleep Mode and the green light will turn off. To wake the Pen, remove the Test Card and reattach it onto the Pen. The green light will illuminate and the Pen will beep.

WARNING: *Only collect tears if the green light is on. NEVER collect tears when the green light is off. If a Test Card is attached and there is no beep and no green light from Pen, DO NOT collect tears.*

QUALITY CONTROL

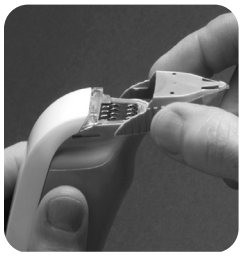
CALIBRATION

The manufacturer calibrates the ScoutPro against a reference standard solution prepared from dried, high-purity sodium chloride traceable to the National Institute of Standards and Technology (NIST). Calibration by the user is not required.

ELECTRONIC CHECK CARD

A blue Electronic Check Card should be tested on the Pen before each day of patient testing, or if the Pen has been dropped or mishandled, to verify that the system is performing within manufactured calibration specifications. Values obtained with the Electronic Check Card should not deviate by more than +/- 3.0 mOsm/L (units of osmolarity) from the expected value.

WARNING: *Fluid samples cannot be collected with the Electronic Check Card. DO NOT try to collect tears or Control Solutions with the blue Electronic Check Card.*



TESTING THE ELECTRONIC CHECK CARD

1. Attach an Electronic Check Card onto a Pen. The green light on top of the Pen will illuminate and the Pen will beep.
2. After the green light turns off, the ScoutPro will display a test result that should fall within the expected value range indicated in the Instructions for Use provided with the Electronic Check Cards.
3. Record the date and the Electronic Check Card test results in a quality log.

CONTROL SOLUTIONS

Good laboratory practice suggests the use of Normal and High Osmolarity Control Solutions to ensure that the ScoutPro is functioning properly. Test 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. To ensure proper performance with the ScoutPro, only Trukera Osmolarity Control Solutions should be used. Osmolarity Control Solutions are not included with the ScoutPro or the Trukera Osmolarity Test Cards. If correct electronic or control solution test results are not obtained, do not test patient samples; instead, contact your local sales representative or Trukera Customer Support in your area.

NOTE: *Please refer to the "Testing Osmolarity Controls" section of this manual for the Osmolarity "Control Solutions" testing procedure.*

CONTRAINDICATIONS

Human tear fluid samples may be used. Collect tear fluid samples directly from the eye.

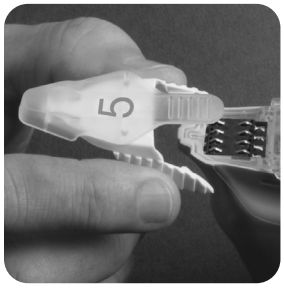
- Do not collect tear fluid from a patient within two hours of medicinal eye drop use or use of topical medications.
- Do not collect or store tear fluid samples for transport or testing at a later time.
- Do not collect tear fluid after ocular surface staining.
- Do not collect tear fluid within 15 minutes of use of anesthetic or mydriatic (dilating) eye drops or after other invasive ocular diagnostic testing.
- Do not collect tear fluid within 15 minutes after a slit lamp examination.
- Do not collect tear fluid within 15 minutes from a patient who has been crying.

WARNING: *If either the Electronic Check Card or the Control Solution test results do not match the expected value range, do not test patients. Contact your local sales representative or Trukera Customer Support for assistance.*

OSMOLARITY TEST

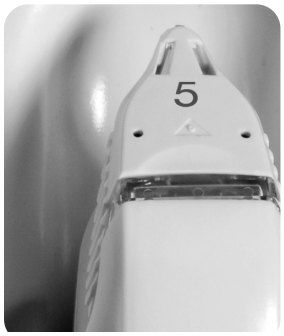
HOW TO PERFORM AN OSMOLARITY TEST

NOTE: *Use appropriate clinically hygienic methods when collecting tears.*



BEFORE EACH TEST

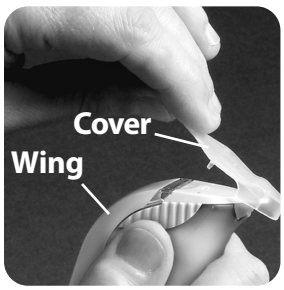
- Remove the ScoutPro Pen from the Charging Base.
- Remove a Test Card from its package and attach it onto the Pen. The Pen will beep and the green light will illuminate when the Card is attached properly. The green light will remain on until tears are collected or the Pen times out (after two minutes).



ENTER THE TEST CARD CODE

- Locate the code on top of the Test Card (see example in picture).
- Press the right (>) button to increase or the left (<) button to decrease the Test Card Code on the Pen.
- Change the number on the Pen until it matches the number printed on the Test Card.

IMPORTANT: *If a code is not selected within eight seconds, ScoutPro will automatically use the code displayed on the LCD and will move to a "Ready" screen. It is important to select the correct code prior to testing to obtain an accurate osmolarity test result. If the correct code was not selected, remove and reattach the test card from the Pen and enter the correct code.*



- Remove the protective cover by holding the wings of the Test Card firmly and pulling the cover up and off of the Test Card.

WARNING: *A Test Card without a protective cover should be considered used. DO NOT use for patient testing.*

TEAR COLLECTION PROCEDURE

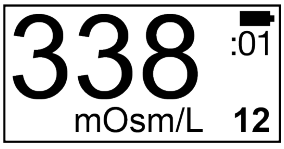
NOTE: *For Osmolarity Controls, refer to the "Testing Osmolarity Controls" section below.*

- Seat the patient with chin tilted upward and eyes directed toward the ceiling and away from the operator.
- Place one hand on the face for stabilization. Do not pull the eyelid down or away from the eye.
- Position the tip of the Pen just above the lower eyelid.
- Gently lower the Pen until the bottom of the tip touches the thin line of moisture between the eyelid and the eye. It is not necessary to press inward toward the eye.
- The Pen will beep and the green light will turn off after a successful tear collection.

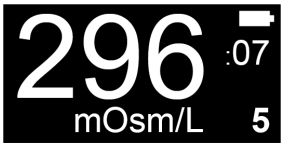
NOTE: *Sometimes when there is very little tear, the act of withdrawing the Pen breaks the surface tension of the tear meniscus and allows tears to enter the microfluidic channel. In this case, the Pen will beep upon withdrawal, indicating a successful tear collection.*

NOTE: *Tear collection should be performed at the lateral (temporal) extent of the eyelid where the risk of inadvertent injury to the cornea can be minimized.*

TEST RESULT DISPLAY



- The test result will display in a few seconds after successful tear collection, along with the units (mOsm/L).
- The Test Card Code used for calculation of the result is shown in the lower right corner of the display. If the entered code does not match the code on the Test Card, the test result will be inaccurate, and the test should be repeated with a new Test Card using the correct code.
- Pressing either button while on a results screen, or when the display is off, will display the previous test result.



PREVIOUS TEST RESULTS

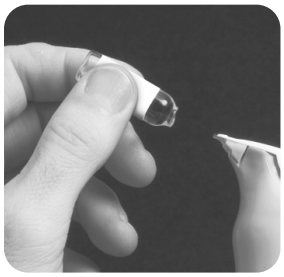
- The most recent test result is shown with black text on a white background. Previous test results are shown in white text on a black background to differentiate them from the most recent result.
- The Pen stores the last three test results.
- The time elapsed since the previous test was performed is shown under the battery icon (e.g., :07 minutes).
- The Test Card Code used for calculation of the result is shown in the lower right corner of the display.
- Pressing any button on the first previous result will cycle to the next result.

NOTE: *Record the test result in the patient chart and remove the used Test Card from the Pen by sliding forward on top of the Test Card with your index finger. Do not pull from the wings. Dispose in an appropriate manner (reference HAZARDS in this document).*

TESTING OSMOLARITY CONTROLS

Test control solution 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 for Use for expected values.

- 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 the "How to Perform an Osmolarity Test" section of this manual).
- 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.
- The Pen will beep and the green light will turn off. A test result will display in a few seconds.
- Check the control solution test result to the expected value.
- If within the expected range, patient testing may proceed.
- If 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.

PERFORMANCE

RESULT INTERPRETATION

Osmolarity test results are displayed on the LCD in mOsm/L. No calculations are required. Osmotic concentration determinations are often expressed as either osmolarity (milliosmoles/liter i.e., mOsm/L or as centiosmoles/liter, i.e., cOsms/L) or osmolality (milliosmoles/kilogram, i.e., mOsms/kg or as centiosmoles/kg, i.e., cOsms/kg). In tear fluid, the difference between osmolarity and osmolality is insignificant, and it is common in the clinical literature to use the terms interchangeably.[5]

ScoutPro measurement range is linear from 275–400 mOsm/L. Test results outside this range will be reported as either "Below Range," indicating a measurement below 275 mOsm/L, or "Above Range," indicating a measurement above 400 mOsm/L. Osmolarities outside the stated range are very rare and should generally be confirmed with a subsequent test, as values outside the measurement range may be indicative of an error (e.g., user error during the test).

EXPECTED RESULTS

Reference tear osmolarity values for Normal and Dry Eye osmolarity levels.

NOTE: *Osmolarity may differ from left eye to right eye, and each eye should be tested and assessed to determine which eye represents higher osmolarity.*

- Normal: Mean 309.9 mOsm/L ± 11.0 (288–331 mOsm/L; 90% CI 288–331)
- Dry Eye Disease: Mean 324.3 mOsm/L ± 20.1 (291–382 mOsm/L; 90% CI 284–392)

The results of the ScoutPro Osmolarity System should be evaluated with all clinical and laboratory data available. If the results do not agree with the clinical evaluation, additional tests should be performed. Osmolarities above or below the measurement range are very rare and should generally be confirmed with subsequent testing, as values outside the measurement range may indicate an error (e.g., user error during the test). Test only on human tears or Trukera Control Solutions.

ACCURACY (METHOD COMPARISON)

The correlation study was performed internally by the manufacturer using contrived tear samples of various osmolarity levels within the clinical reference range on both the ScoutPro and the Wescor Model 5520 vapor pressure osmometer calibrated to NIST- traceable standards.

No. Sites	N	Regression Line	r^2
1	80	y = 0.9146x + 23.061	0.9443

At each of three physician office sites, 40 contrived tear specimens across seven levels of the clinically significant range were prepared and measured on the ScoutPro. The physician office laboratories did not have access to the Wescor 5520 Vapro® vapor pressure osmometer. Wescor values were determined by an average of two to three measurements on each level of osmolarity immediately prior to the beginning of the study.

No. Sites	N	Regression Line	r^2
3	120	y = 0.9402x + 12.512	0.9515

CLINICAL STUDIES

CALIBRATION DATA

To determine clinical performance for tear film hyperosmolarity in the diagnosis of Dry Eye Disease, a meta-analysis was performed on historical published data for tear osmolarity in samples of Normal and Dry Eye subjects. An osmolarity referent value of 316 mOsm/L was found to yield sensitivity of 69%, specificity of 92%, and an overall predictive accuracy of 82% for the diagnosis of Dry Eye Disease. Studies in the meta-analysis used earlier osmolarity devices, not ScoutPro.

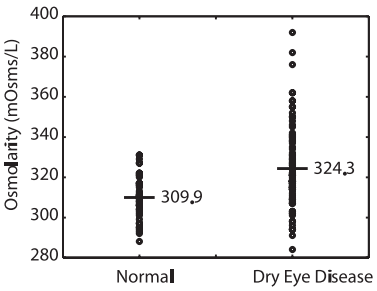
PERFORMANCE OF OSMOLARITY IN META-ANALYSIS*				
	Normal	Dry Eye	Total	
≤316	750	192	942	80% NPV
>316	65	429	494	87% PPV
Total	815	621	1436	
	Specificity 92%	Sensitivity 64%		

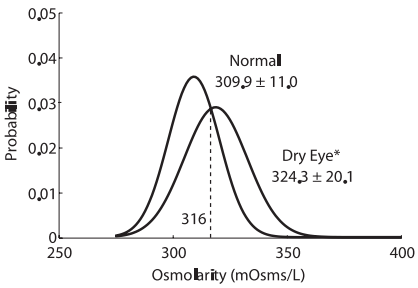
**Tomlinson A, Khanal S, Ramaesh K, Diaper C, McFadyen A. Tear Film Osmolarity: Determination of a Referent for Dry Eye Diagnosis, Investigative Ophthalmology & Visual Science, October 2006; 47(10) 4309-4315*

PERFORMANCE ON PATIENTS WITH OBJECTIVE SIGNS OF DRY EYE

140 subjects were enrolled in a multicenter study (n = 45 Normal, n = 95 Dry Eye). To qualify as a Dry Eye patient, subjects were required to have a positive score on the Ocular Surface Disease Index (OSDI) and 2 or more positive indications of Tear Film Breakup Time (TBUT), Schirmer Test, Corneal Staining, Conjunctival Staining, or Meibomian Gland Dysfunction. Performance using these selection criteria is shown in the table below.

SCOUTPRO DIAGNOSTIC PERFORMANCE FOR DRY EYE DISEASE				
	Normal	Dry Eye	Total	
≤316	32	34	66	48% NPV
>316	13	61	74	82% PPV
Total	45	95	140	
	Specificity 71%	Sensitivity 64%		





SPECIFICATIONS

POWER REQUIREMENTS

- Use only Power Supply Model PDM30US12 (XP Power)
- Power Supply is part of ME Equipment

POWER SUPPLY

- Input voltage: 100–240 VAC
- Input current: 0.6A MAX
- Frequency: 47–63 Hz
- Output voltage: 12 VDC
- Output current: 2.5A
- Class II
- Continuous service

SYSTEM CLASSIFICATION

- Class II: powered by Class II power supply
- Type B applied part
- The Test Card tip is the Applied Part
- Continuous service

PEN POWER SOURCE

- Input: 4.5–5.5 VDC 0.6A
- Internally powered by rechargeable battery
- Continuous service

ENVIRONMENTAL CONDITIONS

- Transport and storage temperature: 2°–35°C/36°–95°F
- Transport and storage relative humidity: 10%–85% noncondensing
- Transport and storage altitude: 0–2,000 meters
- Operating temperature: 15°–30°C/59°–86°F
- Operating altitude: 0–2,000 meters
- Operating relative humidity: 10%–85% noncondensing

HAZARDS

The ScoutPro is designed for stability, reliability, and safety, and it has been developed, manufactured, and marketed under a quality management system certified to ISO 13485 (2012).

The ScoutPro complies with the following materials:

- WEEE Directive 2012/19/EU Waste Electrical and Electronic Equipment
- RoHS Directive 2011/65/EU Restriction of Hazardous Substances
- IEC 60601-1 Medical Electrical Equipment — General Requirements for Basic Safety and Essential Performance
- RDC 306/2004 or any other applicable RDC — Brazilian requirements for disposal

The Osmolarity Test Cards do not contain reagents or chemicals. Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The American Academy of Ophthalmology (AAO) states: “Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA’s [Occupational Safety and Health Administration’s] bloodborne pathogens precautions; but exposure to human tears does require good office hygiene practices such as hand washing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.”[6] Proper handling and disposal methods of used Test Cards should be established according to relevant state and federal regulations. ScoutPro is designed to collect samples of tear fluid from the eye, a nonsterile environment. The AAO has issued guidance to minimize the transmission of ocular surface infectious agents. Prevention of transmission of these pathogens requires good hygienic techniques, such as washing hands and instruments that touch the eye. Refer to the “Maintenance” section of this manual for information about proper cleaning of the ScoutPro. Osmolarity Test Cards are for single use, are clinically hygienic and individually packaged, and contain a protective cover. Never reuse or attempt to clean a Test Card. Do not touch the Test Card tip after removal of the protective cover.

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 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.

PRECAUTIONS

OPERATIONAL PRECAUTIONS

- For professional in vitro diagnostic use only.
- Use only at ambient temperature of 15°–30°C/59°–86°F.
- Pen timer: In order to conserve battery life, the Pen is programmed to enter Sleep Mode automatically two minutes after it powers up.
- Osmolarity Test Cards are stable until the expiration date marked on the label.
- Leave Test Card in its sealed pouch until use.
- Do not remove the protective Test Card cover until the Test Card is attached onto a Pen. Remove the protective cover immediately prior to tear collection.
- Any Test Card that does not contain a protective cover should not be used for patient testing. A Test Card that has been contaminated or dropped without a protective cover should not be used for patient testing.
- A measurement should not be performed if a Pen that contains a Test Card with a patient sample has been dropped. Discard Test Card and perform test with an Electronic Check Card to verify that the Pen is performing correctly.
- Avoid touching the tip of the Test Card.
- Test Cards are for single use only. Never reuse or try to clean a Test Card.
- Tear collection should not be attempted if the green light on the Pen is not illuminated. The green light will not illuminate if battery power is low or the Test Card is used.
- Do not remove a Test Card from the Pen after tear collection until a measurement has been displayed. The Pen will not recognize a fluid-filled Test Card if it is removed and reattached onto the Pen.
- Refer to the “Contraindications” and the “How to Perform an Osmolarity Test” sections of this manual for tear fluid sample collection guidelines.
- Prior to use, inspect the ScoutPro and Test Card for physical damage. If anything is damaged, do not perform testing until the ScoutPro’s performance has been verified with both the Electronic Check Cards and Osmolarity Control Solutions.
- User should not touch Charging Base and patient simultaneously.

MAINTENANCE

The ScoutPro is designed to work without direct service or preventive maintenance. If quality checks fail, contact your sales representative or Trukera Technical Support (Tel: 858-455-6006).

The ScoutPro can be cleaned with a damp cloth or alcohol wipe as required. When cleaning, it is important to keep the electronic contacts of the Pen dry. The electronic contacts and Charging Base should also be kept free of dust and dirt. Cleaning fluids should never be used on the Test Cards.

TECHNICAL SUPPORT

For Technical Support contact your sales representative or Trukera Technical Support. See back cover for contact information.

REPLACEMENT PARTS

To order replacement parts, contact your local sales representative or Trukera Customer Support in your area for assistance.

TROUBLESHOOTING

PROBLEM	EXPLANATION	ACTION
Test Card is attached, green light does not illuminate, and Pen does not beep.	A. Test Card is not properly attached. B. Test Card is used. C. Pen battery is low. D. Pen electrical contacts are worn.	1. Remove Test Card and reattach if protective cover is still on. NEVER use a Test Card that does not have a protective cover. 2. Look at the top right of the ScoutPro display to assess battery charge level. 3. Use the Electronic Check Card to confirm Pen function. 4. Try a new Test Card. 5. Contact Trukera Technical Support.
Pen's green light turns off with an unused Test Card attached prior to tear collection.	A. Two minutes have passed since attachment of Test Card, and Pen has entered Sleep Mode. B. Pen battery is too low for tear collection.	1. Remove unused Test Card and reattach onto Pen. Proceed with tear collection. 2. Dock the Pen to allow battery to recharge. ScoutPro screen will indicate battery charging status.
Electronic Check Card does not fall within the expected value range.	The ScoutPro does not meet manufacturer specifications.	1. Check to see if battery is charged. If not, recharge battery. 2. Re-set the Pen by removing and then replacing batteries. 3. Retest.
Osmolarity Control Solution results do not fall within the expected value range.	Either Test Card or ScoutPro does not meet manufacturer specifications.	1. Check the expiration dates of the Test Card and Osmolarity Control Solutions. 2. Test with the Electronic Check Card. A. If results are out of range, contact Trukera Technical Support. B. If results are in range, retest Osmolarity Controls. If results are still out of range, contact Trukera Technical Support. 3. Do not perform patient testing until Osmolarity Control results fall within the expected value range.
When a Test Card is attached to the ScoutPro, a low battery warning is displayed.	Pen battery is low and testing cannot proceed.	Dock Pen into Charging Base to recharge batteries or replace with new batteries.

PROBLEM	EXPLANATION	ACTION
ScoutPro displays a Used Test Card Warning: “UC.”	Test Card has already been used. Test Cards are for single use. Pen will not accept a Test Card that has been used previously to collect tear fluid samples.	Remove the Test Card. If necessary, the previous test result can be recalled by pressing either button. Attach a new Test Card and proceed with testing.
ScoutPro displays an Above Range result: “AR.”	Test result was above 400 mOsm/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. Once value is confirmed, record patient result as “Above 400 mOsm/L.”
ScoutPro displays an Below Range result: “BR.”	Test result was below 275 mOsm/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. If Below Range persists, contact Trukera Customer Support.
Need to confirm which Test Card code was entered onto ScoutPro after an osmolarity test was performed.	Not sure if correct Test Card code was entered onto ScoutPro during test. Osmolarity test result may be inaccurate.	The Test Card Code used for a test is shown in the lower right corner of the current or previous result screen. Retest with a new test card and the correct code.
ScoutPro Charging Base fails to detect a docked Pen.	ScoutPro Pen or Charging Base electrical contact or battery failure.	Check to confirm that the Charging Base in plugged into an electrical outlet and that the outlet is working. Replace batteries, charge Pen, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact Trukera Technical Support.
ScoutPro LCD displays “ER.”	ScoutPro hardware or software error.	Reset pen by removing batteries. Replace batteries, charge Pen, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact Trukera Technical Support.

WARRANTY

The ScoutPro (“Product”) are warranted against defects in material and workmanship for 12 months from the date of delivery. The foregoing warranty is subject to the following conditions and exceptions:

Warranty excludes repair of failures resulting from mishandling or abuse. Warranty excludes consumable items such as Test Cards. Warranty does not apply to damage sustained in transit. Warranty service may be performed only by Trukera Medical (“Trukera”) or its authorized representative. Warranty is void if the Product has been modified or repaired by anyone other than Trukera or its authorized representative. Warranty is nontransferable. Warranty is void if the serial number tag is removed or altered. If the Product fails to conform to the foregoing warranty, you may return the nonconforming Product during the 12-month warranty period accompanied by (a) a copy of the sales receipt of the Product (for the purposes of evidencing the applicable warranty period) and (b) a Return Goods Authorization (“RGA”) for the defective Product, obtained from Trukera prior to initiating the shipment of the defective Product to Trukera. Products returned without a sales receipt and valid RGA shall be returned to you, with no further obligation by Trukera regarding the Product. If you return a Product in compliance with the foregoing requirements, Trukera shall repair or replace the Product as soon as is practicable.

THE REPLACEMENT OF THE NONCONFORMING PRODUCTS BY TRUKERA AS PROVIDED ABOVE SHALL BE YOUR SOLE AND EXCLUSIVE REMEDY FOR BREACH OF THE FOREGOING WARRANTY.

OTHER THAN AS WARRANTED ABOVE, THE PRODUCT IS PROVIDED AS IS. TRUKERA MAKES NO OTHER WARRANTIES RELATING TO THE PRODUCT, EXPRESS OR IMPLIED, AND EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NONINFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY.

In the event that you experience any difficulty with the ScoutPro, contact your local sales representative or Trukera Technical Support.

EMC AND SAFETY

SPECIFICATION	FREQUENCY RANGE
EN 55011: 2007, Group 1, Class ”A” Conducted Emissions	0.15 MHz–30.00 MHz
EN 55011: 2007, Group 1, Class ”A” Radiated Emissions	30.00 MHz–1000 MHz
EN 61000-3-2: 2000/A2: 2005 Power Line Harmonics	Up to the 40th Harmonic
EN 61000-3-3: 1995/A1: 2001/A2: 2005 Power Line Flicker	Less than or equal to 4% Maximum Relative Voltage Charge; Value of D (T) less than or equal to 3% for more than 200 ms
IEC 61000-4-3:2020 Proximity Fields from RF Wireless	Table 9 in IEC 60601-1-2 (4th editon)
IEC 61000-4-39:2017 Immunity to close proximity Magnetic Fields	30kHz-CW - 8A/m; 134. 2kHz - PM(2. 1kHz) - 65A/m; 1356 MHz PM (50kHz) - 7. 5/m

SPECIFICATION	MINIMUM TEST LEVEL REQUIRED PER EN 60601-1-2 FOR NON-LIFE-SUPPORT EQUIPMENT	TEST LEVEL COMPLETED
IEC 61000-4-2: 1995/A1: 1998/A2: 2000 - Electrostatic Discharge Immunity	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV
IEC 61000-4-3: 2006 - RF Radiated Fields Immunity	Radiation Field Strength of 3V/m 80–6000 MHz (80% AM @ 1 kHz)	Radiation Field Strength of 3V/m 80–6000 MHz (80% AM @ 1 kHz)
IEC 61000-4-4: 2004 + Corrigendum 1: 2006 - Electrical Fast Transient Immunity	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV
IEC 61000-4-5: 2005 - Lightning Surge Immunity	Power line surge of ± 2 kV common, ± 1 kV differential mode	Power line surge of ± 2 kV common, ± 1 kV differential mode
IEC 61000-4-6: 2004/A2: 2006 - RF Common Mode Immunity	150 kHz–80 MHz at 3 V_{RMS} 1 kHz 80% amplitude modulated	150 kHz–80 MHz at 3 V_{RMS} 1 kHz 80% amplitude modulated
IEC 61000-4-8: 1993/A1: 2000 - Power Frequency Magnetic Field Immunity	Helmholtz coil at 50 Hz and 60 Hz, to 3 Amps (RMS) per meter	Helmholtz coil at 50 Hz and 60 Hz, to 3 Amps (RMS) per meter
IEC 61000-4-11: 2004 - Voltage Dips and Short Interruptions	0% UT - 0.5 Cycles @0°, 45°, 90°, 135°, 180°, 225°, 270° & 315°; 0% UT - 1 Cycle; 70% UT - 25/30 Cycles @ 0°0% UT - 250/300 Cycles	Voltage dips of >95%, 30%, and 60%; interruptions of >95%

The ScoutPro is intended for use in an electromagnetic environment with controlled HF disturbances. The user of the ScoutPro Osmolarity System can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the ScoutPro device — depending on the output power of the telecommunication devices, as described below.

	SAFETY DISTANCE DEPENDING ON THE FREQUENCY IN m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz d={3,5/V1}√P	80 MHz to 800 MHz d={3,5/E1}√P	800 MHz to 2.5 GHz d={7/E1}√P
0.01	0.12	0.04	0.08
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.7	1.11	2.22
100	11.67	3.50	7.00

For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance, use the equation in the corresponding column. P is the maximum nominal power of the transmitter in watts (W) according to the specifications of the transmitter manufacturer.

NOTE: *These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects, and people.*

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GLOSSARY OF SYMBOLS			
	Date of manufacture		Use by date
	Manufacturer	SN	Serial number
IVD	In vitro diagnostic device	REF	Catalog number
	Consult Instructions for Use	EC REP	Authorized representative for the European Union
CONTROL	Control		Type B applied part IEC 60601-1

IVD For In-Vitro Diagnositc Use

CE

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EC REP

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E492172

MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA C22.2 No. 60601-1 (2014)

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

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