Performing Osmolality Testing Using the Advanced Instruments OsmoPRO Multi-Sample Micro-Osmometer

Principle

The Advanced Instruments OsmoPRO Multi-Sample Micro-Osmometer measures the freezing point of an aqueous solution to determine solute concentration. The freezing point of a solution is depressed in direct proportion to the solute concentration. Osmolality is the total solute concentration of an aqueous solution.

Purpose

This procedure is used to determine the osmolality of a patient's plasma, serum, or urine specimen. The assessment of osmolality is critical in the diagnosis of disorders of water and solute balance, as well for monitoring mannitol therapy. Osmolality can be altered by hyperuremia, dehydration, overhydration, hyperglycemia, mannitol therapy, toxin ingestion, and inappropriate secretion of antidiuretic hormone.

Specimen Requirements

Specimens:

- Serum (preferred)
- Plasma – Lithium heparin (acceptable)
- Urine – centrifuged to remove particulate matter.

Stability:

- Room temperature: 48 hours.
- Refrigerated: Up to 1 week.

Materials Needed

- Disposable micro-sample tubes (AI #202825)
- Probe wiper rings (AI #202840)
- 20 µL MLA pipette and tips
- Printer paper (AI #FLA835)
- Swab cleaner kit (AI #202850)
- Isopropyl alcohol
- Kimwipes or other lint-free wipes
- Compressed air
- Mild soap

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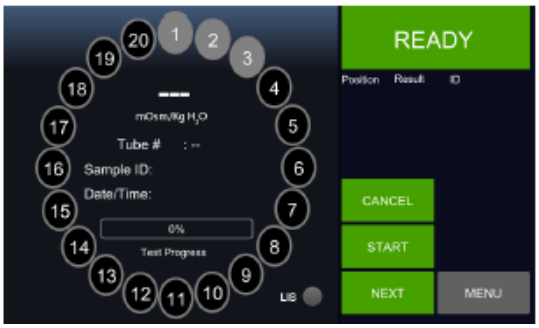
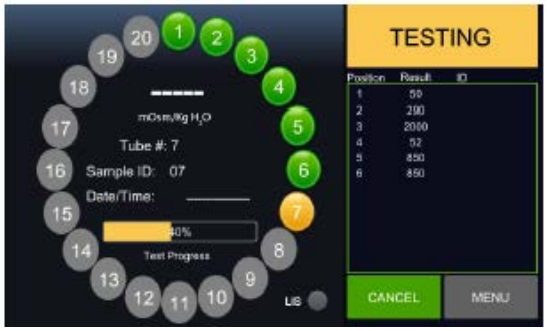
Instrument Icons and Indicators

Icon	Description	Icon	Description	Icon	Description
	Legend Information		Assistance		Error
	LIS connected		LIS disabled		LIS enabled and not connected
	Keyboard		Calendar		USB
	Operator and supervisor access		Supervisor only access		
	Search filter		Clear search filter		Clear selection
	Top page		Page up		Left arrow
	Bottom page		Page down		Right arrow

READY status display:



TESTING IN PROGRESS status display:



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Instrument Icons and Indicators, continued

Turntable position colors:

Color	Status
Black	Unused / Empty
Green	Test complete
Grey	Ready
Yellow	Test in progress
Red	Error

Quality Control

Quality control testing of the OsmoPRO analyzer will be performed once per day of patient testing.

Materials needed:

- Clinitrol 290 Reference Solution (AI #3MA029). Store at 2-30°C, discard open vial after use.
- Serum Controls:
  - (CH1) Liquid Unassayed Multiqual (Bio-Rad Laboratories) Level 1
  - (CH3) Liquid Unassayed Multiqual (Bio-Rad Laboratories) Level 3

  Unopened controls: store in freezer -20 - -70°C.

  Opened controls: store refrigerated 2 – 8°C. Stable for 7 days or manufacturer's expiration, whichever is sooner.
- Urine Controls:
  - (URCH1) Liquichek Urine Chemistry (Bio-Rad Laboratories) Level 1
  - (URCH2) Liquichek Urine Chemistry (Bio-Rad Laboratories) Level 2

  Unopened controls: store in refrigerator 2 – 8 °C.

  Opened controls: store in refrigerator 2 – 8 °C. Stable for 30 days or until the manufacturer's expiration, whichever is sooner.

Quality Control Procedure:

- Run Clinitrol 290 Reference Solution in triplicate with each QC run.
- Run each control (CH1, CH3, URCH1, and URCH2) in triplicate once daily.
- QC must be within acceptable limits prior to reporting patient testing (see Evaluating Results for criteria).
- Record the result for each control in Sunquest, and evaluate for acceptability:
  - Function: **MEM**
  - Worksheet: **RVOSMO**
  - Control mnemonics: **C-CH1, C-CH3, C-URCH1, C-URCH2**

Calibration

Calibration of the OsmoPRO analyzer will be performed:

- When repeated unacceptable results with Clinitrol 290 Reference Solution and/or controls are encountered. (*Note: troubleshoot prior to calibrating, i.e. – clean the cooling well, if necessary. Record action(s) taken in the "Problems/Corrective Action" section of the OsmoPRO Maintenance Log.)*
- When the ambient temperature changes more than 5°C from the last calibration.
- Following major maintenance or repair (i.e., probe change, etc.).

Materials needed:

- Calibration Standards (Advanced Instruments, Inc.). Store at 2-30°C, discard open vial after use.
  - 50 mOsm/kg (AI #3MA005)
  - 850 mOsm/kg (AI #3MA085)
  - 2000 mOsm/kg (AI #3MA200)

Calibration Procedure:

Step	Action
1.	With the instrument in READY status, press MENU.
2.	Press CALIBRATION
3.	Remove and empty the turntable.
4.	Install a new probe wiper ring.
5.	Pipette 20 µl of each standard into *three* sample tubes. Load the sample tubes into designated positions as follows: • 2000 mOsm/kg standard in positions 1 to 3. • 850 mOsm/kg standard in positions 4 to 6. • 50 mOsm/kg in positions 7 to 9.
6.	Re-install the turntable on the instrument with evaporation cover.
7.	Press START
8.	When the calibration has completed, a status window displays:

If	Then
Calibration passed	• Press OK • Proceed with running QC
Calibration failed	• The reason for the failure and follow-up instructions will display. • Follow the instructions displayed, then repeat calibration (Steps 1-7). • If the error persists, refer to the Troubleshooting section of the User's manual for additional corrective action. If unable to resolve, contact the SRMC BioMed / eQuip team.

Loading and Running Samples

Removing / Installing the Turntable and Probe Wiper Ring:

Step	Action
1.	Loosen the turntable locking screw on center knob.
2.	Lift the turntable slightly to clear the drive spindle and pull it forward until clear of the instrument. Take care not to strike or damage the probe assembly.
3.	Set the turntable on a flat surface.
4.	Remove the evaporation cover and discard the used probe wiper ring and sample tubes in the appropriate biohazard container.
5.	Place a new probe wiper ring on the turntable, with the wiper ring locating tab in one of the depressions located at position 1 or 11. Verify all turntable position numbers are visible within the radial holes of the wiper ring.
6.	Place the evaporation cover over the turntable center knob (logo side face up) with the squared slot centered at position 1 and facing the instrument.
7.	Grasp the turntable by the center knob and place it on the drive spindle so that the flat side of the evaporation cover fits into the opening in the instrument cover.
8.	Slowly push the turntable forward, twisting slightly until it aligns and drops down over the drive spindle.
9.	Hold the outer edge of the turntable / evaporation cover and tighten the turntable locking screw. Make sure the locking screw is secure but do not over-tighten it.

Loading Samples:

NOTE: If performing patient testing, print a worksheet first (Function **WO,** Worksheet **RVOSMO**).

Step	Action
1.	With the instrument in READY status, press LOAD. The turntable will move to the next available position.
2.	Scan the specimen CID barcode, or manually enter specimen/ standard/ control ID, then press ENTER.
3.	Pipette 20 µL of sample onto the bottom of a sample tube. **NOTE:** Avoid pipetting sample on the side of the tube or dragging the tip on the interior of the tube while removing.

Loading and Running Samples, Continued

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4.</td><td>Before proceeding, visually inspect the sample tube and verify the entire sample volume is at the bottom of the tube with NO air bubbles present:
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Some sample is on the side of the tube</td><td>Gently tap the bottom of the tube to move the sample to the bottom. If unsuccessful, discard the tube and repeat steps 3 – 4.</td></tr>
<tr><td>An air bubble is present</td><td>Discard the tube and repeat steps 3 – 4.</td></tr>
</table></td></tr>
<tr><td>5.</td><td>Place the sample tube in the load position on the turntable.</td></tr>
<tr><td>6.</td><td>If additional sample(s) are to be loaded, press NEXT. Repeat Steps 2-5 for each additional sample.
NOTE: If loading is interrupted for more than two minutes, the instrument will prompt the user to continue loading. If no response to the prompt entered within 30 seconds, the instrument cancels the loading process and marks the loaded, untested positions as empty.</td></tr>
<tr><td>7.</td><td>When sample loading is complete, press START.</td></tr>
<tr><td>8.</td><td>When testing is complete, record the patient result on the worksheet. Attach printout to the worksheet.</td></tr>
</table>

Evaluating Results

Quality control and patient result replicates must fall within the following parameters of reproducibility before being considered acceptable:

- **Clinitrol 290 Reference Solution:** Report the last replicate result that agrees within 3 mOsm/kg. This result must fall within the acceptable range:

  286 – 294 mOsm/kg.

- **Quality Control:** Report the last replicate result that agrees within 3 mOsm/kg. This result must fall within each control's established and acceptable range.
- **Patient Sample, 0 – 400 mOsm/kg:** Report the last replicate result that agrees within 3 mOsm/kg.
- **Patient Sample, 401 – 2,000 mOsm/kg:** Report the last replicate result that agrees within 1.0%.

Note: If replicates do not agree within the limits of acceptability, then perform additional testing to attain results within limit.

Locating Previous Test Results

Step	Action
1.	With the instrument in READY status, press MENU.
2.	Press RESULTS NOTES: • The instrument stores the last 1,000 test results in its database. • The result database displays Sample ID, Test Result, Date/time of test, and Position.
3.	Search the database to locate the desired result by: • Using the scroll bar to move up/down through the database • Using icons located at the top of the screen to filter and search. o Press SEARCH FILTER icon. o Enter the desired search filter. o Press SEARCH
4.	If needed, result can be printed, or statistics calculated by pressing each desired result (selected results will highlight in blue), then: • Press PRINT to print results, OR • Press STATISTICS to calculate mean, standard deviation, and CV for up to 20 selected results. Press PRINT to print the statistics.
5.	Press EXIT to return to the Main screen.

Reporting Results

- Enter results into Sunquest: Function: **MEM**, Worksheet: **RVOSMO**.
- After accepting a result, verify the accuracy of the reported result and write RVS and your initials or tech code on the testing worksheet.
- Retain the testing worksheet in the designated location.

Reference Ranges

- Serum / Plasma: 278 – 305 mOsm/kg
- Urine: 40 – 1400 mOsm/kg

Critical Value, Serum/Plasma

< 251 mOsm/kg
> 319 mOsm/kg

Technical Limit	0 – 2000 mOsm/kg **NOTE:** If the result is >2000 mOsm/kg, report as >2000 mOsm/kg.

Method Limitations

- Particulate matter can cause premature crystallization. Centrifuge samples prior to testing.
- Samples with air bubbles may yield inaccurate results. Pipetted sample tubes must be visually verified to be free of air bubbles prior to loading on instrument.
- Samples allowed to evaporate will yield higher osmolality values. Protect samples from evaporation by 1) Keeping specimen tubes tightly capped, and 2) using turntable evaporation cover during test runs.
- Non-aqueous solutions may NOT be used.
- Highly viscous solutions may yield inaccurate results.
- High concentrations of ethanol, acetone, methanol, isopropanol, ethylene glycol, diethyl ether, paraldehyde, trichloroethane, or propylene glycol may yield inaccurate results. Appropriate comment will be appended to result when sample is known to contain any of these substances.

Reproducibility Tips

- Treat all samples and standards uniformly.
- Always have samples, controls, and standards at room temperature for testing.
- Avoid contamination and evaporation by covering all samples, controls, and standards when not being tested. Keep samples in the turntable covered with the evaporation plate.
- Serum/plasma samples and urine samples should be batched separately for best results.
- Carefully wipe the loaded sample tip with a lint free tissue without wicking sample from the tip. The sample should not extend beyond the end of the sample tip.
- Dispense the sample to the bottom of the sample tubes, angling the pipette tip slightly to the side. Do not splash or spray the sample on the upper sides of the tube.
- Do not leave air bubbles at the bottom of the tube or voids in the sample.
- Handle the turntable gently. Jarring the turntable may introduce bubbles to the samples or cause the samples to separate.
- Do not rerun the samples in the same tube. Use new aliquots into clean sample tubes to repeat testing.
- Do not reuse wiper rings.

Maintenance

- Completion of maintenance tasks will be documented on Form A: OsmoPRO Maintenance Log
- Quality control testing must be run following maintenance.

Daily: Inspecting/Cleaning the Sample Probe

Step	Action
1.	With the instrument in READY status, remove the turntable.
2.	Lower the sample probe by pressing: a) MENU b) DIAGNOSTICS c) CLEANING d) LOWER PROBE
3.	Inspect the condition of the probe. If damaged, the probe must be changed.
4.	Clean the probe by gently wiping with lint-free wipe dampened with isopropyl alcohol.
5.	When finished, press DONE.
6.	Return to the Main screen by pressing: a) EXIT b) HOME
7.	Re-install the turntable when finished with maintenance.

Weekly: Cleaning the Cooling Well

Step	Action
1.	With the instrument in READY status, remove the turntable (if not already done).
2.	Dampen a flexible swab (from Swab Cleaner Kit) with isopropyl alcohol.
3.	Insert the swab into the round opening of the cooling well and wipe inside of well.
4.	Discard swab when finished.
5.	Re-install the turntable when finished with maintenance.

Monthly: Checking/Cleaning Exhaust Fans

Step	Action
1.	Examine the two exhaust fans at the top and bottom of the analyzer for dust, debris, and/or obstructions: **If** / **Then** Not obstructed / No further action needed Dust/debris/obstruction present / Proceed to Step 2
2.	Locate the power switch on back of instrument and power OFF the instrument.
3.	Use compressed air to remove the dust/debris from the fan(s).
4.	When finished, power ON the instrument.

Semi-Annual: Checking/Cleaning the Solenoid

Step	Action
1.	Locate the power switch on back of instrument and power OFF the instrument.
2.	Disconnect the power cord.
3.	Loosen the screws on the rear access panel and remove the panel.
4.	Loosen the two solenoid bracket screws and *carefully* remove the solenoid plunger and spring.
5.	Examine the solenoid plunger. If the plunger shows signs of fouling or residue, clean the plunger by wiping.
6.	Re-install the solenoid plunger/spring and re-attach the bracket.
7.	Re-attach the rear access panel.
8.	Connect the power cord and power ON the instrument.

Annual: Cleaning the Instrument Exterior

Step	Action
1.	Using gauze dampened with warm, soapy water, wipe down the exterior of the instrument. If needed, isopropyl alcohol can be used to further decontaminate the exterior. NOTE: • DO NOT allow liquid to enter the cooling chamber or other areas of the instrument. • DO NOT use abrasive cleaners or scouring pads.
2.	Remove soap residue by wiping with gauze dampened with water.

As Needed: Loading Printer Paper

Step	Action
1.	Open the printer door at the top of the instrument.
2.	Remove and discard the empty paper roll.
3.	Unroll approximately 4 – 6 inches of paper from a new roll.
4.	Place the paper roll in the printer so that the paper feeds from the bottom of the roll toward the front of the instrument.
5.	Close the printer door until it snaps shut. The unrolled paper should protrude from the printer slot with the door closed.

Document maintenance activities on the OsmoPRO Maintenance Log, CM.ANA09.01-F:A-RV.01.

Consult the user's guide, eQuip and/or Advanced Instruments technical support for additional maintenance and troubleshooting procedures as needed.

Reference

- OsmoPRO Multi-Sample Micro-Osmometer User's Guide, Advanced Instruments, 112005EN Rev0 022217

Attachment

OsmoPRO Maintenance Log, CM.ANA09.01-F:A-RV.01