



Installation & Training Guide

Osmo1 Osmometer



Disclaimer

- For full installation and setup instructions as well as detailed instrument operation please refer to the Osmo1 User Manual.



Topics

Installation and Setup

Instrument Operation

Standards and Controls

Calibration

Maintenance

Installation and Setup

- Step 1 – Find a location for the instrument
 - Ensure adequate space
 - Use a properly grounded, three-prong electrical outlet capable of supplying 0.5 amperes at 100-240 VAC (50-60 Hz) within 5 feet of instrument placement
- Step 2 – Unpack the instrument
 - Use enclosed packing list to verify all accessories and supplies were received
 - If any items are damaged or missing, notify the carrier, dealer, and Advanced Instruments within 24 hours
 - Complete the online warranty card to register your product

Installation and Setup

- Step 3 – Load the printer paper
 - Lift to open printer door located on the top right of the instrument.
 - Unroll 4-6" (15-20 cm) of thermal paper from the roll.
 - Hold the rolls so that the paper feeds upwards from the bottom of the roll towards the front of the instrument, and place the roll into the printer.
 - Gently close the printer door with the unrolled paper end outside the print slot. The door snaps closed.



Installation and Setup

- Step 4 – Place the Micro-Sample Test Kit on the instrument
 - A Micro-Sample Test Kit (part number: 133800) must be in place on the top left of the instrument before testing can begin. The box must be oriented so that:
 - The photo of the instrument and the box label are toward the back.
 - The dispensing flaps for the chamber cleaners and sampling tips are toward the front.
 - If a Micro-Sample Test Kit is not in place on the instrument when you attempt to run a test, you will receive the error “AI consumable box not detected”.



Installation and Setup

- Step 5 – Connecting to a network (optional)
 - To connect the Osmo1 to a laboratory information system (LIS) and/or to a local area network (LAN), plug an Ethernet cable that connects to your network into the Ethernet port on the back of the Osmo1 unit. Refer to the User Guide to configure the communication settings in the Osmo1 software.



Installation and Setup

- Step 6 – Powering up the instrument
 - Connect the power cord to the back of the instrument and insert the plug into the power outlet.
 - Turn on the power to the instrument using the rocker switch on the back. Depress the side marked with the **I** symbol. When the unit powers up, the Welcome screen displays.
 - After a few moments, the Osmo1 Home screen displays. From the Home Screen, you can initiate sample testing and view the results, Initially, the instrument status shown in the green status banner is *Osmometer Ready*.



Installation and Setup

- Step 7 – Configuring the Osmo1 settings
 - Review and/or configure the following instrument settings before using the Osmo1. Refer to the User Guide for instructions.
 - If the unit's language is not set appropriately for your site, change the language settings.
 - If the date or time displayed on the unit is incorrect, set the current date and time.
 - If desired, set up user accounts.
 - If desired, assign restrictions for operator-level accounts, set the password expiration period, define whether the system will use 2-point or 3-point calibration, and configure the system to require a User ID and/or Sample ID before beginning a test.
 - If desired, configure the Osmo1 to communicate with your laboratory information system (LIS).
 - If desired, configure the Osmo1 to connect to your local area network (LAN).
 - If desired, set up control limits.

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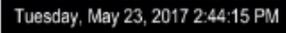
Instrument Operation

- Major components



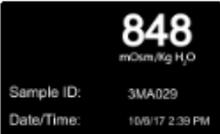
Instrument Operation

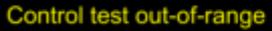
- Touchscreen: Common elements

Item	Description/Use
	Status indicator: <ul style="list-style-type: none">• Green: Normal operation• Red: System error condition• Yellow: Test in progress• Orange: IDs required
	Current date and time
	Sampler-tip status: <ul style="list-style-type: none">• White: Displays number of sampler tips remaining in box (while count is 50 or higher).• Yellow: Displays "<50" when the number of sampler tips remaining is less than 50.
	System tray may contain: <ul style="list-style-type: none">• Legend of LIS connection colors• Assistance contact info• Message alert Tap icon to display contents.
	Tap to display the Home screen (not displayed on the Home screen)

Instrument Operation

- Touchscreen: Home screen elements

Item	Description/Use
	<p>Login button</p> <p>NOTE: The color of the Login button indicates the login status:</p> <ul style="list-style-type: none">• Gray: No one is logged in.• Orange: No one is logged in; login is required to begin testing. (See "Requiring IDs for testing" on page 48.)• Green: A user is logged in. The username displays next to the icon. <p>To log in: Tap the Login button (gray or orange) to display the user list. Then select your username from the list and enter your password.</p> <p>To log out: Tap the (green) Login button.</p>
	<p>Latest test sample osmolality reading, sample ID, date and time of last test</p>
	<p>Test progress bar</p>

Item	Description/Use
	<p>Test progress bar</p>
	<p>Sample ID button</p> <p>Tap the button to display a keyboard and activate the barcode scanner; then use the keyboard or barcode scanner to enter the sample ID.</p> <p>NOTE: The color of the button indicates the Sample ID status:</p> <ul style="list-style-type: none">• Blue: Sample ID is optional.• Orange: Sample ID is required. (See "Requiring IDs for testing" on page 48.)
	<p>Example of a warning message</p>
	<p>Tap to display the Main menu</p>

Instrument Operation

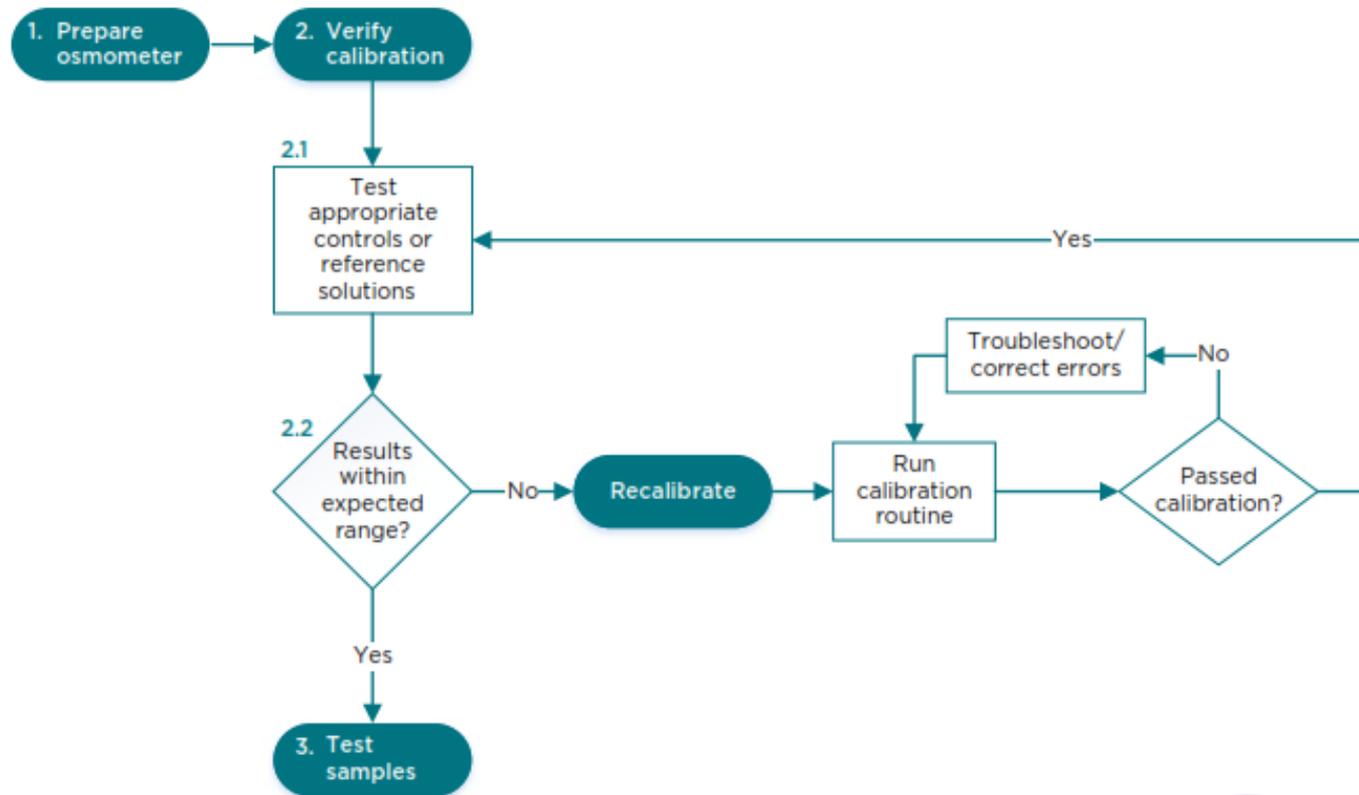
- Touchscreen: Main menu
 - Access to Main menu via Home screen



Function	Description/Use
Calibration	Displays the Calibration screen; see Chapter 4 on page 30 for details. NOTE: The Osmo1 has been calibrated at the factory. However, you should recalibrate it in certain circumstances. See "When to recalibrate" on page 30 for more information.
Results	Displays a list of test results; see Chapter 5 on page 33 for details.
Settings	Displays the Settings menu for access to configuration options; see Chapter 6 on page 35 for details.
Diagnostics	Displays the Diagnostics menu for access to system tests and performance data; see Chapter 7 on page 50 for details.

Instrument Operation

- Daily procedure



Instrument Operation

- Preparing the Osmo1 for testing
 - Before starting a test, verify that:
 - The Osmo1 is displaying the Home screen.
 - The empty operating cradle is in the furthest position from the sample port.
 - Any cleaner from a previous test is removed from the port and discarded.
 - The Micro-Sample Test Kit (part number 133800) is properly installed.

Instrument Operation

- **Testing Procedure**

1. If applicable: Log in with your User ID.
2. If applicable: Enter the Sample ID.
3. Place a new sampling tip on the sampler with the plunger wire inserted carefully into the middle of the tip. Verify that the tip is straight and firmly seated.



Refer to User Guide for more information.

Instrument Operation

- Testing Procedure (continued)

4. With your thumb on the plunger top and fingers grasping the barrel, depress the plunger; then insert the tip into the liquid sample at least $\frac{1}{4}$ " (6 mm) below the surface. Gently release the plunger to load a 20 μ L sample.



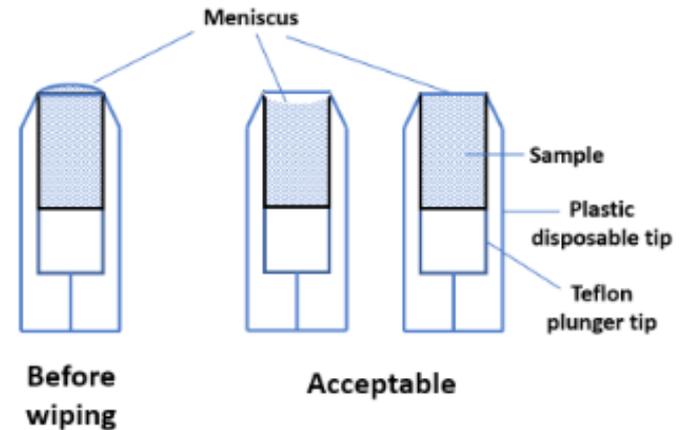
5. Look at the sample you have just drawn. If there are voids or bubbles in the sample, discard it and load another sample that does not contain voids.

Refer to User Guide for more information.

Instrument Operation

- Testing Procedure (continued)

6. Remove any sample on the outside of the tip using a clean, lint-free, non-ionic paper. Quickly swipe the end of the sampler tip to remove any excess sample protruding beyond the tip. Be careful not to remove any of the sample below the acceptable meniscus line.



Refer to User Guide for more information.

Instrument Operation

- Testing Procedure (continued)
 7. Holding the sampler by the barrel, carefully insert the tip into the sample port; then rest the sampler in the operating cradle.
 8. Grasp the operating cradle and push it slowly forward until you feel a positive stop. The test starts when the cradle reaches the forward position.
 9. Wait while the Osmo1 performs the test. When the test completes, the resulting osmolality displays in the middle of the screen.



Refer to User Guide for more information.

Instrument Operation

- Testing Procedure (continued)
 10. Withdraw the operating cradle and remove the sampler from the cradle.
 11. Grasp the sampler tip and depress the plunger to help remove it. Discard the sampler tip.
 12. Wipe the plunger tip with a soft, non-lint, non-ionic paper, being careful not to dislodge the Teflon[®] tip.
 13. Insert a clean, dry chamber cleaner into the sample port until you feel a positive stop. Rotate four or five times in one direction while applying forward pressure.
 14. Withdraw the cleaner and use the other end to clean the probe again in the same manner. Leave the cleaner in the sample port until the next test.



Refer to User Guide for more information.

Instrument Operation

- Sample requirements – Plasma & Serum
 - Volume
 - 20 µL per test
 - Collection/Preparation
 - Follow your laboratory's procedure for collecting and preparing plasma and serum.
 - Evacuated tubes containing gel for serum separation are acceptable for obtaining specimens for determination of osmolality.
 - Storage
 - Plasma and serum specimens should be tested as soon as possible after collection in order to obtain accurate osmolality results in clinical laboratories.
 - When immediate processing of serum specimens is not possible, samples can be refrigerated or stored at room temperature for up to forty-eight (48) hours and can be tested for osmolality without significant bias. It is recommended, however, that user's test plasma and serum specimens within twenty-four (24) hours of collection.¹
 - Prior to analysis, plasma and serum specimens must be warmed to room temperature.

¹Curria A, et. al. 2009. Refrigerated and Room Temperature Storage Stability of Serum Osmolality Measurements. Advanced Instruments Technical Literature

Instrument Operation

- Sample requirements – Urine
 - Volume
 - 20 μL per test
 - Collection/Preparation
 - Follow your laboratory's procedure for collecting and preparing urine.
 - Use containers without preservatives.
 - Centrifuge urine to remove gross particulate matter.
 - Storage
 - Urine specimens should be tested as soon as possible after collection in order to obtain accurate osmolality results in clinical laboratories.
 - When immediate processing of urine specimens is not possible, samples can be refrigerated or stored at room temperature for up to twenty-four (24) hours and can be tested for osmolality without significant bias.¹
 - Prior to analysis, urine specimens must be warmed to room temperature.

¹Curria A, et. al. 2009. Refrigerated and Room Temperature Storage Stability of Serum Osmolality Measurements. Advanced Instruments Technical Literature

Instrument Operation

- Sample requirements – Stool
 - Volume
 - 20 μL per test
 - Collection/Preparation
 - Follow your laboratory's procedure for collecting and preparing stool.
 - Storage
 - Stool specimens should be tested as soon as possible after collection in order to obtain accurate osmolality results in clinical laboratories.
 - When immediate processing of stool specimens is not possible, samples can be refrigerated to minimize changes to the original osmolality due to evaporation or bacterial decomposition.
 - Prior to analysis, stool specimens must be warmed to room temperature.

Topics

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Standards and Controls

- Quality Control
 - This section outlines the quality control materials and their intended use as recommended by Advanced Instruments for the Osmo1 Osmometer. It is recommended that laboratories incorporate these materials into your quality control management system.
- Regulatory Guidance
 - College of American Pathologists (CAP): For quantitative tests, CAP requires that laboratories run 2 controls at 2 different concentrations daily or with each batch of samples/reagents.¹

¹CAP Chemistry Checklist revised 7/28/2015, CHM.13900 Daily QC - Nonwaived Tests.

Standards and Controls

- Clinitrol™ 290 Reference Solution
(Part No. 3MA029)
 - Intended for use in evaluating the performance of your osmometer. Clinitrol is a true reference designed specifically for osmometers and provides results that approximate the osmolality of normal serum. Use Clinitrol:
 - Daily, prior to testing samples, to verify instrument operation and confirm calibration.
 - After performing a calibration.
 - To strengthen your laboratory's Quality Control program by using products made specifically for your osmometer.

Refer to the product insert for more information.

Standards and Controls

- Protinol™ Protein-Based Osmolality Controls (Part No. 3MA028)
 - Intended for use in evaluating the performance of your osmometer. Protinol Controls are formulated to mimic serum at 240, 280, and 320 mOsm/kg H₂O. Use Protinol:
 - Daily, prior to testing samples, to verify instrument operation and confirm calibration.
 - After performing a calibration.
 - To strengthen your laboratory's Quality Control program by using products made specifically for your osmometer.

Refer to the product insert for more information.

Standards and Controls

- Renol™ Urine Osmolality Controls
(Part No. 3LA085)
 - Intended for use in evaluating the performance of your osmometer. Renol Controls are formulated to mimic urine at 300 and 800 mOsm/kg H₂O. Use Renol:
 - Daily, prior to testing samples, to verify instrument operation and confirm calibration.
 - After performing a calibration.
 - To strengthen your laboratory's Quality Control program by using products made specifically for your osmometer.

Refer to the product insert for more information.

Standards and Controls

- Osmolality Linearity Set
(Part No. 3LA028)
 - Designed to help clinical laboratories easily monitor osmometer performance specifications and fulfill CLIA requirements for verifying the reportable range of a laboratory method. Use the linearity set:
 - To verify the linearity and reportable range of the instrument.
 - After performing a calibration.

Refer to the product insert for more information.

Standards and Controls

- Interpreting Results
 - Data generated using Advanced Instruments standards and reference solutions may be analyzed according to the accuracy and precision specifications of the instrument.

	Manufacturer's Specifications
Accuracy	<ul style="list-style-type: none">• ≤ 2 mOsm/kg H₂O from nominal value from 0 to 400 mOsm/kg H₂O (1 SD)• $\leq 0.5\%$ from nominal value from 400 to less than 1500 mOsm/kg H₂O (1 SD)• $\leq 1\%$ from nominal value from 1500 to 2000 mOsm/kg H₂O (1 SD)
Precision (Within-Run Repeatability)	<ul style="list-style-type: none">• Standard deviation ≤ 2 mOsm/kg H₂O from 0 to 400 mOsm/kg H₂O (1 SD)• Coefficient of variation $\leq 0.5\%$ from 400 to less than 1500 mOsm/kg H₂O (1 SD)• Coefficient of variation $\leq 1\%$ from 1500 to 2000 mOsm/kg H₂O (1 SD)

Accuracy and precision (within-run repeatability) specifications apply to Advanced Instruments standards and reference solutions. Performance at Reference Conditions: 20°C to 25°C (68°F to 77°F); 40 to 60% relative

Refer to User Guide for more information.



Standards and Controls

- Expected Ranges (Refer to User Guide for more information)
 - Laboratories may choose to employ one, two, or three standard deviations for accuracy based on what is relevant in their laboratories. For normally distributed data, approximately 68% of the individual data values will fall within one standard deviation of the mean, approximately 95% within two standard deviations, and approximately 99.7% within three standard deviations. Expected ranges using two standard deviations are shown below for Clinitrol 290 Reference Solution and the Osmolality Linearity Set.
 - Clinitrol 290 Reference Solution
 - 286-294 mOsm/kg H₂O (2 SD)
 - Protinol Protein-Based Controls
 - Protinol 280: 233-247 mOsm/kg H₂O (per product insert)
 - Protinol 280: 273-287 mOsm/kg H₂O (per product insert)
 - Protinol 320: 313-327 mOsm/kg H₂O (per product insert)
 - Renol Urine Osmolality Controls
 - Renol 300 mOsm/kg H₂O is 290-310 mOsm/kg H₂O (per product insert)
 - Renol 800 mOsm/kg H₂O is 790-810 mOsm/kg H₂O (per product insert)
 - Osmolality Linearity Set Expected Ranges
 - 100 mOsm/kg H₂O: 98-102 mOsm/kg H₂O (2 SD)
 - 500 mOsm/kg H₂O: 497.5-502.5 mOsm/kg H₂O (2 SD)
 - 900 mOsm/kg H₂O: 895.5-904.5 mOsm/kg H₂O (2 SD)
 - 1500 mOsm/kg H₂O: 1492.5-1507.5 mOsm/kg H₂O (2 SD)
 - 2000 mOsm/kg H₂O: 1990-2010 mOsm/kg H₂O (2 SD)

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Calibration

- The Osmo1 was factory calibrated and the calibration data is stored within its memory.
- The instrument is ready to begin all testing, as soon as the instrument is removed from packaging.

Calibration

- Step 1 – From the Home screen, tap the menu icon. The main menu displays.
- Step 2 – From the Main menu, tap **Calibration**. The system prompts you to log in.
- Step 3 – Login and follow the on-screen instructions to test samples from each specified standard five times. You will test samples of known standards: either 50 and 850 mOsm/kg H₂O for a 2-point calibration; or 50, 850, or 2000 mOsm/kg H₂O for a 3-point calibration.
- Step 4 – Upon completion of the last calibration test, the system displays a “Calibration successful” message or the reason for failure. Click OK to close the success (or failure) message.

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Maintenance

- Osmo1
 - Cleaning the instrument exterior – Periodically wipe the instrument with a barely-damp cloth. Use either warm soapy water or isopropyl alcohol to dampen the cloth.
 - Cleaning air vents – Make sure the fan on the back of the instrument has no accumulated dust and debris that could impede air flow. Dirty air vents can cause instrument overheating and reboots.
 - Chamber cleaning – If you experience multiple “Sample Pre-freeze” errors, or if you suspect contamination of the sample probe, clean the cooling chamber with a chamber cleaner that has been dampened with water.
 - Cleaning the Solenoid – A dirty solenoid can cause “Sample Did Not Freeze” errors and can affect instrument accuracy and repeatability. Instruments used daily should be cleaned monthly, while instruments that are used less frequently should be cleaned every three months.
 - Replacing the fuse – If you determine that your instrument is not functioning because of blown fuses, you will need to replace the fuses.
- 20 µL Ease-Eject™ Sampler
 - To ensure proper instrument operation: you should replace the plunger wire tip of the sampler every 500 tests (or every time you empty a Micro-Sample Test Kit). Failure to replace the plunger wire may affect instrument accuracy and repeatability.
Note: A sampler plunger wire is included with each Micro-Sample Test Kit.

Refer to User’s Guide for additional information



Customer Service/Technical Support

Please review the Osmo1 User Guide for more detailed instructions.

You can contact Customer Service during normal business hours at 800-225-4034 or via email at orders@aicompanies.com.

Technical Support is available 24/7:

- 800-225-4034

