



# OsmoTECH<sup>®</sup> PRO

## Multi-Sample Micro-Osmometer

Because an optimized bioprocess is non-negotiable.

# Designed to meet your most complex bioprocessing needs

We recognize that biopharmaceutical manufacturing involves many complex operational steps. Ensuring that the entire manufacturing process consistently produces a biopharmaceutical product of predetermined yield, purity, and quality is of the utmost importance.

Leveraging our expertise in osmolality testing, Advanced Instruments has developed a portfolio of osmometers to suit the unique needs of the biotech industry.



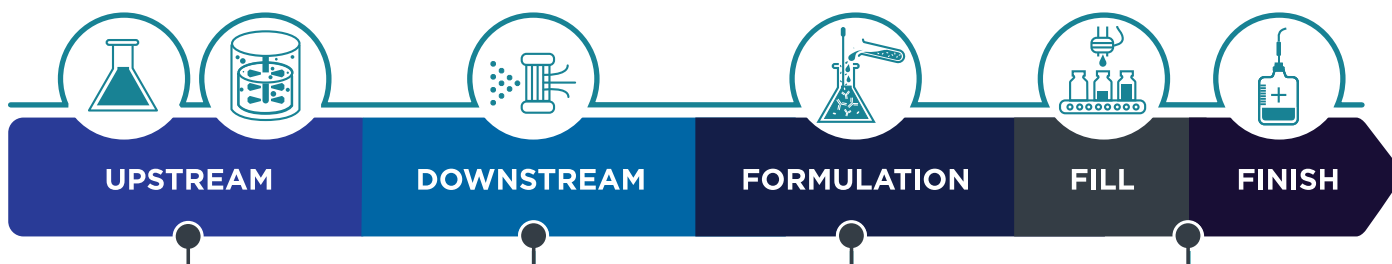
## Optimize your bioprocess with OsmoTECH PRO

The OsmoTECH PRO osmometer is an accurate, precise, and easy to use instrument that incorporates freezing point depression technology to test osmolality—an essential parameter for process control and QC.



In a class of its own, OsmoTECH PRO is enhanced with advanced data management options and can integrate seamlessly into your high throughput workflow.

**Osmolality testing is an in-process control and quality-check used throughout the development and manufacture of biologics.**



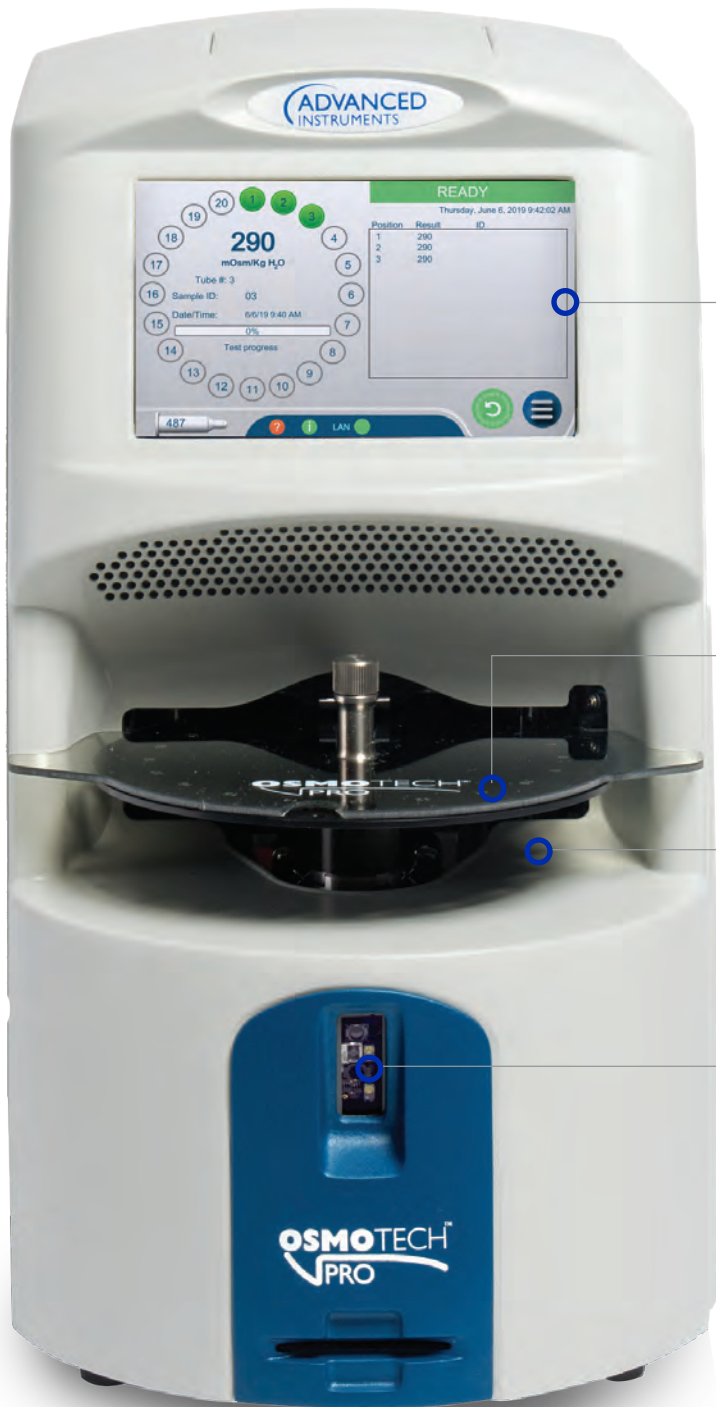
- Guarantee quality, potency and consistency during media development and raw material management.
- Monitor cell culture and fermentation to ensure optimal cell health, and consequently, high product quality and yield.

Ensure precise buffer preparation and prove complete buffer exchange to improve purification efficiency.

Safeguard your biologic as it passes through storage, reconstitution and injection.

Ensure that the final product meets your quality standards and release criteria.

# Built for Biotech



## User-friendly interface

The menu-driven operating system, multi-language capability and touchscreen graphical user interface all make for easy operation

## Run multiple samples effortlessly

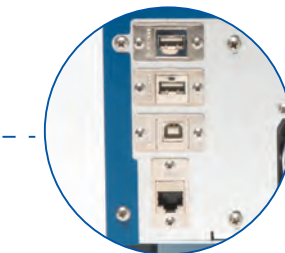
Its 20-position turntable allows for walkaway testing

## Small sample requirement

Just a 30  $\mu$ L sample volume is needed for sample-limited applications

## Maintain traceability

The integrated barcode scanner helps with sample identification and reduces transcription errors



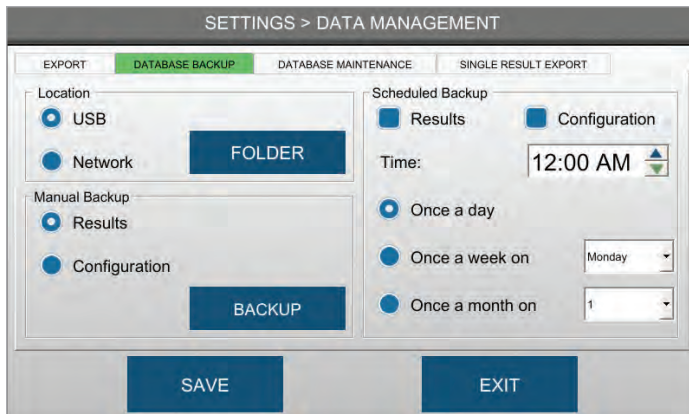
## Manage and export data with ease

Several ways, including Open Protocol Communication (OPC-UA), USB download, Network share, LIS (TCP/IP communication), or an Optional printer

# Support compliance. Streamline workflow.

The most data management features of any osmometer on the market

## Security features support 21 CFR Part 11 and EU Annex 11 Compliance



- **Three levels of user access:** Set up to reflect the hierarchy of your team
- **Active directory/LDAP:** Harmonize with network credentials for easy login and user management
- **Password protection:** Configurable password to match internal security requirements
- **Pre-expire passwords:** Force password change on first login to ensure maximum security
- **Automatic logout timer:** Keep your data safe during idling
- **Audit trail:** Preserve detailed record of all events and results
- **Change management:** Require reason for changing settings
- **Data capacity:** Unlimited storage and no overwriting of data.

Sample ID	mDCL	Date/Time	User ID	Description
18A040	ERROR	4/20/20 11:57 AM pm		* Review Required
18A181	ERROR	4/20/20 11:57 AM pm		* Review Required
18A000	ERROR	4/20/20 11:58 AM pm		* Reviewed by Admin at 4/19/20 3:55:14 PM. Result
18A040	ERROR	4/20/20 11:58 AM pm		* Review Required
18A040	ERR	4/20/20 11:58 AM pm		* Review Required
18A040	ERR	4/20/20 11:58 AM pm		* Review Required
18A040	ERR	4/20/20 11:58 AM pm		* Review Required
18A181	ERR	4/20/20 11:58 AM pm		* Review Required
18A181	ERR	4/20/20 11:58 AM pm		* Reviewed by Admin at 4/19/20 4:38:19 PM. All tests within spec
18A040	ERR	4/20/20 11:58 AM pm		* Review Required
18A040	ERR	4/20/20 11:58 AM pm		* Review Required

## Electronic signature of all results!

Review and approve data electronically on the instrument to ensure traceability and control of all data generated on the instrument.

## Flexible data management options to fit your workflow



- **OPC-UA:** Easily integrate your results into a data management system and batch records
- **PDF or CSV export:** Quickly save data to network folder or USB
- **Database backup:** Protect your data with automatic or manual backups
- **Network time synchronization:** Eliminate the need to manually manage date and time
- **Embedded web server:** Remotely view and manage data for additional walkaway time
- **Results database on/off:** Decide whether results are stored on the system
- **LIMS/LIS:** Effortlessly connects for sample and data tracking
- **Dot matrix printer (optional):** Prevents records from fading

## Seamless data integration and process control with bi-directional capability:

Using OPC-UA connect to lab management and middleware software such as Sm@rtline Data Cockpit® (SDC) and more

## Compliance with Quality Assurance demands

**Surpassing all expectations**—the OsmoTECH PRO is built to exceed your most demanding needs. It is perfectly suited for mid to high throughput areas across the bioprocessing value chain, thus streamlining efficiency and allowing customers more time to focus on other areas of work. It also helps support compliance within 21 CFR Part 11 and EU Annex 11 with robust data security features that can be easily adapted for your organization's unique structure.

OsmoTECH PRO meets osmolality testing guidelines in the biopharmaceutical industry to control the quality of medicines and the materials used to manufacture them as described by the organizations below:

- European Pharmacopeia
- United States Pharmacopeia
- Japanese Pharmacopeia
- Chinese Pharmacopeia



## Evolves with your data management needs

OsmoTECH PRO's new and innovative features let you customize testing and data reporting to best fit your workflow and existing structure.

### You can:

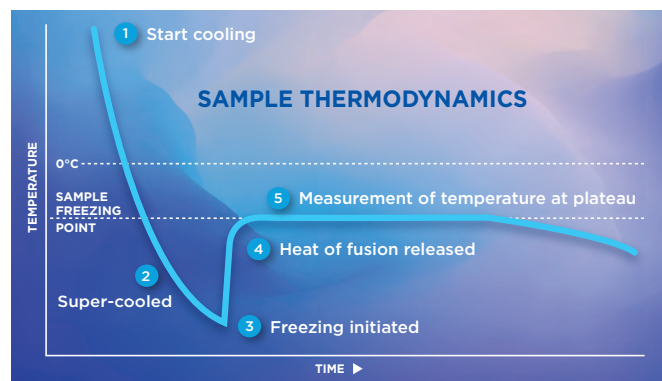
- Choose from configurable data settings to match your needs as they evolve during R&D, preclinical research, clinical testing and GMP compliance
- Explore several options for data management and connectivity. You can fully integrate data into a centralized system; turn off data connectivity and storage if your process is paper-based; or choose any extent in between

## Delivers accurate and precise results

**The OsmoTECH PRO utilizes freezing point depression**— the gold standard method of testing osmolality. Freezing point depression is preferred by biotechnology labs worldwide because it assures:

- Fast 90-second test time and accurate measurements
- Consistently reliable results using a small sample requirement (30  $\mu$ L)
- Compatibility with virtually any liquid matrix
- Full characterization of concentration, including volatiles, such as alcohol

Only freezing point osmolality is a truly comprehensive measurement of samples, as it is independent of the size, ionization status, shape and other physical characteristics of the liquid solutions it measures.



## Experience unrivaled user friendliness

OsmoTECH PRO guarantees you a simple and fluid experience:

- Interactive and intuitive touch screen with multi-language capability
- Arrives factory-calibrated, with no need for routine calibration
- Short start-up time; start testing quickly
- 20-position turntable for easy sample loading and walkaway testing
- Color-coding with on-screen messages to let you know the instrument's status
- Calibration options across the range – 0\*, 50, 850, 2000\*

\* Optional

## Parts and supplies

Part number	Product description
<b>Instrument</b>	
OsmoTECH PRO	Multi-Sample Micro-Osmometer
<b>Calibration standards, reference solutions and testing supplies</b>	
<b>SK-TECHPRO</b>	<p><b>Convenience Kit includes:</b></p> <ul style="list-style-type: none"> <li>• Micro-Sample Tubes; disposable, Pkg 500 (222825)</li> <li>• Calibration Standard; 0 mOsm - 2 mL Ampule, Pkg 10 (3MA000)</li> <li>• Calibration Standard; 50 mOsm - 2 mL Ampule, Pkg 10 (3MA005)</li> <li>• Reference Solution; Clinitrol 290 - 2 mL Ampule, Pkg 10 (3MA029)</li> <li>• Calibration Standard; 850 mOsm - 2 mL Ampule, Pkg 10 (3MA085)</li> <li>• Calibration Standard; 2000 mOsm - 2 mL Ampule, Pkg 10 (3MA200)</li> <li>• Osmolality Linearity Set; 5-Level, 5 mL Ampule, Pkg 10 (3LA028)</li> <li>• Probe Wiper Rings; 20-position, Pkg 50 (222840)</li> <li>• Tips, Pipette; Pkg 50 (240821)</li> <li>• Swab Cleaner Kit; Pkg 50 (202850)</li> </ul>

1. Subject to change
2. Advanced Instruments completes testing from 0 mOsm/kg sample to 2000 mOsm/kg sample during in-house linearity testing.
3. Performance at reference conditions: 20 °C to 25 °C (68 °F to 77 °F); 40 to 60% relative humidity.

## Specifications<sup>1</sup>

<b>Sample type</b>	Aqueous-based solution
<b>Sample volume</b>	30 ± 1 µL
<b>Test time</b>	90 seconds (typical) to test single sample 40 minutes (typical) to test 20 samples
<b>Sample capacity</b>	Multi sample
<b>Resolution</b>	1 mOsm/kg H <sub>2</sub> O
<b>Range<sup>2</sup></b>	0-2000 mOsm/kg H <sub>2</sub> O
<b>Accuracy<sup>3</sup> (AI standards and reference solutions)</b>	Mean value ± 3 mOsm/kg H <sub>2</sub> O from nominal value between 0 and 400 mOsm/kg H <sub>2</sub> O (1 SD) Mean value ± 0.75% from nominal value between 400-2000 mOsm/kg H <sub>2</sub> O (1 SD)
<b>Within-Run Repeatability<sup>3</sup> (AI standards and reference solutions)</b>	Standard deviation ≤ 3 mOsm/kg H <sub>2</sub> O between 0 and 400 mOsm/kg H <sub>2</sub> O Coefficient of variation ≤ 0.75% between 400 and 2000 mOsm/kg H <sub>2</sub> O
<b>Temperature effects</b>	Less than 1 mOsm/kg H <sub>2</sub> O per 5 °C (9 °F) ambient temperature change
<b>Supported languages</b>	Simple Chinese, English, French, German, Italian, Japanese, Korean, Russian, Spanish, Turkish
<b>Storage temperature</b>	-20 °C to +45 °C (-4 °F to +113 °F)
<b>Electrical voltage</b>	100 to 240 VAC (50/60 Hz)
<b>Power consumption</b>	60 Watts
<b>Dimensions (D x W x H)<sup>4</sup></b>	39 cm x 25 cm x 46 cm (15.3" x 10" x 18")
<b>Net weight</b>	13.2 kg (29 lb.)
<b>Shipping weight</b>	17.7 kg (39 lb.)
<b>Warranty</b>	One-year limited warranty on workmanship and parts



### Optimal performance requires quality test supplies.

Advanced Instruments provides a full line of calibration standards and consumables. These supplies ensure optimal system performance and accurate test results.

Not for patient diagnostic use



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Advanced Instruments certifies that the technical features needed for 21 CFR Part 11 and EU Annex 11 compliance are built into OsmoTECH PRO. It is your responsibility to implement the necessary controls in your laboratory to comply with 21 CFR Part 11 and EU Annex 11 requirements

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