



## OsmoTECH® Portfolio

Powering Osmolality Testing for Biotech



Advanced osmometers for all stages of bioprocess development and manufacturing



## Your partner for osmolality testing

Experience trusted performance, robust compliance, and seamless workflow integration with Advanced Instruments portfolio of osmometers for biotech

Since 1956, Advanced Instruments has been a global leader of freezing-point osmometry. That experience gives us a deep understanding of the needs and challenges you face in drug discovery, development and manufacturing, including balancing tight deadlines with a rigorous commitment to quality and regulatory compliance. We know that bringing new therapeutics to market globally also requires innovations in supporting technology that can drive decision-making and simplify workflows.



**Our world-leading portfolio of osmometers offers a wide range of applications for osmolality testing with the precision and ease of use Advanced Instruments is known for. Across development and manufacturing workflows, our osmometers ensure that you consistently produce biopharmaceutical products of predetermined yield, purity and quality.**

### **Trusted and Reliable Performance**

The gold standard method of testing osmolality, freezing point depression assures fast test times, accurate measurements and consistently reliable results with a small sample volume. We've taken this freezing method into a new era with Intelligent freezing technology, which monitors, controls and accurately measures solutions across a diverse range of samples, osmolalities and applications.

### **Robust Data Compliance & Management**

Data integrity is paramount to ensuring the validity of the data and its analyses. Advanced Instruments osmometers help you meet the strict data integrity requirements of 21 CFR part 11 and EU Annex 11, ensuring your electronic data is always complete, consistent and accurate.

### **Scalable and Seamless Integration**

The bioprocessing workflow is complex and multifaceted, which leads to a varying set of requirements depending on the stage of bioprocessing you're in. Designed in close collaboration with customers, the OsmoTECH portfolio of osmometers perfectly meets your osmolality testing and data management requirements, allowing easy integration into the workflow to get your lab ready to go.

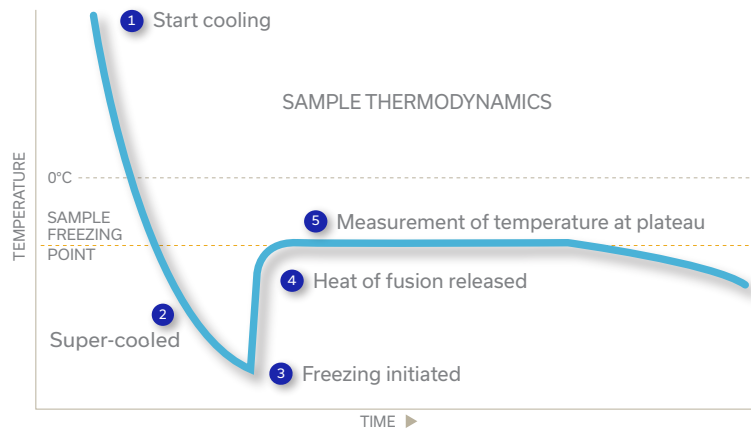
### **Comprehensive and Expert Service Offerings**

We provide a range of services and service plans to meet your unique needs. Our certified Field Service Engineers provide on-site professional support for the installation, validation, training and maintenance of your osmometers to avoid disruptions to your valuable work.

**Read more about the OsmoTECH portfolio and learn how we can support you in bringing your innovative therapeutics to market.**

# What Is Osmolality?

Osmolality is a property of any liquid that describes how much of a solute is present. For more complex solutions, it reflects the overall concentration and provides a valuable measurement standard within the biopharmaceutical realm. Osmolality is concentration as a function of mass, which is not sensitive to temperature and pressure, which is particularly beneficial during bioprocessing changes. Osmolality is used to describe the concentration of a solution as it relates to the properties of osmosis. As a compendial release test for biological manufacturing, osmolality testing is prevalent within bioproduction; however, there are numerous applications for testing throughout the workflow, not just for release.



# Value of Osmolality Testing

Advanced Instruments is speeding bioprocess development and manufacturing while ensuring quality and compliance across a variety of therapies and applications.

<b>Personal Care</b> Ensure the ideal osmolality range to have a moisturizing or drying effect	<b>Oligonucleotides</b> Verify the concentrations of your solutions during manufacturing	<b>Protein Therapies</b> Accelerate therapeutic protein cell line development
<b>Cell Therapies</b> Accelerate cell based workflows for quicker cell therapy process development	<b>Gene Therapies</b> Deliver assurance and maintain consistency throughout your viral vector production	<b>Vaccines</b> Ensure that the final vaccine product is safe for administration

# Compliance at the Core of Design

## Meet Pharmacopeia Guidelines

Pharmaceuticals are required to propose specifications for the excipients, drug substances, and final drug products. These specifications should meet the quality standards in the United States Pharmacopeia/National Formulary (USP/NF), the European Pharmacopoeia (EP), the Japanese Pharmacopoeia (JP), or the Chinese Pharmacopoeia (CP). Compendial pharmacopeial tests are standardized protocols for many pharmaceutical raw materials and finished products. The OsmoTECH portfolio of osmometers meets osmolality testing guidelines stated in the above mentioned pharmacopeias. Thereby ensuring the quality of products manufactured, released, and distributed globally in the biopharmaceutical industry.

## Ensure Data Integrity and Data Management

Data integrity is the completeness, consistency, and accuracy of data. In the pharmaceutical and biotechnology industries, this can be achieved by ensuring the trustworthiness and reliability of electronic records. The OsmoTECH portfolio of osmometers helps you maintain compliance with built-in data integrity features that help support 21 CFR Part 11 and EU Annex 11 regulations. To list a few features, the OsmoTECH portfolio of instruments has three-level user access, password protection (LDAP), complete audit trail, secure electronic signature, and more.

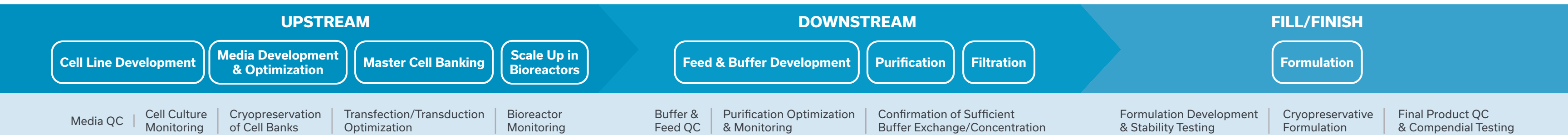


In addition to data integrity, our osmometers come with powerful data management features that allow the instrument to seamlessly connect to any digital environment helping to minimize data errors. OsmoTECH micro-osmometers are designed to easily integrate your results and events into a data management system including, a laboratory information management systems (LIMS), electronic lab notebooks (ELN), and middleware with OPC-UA bi-directional communication. All the data can be automatically transferred to a network folder in pdf or csv format. All critical data can be safely backed up to the network based on a range of different frequencies from every 5 mins to once a month.

## Confirm Confidence in Osmometers Performance

Advanced Instruments offers a wide range of Calibrators and Controls to ensure osmometers' optimal performance and accuracy of your osmolality test results across instrument reportable range. The calibrators and controls enable compliance with pharmacopeia guidelines for osmolality testing, calibration and verification.

Our calibrators and controls are manufactured to a tight tolerance, enabling you to quickly see changes in performance. Premixed in individual ampules, these products can be used right out of the box and are specifically made to work with our Advanced Instruments osmometers.



# OsmoTECH<sup>®</sup> HT Automated Micro-Osmometer



The OsmoTECH HT is built for your early process development and drug formulation needs. Automation-friendly features support your high-throughput environment, streamlining efficiency and reducing hands-on operator time. The OsmoTECH HT delivers the accuracy, precision, and compliance to pharmacopeia guidelines you've come to expect from Advanced Instruments. It uses freezing point depression—the gold standard method of testing osmolality.

- The SBS-compliant 96 well plates can be integrated seamlessly with your high volume workflow and/or liquid handling automation workflow, significantly reducing hands-on time and the potential for human error.
- Instrument pipettes required volume for measurement and cleans the probe for a walk-away experience.
- Customize and store templates on the device or simply import from network or USB to reduce testing set up time.
- Load up to two plates onto the device for 192 tests and perform up to 1,000 tests before a consumables change is required.

# OsmoTECH<sup>®</sup> PRO Multi-Sample Micro-Osmometer



Built for mid to high sample throughput bioprocessing and biomanufacturing labs, the OsmoTECH PRO combines ease of use with accurate and precise osmolality measurements for reliable and reproducible results. The instrument assures compatibility with virtually any liquid matrix as well as full characterization of concentration, including volatiles. OsmoTECH PRO delivers extensive data management features to support compliance and streamline your workflow.

- A 20-position sample turntable allows for walk-away testing with a user-friendly touchscreen interface for easy operation.
- With just a 30  $\mu$ L sample volume required, the OsmoTECH PRO is ideal for process development customers who have limited sample volume available.
- Data integrity features support 21 CFR Part 11, GMP and EU Annex 11 compliance guidelines. Also meets pharmacopeia osmolality testing guidelines.
- Flexible data management options include OPC, network share, USB download, embedded Web server, and LIMS/LIS for data export and backup.

# OsmoTECH® XT Single-Sample Micro-Osmometer



The OsmoTECH XT was designed in collaboration with customers to provide an easy-to-use instrument that can detect osmolality in a wide range of samples. OsmoTECH XT uses Intelligent freezing technology to monitor, control and measure samples with high concentration/viscosity. The instrument is ideally suited for laboratories that need to measure a wide variety of sample types across bioprocessing and cell and gene therapy workflows.

- The instrument offers the widest range of osmolality testing (0-4000 mOsm/kg of H<sub>2</sub>O) with only 20 µL sample volume.
- Measure highly concentrated solutions, including proteins and sugars, and highly viscous solutions, such as hyaluronate and cryopreservatives.
- Data integrity features support 21 CFR Part 11, GMP and EU Annex 11 compliance guidelines with eSignature. Also meets pharmacopeia osmolality testing guidelines.
- Robust and flexible data management features include network share, USB download, Open Protocol Communication (OPC), LIS, and bi-directional data management.

## Advanced Services for Maximum Productivity

Keep your lab running smoothly and your costs under control with support services from Advanced Instruments. To maximize productivity in your lab and meet your unique needs, we offer a range of services, including installation and training, qualification services, and service agreements.

### Improve Productivity with Installation and Training Services:

Get your instrument installed fast and your team trained quickly to maximize productivity. Our certified service engineers follow strict standard procedures, use only genuine parts, and provide a formal service report in line with quality assurance guidelines.

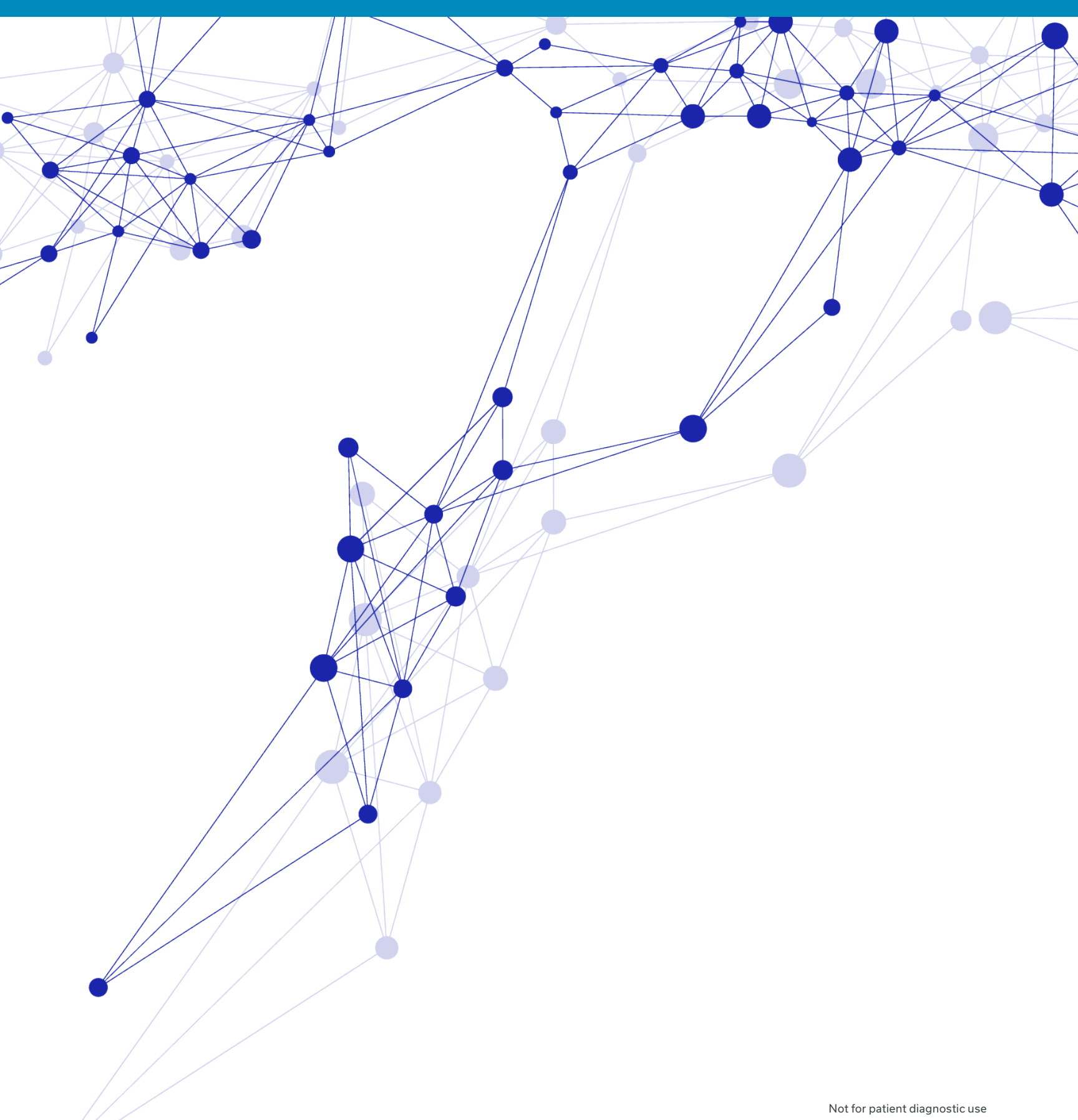
### Ensure Instrument Compliance with Qualification Services:

Be audit ready with our comprehensive qualification documentation. Our Installation and Operational Qualification services ensure your instrument is installed and configured according to the manufacturer's standards. Requalification ensures performance of your instrument within operating ranges as per specifications.

### Guaranteed Coverage with Advanced Care Service Agreements:

Protect your investment and take the worry out of service costs with an Advanced Care service agreement. Service agreements include qualification, annual preventive maintenance and protection in case of instrument downtime.





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