



olera Operation Manual

Document: 3800-0400 Rev. A

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Helping Science Improve Lives

Original Instructions

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Overview

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1 Overview

OLERA Dissolution Systems

Redefining Flexibility in Dissolution Testing

Welcome to the next generation of dissolution testing innovation.

The **OLERA** dissolution baths deliver unmatched versatility and precision, designed to meet the evolving needs of both **Quality Control (QC)** and **Research & Development (R&D)** environments. This advanced system supports configurations for **USP Apparatus 1, 2, 5, and 6**, as well as **intrinsic dissolution**, offering a comprehensive solution for a wide range of testing protocols.

Key Features:

- **Intuitive Touchscreen Interface**
Effortlessly manage users, methods, and reports with a vibrant, user-friendly 10-inch display.
- **Smart Instrument Control**
Enjoy seamless operation with automatic component serial number tracking and built-in qualification reminders.
- **Robust & Reliable Performance**
Engineered for high-throughput QC applications while maintaining the flexibility required for exploratory R&D work.

Whether you're streamlining routine testing or pushing the boundaries of pharmaceutical research, the OLERA dissolution system is your trusted partner in precision and productivity.



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Notices

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II

2 Notices

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Manual Part Number

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Document Revision History

REVISION	DATE	CHANGES
A	06 Jan 2026	Initial



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Instrument Specifications

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3 Instrument Specifications

SPECIFICATION	OLERA standard	OLERA plus	OLERA select
DISSOLUTION VESSELS	6 Vessels – 7 or 8 optional vessels		
SUPPORTED APPARATUS	USP 1, USP 2, App 5, App 6, Intrinsic	USP 1, USP 2, App 5, App 6-Short, Intrinsic	USP 1, USP 2, App 5, App 6-Short, Intrinsic
TEMPERATURE MONITORING	In-bath temperature probe	Wireless in-shaft temperature sensor	Wireless in-shaft temperature sensor
BATH HEATING TIME	< 30 minutes	< 30 minutes	Not applicable
VESSEL MEDIA HEATING TIME	< 30 minutes	< 30 minutes	< 15 minutes
MEDIA TEMPERATURE RANGE	Ambient to 55°C	Ambient to 55°C	Ambient to 99°C
TEMPERATURE ACCURACY	± 0.25°C	± 0.25°C	± 0.25°C up to 45.0°C ± 0.50°C from 46.0 °C to 99.0 °C
TEMPERATURE CONTROL	On-board bath heater	On-board bath heater	Independently controlled heater jackets
MEDIA VOLUME *	25 mL to 1000 mL	25 mL to 1000 mL	500mL to 1000 mL
USERS, METHODS, & REPORTS	Users= 250 Methods= 500 Reports= 1000		
DISPLAY	10-inch capacitive color touch screen		
REMOTE INSTRUMENT CONTROL	Eclipse 5300, Distek Cipher software, Opt-Diss 410		
INTERFACE PORTS	x1 Ethernet port, x2 USB-C		
DIMENSIONS	70 cm x 98 cm x 50 cm W x H x D		
WEIGHT	36 kg	36 kg	34 kg
ELECTRICAL POWER	115VAC ±15VAC 10A 230VAC ±15VAC 6A	115VAC ±15VAC 10A 230VAC ±15VAC 6A	115VAC ±15VAC 15A 230VAC ±15VAC 8A

SPECIFICATION	OLERA standard	OLERA plus	OLERA select
	Factory voltage pre-set	Factory voltage pre-set	Factory voltage pre-set

* Volumes below 500 mL require a small volume Kit

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Regulatory and Safety Compliance

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4 Regulatory and Safety Compliance

CATEGORY	REQUIRED INFORMATION
ELECTRICAL SAFETY	UL 61010-1:2012 Ed.3+R:15Nov2024 UL 61010-2-010:2019 Ed.4+R:29Sep2023 CSA C22.2#61010-1-12:2012 Ed.3+U1;U2;A1;U3;U4 CSA C22.2#61010-2-010:2019 Ed.4 EN 61010-1:2010+A1 EN 61010-1:2010
FCC	FCC ID: 2BUPX-OLERA Statement 15.19(a)(3): This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Distek could void the user's authority to operate the equipment.
CE / EU COMPLIANCE	This product complies with applicable European Union legislation and bears the CE marking. It conforms to the following EU requirements: • 2014/53/EU – Radio Equipment Directive • 2006/42/EC – Machinery Directive • 2011/65/EU, as amended – Restriction of Hazardous Substances (RoHS) The product is also placed on the market in accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
Radio Equipment Directive	Operating frequency: 13.56 MHz Maximum RF output power: 2.8dBuA/m at 3 meters
ISED (Canada)	IC ID: XXXXXXXX-XXXXXXX

CATEGORY	REQUIRED INFORMATION
	This device complies with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device. Le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage; (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
PHARMACEUTICAL COMPLIANCE	USP <711>/<724> EP 2.9.3/2.9.4/2.9.25 JP 6.10 ChP 0931
SAFETY WARNINGS	Refer to section Safety Information 
ENVIRONMENTAL WARNINGS	Refer to section Environmental Conditions 
LABELING	Serial number, input AC voltage, manufacturing info



Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.



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Safety Information

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5 Safety Information

The following general safety precautions are essential and must be strictly observed during all phases of **operation, maintenance, repair, and servicing** of this instrument. Failure to adhere to these guidelines, or to any warnings and instructions provided elsewhere in this manual, constitutes a violation of the safety standards established for the design, manufacturing, and intended use of this equipment.

Distek, Inc. assumes no responsibility or liability for any injury, damage, or malfunction resulting from failure to comply with these safety requirements. It is the responsibility of the customer and end-user to ensure safe and proper use of the instrument.

Operational Safety Guidelines

Before powering on the instrument, verify that all **installation requirements** have been met. In addition, the following precautions must be followed:

- **Do not remove instrument covers** while the system is in operation. Exposed internal components may pose electrical or mechanical hazards.
- Ensure the instrument is connected to a **protective earth ground socket**. Any interruption or absence of proper grounding may result in a **shock hazard**, potentially causing serious personal injury.
- Only use **replacement fuses** that match the specified type and current rating. Using incorrect fuses may compromise safety and damage the instrument.
- All servicing must be performed by **qualified personnel** who are trained in the safe handling, repair, and maintenance of this equipment. Untrained individuals should not attempt to service the instrument.
- **Never replace components** or perform internal adjustments while the power cable is connected. Disconnect power before servicing.
- Do not operate the instrument in environments containing **flammable gases, vapors, or fumes**, as this may lead to fire or explosion hazards.

Do not install **substitute parts** or make **unauthorized modifications** to the instrument. Doing so may impair performance, void warranties, and create unsafe operating conditions.



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Environmental Conditions

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6 Environmental Conditions

To ensure optimal performance and longevity of the **OLERA Dissolution System**, it is essential to maintain appropriate environmental conditions within the laboratory. Both **humidity** and **airflow** play critical roles in protecting sensitive components and ensuring accurate test results.

Ambient Laboratory Humidity

Distek strongly recommends that the **laboratory humidity control system** - including fans and ventilation—be kept **active at all times**, if possible. Continuous airflow helps regulate moisture levels and prevents the accumulation of vapors that may compromise the instrument's integrity.

Maximum Humidity Threshold

During operation, the OLERA dissolution bath may contribute to increased humidity levels in the laboratory, particularly when vessels are filled and left **uncovered**. Evaporation of water or dissolution media—especially those containing **hydrogen chloride** - can release vapors that, when condensed, may cause **corrosion or electrical failure** in sensitive components. To mitigate this risk, the laboratory's environmental control system should maintain **relative humidity below the dew point**, ideally **not exceeding 70%**. This precaution helps prevent condensation on electrical contacts and circuit boards, which could lead to malfunction or damage.

Minimum Humidity Threshold

The OLERA dissolution bath incorporates **solid-state semiconductor devices** that are vulnerable to **electrostatic discharge (ESD)** in low-humidity environments. To reduce the risk of ESD-related damage to control circuits and internal electronics, the laboratory should maintain a **minimum relative humidity of 25%**.

Humidity levels below this threshold can increase static buildup, especially in dry climates or during winter months when indoor air tends to be drier.

Maintaining humidity within the recommended range - **25% to 70% relative humidity** - is essential for safe, reliable, and accurate operation of the Model 2500 Dissolution System. For best results, laboratories should implement continuous environmental monitoring and control systems.

Ambient Laboratory Temperature

Maintaining a stable and controlled temperature environment is essential for the accurate and reliable operation of the **OLERA Dissolution System**. The following guidelines outline the recommended temperature conditions and considerations for laboratory setup and ongoing use.

General Recommendation

Distek strongly recommends that the **laboratory temperature control system** remain **active at all times**. Continuous regulation of ambient temperature ensures consistent instrument performance and protects sensitive components from thermal stress.

Maximum Operating Conditions

To achieve the full operational temperature range of **20°C to 65°C** within specified tolerances, the Model 2500 is designed to function optimally in laboratories where the **ambient temperature does not exceed 25°C**.

- The **absolute maximum allowable ambient temperature** for safe operation is **30°C**.
- Operating the instrument in environments above **25°C** may restrict its ability to maintain precise internal temperature control, potentially affecting dissolution accuracy and system stability.

Minimum Operating Conditions

The Model 2500 is engineered to operate reliably in laboratories where the **ambient temperature does not fall below 20°C**. Temperatures below this threshold may impair the system's ability to reach and maintain target dissolution temperatures, especially during pre-heating and testing phases.

Temperature Stability and Fluctuations

To ensure controlled operation within the instrument's specified tolerances, the laboratory's temperature control system must be capable of maintaining the ambient air temperature within **±2.5°C of the set point**, even under worst-case conditions.

- Short-term fluctuations or variability beyond this range can lead to inconsistent test results and may affect the performance of temperature-sensitive components.

Thermal Loading Considerations

Each OLERA dissolution bath contributes an average **thermal load of approximately 0.6 kW** during operation. Laboratories with multiple units installed must account for the **aggregate thermal output** when designing or adjusting HVAC systems.

- The **cooling system** must have sufficient excess capacity to dissipate the heat generated by all units in use.
- The **heating system** must be responsive enough to adjust for increased thermal input, potentially requiring throttling or redistribution of airflow.

In laboratories where **precise temperature control is critical**, installation of multiple dissolution systems may necessitate **rebalancing the HVAC system**. This may include:

- **Relocating thermostats** to ensure accurate temperature sensing.
- **Adjusting airflow patterns** to maintain uniform temperature distribution throughout the room.

Maintaining ambient temperature within the recommended range and ensuring system stability are key to achieving consistent, high-quality dissolution results. Distek recommends periodic evaluation of environmental controls, especially when expanding system capacity or modifying lab infrastructure.

Air Quality Considerations

The **OLERA Dissolution System** is engineered for use in clean, controlled laboratory environments. Proper air quality is essential to ensure the integrity of test results and the longevity of the instrument's components. The following guidelines outline the recommended air quality conditions and potential risks associated with suboptimal environments.

General Air Quality Requirements

- The laboratory should be free from **visible dust accumulation** and maintain **low levels of organic solvent vapors**.
- Operation in environments with **high dust levels**, or with significant concentrations of **chlorinated or reactive solvent vapors**, is **not recommended**. These conditions can adversely affect both the mechanical and electronic components of the system.

Impact on Instrument Components

- Dust particles can infiltrate sensitive areas of the instrument, leading to **mechanical wear, sensor interference, and electrical contact degradation**.
- Reactive vapors, particularly those from **chlorinated solvents**, may **corrode internal components**, damage circuit boards, and compromise the system's performance over time.

Impact on Test Accuracy

- Vapors present in the laboratory air may be **absorbed into the dissolution media**, especially when vessels are left uncovered. This can lead to **biased test results and inconsistent drug release profiles**.
- Certain dissolution tests require media prepared from **USP-grade water**, which must remain free from contamination. The absorption of airborne vapors into this media may result in **non-compliance with USP standards**, affecting both the validity and reproducibility of test outcomes.

Maintaining a clean, well-ventilated laboratory environment with **minimal airborne contaminants** is critical for ensuring the accuracy, reliability, and regulatory compliance of

dissolution testing using the OLERA dissolution baths. Distek recommends regular air quality assessments and the use of appropriate filtration or ventilation systems where necessary.

Noise Emission Level

The A-weighted emission sound pressure level at the workplace does not exceed 70 dB(A) under normal operating conditions.

The measurement was determined in accordance with applicable noise measurement standards for machinery. This value represents the emission sound pressure level at the operator position.

The equipment does not require special noise protection measures under typical laboratory operating conditions.

Distek & the WEEE Directive (Waste Electrical & Electronic Equipment)

At **Distek, Inc.**, environmental responsibility is a core value. We are committed to minimizing the ecological impact of our products and promoting sustainable practices throughout their lifecycle. As part of this commitment, Distek fully supports and complies with the **European Union's WEEE Directive**, which governs the proper disposal and recycling of electrical and electronic equipment.

Product Labeling and Disposal

Products manufactured by Distek that fall under the scope of the WEEE Directive are marked with the **"crossed-out wheelie bin" symbol**, either on the product itself or on its packaging. This symbol indicates that the product must **not be disposed of with regular household waste**.

Instead, it is the **user's responsibility** to ensure that the equipment is disposed of in an environmentally responsible manner by delivering it to a **designated collection facility** for the recycling of electrical and electronic waste.

Why Proper Disposal Matters

- **Environmental Protection:** Electrical and electronic equipment may contain substances that, if not properly handled, can be harmful to the environment and human health.
- **Resource Conservation:** Recycling helps recover valuable materials, reducing the need for raw resource extraction and minimizing waste.
- **Regulatory Compliance:** Proper disposal ensures compliance with local and international regulations, including the WEEE Directive.

How to Recycle Your Distek Equipment

To find out where you can drop off your Distek equipment for recycling:

- Contact your **local municipal office** or **waste management authority**.

- Reach out to your **authorized Distek distributor**.
- Contact **Distek, Inc.** directly for guidance on approved recycling partners or programs in your region.

By following these guidelines, you help ensure that your Distek equipment is recycled safely and responsibly, contributing to a cleaner environment and a more sustainable future.

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Installation and Site Preparation Guidelines

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7 Installation and Site Preparation Guidelines

Physical Site Consideration

Proper installation of the **OLERA Dissolution System** requires careful attention to the physical layout and structural integrity of the installation site. The following guidelines ensure safe operation, optimal performance, and ease of access for routine use and maintenance.

Bench Dimensions & Placement Requirements

- **Minimum Bench Depth**

The bench must have a minimum depth of **22 inches (56 cm)** from the front edge to the back wall or backsplash. However, for optimal airflow and ventilation, a depth of **25 inches (64 cm)** is **strongly recommended**.

- **Minimum Linear Bench Space**

The system requires at least **28 inches (71 cm)** of horizontal bench space. Suppose manual operations—such as sample handling or accessory adjustments—are expected to occur adjacent to the unit. In that case, **Distek recommends allocating a minimum of 33 inches (84 cm)** to ensure safe and comfortable working conditions.

- **Vertical Clearance**

Ensure that there are **no obstructions** (such as cabinets, shelves, or electrical outlets) within the unit's footprint up to a height of **39 inches (99 cm)** above the bench surface. This clearance is necessary to accommodate the full height of the instrument and allow for unobstructed access during operation and maintenance.

Structural Support Requirements

- **Bench Load Capacity**

The bench must be structurally sound and capable of supporting the full weight of the instrument and its accessories without bending or warping. The dissolution bath transfers its weight through **five circular, padded, adjustable leveling feet**, which concentrate the load. The bench surface should be able to withstand a pressure of **4 kilograms per square centimeter** at each contact point.

- **Leveling & Slope Tolerance**

To ensure proper alignment and stability, the bench surface must be relatively level. The slope should not exceed **1.9 cm** from front to back or side to side across the instrument's footprint. Excessive slope may interfere with the leveling feet's adjustment range and compromise the instrument's performance.

Electrical Requirements

To ensure safe and reliable operation of the OLERA Dissolution System, the following electrical specifications and precautions must be observed during installation and use.

Power Supply Specifications

- The instrument is designed to operate online voltage of either $115V \pm 15V$ at 50/60 Hz or $230V \pm 15V$ at 50/60 Hz.
- The system is pre-configured at the factory for one of these voltage ranges. As such, there is no voltage selector switch and no externally accessible fuses for user replacement.

Refer to the Instrument Specifications section for details regarding current ratings, which may vary depending on the number of modules or operational positions configured in the system.



Important: Do not connect the instrument to a power source that exceeds the specified voltage range. Doing so may result in electrical shock, equipment damage, or voiding of warranty.

Power Disconnection and Residual Energy

- To fully disconnect the instrument from the power source, remove the power cord from the wall outlet.
- Be aware that the internal power supply may retain residual energy even after the power switch is turned off or the cord is unplugged. Exercise caution when servicing or handling internal components.

Accessory Power Requirements

- Accessories such as printers and other peripherals typically accept a nominal line voltage of 115V or 230V at 50/60 Hz.
- Always consult the manufacturer's documentation for each accessory to confirm compatibility and power requirements.

Power Cord Configuration

- Distek provides region-specific power cords to accommodate different international standards.

- The female end of the power cord is standardized and connects to the power inlet socket located on the right side of the instrument.

The male end varies by country or region and is designed to fit the appropriate wall outlet configuration.

- ✓ **Always use the power cord supplied by Distek with your instrument.**
- ✓ **Always connect the instrument to a properly grounded wall outlet to ensure user safety and prevent electrical hazards.**

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Unpacking Your olera Dissolution System

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VIII

8 Unpacking Your olera Dissolution System

Start Your Journey with Precision and Innovation

Congratulations on your new **Distek OLERA Dissolution System**—a powerful step forward in dissolution testing. Before you begin exploring its advanced capabilities, let's make sure your unpacking process is smooth, safe, and complete.

Before You Begin

Take a moment to review the **packing list** included with your shipment. Carefully verify that all components and accessories are present. If you notice any missing items or damage to the packaging or contents, **contact Distek or your shipping provider immediately** to report the issue.



Safety First: The OLERA dissolution bath is a precision instrument and weighs significantly. To prevent injury or damage, **at least two people** should work together to remove it from its shipping container.

Step-by-Step Unpacking Instructions

1. Remove External Packaging

Cut the straps securing the shipping box and open the top flaps to access the contents.

2. Retrieve Accessories

Locate the individually packaged accessories. Carefully remove them and place them in a **safe, clean area** for later installation.

3. Clear Internal Packing Materials

Remove all foam inserts, protective wraps, and any other packing materials surrounding the instrument.

4. Lift the Instrument Safely

With two people, grasp the **top and front of the base** and gently lift the OLERA unit out of the box. Place it onto a **stable cart** or directly onto the **designated bench top** where it will be installed.

5. Dispose of Packaging Responsibly

Recycle or dispose of all packing materials in accordance with your facility's waste management guidelines.

Ready to Power Up?

Once unpacked, your OLERA dissolution bath is ready for installation and setup. Be sure to follow the **installation and site preparation guidelines** to ensure optimal performance from day one.

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9 Installation

Proper installation of the dissolution bath is essential to ensure accurate, repeatable testing and long-term system performance. This chapter provides step-by-step instructions to prepare the instrument for operation and verify that all components are correctly installed and aligned.

Before beginning, confirm that the instrument has been unpacked and positioned on a suitable laboratory bench. Following the procedures outlined in this chapter will help ensure stable operation, consistent bath temperatures, and compliance with applicable testing standards.

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9.1 Leveling Your olera Dissolution Bath

Precision Starts with a Solid Foundation

Before you begin using your new **Distek OLERA Dissolution Bath Unit**, it's essential to ensure the system is properly leveled. A stable and level setup is key to achieving accurate and consistent dissolution results.

Let's walk through the process step by step to get your OLERA unit perfectly balanced and ready for action.

Step-by-Step Leveling Instructions

1. Locate and Prepare the Leveling Feet

- Your OLERA unit is equipped with **five leveling feet**—two at the front, two in the middle, and one at the rear.
- Using an **open-end wrench**, gently **loosen the locking nuts** on the two front feet and the two middle feet.
- Loosen the two middle feet so they **do not touch the bench surface** during the leveling process.

2. Measure and Adjust for Level

- Place a **digital or carpenter's level (minimum 6 inches)** across the **front of the vessel plate** to check **side-to-side alignment**.
- Next, position the level along the **left and right sides** of the vessel plate to measure **front-to-back alignment**.
- Adjust the two front and rear leveling feet as needed until the unit is **perfectly level in both directions**.

3. Lock and Stabilize

- Carefully **lower the middle feet** until they **contact** the bench surface—enough to provide support without altering the level.
- Once the unit is level, **tighten the locking nuts** on each foot using your wrench to secure the position.

4. Optional: Mark the Footprint

- For added convenience, you may **mark the location of the leveling feet** on the bench. This helps maintain alignment if the unit is moved or repositioned.

- After installation or relocation, **recheck the level** from front to back and side to side to confirm stability.

You're Almost There!

With your OLERA dissolution bath now leveled and secure, you're one step closer to unlocking its full potential. Proper leveling ensures consistent bath temperatures, accurate readings, and optimal performance.

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9.2 AC Power Installation

Powering Up Your OLERA Dissolution Bath Unit

Now that your **Distek OLERA Dissolution Bath Unit** is leveled and in place, it's time to bring it to life. Connecting the power is simple, but it's important to follow these steps to ensure safe and proper installation.

Step-by-Step Power Connection

1. **Locate the Power Port**

With the instrument positioned and leveled on the bench, find the **AC power inlet** located on the **lower right-hand side** of the unit.

2. **Connect the Main Power Cord**

Take the **supplied power cord labeled "AC In"** and plug it securely into the **AC inlet** on the instrument.

3. **Plug into a Wall Outlet**

Connect the other end of the power cord to a **properly grounded AC outlet** that matches the voltage requirements for your region.



Important: Always use the power cord provided by Distek. Do not use third-party cables and never connect the unit to an outlet that exceeds the specified voltage range.

You're Ready to Go!

Once connected, your OLERA unit is ready for initialization and setup. Be sure to follow the next steps in the installation guide to configure your system and begin testing.

9.3 Filling Up your Dissolution Water Bath

Prepare Your System for Precision Testing

Before you begin your dissolution testing, it's important to properly fill the water bath of your **Distek OLERA Dissolution Unit**. This step ensures consistent temperature control and optimal performance throughout your testing process.

WATER TYPE	ALLOWED?	NOTES
Distilled/Deionized (Type II or III)	 Best Choice	Minimizes scaling, safe for stainless steel and heaters
RO (Reverse Osmosis) Water		Acceptable alternative if DI/distilled not available
Tap Water	 Avoid	Causes mineral buildup, corrosion, and heater damage
Ultrapure Type I (18 MΩ)	Not ideal	Can be <i>too aggressive</i> on metal surfaces over time

1. Remove a Front Vessel

Start by carefully removing **one of the front vessels** from the bath. Set it aside in a **clean, safe location** to allow easy access to the bath reservoir.

2. Prepare Your Filling Container

Use a **bucket** or a **graduated cylinder** to carry the water or dissolution medium. Make sure the container is clean and suitable for laboratory use.

3. Prepare Your Filling Container

Pour the medium **slowly and steadily** into the bath through the open vessel position. This helps prevent splashing and ensures even distribution.

- **Watch the fill level closely** to avoid overfilling.
- Fill until the water reaches the **recommended level** for your configuration.

Typical Fill Volumes by Configuration

Configuration	Typical water bath fill volume
6-vessel setup	~22 liters
8-vessel setup	~20 liters

Extra Tips

- **Change the bath water regularly** (per SOP) to prevent biofilm formation.
- If microbial control is a concern, Aquastabil, Aquaguard, and Copper Sulfate (or other copper products) are a relatively safe option, but shouldn't exceed the label requirements, and only if allowed by your lab policies.

Final Check

Once filled:

- Reinstall the removed vessel securely.
- Verify that the water level is stable and appropriate for your configuration.
- You're now ready to proceed with the shaft installation.

9.4 Installing the Shaft, Paddle, and Basket

Apparatus Setup for Reliable and Repeatable Performance

Your **Distek OLERA Dissolution Bath Unit** is designed for precision, and proper installation of the shafts, paddles, baskets, and vessel covers is essential for achieving consistent, USP-compliant results. Whether you're using the **Standard**, **Plus**, or **Select** model, follow these steps to ensure everything is aligned and ready for testing.



Note: If your shafts are **serialized**, refer to the **Production Final Test Report** to ensure each shaft is placed in its designated spindle

Distek supplies highly uniform shafts that fit properly into the OLERA dissolution baths. Use of shafts other than those supplied by Distek may result in unsatisfactory operation and potentially void the warranty or may cause faulty results.

Shaft Installation

1. Lower the Drive Head

Begin by gently lowering the drive head to access the spindle positions

2. Insert Each Shaft

- For Plus and Select units, insert the RTD-equipped shafts to enable individual vessel temperature monitoring.
- Thread in the shaft guide and carefully insert each shaft from the top, with the collars still attached.
- If a shaft doesn't slide in easily, do not force it—check alignment and try again.

Setting Shaft Height

1. Set the height block to the neutral (horizontal) position.
2. Install the paddles onto each shaft.
3. Lift each shaft halfway upward.
4. Using the provided 5/64 hex key wrench, loosen the shaft collars and slide them down 5–7 cm from the top.

5. Gently lower the shaft until the paddle blade touches the bottom of the vessel.
6. Raise the shaft slightly until you can get access to the shaft collar and tighten the collar to lock the height.
7. Move the height block to the paddle position and verify that each paddle tip is 25 ± 2 mm above the vessel bottom, per USP specifications.

Basket Installation

1. Switch the height block to the basket position.
2. Remove the paddles and install the basket adapter and basket.
3. Ensure the basket screen bottom sits 25 ± 2 mm above the vessel bottom, in line with USP standards.

Final Check

- Confirm all shafts are securely installed and properly aligned.
- Verify paddle or basket height using the height block.

9.5 Installing Vessels and Vessel Covers

Precision Placement for Reliable Performance

With your **Distek OLERA Dissolution Bath Unit** powered and leveled, it's time to install the vessels—an essential step in preparing for accurate and consistent dissolution testing. Follow these steps to ensure each vessel is properly aligned and seated.



Important: Each vessel is **serialized** and assigned to a specific position. Refer to the **Production Final Test Report** included with your unit to confirm the correct placement of each vessel.

Use of vessels other than those supplied by Distek may result in unsatisfactory operation and potentially void the warranty or may cause faulty results.

1. Raise the Drive Unit

Begin by gently raising the **drive unit** to allow clear access to the vessel positions

2. Align and Insert Each Vessel

- For both **OLERA standard** and **OLERA plus** models, insert each vessel into its designated position.
- Make sure the **white arrow on the vessel flange** is pointing **toward the front** of the unit.
- For **OLERA select**, insert each vessel into place, aligning the white arrow approximately with the **centerline of the heater jacket window**.
- Make sure the **white arrow on the vessel flange** is pointing **toward the front** of the unit.
- For **OLERA select**, insert each vessel into place, aligning the white arrow approximately with the **centerline of the heater jacket window**.

3. Seat the Vessel Securely

- For both **OLERA standard** and **OLERA plus** models, make sure that the vessel retaining rings engage with the magnetic vessel plate.
- For **OLERA select**, lower the vessel until it rests **squarely on all three support posts**.
- Ensure vessels are stable and properly seated—this is critical for consistent temperature control and mechanical alignment.

Vessel Cover Installation

To minimize evaporation and maintain sampling accuracy, install the Distek vessel covers:

1. Slightly fold the cover to allow it to slide over the shafts.
2. Rotate the cover so that the probe holes face the front of the instrument.
3. All Distek covers are designed to position sampling probes at the USP, BP, EP, and JP-specified height—midway between the top of the stirring element and the top of the media.

Final Check

Once all vessels are installed:

- Double-check alignment and seating.
- Confirm that each vessel matches its assigned location per the test report.
- Ensure vessel covers are correctly positioned.



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Installation of Accessories and Interfaces

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10 Installation of Accessories and Interfaces

Expand Your olera Dissolution Bath

The olera Dissolution Bath is designed to integrate with a range of accessories and laboratory software solutions that enhance automation, connectivity, and data management.

This chapter walks you through the setup and connection of supported accessories and system interfaces. Once installed, these components allow your olera system to work seamlessly with printers, autosampler, analytical software, and automated dosage delivery systems.

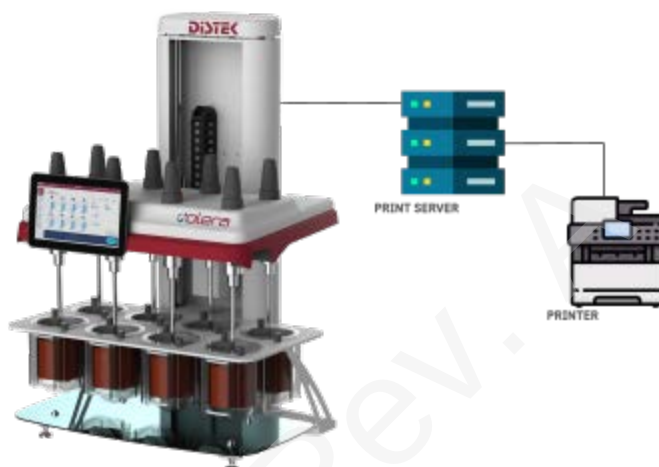
Follow the instructions in this chapter to configure each accessory and ensure reliable communication between devices.

Once these accessories and interfaces are installed and configured, your olera dissolution system can operate as part of a fully integrated dissolution workflow-supporting automated testing, streamlined data management, and enhanced laboratory productivity.

10.1 Connecting olera to a Print Server

Streamline Your Workflow with Automated Result Printing

The **Distek olera Dissolution Bath Unit** supports direct connection to a **print server**, allowing you to automatically print test results for documentation, compliance, or review. This feature enhances lab efficiency and ensures consistent record-keeping across tests.



Connecting your OLERA unit to a print server is quick and straightforward using the built-in **user interface**. Once configured, the system will send results directly to your designated printer. This connection can be established through A **domain-based network** within your organization.

Step-by-Step Setup Instructions

1. Access the Printer Configuration Menu

On the olera touchscreen interface:

- Tap **Settings**
- Navigate to **Instrument**
- Select **Accessories**

This will open the configuration panel for external accessories, including the print server.

2. Enter Required Printer Parameters

To complete the setup, you'll need to provide the following information:

- **Printer Address**

The IP address of the printer.

- **Username**

The log in name used to access the print server (if authentication is required).

- **Username Password**

The corresponding password for the username.

- **Printer Name**

The name or identifier of the printer on the network.

3. Print Test

Select the print icon next to the printer's name to perform a print test page.

10.2 Eclipse 5300 Autosampler

The olera dissolution baths can be coupled with the Eclipse 5300 (Parent-Child setup), which can control up to two baths as needed for easy method setup. If so configured, it allows the instrument's versatility to be controlled by the autosampler using the same operator.



Important: The Eclipse 5300 must have the Application updated to **Revision 5.03 or later**.



Connecting the olera System to an Eclipse 5300

Connecting your olera unit to an Eclipse 5300 is quick and straightforward using the built-in **user interface**. Once configured, the olera bath can be controlled by the autosampler. This connection can be established through:

- A **local L3 Ethernet switch (OPTION)** - supports static and dynamic routing protocols, or
- A **domain-based network** within your organization.

Ethernet Connections

1. Connect the olera and the Eclipse 5300 to a **Layer 3 Ethernet switch** or to a domain network connection.

2. On the olera dissolution bath, log in as part of the admin group and select **Settings | Network Settings** menu.
3. Set the **Network type to Manual**
 - Using a local Layer 3 Ethernet switch – set your desired IP address.
 - Using a domain network – set the **IPv4 address** based on your company-assigned IP addresses.
4. Select Save.
5. On the Eclipse 5300 sampler, log in as part of the admin group and select **Settings | System Setup | Advanced** menu.
6. Scroll down to locate **olera Bath IP** and enter the appropriate IP address (from step 3).
7. Locate Bath A Type, then select Search Bath Type.
8. A response is automatically generated showing that the olera bath was (step 3) was located.
9. Select Accept Bath Type.
10. Enter Bath A ID appropriately – on olera, select Settings | Instrument | Instrument ID.
11. Repeat the above steps if connecting a second olera dissolution bath to the child Eclipse 5300 sampler.

10.3 Dosage Delivery System

Automated Precision for Unattended Testing

The **Dosage Delivery System (DDS)** is designed to streamline your dissolution workflow by enabling **automated, unattended introduction of dosage forms** at the start of a test. Whether triggered by **temperature** or **timed release**, DDS ensures consistent and precise delivery—saving analysts valuable time and eliminating variability between users.

Installing the DDS Modules

Follow these steps to install the DDS modules on your olera unit:

1. Install DDS-Compatible Vessel Covers

Begin by installing the **vessel covers designed for DDS use**. These covers feature **dual slotted holes** to hold the DDS modules securely.

2. Attach DDS Modules

- Align each **DDS module** with the slotted holes on the vessel cover.
- Gently press the module down until the **pegs fit securely** into the slots.

3. Connect the DDS

- Set the height block for paddles, then lower the drive head.
- Remove the **rubber plugs** from both sides of the DDS connectors.
- Plug each DDS connector into the **underside of the drive plate**.
- The connectors are **keyed** for proper alignment—use the **white arrow indicator** on each connector as a guide.

When properly installed, the DDS modules should sit flush and securely on each vessel cover, ready for automated operation.

Storage & Usage Guidelines

How you store and manage your DDS modules depends on your lab's workflow:

- **Frequent Use:**

If DDS is used regularly, keep the modules **connected** and store them on the **magnetic rail** when not in use. This allows for quick deployment and minimizes handling.

- **Occasional Use:**

For selective use with specific methods or products, you can **disconnect the DDS modules** and store them in a **drawer or designated container**.



Tip: Use the **rubber connector caps** when storing DDS modules to prevent **corrosion** or damage to the electrical contacts.

Ready for Automation

With DDS installed, your OLERA system is now equipped for **automated dosage delivery**, helping you achieve consistent, reproducible results with less manual intervention.

10.4 Distek Cipher Software Integration

Centralized Control and Data Integrity for OLERA Systems

Cipher Dissolution Control Software, developed by **Distek**, is a powerful Windows-based application designed to seamlessly control and manage dissolution testing instruments—including the **olera Dissolution Bath Unit**. Cipher provides a centralized platform for instrument control, data capture, and regulatory compliance, making it an essential tool for modern pharmaceutical laboratories.

What Is Cipher?

Cipher is more than just a control interface—it's a comprehensive solution for:

- **Instrument Control:** Operates Distek dissolution testers, autosamplers, and disintegration testers.
- **Data Management:** Automatically captures and stores all test data, eliminating manual logging.
- **Regulatory Compliance:** Fully supports **21 CFR Part 11** and **Data Integrity** standards, including audit trails and electronic signatures.

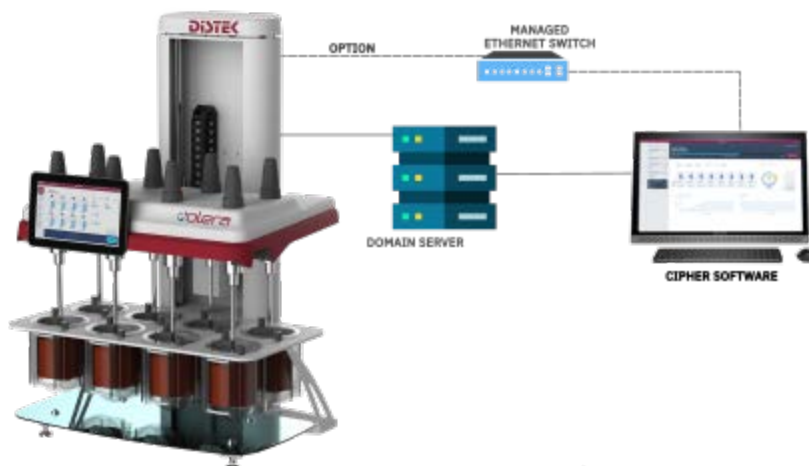
Connecting the olera System to Cipher

The **olera Dissolution Bath Unit** connects to Cipher via **Ethernet**, allowing real-time control and monitoring. This connection can be established through:

- A **local L3 Ethernet switch** - supports static and dynamic routing protocols, or
- A **domain-based network** within your organization.



Important: For detailed setup instructions, refer to the **Distek Cipher Operation Manual (Document #3800-0155)**.



Once connected, all test parameters, results, and system interactions are securely stored within Cipher, ensuring traceability and compliance.

Key Features for olera Users

- **Automated Data Capture:** Every test run on the olera unit is logged and stored within Cipher.
- **Electronic Signatures:** Apply signatures to methods and reports with customizable roles (originator, approver, reviewer).
- **Security Customization:** Tailor access levels and permissions to match your company's policies and regulatory needs.
- **Flexible Deployment:** Install Cipher as a standalone application or across a network for multi-user access.

Why Use Cipher with olera?

Pairing Cipher with the olera system transforms your dissolution workflow by:

- Reducing manual errors
- Enhancing data security
- Simplifying audit readiness
- Improving operational efficiency

10.5 Distek Opt-Diss Software Integration

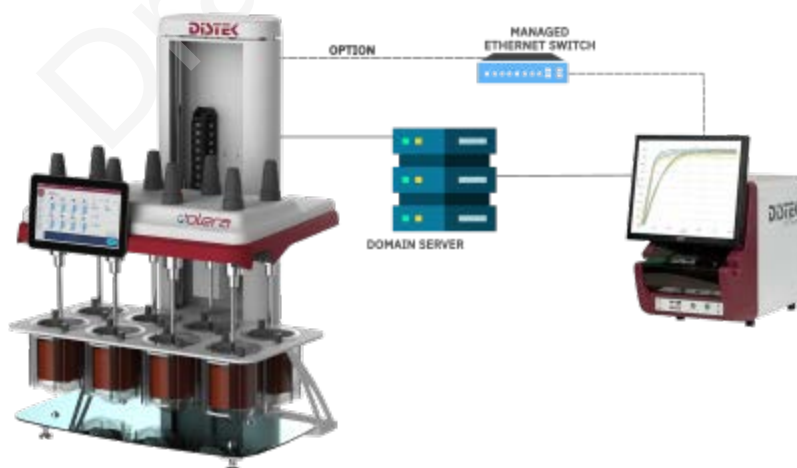
Real-Time, In-Situ UV Analysis for OLERA Dissolution Baths

The **Opt-Diss 410 System**, developed by **Distek**, revolutionizes dissolution testing by bringing **UV measurement directly into the vessel**. This eliminates the need for manual or automated sampling, along with the associated consumables, labor, and off-line analysis. When paired with the **olera Dissolution Bath Unit**, Opt-Diss enables high-frequency, real-time data collection with unmatched efficiency.

Why Opt-Diss?

- **No Sampling Required:** Optical probes measure directly in the vessel—no filters, tubing, or syringes needed.
- **Rapid Data Collection:** Capture sample points as frequently as **every five seconds**.
- **Reduced Costs & Labor:** Eliminate consumables and manual handling.
- **Flexible Probe Options:** Choose between patented **ARCH probes** or the new **Variprobe Adjustable Pathlength Dip Probe**.

Software Control & Connectivity



Connecting the olera System to an Opt-Diss

The **Opt-Diss Software** is designed to remotely **access and control Distek dissolution baths**, including the olera system. It enables synchronized operation and data acquisition,

streamlining your workflow and enhancing data integrity. This connection can be established through:

- A **local L3 Ethernet switch** - supports static and dynamic routing protocols, or
- A **domain-based network** within your organization.

Connection Requirements

To connect the olera bath to the Opt-Diss software:

1. Ethernet Connection

Use an Ethernet cable to connect the olera bath's Ethernet port to the **Opt-Diss workstation** via a **local hub** or **network domain**.

2. Power On the Spectrometer

Flip the **rear On/Off switch** to power on the spectrometer.

3. Start the PC and Spectrometer

- If the PC doesn't boot automatically, press the **PC button** on the front panel.
- Then press the **Source & Detector** button to initialize the spectrometer.

4. Log in to the System

Log in as a **local Administrator** who is part of the **OPT-DISS™ Administrators Group**.

Wait at least **30 seconds** before proceeding.

5. Launch the Software

Double-click the **OPT-DISS shortcut icon** on the desktop.

Enter your password when prompted.

6. Configure the Bath Connection

Navigate to:

Tools → System Configuration → Bath Configuration

Enter the **IP Address of the olera dissolution bath** to establish control.



Important: For detailed setup instructions, refer to the **Opt-Diss Operation Manual (Document #3881-0001)**.

Unlock the Power of In-Situ Analysis

With Opt-Diss and olera working together, your lab gains:

- Faster turnaround times
- Reduced operational complexity
- Enhanced data accuracy and integrity
- Full compliance with regulatory standards

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Dashboard

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11 Dashboard

Your Command Center for Dissolution Testing

The **Dashboard** is the heart of the olera system's **Graphical User Interface (GUI)**, designed to make controlling your dissolution bath intuitive and efficient. By using **visual icons, indicators, and menus**, the Dashboard provides a clear, real-time view of instrument status and test parameters—all at your fingertips.

Why the Dashboard Matters

The GUI eliminates complexity by replacing text-heavy commands with **easy-to-understand graphics**. This approach allows users to:

- Monitor all vessels at a glance (plus and select models)
- Adjust critical parameters quickly
- Start, pause, or stop tests with a single tap



USB-C Thumb Drive Formatting Requirements

For methods, reports, and firmware upgrades, the USB-C thumb drive must be formatted as follows:

- **SDHC (Secure Digital High Capacity) drives**
(2 GB to 32 GB): Format using FAT32
- **SDXC (Secure Digital eXtended Capacity) drives**
(64 GB to 2 TB): Format using exFAT

11.1 standard Layout Overview

Navigation Menu

Located on the left sidebar, the navigation menu provides quick access to all major functions:

- **DASHBOARD:** Returns to the main control screen for real-time monitoring and test execution.
- **METHODS:** Access, create, and manage stored test methods for routine or specialized dissolution tests.
- **REPORTS:** View completed or aborted test reports, print them, or export data.
- **SETTINGS:** Configure instrument parameters, accessories, security, and system preferences.
- **LOGOUT:** Securely exit the system to maintain data integrity and user accountability.

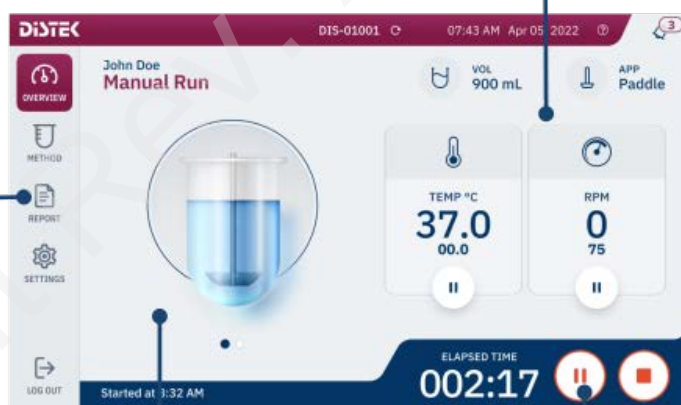
Status Panel

Located in the center of the Dashboard, this section provides real-time monitoring of individual vessels:

- **VESSEL STATUS:** Vessel icon shows status for active or inactive tests.
- **APPARATUS ID:** Displays serial numbers for components such as shafts, paddles, baskets, and vessels for traceability.

Test Parameters

- **Volume Setting:** Shows current media volume used.
- **Apparatus:** Displays the current used for the test.
- **Temperature Control:** Shows temperature and setpoint.
- **RPM Control:** Displays current spindle speed and target speed.
- **Start/Pause Buttons:** Provide quick control for starting and stopping stirring and temperature.



Sampling & Timer Panel

- **ELAPSED TIME:** Tracks test duration in real time.
- **SAMPLING:** Running methods, display the number of samples.

11.2 plus & select Layout Overview

Navigation Menu

Located on the left sidebar, the navigation menu provides quick access to all major functions:

- **DASHBOARD:** Returns to the main control screen for real-time monitoring and test execution.
- **METHODS:** Access, create, and manage stored test methods for routine or specialized dissolution tests.
- **REPORTS:** View completed or aborted test reports, print them, or export data.
- **SETTINGS:** Configure instrument parameters, accessories, security, and system preferences.
- **LOGOUT:** Securely exit the system to maintain data integrity and user accountability.

Status Panel

Located in the center of the Dashboard, this section provides real-time monitoring of individual vessels:

- **TEMPERATURE:** Each vessel icon shows its current temperature.
- **VESSEL SELECTIONS:** Vessels are numbered for easy identification and can be individually selected.
- **APPARATUS ID:** Displays serial numbers for components such as shafts, paddles, baskets, and vessels for traceability.

Test Parameters

- **Volume Setting:** Shows current media volume used.
- **Apparatus:** Displays the current used for the test.
- **Temperature Control:** Shows temperature and setpoint.
- **RPM Control:** Displays current spindle speed and target speed.
- **Start/Pause Buttons:** Provide quick control for starting and stopping stirring and temperature.



Sampling & Timer Panel

- **ELAPSED TIME:** Tracks test duration in real time.
- **SAMPLING:** Running methods, display the number of samples.

11.3 Methods

Create, Save, and Run Your Dissolution Methods with Ease

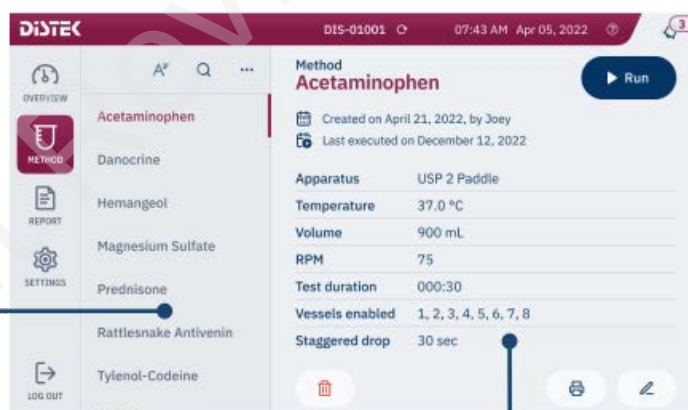
The **Methods** menu is your gateway to building and managing test protocols for the olera dissolution bath. This feature allows you to **create, store, and execute methods** for routine or specialized dissolution tests, ensuring consistency and compliance across all sessions.

Why Use Methods?

By saving your test parameters as a method, you eliminate repetitive setup steps and reduce the risk of manual errors. olera can store methods, making it ideal for labs with multiple products or test conditions.

Method Listing

- **View all methods** - Displays a scrollable list of all saved methods.
- **Sort methods** - Displays scrollable list of all saved methods.
- **Search Methods** - Quickly locate a specific method using the search bar.
- **Create, Export, Import**
 - **Create**: Build a new method from scratch.
 - **Export**: Save a method externally for backup or sharing.
 - **Import**: Load a method from another OLERA system or network.



Method Summary Panel

When you select a method from the list, the summary panel displays its parameter settings.

Delete, Print, Edit:

- **Delete** - Allowed members of the admin group to delete the method.
- **Print** - Allows the user to preview or print the method.
- **Edit** - Allowed members from the admin group to edit the settings.

11.4 Reports

Access, Review, and Export Your Test Results

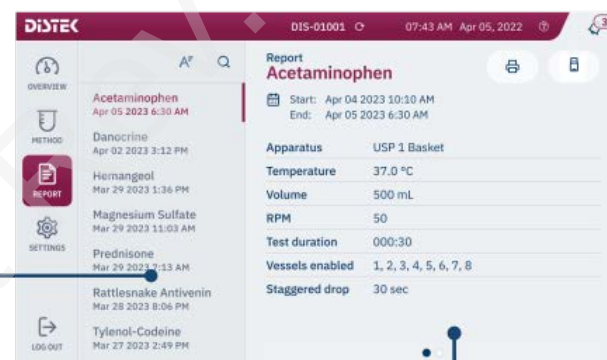
The **Report** menu is your central hub for managing all completed and aborted dissolution tests. Whether a test was executed using a saved method or run manually, every session is logged and stored for easy retrieval, review, and documentation.

Best Practices

- Regularly export reports to maintain backups and ensure compliance with data integrity requirements.
- Use CSV format for advanced data analysis in spreadsheet applications.
- Confirm printer connectivity before initiating print jobs.

Report Listing

- **View all reports** - Displays a scrollable list of all saved reports.
- **Sort methods** - Allows user to sort reports in ascending or descending order.
- **Search reports** - Quickly locate a specific report using the search bar.



Report Summary Panel

When you select a report from the list, the panel displays a summary of the report.

Print, Export:

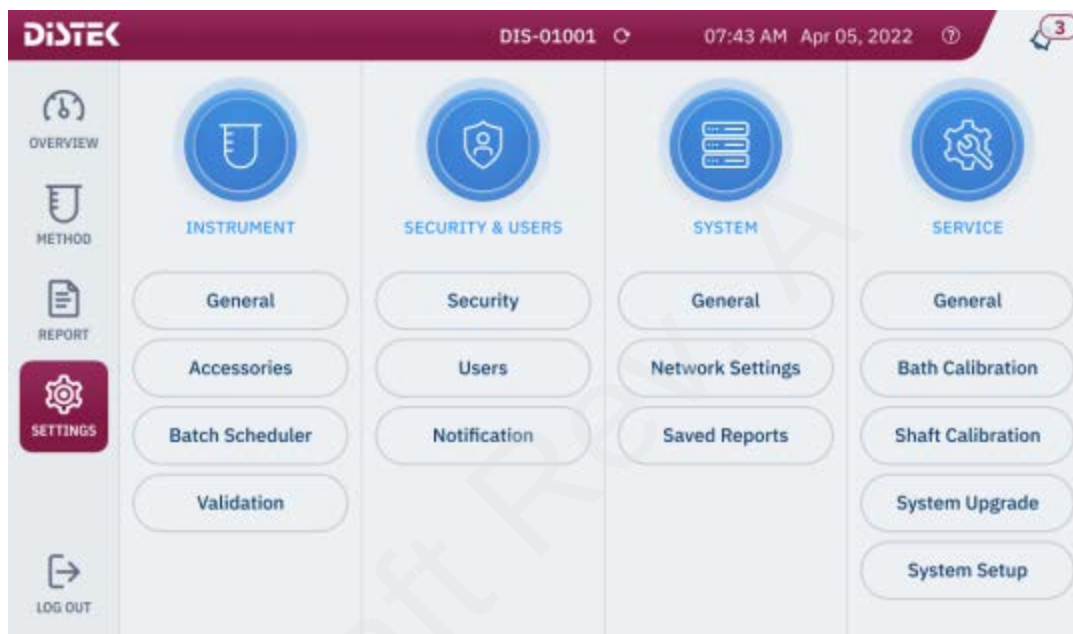
- **Print** - Allows the user to preview or print the report.
- **Export** - Allows the user to export the report as CSV or a PDF file using a thumb drive.

Use your finger to swipe back and forth to view more pages of the report.

11.5 Settings

Customize and Control Your olera System

The **Settings** menu provides access to all configuration options for the olera dissolution bath. From instrument setup to user security and system maintenance, this section allows you to tailor the system to your laboratory's requirements and ensure compliance with operational and regulatory standards.



The Settings screen is divided into **four main categories**, each containing specific configuration options:

Instrument

- **General**
 - Assign an **Instrument ID** for easy identification.
 - Configure **USP tolerances** for temperature and RPM.
 - Adjust **temperature control parameters** for precise operation.
- **Accessories**
 - Set up connected accessories such as:
 - **Printer** for report output

- **Dosage Delivery System (DDS)** for automated dosage introduction
- **Bath lighting** for visibility
- **Small-volume and low-temperature bath options** for specialized tests
- **Validation**
 - Schedule and manage **electronic validation tags** for routine maintenance and compliance checks.

Security and Users

- **Security**
 - Configure **security settings**, including password policies and inactivity lock screens.
- **Users**
 - Admin-level users can **create and manage user accounts**, assigning roles and permissions.
- **Notifications**
 - Set **contact preferences** for alerts related to alarms, events, or system status changes.

System

- **General**
 - Enter **company name, instrument location**, and set **date and time** for accurate reporting.
- **Network Settings**
 - Configure the **IP address** for Ethernet connectivity, enabling integration with software like Cipher or Opt-Diss.
- **Saved Reports**
 - Define a **domain location** for storing reports, ensuring centralized data management and compliance.

Service

- **General**
 - Access the **maintenance log** for tracking service history and part replacements.
- **Bath Calibration**
 - Perform **temperature calibration** to maintain accuracy.
- **Shaft Calibration**
 - Calibrate shafts for **olera Plus and Select models**, ensuring precise vessel temperature responses.
- **System Upgrade**
 - Update the **olera application and firmware** to the latest version for improved functionality.
- **System Setup**
 - Configure **instrument type, number of vessels**, and **Halo LED lighting control**.

Best Practices

- Regularly review validation schedules to maintain compliance.
- Perform calibration checks after major maintenance or relocation.



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Manual Test Operation

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12 Manual Test Operation

This chapter describes the operation of running manual tests, creating methods, running a method, and printing or exporting the report. Follow these steps to perform a manual dissolution test without using a pre-saved method:

Access the Dashboard

- From the **navigation menu**, select **Dashboard**.
- Confirm that all vessels, shafts, and paddles/baskets are correctly installed and fill the vessels appropriately.

Set Test Parameters

- **Apparatus Type:** Select USP Apparatus (e.g., Paddle or Basket).
- **Media Volume:** Enter the desired volume (e.g., 900 mL).
- **Temperature Setpoint:** Set the bath temperature (e.g., 37.0°C).
- **RPM:** Enter the spindle speed (e.g., 75 RPM).

Enable Vessels

- For **plus & select** models, select the vessels you want to use for the test by tapping their icons.

DISSOLUTION MANUAL BATH QUICK GUIDE

- 1. Access the Dashboard**

From the navigation menu, select the Dashboard


- 2. Set the Test Parameters**

Enable vessels
Apparatus
Temperature
RPM
Volume

 - For plus and select models, select to enable the vessels
 - Apparatus Type: select USP apparatus
 - Volume: set volume and fill the vessels accordingly
 - Temperature Setpoint: set the bath or vessels temperature
 - Stirring Setpoint: enter RPM speed
- 3. Start the Test**

Tap TEMP play button
Tap RPM play button
Start timer

 - Press the **Start** buttons on the **RPM** and **TEMP**
 - The system will begin heating and stirring according to the parameters you entered
 - Stop the stirring to introduce dosages at desired temperature
 - **OPTION:** Press the Start button on the timer panel. This allows users to visually see the elapse time
- 4. Monitor Progress**

Observe real-time data on dashboard

 - Temp. vs. setpoint
 - RPM vs. target speed
- 5. Pause or Stop**
 - Use the Pause button to temporarily halt the test
 - Press Stop when the test is complete or if you need to end it early
- 6. Review or Print Report**

Navigate to the **Report** menu and select the completed mannua from the report list
- 7. End Session**

Return to the **Dashboard** or log out

Start the Test

- Press the **Start** buttons on the RPM and TEMP.
- The system will begin heating and stirring according to the parameters you entered.
- OPTION: Press the Start button on the timer panel.

Monitor Progress

- Observe real-time data on the Dashboard:
 - o Bath temperature vs. setpoint
 - o RPM vs. target speed
 - o Slide the vessels panel to display the **test details** screen
 - o Individual vessel temperatures (plus & select)
 - o Elapsed time counter

Pause or Stop (If needed)

- Use the **Pause** button to temporarily halt the test.
- Press **Stop** when the test is complete or if you need to end it early.

Save or Print Report

- After the test ends, go to **Report** in the Navigation Menu.
- View the test summary and choose to **Print** or **Export** the report (PDF or CSV) to USB.



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Method Test Operation

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13 Method Test Operation

A Method Test allows you to execute a **pre-configured dissolution method** that contains all test parameters—temperature, RPM, media volume, apparatus type, timing, and enabled vessels. Running a method ensures consistency, repeatability, and regulatory compliance across multiple analysts and test sessions.

Access the Dashboard

- From the **navigation menu**, select **Methods**.

Select the Desired Method

- Scroll or use the search function to locate the method you wish to run.
- Highlight the method to display the **Method Summary**, which includes:
 - Method name
 - Creation and last execution date
 - Apparatus type (USP 1/2/5/6)
 - Target temperature
 - RPM
 - Media volume
 - Enabled vessel numbers
 - Stagger or synchronized start times
 - Test duration
 - Review the details to ensure you have selected the correct method.

DISSOLUTION METHOD BATH QUICK GUIDE

- 1. Access the Dashboard**

From the Dashboard, select **Methods** menu
- 2. Select the Desired Method**

Select the Desired Method
 - Scroll or search for the method
 - Highlight the method to display the **Method Summary**
 - Verify the method details for accuracy

Method Name
Apparatus
Temperature
RPM
Volume
Sampling time
- 3. Prepare the Instrument**

Verify that the physical setup matches the method requirements:
 - Correct apparatus are installed
 - Vessels are in their correct location
 - Vessels are filled with correct media & volume

With the method selected, tap on **Run** button. This will automatically start pre-heating the media and stirring.
- 4. Begin the Method**

Once the TEMP & RPM meets the criteria, follow the prompts to introduce the dosages. After introducing the dosages, the timer starts.
- 5. Test Completion**
When the method reaches its end point, the OLERA bath will stop stirring and depending on the bath type, the heating stops. A completion message will appear on the screen. At this point, proceed with test cleanup.
- 6. Review/Print the Report**
Navigate to the **Report** menu and select the completed method from the report list
- 7. End Session**
Return to the **Dashboard** or log out

Prepare the Instrument

Before running the method, verify that the physical setup matches the method requirements:

- Install the correct **apparatus** (paddles, baskets, or stations).
- Confirm the correct **vessels** are installed and serialized properly.
- Ensure the **media volume** is correct, and the bath is filled to the proper level.
- Confirm that the **temperature setpoint** in the method aligns with your test requirements.
- Install vessel covers, probes, or accessories if required.

Load the Method

- Tap the **Run** button to load the method into the control screen.
- The instrument will automatically populate all test parameters based on the saved method file.

Begin the Method Test

- Press **Start** to begin the dissolution run.
- The OLERA bath will:
 - Heat the bath to the programmed temperature
 - Start stirring at the set RPM
 - Begin any staggered or timed dosage introduction events (if configured)
 - Track elapsed test time automatically

Monitor Progress

During the method execution, the Dashboard displays:

- Real-time temperature readings
- Actual vs. target RPM
- Individual vessel temperatures (RTD equip baths)
- Elapsed test time
- Apparatus type and active vessels

Test Completion

- When the programmed method reaches its endpoint, the OLERA bath, depending of the instrument type, will automatically stop heating and stirring
- A completion message will appear on the screen.
- At this point, remove samples (if applicable) or proceed with post-test cleanup.

Review or Print the Report

- Navigate to the **Report** menu.
- Select the completed method run from the report list.
- You may:
 - o **View** the report on screen
 - o **Print** the report to a connected printer
 - o **Export** the report to USB in PDF or CSV format

End Session

Return to the Dashboard or log out using the **Log out** button to maintain data integrity.



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Bath and Shaft Calibration

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14 Bath and Shaft Calibration

Purpose

This procedure describes the method for verifying and calibrating the bath and shaft temperature sensors of the Distek olera instrument to ensure accurate temperature control and compliance with Distek specifications.

Scope

This procedure applies to all **Distek olera instruments**, including **standard, plus, and select models**, used in laboratory environments requiring controlled temperature conditions.

Calibration Frequency

- Temperature sensors are factory calibrated to **± 0.2 °C accuracy** using a **NIST-traceable digital thermometer**.
- Distek recommends **verification every six (6) months**.
- Recalibration should be performed if readings fall outside the acceptable tolerance.



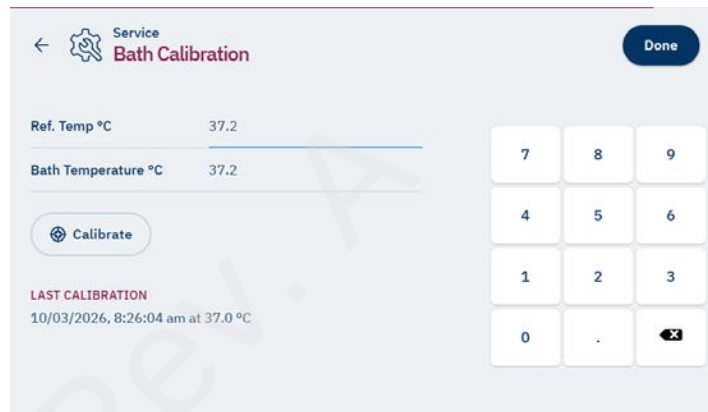
Only users that belong to the Administrator and Manager groups can perform temperature calibration.

Access the Calibration Menu

1. Open the **Settings | Service** menu.
2. Select one of the following options depending on the instrument configuration:
 - **Bath Calibration** – for **Standard** and **Plus** units
 - **Shaft Calibration** – for **Plus** and **Select** units

Bath Calibration Procedure

1. Set the **bath temperature to 37.0 °C** and allow the system to begin heating.
2. Insert the **reference thermometer** into the **center port of the vessel plate**.
3. Allow the bath temperature to **stabilize at the set temperature**.



4. Navigate to **Settings | Service | Bath Calibration**. A calibration dialog window will appear:
 - o Select **No** if only minor adjustment is required.
 - o Select **Yes** if major adjustment is required.
5. Select **Ref. Temp °C** and enter the reference thermometer reading using the numeric keypad.
6. Select **Calibrate**.
7. Wait until the **Bath Sensor °C** reading matches the reference temperature within **±0.2 °C**.
8. Confirm that the **Last Calibration** field has been updated to record the calibration event.
9. Select **Done** - completes the bath calibration.

For Shaft Calibration

LOW - CALIBRATION

1. Set the temperature as follows:

- o For **plus**, let the bath cool to room temperature and fill vessels with 20 to 23°C media.
- o For **select**, fill vessels with 20 to 23°C media.

2. Allow the bath or vessels to **reach and stabilize at the set temperature.**

Service
Shaft Calibration

Ref. Temp °C 36.91

Shaft Sensor °C 36.91

Calibrate

LAST CALIBRATION
10/03/2026, 8:27:08 am
Lo-Cal 25.00 °C
Hi-Cal 36.65 °C

3. Navigate to **Settings | Service | Shaft Calibration**. A calibration dialog window will appear:
 - o Select **No** if only minor adjustment is required
 - o Select **Yes** if major adjustment is required.
4. Place the reference thermometer in vessel position #1.
5. Select vessel position #1 icon.
6. Allow for the reference thermometer to equilibrate.
7. Select **Ref. Temp °C** and enter the reference thermometer reading using the numeric keypad.
8. Select **Calibrate**.
9. Wait until the **Shaft Sensor °C** reading matches the reference temperature within **±0.2 °C**.
10. Confirm that the **Last Calibration** field has been updated.
11. Repeat **Steps 4–10** for each remaining shaft position.

HIGH - CALIBRATION

1. Set the temperature as follows:

- o For **plus**, set the bath temperature to 41°C
- o Fill vessels with 40-42°C media.

- o For **select**, fill vessels with and set the temperature to 41°C.
2. Repeat **Steps 2–11** for each remaining shaft position.
 3. Select **Done** - completes the shaft calibration.

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System Upgrade

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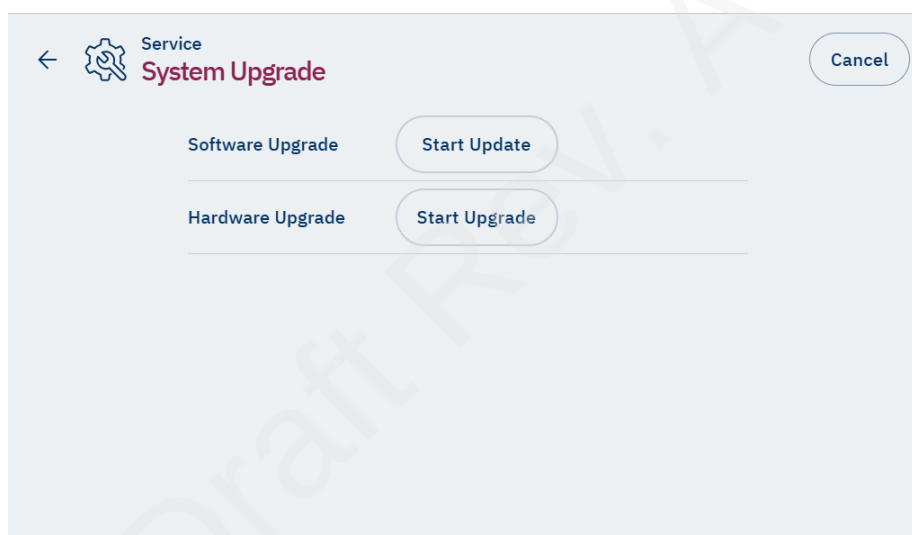
15 System Upgrade

Purpose

This procedure describes the method for upgrading the User Interface (UI) application software and hardware firmware for the dissolution bath instrument. Performing periodic upgrades ensures the system operates reliably and continues to meet Distek performance specifications, system stability requirements, and compliance expectations.

Only users that belong to the Administrator and Manager groups can perform upgrades.

Upgrades may include improvements such as software enhancements, bug fixes, performance optimizations, and compatibility updates.



Scope

This procedure applies to all Distek Olera Dissolution Instruments, including the following configurations:

- olera Standard
- olera Plus
- olera Select

These instruments are designed for laboratory environments requiring controlled temperature conditions and regulated dissolution testing.

This procedure applies only to authorized firmware and application update files provided by Distek.

Responsibilities

Laboratory Personnel

- Ensure the instrument is not actively running a test before performing an upgrade.
- Follow this procedure when installing UI or firmware updates.
- Report any errors or irregularities observed during the upgrade process.

Laboratory Supervisor or System Administrator

- Ensure the correct and approved firmware files are used.
- Maintain documentation of performed upgrades if required by laboratory quality systems.

Distek Technical Support

- Provide approved firmware and UI upgrade files.
- Assist with troubleshooting if an upgrade fails or the instrument does not operate as expected after an update.

Safety and Precaution

Before performing a software or firmware upgrade, observe the following precautions:

- Ensure the instrument is **not actively running a dissolution test**.
- Do **not disconnect power** during the upgrade process.
- Do **not remove the USB drive** while the update is in progress.
- Use only **approved firmware files provided by Distek**.
- Interrupting the upgrade process may cause **system malfunction or incomplete installation**

Required Materials

The following items are required to perform the upgrade:

- **USB-C flash drive**
- **Approved UI or firmware upgrade files provided by Distek**
- Access to the instrument display interface

Preparation

Before starting the upgrade procedure:

1. Verify that the instrument is powered on and operating normally.
2. Confirm that no dissolution tests are currently running.
3. Ensure the USB-C flash drive contains the correct upgrade files
4. Verify the USB drive is compatible and functioning properly
5. Locate the USB-C port on the right side of the instrument display.

Upgrade Procedures

Follow the steps below to perform the upgrade:

Step 1 – Insert the USB Drive

Insert the USB-C flash drive containing the upgrade files into the **USB-C port located on the right side of the display.**

Step 2 – Select the Upgrade Type

Start Update (Application)

Updates the User Interface (UI) application software.

Start Upgrade (Hardware)

Updates the **instrument hardware firmware.**

Select the appropriate option depending on the update provided.

Step 3 – Begin the Upgrade

After selecting the upgrade option:

1. Confirm the update selection.
2. The instrument will begin the upgrade process automatically.

The upgrade may take **several minutes** to complete depending on the update type.

During this time:

- Do **not power off the instrument**
- Do **not remove the USB drive**
- Do **not attempt to operate the instrument**

Progress may be displayed on the screen.

Step 4 – Completion

Once the upgrade process is complete, the system will indicate that the update has finished.

Instrument Restart

After the upgrade completes:

1. Remove the USB flash drive
2. **Reboot the instrument** using the system restart option or by cycling power if required.

3. Allow the instrument to fully restart.

Restarting the system allows the **new software or firmware changes to take effect**.

Post-Upgrade Verification

After the instrument restarts, verify that the system is functioning properly.

Check the following:

- The instrument display loads normally.
- The user interface responds correctly to input.
- Temperature control and system functions operate normally.
- No error messages are present.

Verify the **software or firmware version number** through the system information menu.

Troubleshooting

If the upgrade process fails or the instrument does not operate as expected, perform the following checks:

Upgrade does not start

- Verify the USB drive contains the correct firmware files.
- Ensure the USB drive is fully inserted.
- Confirm the USB drive is compatible and functional.

Upgrade process stops or freezes

- Wait several minutes to confirm the system is not still processing.
- If the system remains unresponsive, contact Distek Technical Support.

Instrument does not restart properly after upgrade

- Power cycle the instrument.
- If the issue persists, contact Distek Technical Support before attempting further actions.

Technical Support

If assistance is required during or after the upgrade process, contact support@distekinc.com for guidance before attempting additional repairs or modifications.



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Maintenance

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16 Maintenance

General Maintenance

This section provides guidelines for maintaining the dissolution bath to ensure reliable operation and consistent test results. Perform the following maintenance steps regularly.

Instrument Cleaning

Clean the exterior surfaces of the instrument periodically using a soft cloth lightly dampened with water. Do not use harsh chemicals, abrasive cleaners, or detergents, as these may damage the instrument surfaces.

Vessel Support Plate Care

The vessel support plate requires special attention during cleaning and operation. Do not allow acids, buffers, or other test media to remain on the plate for extended periods. After each use, wipe the plate clean and dry with a soft cloth. Avoid scratching or damaging the painted surface.

Shafts, Paddle Blades, and Baskets

Do not allow acids or buffer solutions to dry on the shafts, paddle blades, or baskets. After each use, thoroughly rinse these components with deionized (DI) water and dry them completely before storage or reuse.

Bath Cleaning

The dissolution bath is constructed from acrylic. Acrylic can be damaged by certain chemicals and solvents. Do not clean the bath with alcohol (including isopropyl alcohol), acetone, ammonia-based cleaners, or similar chemicals, as these may cause cracking or surface crazing. Clean the bath using mild soap and water only.

Instrument Level Check

Periodically verify that the instrument is properly leveled. An unlevel instrument can affect test performance. Adjust the leveling feet as necessary to maintain proper alignment.

Electronics

The electronic components of the instrument do not require routine user maintenance. If the instrument experiences an electronic malfunction, contact Distek technical support before attempting any repairs.

Lubrication

This describes the proper procedure for lubricating the drive belts to ensure smooth operation. To maintain consistent performance, apply a small amount of high-vacuum grease to the toothed portion of the drive belt while the shaft spindles are rotating. After application, remove any excess grease using a clean cloth or paper towel.

Only a minimal amount of grease is required. Excess lubricant may attract dust or debris and should be removed.

Belt Tension Adjustment

This section describes how to check and adjust the drive belt tension.

1. Run the stirring mechanism at **300 RPM**.
2. Observe and listen to the drive belts during operation.

Indicators of incorrect belt tension:

- **Loose belt:** The belt may skip on the pulley, producing a noticeable skipping sound or visible slippage.
- **Over-tightened belt:** Excessive vibration may be felt on the drive plate and vessel plate.

If adjustment is required, modify the belt tension by repositioning the **movable cog spindle**:

- Slide the spindle **toward the front** of the instrument to **tighten** the belt.
- Slide the spindle **toward the rear** of the instrument to **loosen** the belt.

Adjust the belt gradually and recheck operation at 300 RPM to ensure proper tension.