

DISSOLUTION
UV FIBER OPTIC DISSOLUTION
MEDIA DEGRASSING, DISPENSING, AND DISPOSAL
BATHLESS TABLET DISINTEGRATION
TESTING
CERTIFIED PRE-OWNED INSTRUMENTS
DISSOLUTION
WATER BATH DISSOLUTION
DISSOLUTION AUTOSAMPLER

DiSTEK

MODEL 2500

The Distek Model 2500 Dissolution System offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen. Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 robust and reliable enough for QC applications yet flexible enough for R&D use.

- **VOLUME FLEXIBILITY**

Accommodates up to 8 vessels ranging in size from 100 mL (utilizing Distek's small volume conversion kit) to 2L, allowing the user to run a diverse range of tests.

- **SELF-PRIMING WATER CIRCULATOR / HEATER**

The self-priming design and precise microprocessor control allow for improved temperature uniformity and reduced heating times. The low-profile design allows the circulator to be stowed behind the bath, requiring no additional bench space.

- **ELECTRONIC QUALIFICATION GUIDANCE**

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

- **COLOR TOUCH SCREEN DISPLAY**

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the dissolution test.

- **QUICK CHANGE PADDLES AND BASKETS**

Interchangeable stirring elements coupled with the automatic height adjustment provide a fast transition between Apparatus 1 and 2 without having to remove the shaft.

- **AUTOMATIC HEIGHT ADJUSTMENT**

Setting the height is done through a one-time adjustment and utilization of the interchangeable paddles and baskets.

- **WAKE UP AND SLEEP MODE**

Programmable wake up and sleep modes allow the user to schedule thermocirculator start up and shutdown times to save time and conserve energy.



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MODEL 2500 RTD

The Distek Model 2500 RTD Dissolution System offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen.

Patented wireless temperature sensors continuously monitor and display the in-vessel temperature for each vessel. Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 RTD robust and reliable enough for QC applications yet flexible enough for R&D use.

- **WIRELESS IN-SHAFT TEMPERATURE SENSORS**

Patented wireless temperature sensors control and monitor the temperature.

- Continuously monitor, display and record the in-vessel temperature for each vessel
- Ensure and document temperature compliance throughout the entire dissolution test
- Eliminate additional labor to measure actual temperature in vessels

- **VOLUME FLEXIBILITY**

Accommodates up to 8 vessels ranging in size from 100 mL (utilizing Distek's small volume conversion kit) to 2L, allowing the user to run a diverse range of tests.

- **SELF-PRIMING CIRCULATOR / HEATER**

The self-priming design and precise microprocessor control allow for improved temperature uniformity and reduced heating times. The low-profile design allows the circulator to be stowed behind the bath, requiring no additional bench space.

- **ELECTRONIC QUALIFICATION GUIDANCE**

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

- **COLOR TOUCH SCREEN DISPLAY**

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- **QUICK CHANGE PADDLES AND BASKETS**

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- **AUTOMATIC HEIGHT ADJUSTMENT**

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- **WAKE UP AND SLEEP MODE**

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MODEL 2500 SELECT

The Distek Model 2500 Select Bathless Dissolution System is the culmination of three generations of patented bathless technology with extremely short media heating times and dramatically smaller energy use. The system offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen. Patented wireless temperature sensors continuously monitor and display the in-vessel temperature for each vessel. Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 Select robust and reliable enough for QC applications yet flexible enough for R&D use.

- **BATHLESS HEATING**

Eliminates the water bath and all associated maintenance. Heater jackets raise media temperatures from ambient to 37°C in less than 15 minutes, using considerably less energy in the process. Bathless design also allows high temperature operation up to 99°C.

- **WIRELESS IN-SHAFT TEMPERATURE SENSORS**

Patented wireless temperature sensors control and monitor the temperature.

- Continuously monitor, display and record the in-vessel temperature for each vessel
- Ensure and document temperature compliance throughout the entire dissolution test
- Eliminate additional labor to measure actual temperature in vessels

- **SERIALIZED COMPONENT TRACKING**

Enter and track all serialized components including; paddles, baskets, basket adapters, shafts and vessels.

- **COLOR TOUCH SCREEN DISPLAY**

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the dissolution test.

- **ELECTRONIC QUALIFICATION GUIDANCE**

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

- **QUICK CHANGE PADDLES AND BASKETS**

Interchangeable stirring elements coupled with the automatic height adjustment provide a fast transition between Apparatus 1 and 2 without having to remove the shaft.

- **USP COMPLIANT**

The use of bathless heating is fully compliant per USP General Chapter <711>.



SMALL VOLUME

Performing dissolution tests on high potency drugs with low concentrations of active pharmaceutical ingredients is difficult, if not impossible, with a standard apparatus 1 or 2 dissolution bath. Common analytical instruments are not sensitive enough to detect such low concentrations. Similar difficulties occur during dissolution testing of medical devices, microparticles, beads, and topical drugs, such as creams, gels, and ointments. Distek's Small Volume Conversion Kit offers the perfect solution to all of these common dilemmas.

- **INTERCHANGEABLE PADDLES & BASKETS**

Interchangeable mini stirring elements allow the shaft to remain in place for a quick changeover between paddles and baskets.

- **VOLUME FLEXIBILITY**

The Small Volume Conversion Kit is available in 100 mL and 200 mL volumes offering improved sensitivity and analytical results.

- **AVAILABILITY**

Distek's Small Volume Conversion Kit is available for use with these Distek dissolution instruments: Model 2100 Series, Model 2500, Model 2500 RTD, Evolution 6300 and symphony 7100.

- **ATTACHES DIRECTLY TO A STANDARD DISTEK DISSOLUTION SHAFT**

When using a standard Apparatus 1 or 2 Dissolution system from Distek with detachable stirring elements the mini shaft attaches directly to the end of the shaft for quicker change over from conventional to mini dissolution tests.

- **FLEXIBILITY BY DESIGN**

Ability to run mini versions of paddles, baskets, intrinsic, and ointment cell applications provides unmatched versatility for the laboratory.



ECLIPSE 5300

The Distek Eclipse 5300 Automated Dissolution Sampler offers rapid, accurate sampling using precision syringe pumps. The elimination of valves and rotary pumps along with the optimized sample pathway with a minimal 4.5 mL internal volume increases reliability while reducing common sources of sample carryover. Adding a lower-cost 'child' sampler is a cost-effective way to sample from two baths. Each of the baths may run the same method or two different independent ones. The integrated optional filter changer enables the use of most common 25 mm syringe filters instead of requiring custom filter plates and also additional bench space.

- **RAPID / ACCURATE SAMPLING**

Precision syringe pumps and reduced sample pathway allows for rapid time point high precision collection. Unique fluid handling closely mimics manual sampling.

- **NO VALVES OR ROTARY PUMPS**

The elimination of valves and rotary pumps along with the optimized sample pathway with a minimal internal volume of 4.5 mL increases reliability while eliminating and reducing common sources of sample carryover.

- **COST-EFFECTIVE DUAL BATH SOLUTION**

Adding a lower-cost 'child' sampler is a cost-effective way to sample from two baths. The dual bath configuration allows two different and independent dissolution methods to be run at any time.

- **MEDIA RECYCLING AND REPLACEMENT**

Media Recycling and Replacement offer the advantage of returning unused media and replacing the collected sample volume for ease of dissolution calculations.

- **COLOR TOUCH SCREEN DISPLAY**

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the autosampler.

- **FILTER CHANGER**

The optional, integrated filter changer uses readily available 25 mm syringe filters without the need for custom filter plates or additional bench space.



OPT-DISS₄₁₀

No more sampling! The Distek Opt-Diss 410 in-situ fiber optic UV system measures directly in the vessel, eliminating the need for conventional sampling, and with-it consumables like filters, tubing and syringes, saving time, labor, and money. Moving light rather than liquids also allows generating near real-time dissolution data and nearly limitless sample points as frequently as every five seconds.

- **SIMPLE & EFFICIENT DISSOLUTION TESTING**

Truly automated data collection and analysis means start of test to a complete report only takes as long as the test itself, with no operator interaction required. And collecting data as fast as every 5 seconds is no more effort.

- **MULTICOMPONENT ANALYSIS**

Measure two components in the same dissolution test without the need for LC, including products with two APIs or interaction with excipients, coatings, capsules, or any other source of deviation of the UV spectra.

- **RAPID AND ROUTINE DATA COLLECTION**

With acquisition speeds as fast as 5 seconds for all vessels, collecting near real-time dissolution profiles is ideal for formulators to understand complicated release dynamics as it occurs.

- **IN-SITU UV MEASUREMENTS**

Keeping the science in the vessel! The Opt-Diss 410 measures directly in the vessel, eliminating manual or automated sampling along with the associated consumables, labor and off-line analysis.

- Choose from patented ARCH probes designed specifically for dissolution testing with negligible hydrodynamic effect
- Or conventional dip probes with fixed or interchangeable pathlengths

- **SINGLE SOFTWARE PACKAGE**

21 CFR Part 11 compliant, the Opt-Diss 410 is the only fully integrated UV fiber optic dissolution solution with a single software package controlling the entire system.

- **INDUSTRY APPROVED**

Top pharmaceutical companies as well as the FDA and USP have adopted the Opt-Diss by Distek.

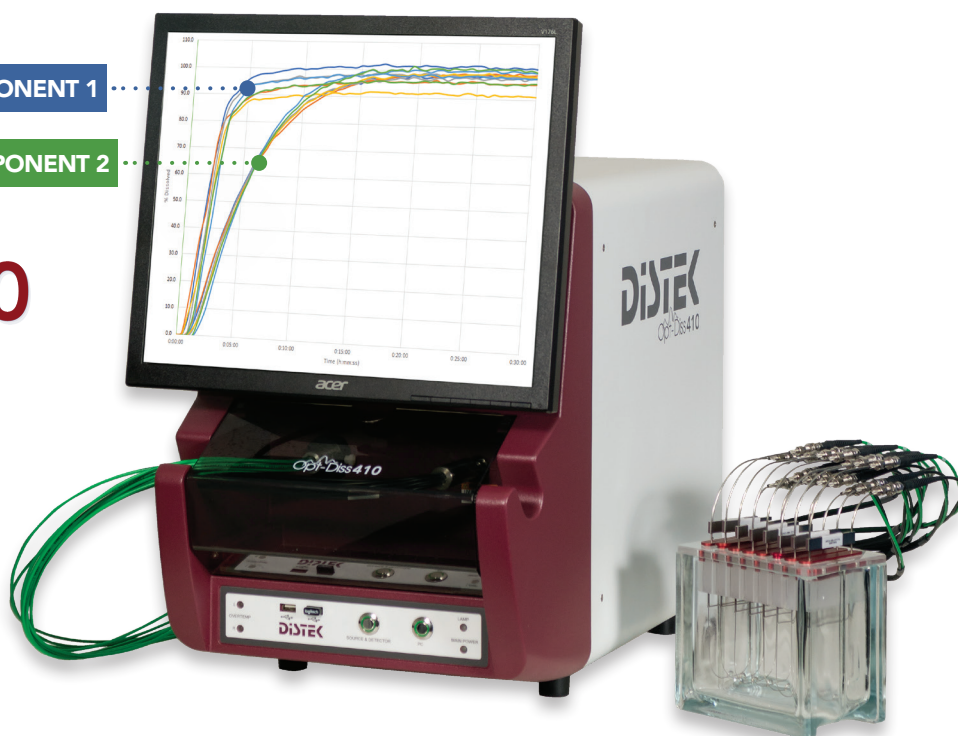
Opt-Diss 410

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COMPONENT 1

COMPONENT 2



EZFILL+

Many of the main causes of OOS dissolution tests and qualification failures are related to media deaeration and dispensing. The ezfill+, with method controlled automated deaeration and dispensing, makes media preparation simple and error free. Reports that include method parameters and user information allow tracking your media preparation as part of a complete data integrity solution. All made possible on a stand-alone basis by a built-in controller using a brilliant touch screen. The unique compact design and optional mobile cart lets one easily move the unit from bath to bath, while the available remote dispensing nozzle allows directly filling vessels in place. The ezfill+ is compatible with most dissolution baths on the market.

- **FAST, RELIABLE & CONSISTENT RESULTS**

In-line heating eliminates the time delay and wasted energy heating bulk media tanks. Combined with high vacuum for effective deaeration and precise media volume delivery in approximately 90 seconds*.

- **COLOR TOUCH SCREEN DISPLAY**

Run stored methods and view/print reports that include dispensing parameters, user information and more.

- **AUTOMATIC ERROR-PROOF MEDIA SETTINGS VIA METHODS**

Set volumes and temperatures manually or via stored methods.

- **TRACK MEDIA PARAMETERS FOR DATA INTEGRITY COMPLIANCE**

Track volumes, temperatures, operator and dispensing time via stored reports.

- **VARIABLE DISPENSE VOLUMES & TEMPERATURE**

User or method selectable volumes from 250 mL to 1000 mL with temperatures from ambient to 45°C.

- **SURFACTANT CAPABLE**

Compatible with media containing up to 2% surfactants. Minimizes foaming issues present in other media preparation systems.

- **COMPACT DESIGN**

Easily fits on a bench or move amongst baths with the optional mobile cart.

*Cycle time is volume and temperature dependent.

**Image shown with "optional" remote dispensing nozzle.



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SENSIR₃₂₀₀

The Distek sensIR 3200 combines two exclusive technologies – bathless heating and Near IR sensing to offer the most innovative disintegration tester. Bathless heating not only reduces warm-up times but eliminates the inconveniences associated with conventional water bath-based instruments. To match your throughput requirements, the sensIR 3200 is available in two, four or six positions in the smallest foot print of any comparably equipped model.

- **BATHLESS HEATING**

Patented Distek heater jackets raise media temperature from ambient to 37°C in less than 8 minutes, doubling the number of tests that can be performed daily. Also uses much less electricity and no algicide, further reducing operating costs.

- **AUTO ENDPOINT DETECTION**

Optional Auto Endpoint Detection uses “Patent Pending” Near Infrared to automatically record actual disintegration times. And it works without the need for modified fluted disks, eliminating method revalidation for products not tested using modified fluted disks.

- **RUN MULTIPLE METHODS SIMULTANEOUSLY**

Run up to three independent methods to simultaneously test different products and/or minimize method development time.

- **ADVANCED USER INTERFACE**

Includes robust features such as: storing of 100 reports and records, running of three unique methods simultaneously, managing 50 users, setting qualification reminders and much more.

- **INTEGRATED TEMPERATURE SENSOR**

Enables the monitoring and documenting of the individual beaker temperatures for improved regulatory compliance while eliminating the need for manually verifying temperature equilibration prior to tablet introduction.

- **SCALABILITY**

Available in 2, 4, or 6 standard positions to meet your productivity needs.

- **SEMI-CIRCLE FOOTPRINT**

Maximizes the placement of up to 6 disintegration stations while minimizing the amount of bench space required.

* The accuracy of auto endpoint detection is not guaranteed and results can be influenced by product and media types. Distek does not warrant the use of NIR detection technology for all products and media types.



CIPHER SOFTWARE

The Cipher dissolution control software is a Windows based application designed and developed by Distek which can be installed locally or networked providing full access to any Distek dissolution instrument on the network. Cipher offers the flexibility to set the level of security appropriate for your laboratory. When enabling all available security features and audit trails and combined with the appropriate customer developed policies, Cipher will meet 21 CFR part 11 compliance. Easy to use and intuitive, the Cipher software features make preparing, running, monitoring, and reporting dissolution test results quick and easy.

- **21 CFR PART 11 COMPLIANCE**

Combined with the appropriate customer policies, Cipher balances the requirements of compliance with limited intrusion on user activities.

- **METHOD WIZARD**

The user is walked through method setup for a dissolution instrument and autosampler.

- **LIMS COMPATIBLE**

When configuring the system, two clicks of the mouse permit the automatic exporting of result files in an ASCII format for access and use by a LIMS package.

- **eSIGNATURES**

The use of electronic signatures guarantees that only approved methods can be used and reports released.

- **INSTRUMENT NETWORKING**

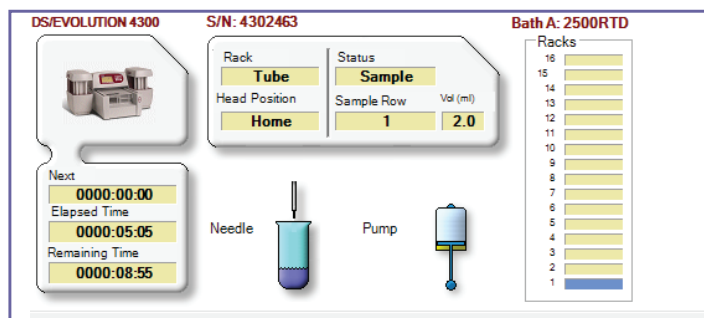
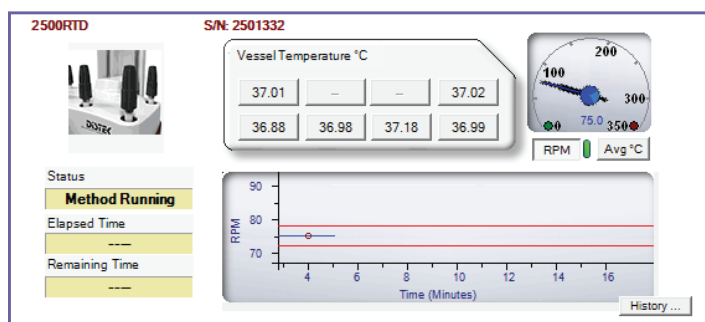
Users are able to log on to a client work station and view the current status of any Distek system on the network. Permits real time, remote instrument setup and monitoring.

- **AUDIT TRAIL**

Event, system and method changes are tracked with a computer generated date and time stamp. Additional information logged includes the user, old and new values, and the reason for change.

- **COMPENDIA ALERTS**

The user can set the specific tolerance parameters for rpm and temperature requiring the system to alert the user should a reading fall outside the acceptable range.



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VALIDATION SERVICES

LET DISTEK HANDLE ALL YOUR VALIDATION NEEDS

Distek provides a large variety of service and validation offerings. All qualifications include cGMP documentation with evidence and verification according to the most recent USP/ASTM specifications. After execution of the applicable tests, Distek's validation engineer will prepare a comprehensive final report. All Distek field service engineers are industry professionals, thoroughly trained and certified with hands on experience. Distek has been an ISO 9001 certified since 2002.

SERVICES & CAPABILITIES

- Asset Management
- Calibration
- Multi-Vendor Services
- Preventive Maintenance
- Qualification (IQ/OQ/PQ/PVT)
- Repairs
- Setup & Installation
- Spare Parts Inventory
- Technical Support
- Validations
- and More

MARKETS SERVED

- Academia
- Agricultural Sciences
- Animal Health
- Bioprocessing
- Biosimilars
- Cannabis
- Food & Flavors
- Generics
- Government Agencies
- Nutraceuticals
- Pharmaceuticals
- and More





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