



ARGUS/Dissolution version 4

Dissolution Automation & Data Management

ARGUS/Dissolution is a scientific dissolution data management software for instrument control, data acquisition, data management, processing and reporting – designed by users for users. Whether you perform dissolution tests occasionally or several times each day ARGUS/Dissolution will make you more productive in running tests and analyzing results.

ARGUS/Dissolution simplifies how you collect and report dissolution test results by letting you choose the analysis template that matches the way you work. Whether you are in QC concerned about data integrity, compliance and validation, or need maximum flexibility in the R&D, ARGUS/Dissolution can help your lab perform more efficiently. Intuitive wizards help anyone in your lab work better – your next dissolution test is running in just a few clicks.

Bringing You Faster to Reliable Results

- Access dissolution data quickly from a database
- Analyze multi component drugs
- Drives spectrophotometers and baths of market leaders
- Grow from single workstations to a laboratory network
- Have data integrity and 21 CFR Part 11 compliance

ARGUS/Dissolution allows you to multi-task without using multiple software packages. You can acquire data and control baths, pumps, auto samplers and spectrophotometers. You can apply advanced calibration algorithms such as MCA and PLS with an instant display of calculated data. You can deploy methods and report templates for common use.

Maximize Productivity

ARGUS/Dissolution is a fundamental shift in dissolution software usability. With its unique Analysis Template Technology, the software is designed for every user in your lab – regardless of their task or skill level. Use the Analysis Wizard to complete parameter sets and run tests with minimal input or maximum flexibility. Navigate the entire

environment from the ARGUS/ Dissolution desktop, including instrument control, real-time dissolution profiles, and a work area to recalculate raw data or to create reports. Review your data without the need of creating reports. Data is displayed “What-you-see-is-what-you-get” and can be signed off electronically.

Exchange Data and Reports

With raw data, methods and report templates stored centrally within the same database, you can easily share information with colleagues or print reports that include only the details you want. Export data into CSV and JCAMP-DX format to feed your dissolution profiles and spectra into third party software like LIMS or office applications.



Compliance

Maintaining regulatory compliance is easy with ARGUS/Dissolution . With the System Qualification Wizard you can schedule your next qualification tasks. Validation protocols covering software, spectrophotometer, baths and accessories are available for systems driven with ARGUS/Dissolution. ARGUS/Dissolution automatically creates detailed audit trails to record changes of methods, analyses, system configurations and other relevant data. Every entry is identified with the date and time of the modification together with the operator's name. Secure system authentication ensures that only authorized users are able to access the system. Permissions for each action can be combined into roles that represent method developers, system administrators, operators or whatever is required in your working environment. As a system administrator you can assign one or more role to each individual user.

Get More Information from Your Test

ARGUS/Dissolution works with full spectra, providing more reliable detection of scattering and making multi linear regression models possible resulting in more accurate multi-component analysis.



Dissolution Calculations

ARGUS/Dissolution has already built-in calculations that corrects for volume changes and mass loss. With this all-in-one approach, time consuming and error-prone transcription of data collected from various sources into spreadsheets will be a thing of the past.

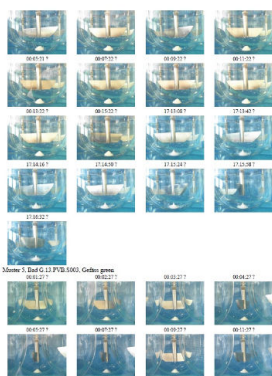
Forge Your Automatic Cleaning Program

ARGUS/Dissolution let you translate your experience with best cleaning procedures into a permanent program. Cleaning tubing and flowthrough cells of an online dissolution system with multiple baths is reliably accomplished with a simple click.

Video & Pictures

A picture tells a thousand words. Consequently ARGUS/Dissolution allows to use standard USB web cameras to take pictures during a dissolution test or to record a

video. Pictures can be included in the report which can be a tremendous help during analytical development. Video monitoring on the other hand can help to understand the dissolution processes better especially for new formulations.



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Enhanced Data Management

ARGUS/Dissolution manages all your data needs From instrument control to final reports, and makes your lab more productive. No matter what type of lab you are working in, you focus on science, not on data transcription or file management. The strength of ARGUS/ Dissolution is its reliability.

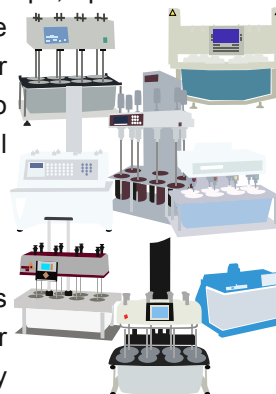
- It collects and stores test results, automatically linking system configuration and method parameter with each dissolution test
- It connects data and any modification applied afterwards with the identity of the operator using the computer system
- It logs relevant events, errors or login failures

Future-Proof Technology

Built on industry standards, developed according regulations and guidance set forth in 21CFR Part11 and GAMP5, ARGUS/Dissolution is designed to be your versatile tool to manage your lab's dissolution test workload while reducing your validation effort to a minimum. Whether you need to control a single bath or support dissolution workflows that span the entire laboratory and even offices, ARGUS/ Dissolution offers the right configuration for you. The database can run on a single workstation or on a server. You can easily add new clients to both and migrate from a standalone system to a dissolution laboratory network.

Drive the Equipment That You Need

ARGUS/Dissolution drives almost all dissolution equipment of any vendor on the market. You can choose your favorite baths, pumps, spectrometers and accessories and build the dissolution system you need or advance existing devices to automated systems at minimal cost.



Spectroscopy System

Designed for sample analysis by means of UV/Vis. Whether you withdraw your aliquots by hand or automatically with an offline system ARGUS/Dissolution provides the appropriate counterpart to continue your dissolution test workflow with only a few clicks. Arrange sample sequences from various baths on your xyz-auto sampler for unattended analysis. Spectra are automatically linked to your analysis dataset with instant calculation of dissolution values.

Offline System

Designed for systems of one or more baths that do automated or manual sampling into vials for offline analysis by HPLC or UV/Vis. With ARGUS/Dissolution you can record stirrer speed, temperature, sampling, and other events required for accurate calculation of dissolution results. You can easily process raw data into a report and add analytical data when available.

Online UV/Vis System

For unattended withdrawal and analysis of samples which recently became indispensable whenever dissolution profiles are required or when the throughput of your bath should be high even during the night or on weekends.

Online HPLC System

For parallel sampling from one or more dissolution baths with subsequent sequential analysis of samples by HPLC. ARGUS/Dissolution transfers work lists or sample sets to the CDS, triggers the start of the chromatogram and imports peak lists or result sets to calculate dissolution profiles.

Fiber-Optic System

Designed for in-situ analysis in the vessel. ARGUS/Dissolution copes with the challenges of multi-channel fiber optic measurement and allows data collection rates limited only by the capabilities of the spectrometer.

Data Client

To review or recalculate dissolution tests from the office. It includes the powerful toolset that can be found in other configurations like profile comparison (f1,f2 calculation), intrinsic dissolution calculation, electronically signing and exporting into LIMS, text files or PDF.

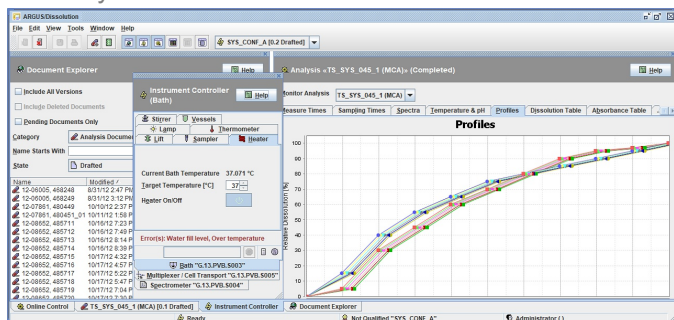
Multiple Baths

Adding a second or a third bath to your dissolution system can be done with a minimum of fuss. Even if it is another make and model ARGUS/Dissolution will simply incorporate it into the new configuration and reliably detect sampling time collisions - before the pill drops.

Analyze Combination Drugs in One Effort

You wish to analyze two or more active ingredients in one drug without the cost and time overhead of HPLC analysis but with maximal convenience and automation? ARGUS/ Dissolution has the chemometric power. You have the choice between multilinear regression or even more sophisticated models like PLS created with the well-known CAMO The Unscrambler®. With the intuitive one-stop design of ARGUS/Dissolution handling of these calibration models is straightforward and as easy as applying common calibration types.

Usability



- Wizards for major functions

- Tooltips and context sensitive online help
- Document search capabilities
- Analysis template technology
- Emergency stop capability
- English and German user interface
- Detection of possible timing problems
- Real time dissolution profiles
- Customizable report templates
- "WYSIWYG" method- and analysis display
- Raw data export (Excel or JCAMP-DX)
- Power and lamp saving functions
- Programmable cleaning procedures

Analytical Capabilities

- Full spectrum support
- Peak picking on all spectra charts
- Savitzky-Golay second derivative
- Turbidity baseline
- Placebo effect elimination
- Single and Multi Component Analysis
- CAMO The Unscrambler model support
- Recalculation of analyses
- Statistics (pH, temperature, dissolution)
- Infinity test, temperature profile
- Automated media change
- Profile comparison (f1/f2)
- Intrinsic dissolution



USP and Pharm. Eur. Acceptance

- One or more Q-values for each API
- High/low dissolution boundaries
- USP S1, S2 and S3 testing in one record

Data Integrity and 21 CFR Part 11

- Instant recording of raw data
- Standard database backup and recovery procedures
- Long term persistence in XML
- Detailed audit trail for electronic records
- System log for tracking application events
- Electronic signature support
- Cryptographical record protection
- Role specific access to program functions
- IQ/OQ/PQ support with reminder function
- Built in system suitability check
- Failsafe technology for data recovery
- Full Spectrometer OQ (as outlined in USP38)

Features

- ARGUS/Dissolution controls your dissolution tester hardware. Data is acquired from all devices you use in your dissolution test setup, including bath, spectrometer and pump. Methods and analyses are

retrieved from and stored to the documents database.

- Connect multiple dissolution test laboratories to one central database
- ARGUS/Dissolution can be used offline to query, review, approve, release and electronically sign methods and analyses.
- Use ARGUS/Dissolution to exchange data with your LIMS or enterprise document management system (EDMS).
- Query or browse methods, analyses and other data by using any standard web browser.
- ARGUS/Dissolution runs on a Java Virtual Machine which makes the application secure and extremely stable as required in highly regulated GxP environments. With the ARGUS Software Deployment Server centralized deployment and version control is easily accomplished.
- If you are already running the standalone version of ARGUS/Dissolution migration to an enterprise version is always possible. All data (methods, analyses, ...) can easily be transferred.

Enterprise Integration

ARGUS/Dissolution is based on the reliable ARGUS platform which seamlessly integrates dissolution testing into your corporate environment, e.g. LIMS. Exchange methods and analyses between development and QC laboratories. ARGUS/Dissolution is compatible to your existing dissolution testers and also integrates additional hardware such as spectrophotometers. The client-server architecture of the ARGUS platform perfectly fits into your corporate network.

Groupware Functionality (Enterprise Edition)

- Method deployment via shared database
- Centralized user account management
- LDAP authentication (ActiveDirectory)
- Prepared for LIMS connectivity
- Review Data through your web browser

Database Compatibility

- MariaDB
- MySQL
- Microsoft SQL Server
- Oracle

Spectrophotometer Driver

Agilent 8453,8454;
AnalytikJena
200/205/210/250; Beckman
DU800; Kontron Uvikon XL;
Cecil 2000/3000/4000/
7000/9000 series; PerkinElmer



LAMBDA 2/20/25/35/45; PharmaTest SA500; Shimadzu UV1700 PharmaSpec, UV1800; Tec5 Multi-Spec; Thermo Evolution 300; Tidas II (9-channel fiber optic); Varian Cary50; Zeiss MCS5XX, MCS6XX(2-channel fiber optic); Agilent 8452A*; Beckman Du600*; Distek 2230A*, PerkinElmer L265,365,465* (*on demand)

Dissolution Tester Driver

Hanson SR8 Plus, Vision Elite & Classic 6, Vision G2 Elite & Classic 6 ; Pharma Test PTWS/IDS1000, PTDT8, PTWS1210,PTWS300,PTWS820; Sotax AT7/ AT7smart, AT Xtend; Varian VK70XX; Distek 2100, 5100, Evolution series; ERWEKA DT800, DT700, DT720; Copley DT600, DT800

Pump Driver

Hanson AutoPlus MAXIMIZER, Vision G2 AutoPlus; Hamilton Dynamix III; ISMATEC IPC/IPC-N; Sotax CY-750, CP7; Varian Vk806; Watson Marlow 323Du; Distek Evolution 4300; Solvias Micamix Dual Syringe Dilutor

Autosampler & Fraction Collector & Valve Driver

Gilson 223 (Agilent G1811A), Hanson AutoPlus MultiFill, G2 AutoFill; PerkinElmer AS90, AS93plus, S10; Sotax C613/C615; Varian Vk8000; Distek Evolution 4300;Hamilton MVP, Rheodyne MX Series II Injector

System Requirements

- 1 GB RAM recommended minimum
- 200 MB hard disk space recommended minimum
- Intel® Pentium® III or compatible at 800 MHz or better
- CD-ROM drive (only for installation)
- Monitor (1280x1024 or higher, 256 colors or better)
- Mouse or other pointing device
- RS232/Ethernet/USB (USB adapters can be used)
- Microsoft® Windows® XP, Vista, 7, 8, 8.1 or 10
- Adobe® Acrobat® Reader (to view manual), Microsoft® WinHelp (to view online help)

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