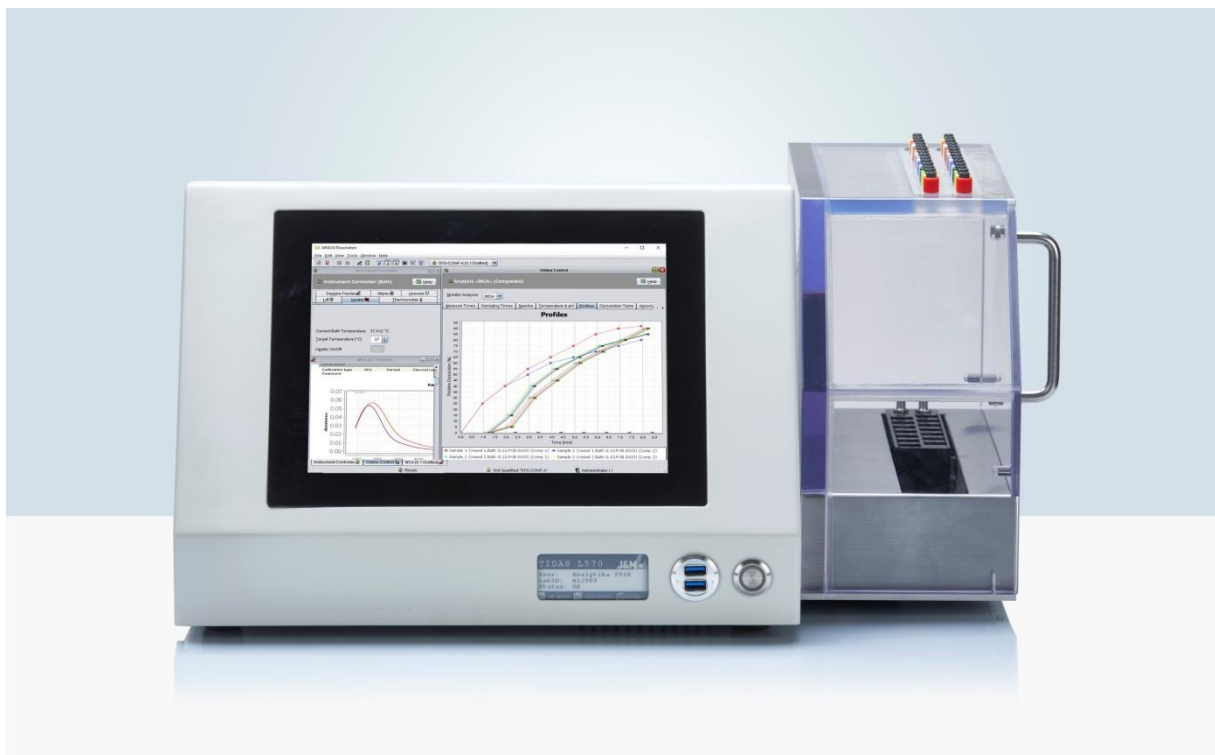


WinDiss ARGUS

21 CFR Part 11 Compliance as well as Compliance to the New Requirements for Data Integrity

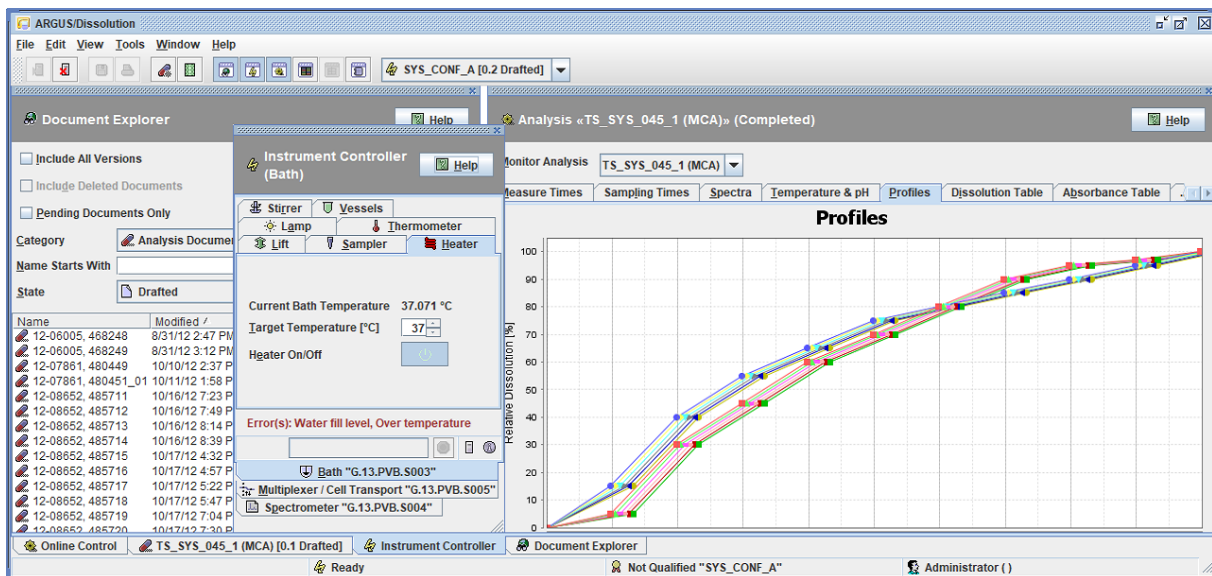
The WinDiss ARGUS Dissolution Software is a scientific dissolution data management software for instrument control, data acquisition, data management, processing and reporting – designed by users for users. WinDiss ARGUS is compatible to almost all dissolution systems in the laboratory. Just one software needs to be trained and qualified. 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.



The ARGUS WinDISS Software installed on the Tidas by default

Data Integrity, 21 CFR Part 11

Have data integrity and 21 CFR Part 11 compliance ARGUS/ Dissolution allows you to multi-task without using multiple software packages. 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.



Data Management Handling of ARGUS

Complete Data Management

Enhanced Data Management ARGUS/Dissolution manages all your data needs from instrument control to final reports, and makes your lab more productive.

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 TechnologyBuilt 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.

Dissolution CalculationsARGUS/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.

Flexibility

WinDiss ARGUS can be used for all Pharma Test Dissolution Testers as well as for other brands. For more information refer to section "Specifications".



Example Test Report Dissolution Profile

Advantages

- » 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)
- » 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

Features

- » 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).
- » Database Compatibility
 - » MariaDB
 - » MySQL
 - » Microsoft SQL Server
 - » Oracle
- » Additional USP/EP compliance features:
 - » One or more Q-values for each API
 - » High/low dissolution boundaries
 - » USP S1, S2 and S3 testing in one record

Technical Specifications

Parameter	Specification
Drivers for Dissolution Tester	Pharma Test PTWS/IDS1000, PTDT8, PTWS1210/20, PTWS300/310, PTWS820; PTWS120D, Pharma Test PTWS610/620; Hanson SR8 Plus, Vision Elite & Classic 6, Vision G2 Elite & Classic 6 ; Sotax AT7/AT7smart, AT Xtend; Varian VK70XX; Distek 2100, 5100, Evolution series; ERWEKA DT800, DT700, DT720; Copley DT600, DT800
Drivers for Spectrophotometers	Pharma Test SA500, Pharma Test TIDAS L, Pharma Test PT T70; 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; Shimadzu UV1700 PharmaSpec, UV1800; Tec5 MultiSpec; Thermo Evolution 300; Tidas II (9-channel fiber optic); Agilent/Varian Cary50; Zeiss MCS5XX, MCS6XX(2-channel fiber optic)
Drivers for Pumps	Pharma Test SP6/8; ISMATEC IPC/IPC-N; Hanson AutoPlus MAXIMIZER, Vision G2 AutoPlus; Hamilton Dynamix III; Sotax CY-7-50, CP7; Varian Vk806; Watson Marlow 323Du; Distek Evolution 4300; Solvias Micamix Dual Syringe
Drivers for Dilutor Autosampler & Fraction Collector Driver	Pharma Test DSR, Pharma Test PTFC; Gilson 223 (Agilent G1811A), Hanson AutoPlus MultiFill, G2 AutoFill; PerkinElmer AS90, AS93plus, S10; Sotax C613/C615; Varian Vk8000; Distek Evolution 4300 Valve Driver • Hamilton MVP, Rheodyne MX Series II Injector Drivers available on demand • Agilent 8452A; Beckman Du600; Distek 2230A, PerkinElmer L265,365,465

We reserve the right to make technical changes without any prior notice.