



# Disso.NET 4

## Advanced Dissolution Software

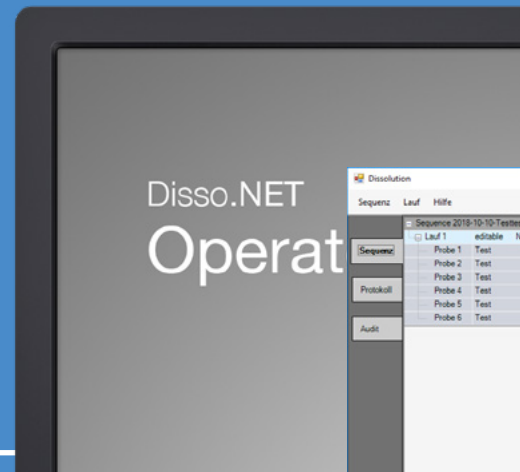


# The highlights of the Disso.NET 4 dissolution software

The ERWEKA Disso.NET 4 is the perfect 21 CFR Part 11 compliant companion to all our Dissolution Systems, ranging from Dissolution Offline over Online to On-/Offline Systems up to the fully automated RoboDis II+ system.

The software helps you with standard dissolution jobs, easily handles qualification tasks and provides control over each single function and connected devices (e.g. dissolution tester with UV-Vis spectrophotometer). After finishing those tests, Disso.NET creates extensive reports with corporate logos for PDF-file export or exports your results in XLS or XML.

Our extensive Audit Trail according to latest 21 CFR part 11 thoroughly documents all changes done to the system (what, who, when and why) and can be easily searched and filtered by the Audit Trail Viewer.

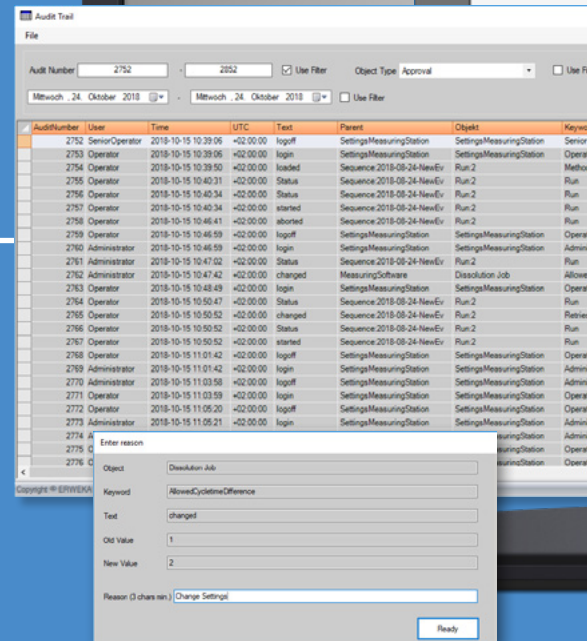


**Supports Dissolution Systems and RoboDis II+**

The Disso.NET 4 supports all ERWEKA Dissolution Systems and the fully automated RoboDis II+.

**Full Audit Trail according to 21 CFR Part 11**

The Audit Trail feature is implemented throughout the whole software, tracking each and every change (What, Who, When and Why). If data is changed by the user (e.g. when editing methods), the software requires a reason entered by the user. In combination with our easily search- and filterable audit trail viewer, changes to the system and its data can be easily traced back to its origin and originator. With Disso.NET 4, it is not possible to delete data from the system



Automated prompt for reason of change

**100%** Full Audit Trail according to 21 CFR Part 11

Support for USP methods 1, 2, 5 and 6

MS SQL Database

User Management

## Easy documentation with industry proven features

The documentation features of the Disso.NET 4 are vast: Easily generate reports about products, tests, audit trail, measurement conditions, UV-Vis and HPLC workflows and export data as PDF, XML and Excel format.

**Report: Audit Print**

ERWEKA

11:29:39 ringStation ringStation T-SN\_Labor

2442 DBAdmin 09.10.2018 +02:00:00 login SettingsMeasu SettingsMeasu DBAdmin ringStation ringStation Disso.NET\_D T-SN\_Labor

**Report: Audit Print**

ERWEKA

**Filters**

Type	Column	Condition	Value
Prefilter	Parent	SettingsMeasuringStation	
Prefilter	Time	GreaterThanOrEqualTo	01.10.2018
Prefilter	Time	LessThanOrEqualTo	24.10.2018

**Audit**

AuditNumber	User	Time	UTC	Text	Parent	Objekt	Keyword	OldValue	NewValue	Reason	MeasuringStation
2253	DBAdmin	08.10.2018 15:36:06	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2255	DBAdmin	08.10.2018 15:39:19	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2399	DBAdmin	08.10.2018 15:42:02	+02:00:00	created	SettingsMeasu ringStation	SettingsMeasu ringStation	Checksum			recalculate	Disso.NET_D T-SN_Labor
2436	SeniorOperato	08.10.2018 10:29:21	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	SeniorOperato				Disso.NET_D T-SN_Labor
2437	DBAdmin	09.10.2018 10:25:56	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2438	DBAdmin	08.10.2018 10:30:40	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2439	DBAdmin	09.10.2018 10:38:10	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2440	DBAdmin	08.10.2018 10:49:46	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor
2441	DBAdmin	09.10.2018	+02:00:00	login	SettingsMeasu ringStation	SettingsMeasu ringStation	DBAdmin				Disso.NET_D T-SN_Labor

Instrument SN: Disso.NET\_DT-SN\_Labor  
Disso.NET V 4.0.0

print date: 2018-10-24T14:19:46.3460529+02:00  
printed by: Administrator

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# From DT to RoboDis II+

## Full control for all our systems

Disso.NET 4 allows control over all our Dissolution Systems. Simpler Dissolution Online Systems, more complex Dissolution On-/Offline HPLC Systems or the advanced RoboDis II+ can all be controlled by Disso.NET 4 and reduce the device and system complexity to a few intuitive screens with a logic top to bottom approach.

Dissolution Online System with UV/Vis (USP Meth. 1, 2, 5 and 6)



RoboDis II+ Fully automated Dissolution System (USP meth. 1 and 2)



Stand-Alone Dissolution Tester DT 950



Dissolution On-/Offline System with HPLC or UV/Vis (USP meth. 1 and 2)



# Highly flexible

## The main features of Disso.NET 4

### Easy data management



Users, methods, reports and more can be easily managed with Disso.NET 4. Multi-user support with different user roles (Operator, Senior Operator, Administrator - all configurable) allow fine access control to the system and data and can be even fine tuned with single permissions. The automatic log off rounds up the access safety features and makes sure only approved personal have access.

### System Suitability and Multitasking



Constant system suitability tests ensure highest reliability by constantly checking the system. The JobController principle allows easy multitasking while testing.

### Documentation and Reports



Disso.NET 4 fully documents tests. By clicking a button customers can easily generate reports with customized logos - from compact analytical reports to method data, calibration data or raw data. The integrated workflow allows easy approval and review before publishing reports for the paperless lab.

### Database with back-up and restore



Our reliable and industry proven MS SQL database easily stores all your data - from methods to users, UV-Vis measurement data, reports and raw data. Additionally, easy to use MS SQL back-up and restore functions mean improved integrity and prevents loss of data!

### Language support






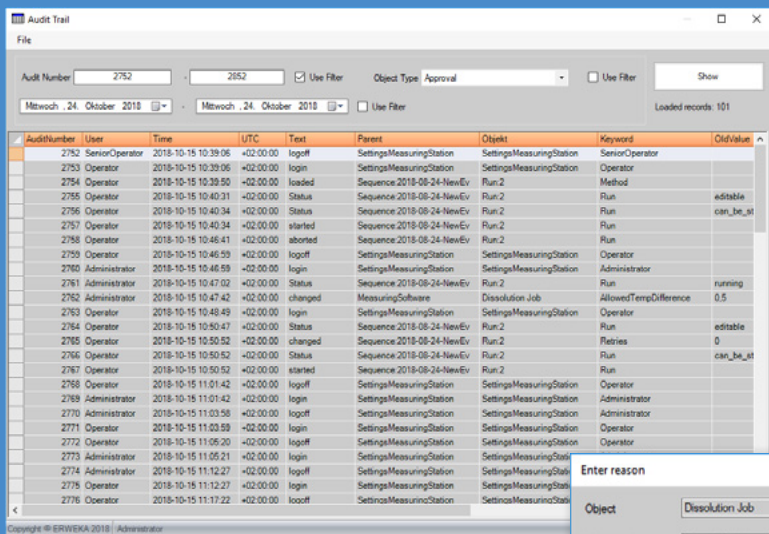
Language support for English and German is already built into Disso.NET 4. More languages can be easily added via language file.

# According to 21 CFR Part 11 Audit Trail

Disso.NET 4 features a comprehensive audit trail, tracking all changes throughout the system (what, who, when and why). Whenever an authorised user makes changes to any data on the system that needs to be tracked, an audit trail prompt appears and forces the user to enter a reason for this change. Whenever data is created from scratch (e.g. a new method), the system automatically evaluates this audit entry and automatically adds a reason (e.g. "created").

All audit data can be comfortably searched and filtered using our new Audit Trail Viewer - allowing easy tracking of any change to the system with a consecutive audit number. This new feature complies to 100% to latest regulatory rules.

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**100%** Tracking What, Who, When and Why
-  Comfortable Audit Trail Viewer for easy search
-  Enforced Audit Trail - entering of data can not be omitted



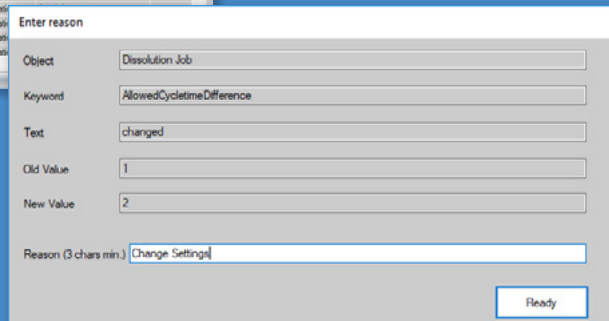
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2754	Operator	2018-10-15 10:39:50	+02:00:00	loaded	Sequence 2018-08-24-NewEv	Run:2	Method	
2755	Operator	2018-10-15 10:40:31	+02:00:00	Status	Sequence 2018-08-24-NewEv	Run:2	Run	editable
2756	Operator	2018-10-15 10:40:34	+02:00:00	Status	Sequence 2018-08-24-NewEv	Run:2	Run	can_be_st
2757	Operator	2018-10-15 10:40:34	+02:00:00	started	Sequence 2018-08-24-NewEv	Run:2	Run	
2758	Operator	2018-10-15 10:46:41	+02:00:00	aborted	Sequence 2018-08-24-NewEv	Run:2	Run	
2759	Operator	2018-10-15 10:46:59	+02:00:00	logout	SettingsMeasuringStation	SettingsMeasuringStation	Operator	
2760	Administrator	2018-10-15 10:46:59	+02:00:00	login	SettingsMeasuringStation	SettingsMeasuringStation	Administrator	
2761	Administrator	2018-10-15 10:47:02	+02:00:00	Status	Sequence 2018-08-24-NewEv	Run:2	Run	running
2762	Administrator	2018-10-15 10:47:42	+02:00:00	changed	MeasuringSoftware	Dissolution Job	AllowedTempDifference	0.5
2763	Operator	2018-10-15 10:48:49	+02:00:00	login	SettingsMeasuringStation	SettingsMeasuringStation	Operator	
2764	Operator	2018-10-15 10:50:47	+02:00:00	Status	Sequence 2018-08-24-NewEv	Run:2	Run	editable
2765	Operator	2018-10-15 10:50:52	+02:00:00	changed	Sequence 2018-08-24-NewEv	Run:2	Retries	0
2766	Operator	2018-10-15 10:50:52	+02:00:00	Status	Sequence 2018-08-24-NewEv	Run:2	Run	can_be_st
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2775	Operator	2018-10-15 11:12:27	+02:00:00	login	SettingsMeasuringStation	SettingsMeasuringStation	Operator	
2776	Operator	2018-10-15 11:17:22	+02:00:00	logout	SettingsMeasuringStation	SettingsMeasuringStation	Operator	

## Audit Trail Viewer

With the help of the Audit Trail Viewer, an authorized user can easily track all changes done to any audited data on the system.

### Automated prompt

Whenever data that requires audit is changed, a prompt appears and can not be omitted.



Enter reason

Object:

Keyword:

Text:

Old Value:

New Value:

Reason (3 chars min.):

Powerful modules

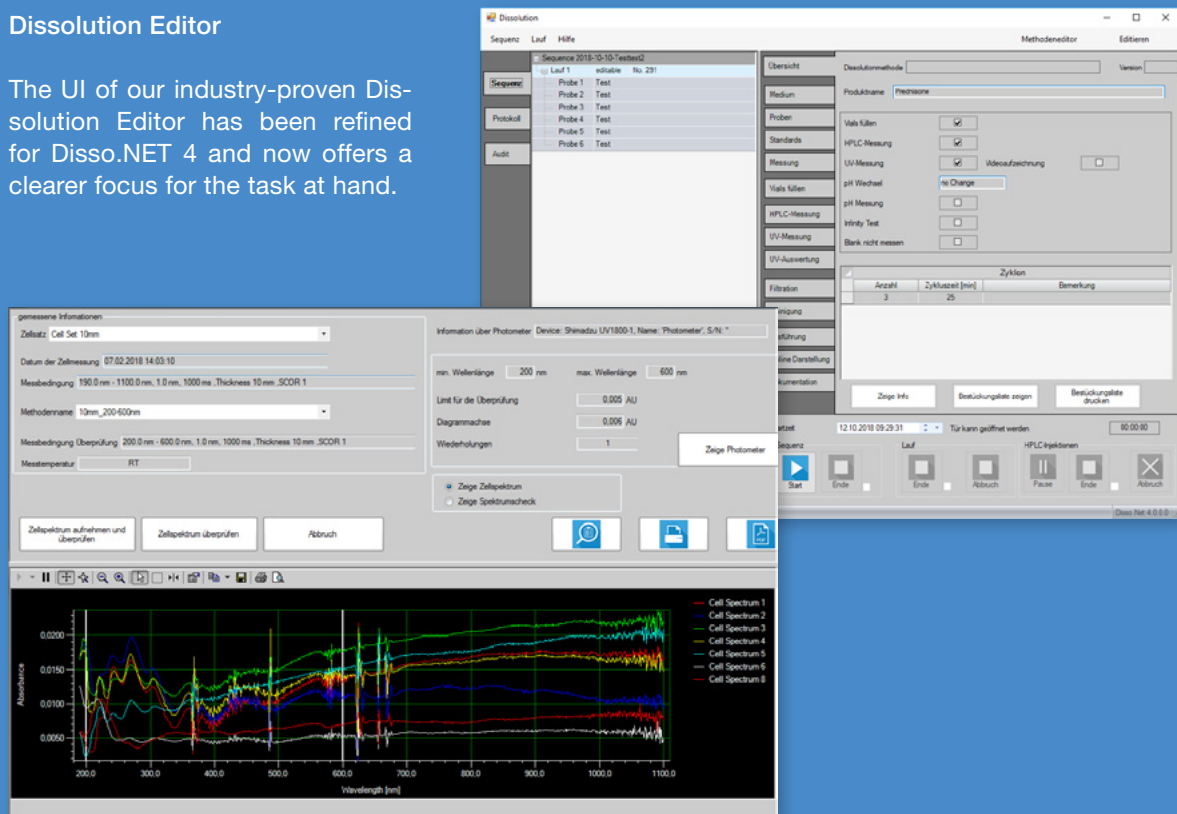
# The Disso.NET Editors

All main features of the Disso.NET 4 are located in separate windows, enabling a clear focus on the task at hand. These editors can be used to change media, edit filters and create new measurement, evaluation and medium preparation methods.

Even for UV calculations, Disso.NET offers a unique interface specifically focused on its main task.

## Dissolution Editor

The UI of our industry-proven Dissolution Editor has been refined for Disso.NET 4 and now offers a clearer focus for the task at hand.



## Qualifying Tasks directly in the software

- Semi-annual check of the photometer according to EP
- Photometer qualification according to USP\*
- Daily check of the Agilent photometer
- Temperature check of all sensors
- Pump check
- Complete reports of qualifying jobs

# Dissolution features

## General features

- Sequences for several dissolution tests
- Flexible measurement for calibration and control standards (System Suitability Test, SST)
- Import / Export of XML method files
- pH-change support\* according to USP-Method A and B
- Easy, flexible definition of measuring time points
- Automatic calculation of required pump time
- Infinity test
- Working with absolute & relative standard concentration
- Heater switch off after last run
- Automated parameter check
- Log file with all information
- Simple time control
- Timelapse functions\*

## Different measuring methods

- Sample collection
- UV/Vis and HPLC
- On-/Offline measurement

## Online views

- Dissolution curve
- Measured absorptions and calculated concentration
- Measured spectra, including overlay

## Sampling routine

- Optimized sampling routine for low hydrodynamic impact
- Emptying whole tubing during run possible
- Sampling tubes always down possible
- Automated inline filtration

## UV/Vis

- UV/Vis evaluation with different types of baseline correction (single point, parallel translation, linear)
- Recording of measuring parameters and individual evaluation method
- Complete calculation/recalculation of dissolution results

## HPLC & sample collection

- Precise withdrawn volume
- HPLC injection parameters adjustable in broad range
- Flexible standard measurement for calibration & SST
- Media replacement
- HPLC sample collection independent from HPLC
- Support for Agilent, Waters, Shimadzu and more

# Report generation

## Report data

- Product name with batch-ID, method name, date and time
- Measurement conditions, e.g. sampling time, media, temperature, rotational speed, filtration, etc.
- System configuration
- Customized logo

## UV-Vis report

- Measuring method
- Calibration data
- Sample results overview including dissolution curve
- Overlay spectra

## HPLC reports

- Withdrawn volume and time
- Documentation of all automated working steps e.g. filling/measuring time of the sample

## Format and export

- Generation of reports in different formats
- Integrated paperless GMP workflow
- XML, PDF, Excel ex-/import

*\*optional hardware required for RoboDis II+*

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