

RESTEK

Dissolution Test Systems





integrate your DissoPrep in your IT-infrastructure





integrate your DissoPrep in your IT-infrastructure

- Connect your DissoPrep via LAN to your local PC or to your company network
- and administrate your DissoPrep easily via your (Internet-)Browser without any further softwareinstallation!



integrate your DissoPrep in your IT-infrastructure

Administrate via the Browser-Interface:

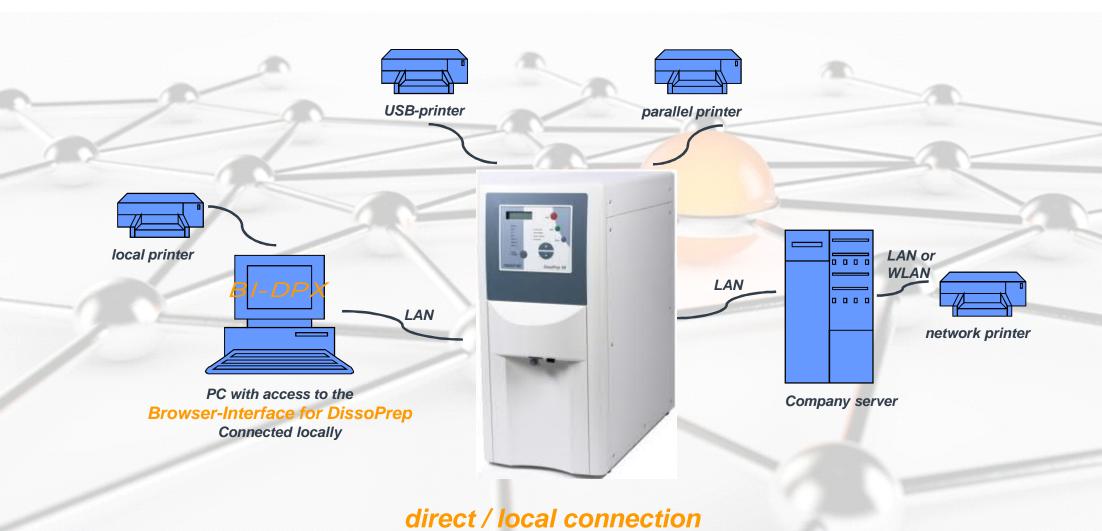
- methodsuser permissions
- reports
- users
- audit trail
- backup*

- security settings*
- electronic signature*
- system settings



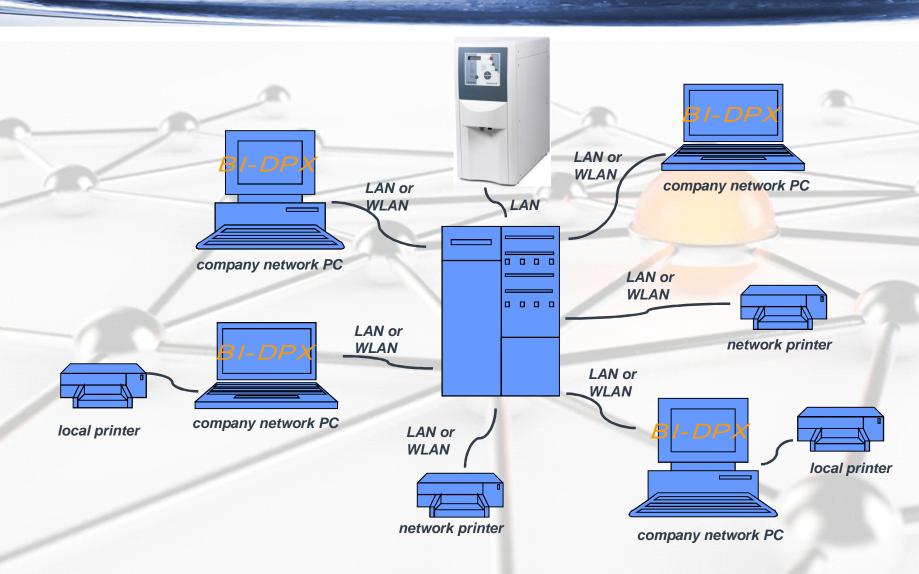


integrate your DissoPrep in your IT-infrastructure





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connection via company network



Data Integrity

The Browser-Interface is installed and running on the DissoPrep, so NO more software-installation on any external PC is necessary. That 's why there is NO data exchange of test results between the DissoPrep and the Browser-Interface, so one single place where the data is saved.

The DissoPrep is saving and controlling all data. It is not possible to change any data / test results like test reports, calibration reports, etc.. Data backups can be done manually, automatically or the printouts can be used as individual backups of these data.

The Browser-Interface is NOT controlling the DissoPrep, it is just an interface to administrate methods, reports, etc. on the DissoPrep itself with individual user permissions.

Because of not having any data exchange and only one place of saving the data, all demands on data integrity are fulfilled without a software-validation!



21 CFR Part 11

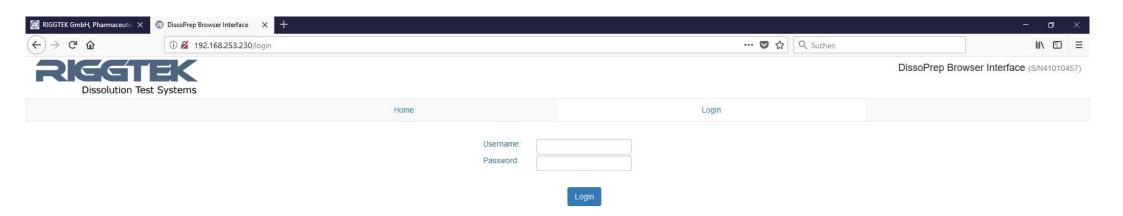
With the optional "CFR Package" it is possible to achieve full 21 CFR Part 11 compliance.

- Individual user permissions,
- individual usage settings (e.g. automatic logout),
- individual password policy as well as
- electronic signature and
- commenting on the Audit Trail

are the features enabling to work with the DissoPrep 21 CFR Part 11 compliant.



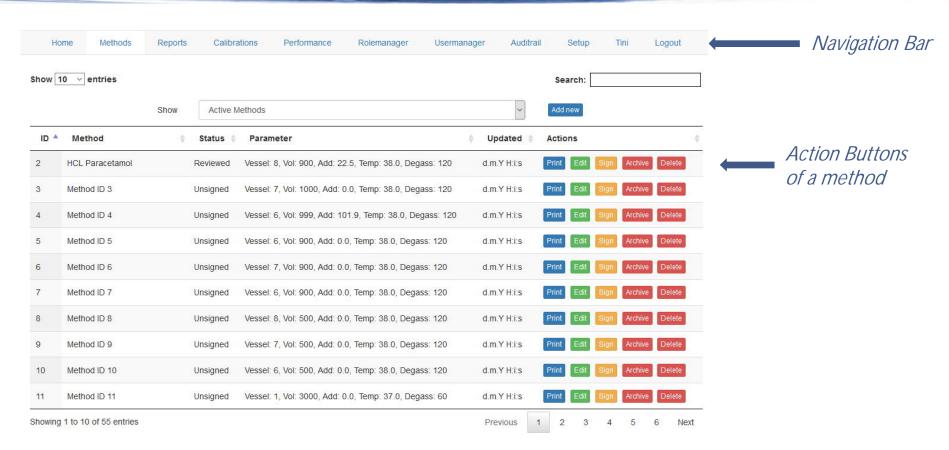
Login



If the DissoPrep is connected to your local PC or your company network, you only have to type in the IP-address of your DissoPrep in your (Internet)-Browser to reach the Login-Screen – as shown above.



Navigation Bar and Method List

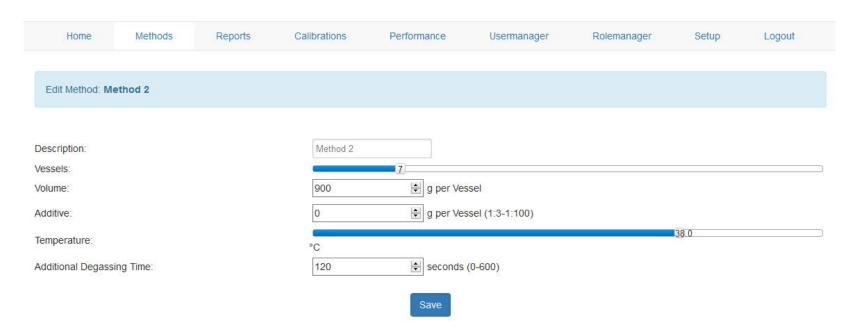


After the successful login, you will see the Navigation Bar, which will always be shown at the top of the screen. The tab "Methods" is showing the list of stored methods. Searching, sorting and filtering the method list is easily possible.

For printing, editing or electronically signing*, archiving or deleting a method, the appropriate Action Buttons are available for each method (if available according the user 's permissions and options).



editing methods



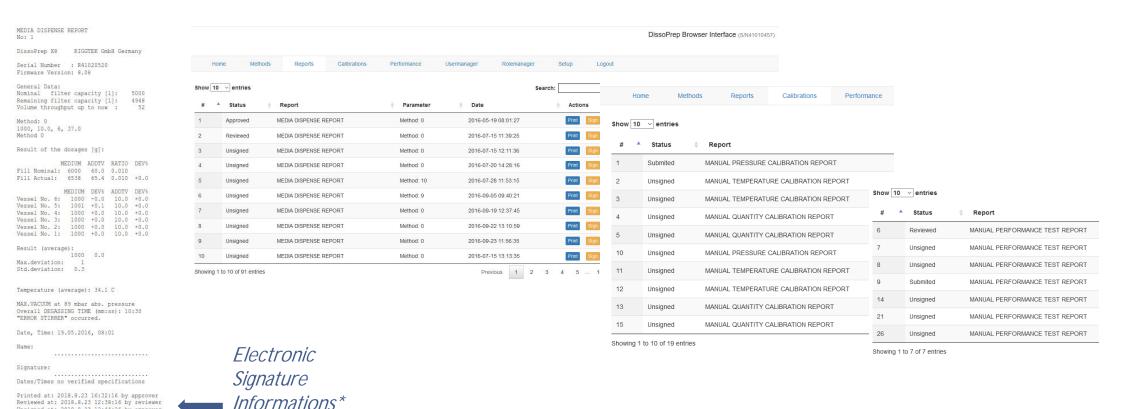
After selecting a method, all shown parameters can be changed.

Interdependent parameters as Number of vessels and Volume per vessel will be adapted automatically to possible values if applicable.

Press the "Save-Button" for saving the changes.



viewing, printing and saving of reports

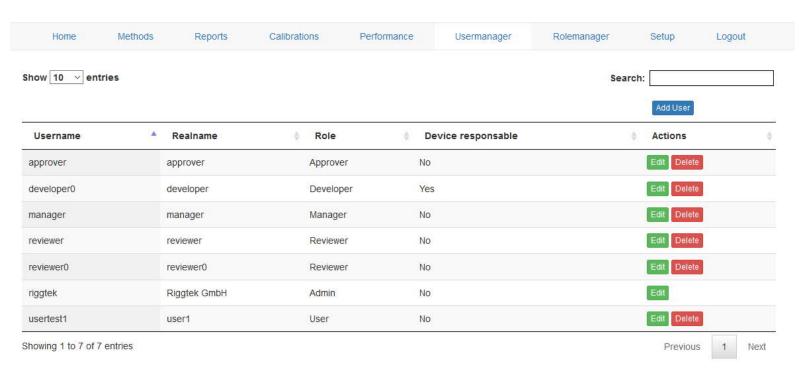


The DissoPrep will save the following reports, which can be shown, printed or saved via the Browser-Interface: Media-Dispense-Reports, Calibration-Reports, Performance-Test-Reports. By pressing the the appropriate button, the report can be signed* or the report will be shown as pdf-document, which can be printed or saved. The last four electronic signatures* are shown on the printout. All reports are saved securely at the DissoPrep and can´t be deleted or changed in any way.

Unsigned at: 2018.8.23 12:44:26 by approver Submited at: 2018.8.23 16:31:05 by usertest1

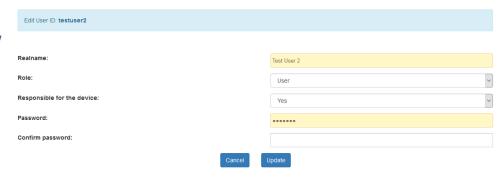


Usermanager



The "Usermanager" allows to add, delete and edit users. It is possible to edit the

- Realname
- Role user roles are possible to define individually (see "Rolemanager")
- Responsibility for the device
- the password





Rolemanager

Edit Role ID: 0

Role Name: Role Rights: Admin

Methods

Add Method

☑ Archive Methods

☑ Import Methods

Users

✓ View Users

☑ Edit User

Unlock User

Roles

☑ View Roles

☑ Edit Role

Audittrail

☑ View Auditrail

☑ Update Auditrail

Setup

✓ View Setup

☑ Upload Product Key

Signature

☑ Submit Report & Methods

Approve Report & Methods

☑ Same user Unsign & Submit Report & Methods

☑ Same user Review & Approve Report & Methods

Fdit Method

☑ Delete Method

☑ Empty and Import Methods

☑ Add User

☑ Archive User

☑ Add Role

☑ Archive Role

☑ Archive Audit Entries

☑ Download Auditrail

✓ Update Setup

☐ Download Backup

Review Report & Methods

☑ Unsign Report & Methods

☑ Same user Submit & Review Report & Methods

☑ Same user Approve & Unsign Report & Methods

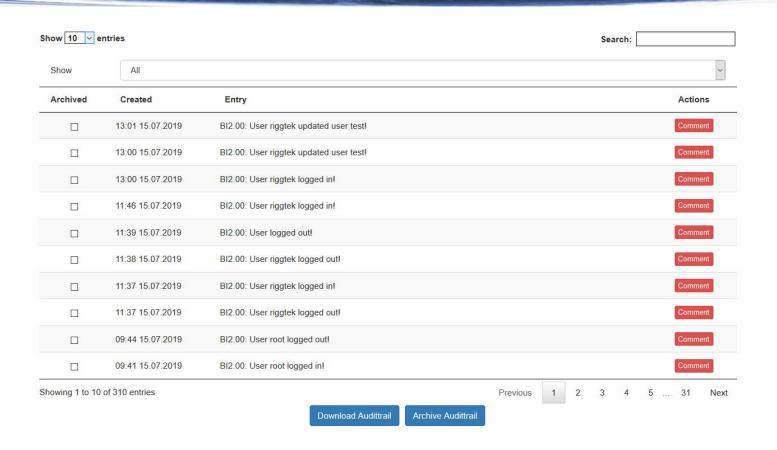
The "Rolemanager" allows to set the permissions of the created roles individually according to the user 's/ company 's demands.







Audit-Trail



The Audittrail documents all relevant actions of the device including error-messages.

Depending on the individual permissions and options, it is possible to download the Audittrail, archive selected Audittrail entries and make comments* to individual Audittrail entries.



Setup

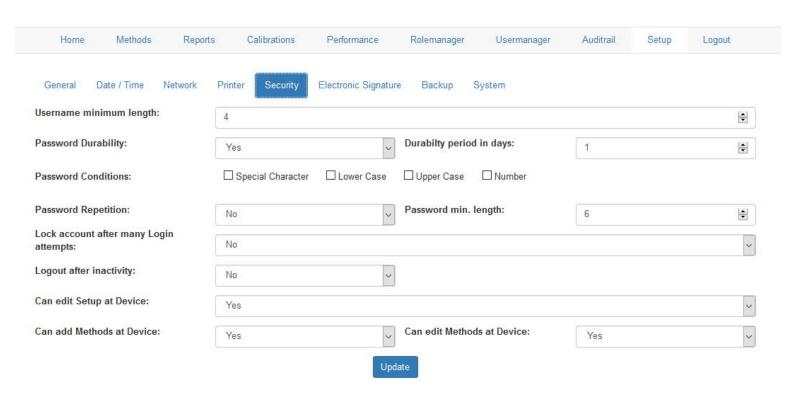
General Date / Ti	me Network	Printer S	Security	Electronic Signature	Backup	System			
Upload Product Key:	Durchsuche	Durchsuchen Keine Datei ausgewählt.						Upload	
Device ID:	Test RIGGTEK TRAD								
				Update					

The "Setup" allows to easily edit general settings like

- Device ID (customers internal ID for the device)
- date and time,
- network configuration,
- printer configuration,
- security settings* (see more details on following pages),
- settings for the Electronic Signature* (see more details on following pages),
- settings for the Backup* (see more details on following pages),
- system settings of the Sampilio (see more details on following pages).



Security

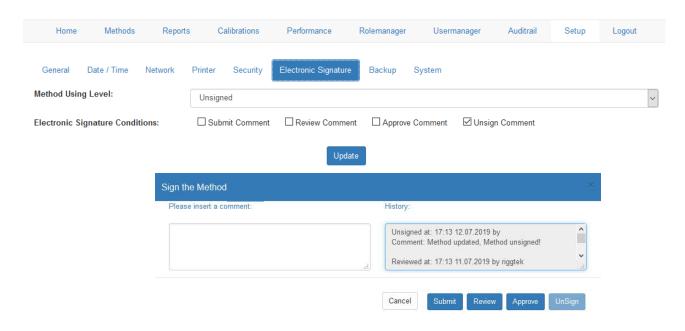


The Security Settings are part of the optional "CFR-Package". With the Security Settings* it is possible to individually define

- the password policies,
- the automatic logout setting,
- if changes can be made at the device without user login.



Electronic Signature



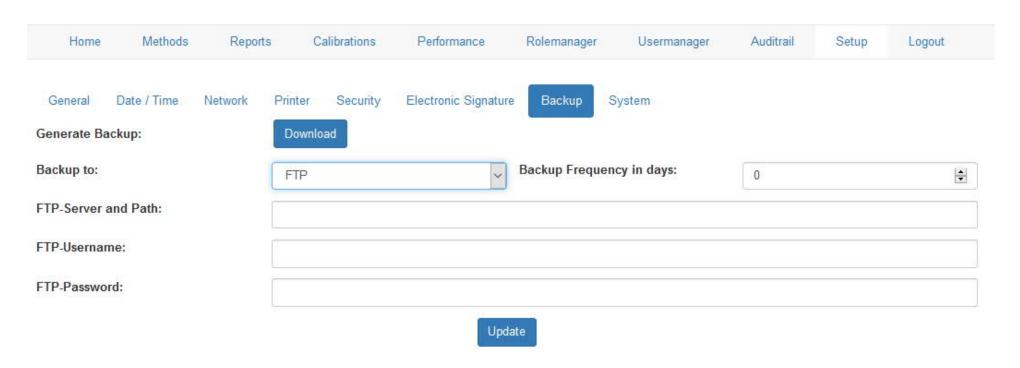
Optional it is possible to sign reports and methods electronically*. The electronic signature status "Submit", "Review", "Approve" and "UnSign" are available according to the Rolemanager and the individual permissions.

In the settings, the user can determine which status is necessary to use a method and for which status the user needs to make a comment.

The current status of the approval can be seen in the method- and report-list. When signing, the approval history will be shown as above. Additionally the last 4 steps of the approval will be printed on the report.



Backup



The optional "Backup-Package"* allows to make backups to USB or to an FTP-Server. The backup can be done manually or automatically.



Optional Packages

For the Browser-Interface, the following optional packages are available:

CFR-Package:

This package includes the features

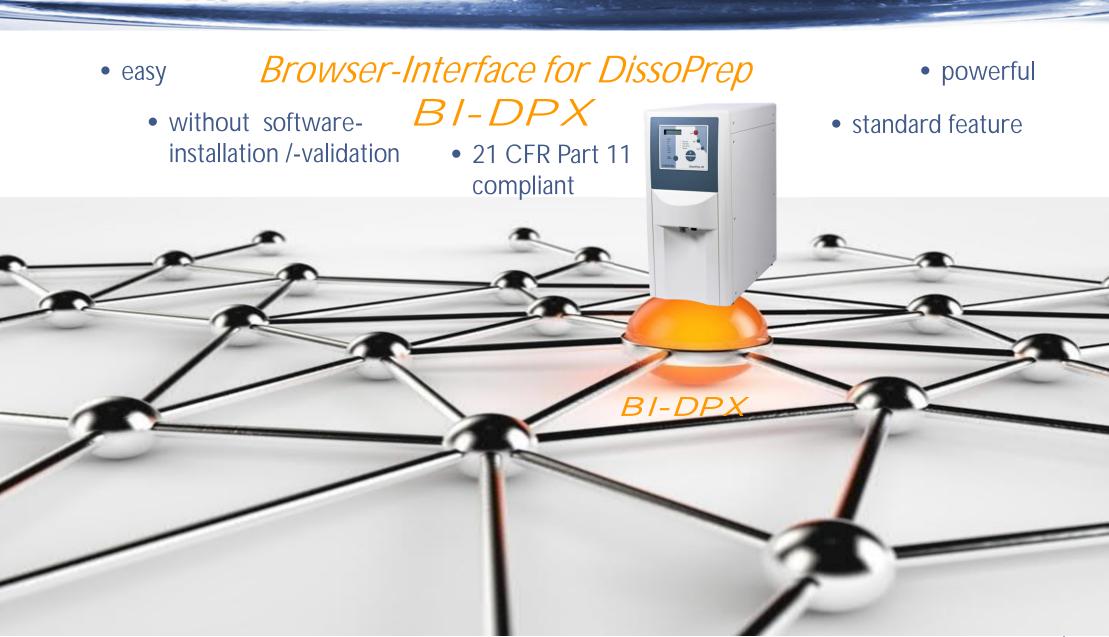
- Electronic Signature
- Security Section / Password Policy
- Parent-Child-functionality
- Commenting of the Audittrail

Backup-Package:

This feature enables to make manual or automatic backups to USB or FTP.



summary







Do you have any further questions?

- Visit our webpage <u>www.riggtek.com</u> or
- give us a call *Tel.: +49 89 2302469-0* or
- email us to <u>support@riggtek.com</u>

We are available!
your RIGGTEK-Team

