RIGGTEK
Dissolution Test Systems

Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure

Browser-Interface for the Sampilio X8
BI-SX8

BI-SX8

Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure

- Connect your Sampilio X8 via LAN to your local PC or to your company network
- Administrate your Sampilio X8 easily via your (Internet-) Browser without any further software-installation

BI-SX8

Browser-Interface for Sampilio X8

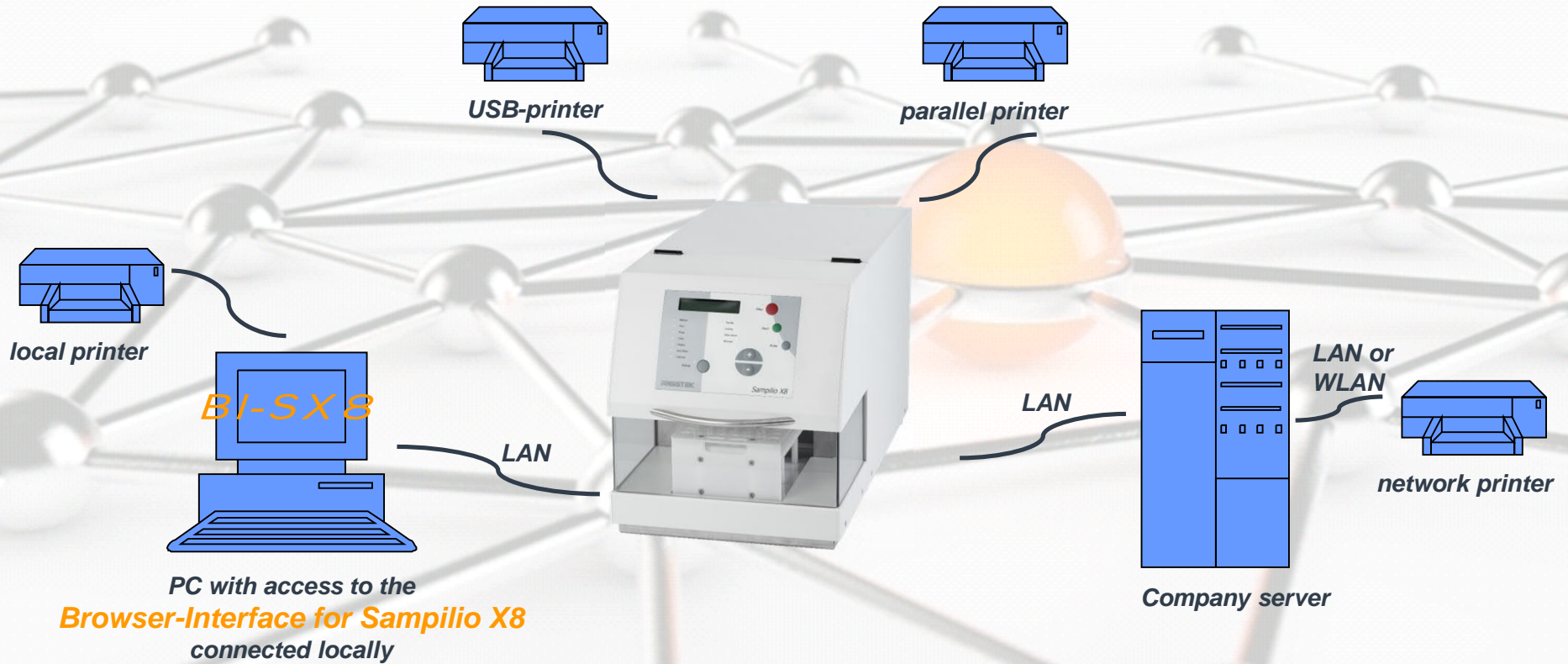## integrate your Sampilio X8 into your IT-infrastructure

Administrate via the Browser-Interface:

- methods
- reports
- users

- user permissions
- audit trail
- Backup*

- security settings*
- electronic signature*
- system settings

BI-SX8

Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure

USB-printer

parallel printer

local printer

BI-SX8

LAN

PC with access to the
Browser-Interface for Sampilio X8
connected locally

LAN

LAN or
WLAN

network printer

Company server

direct / local connection

Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure

BI-SX8

company network PC

LAN or WLAN

LAN or WLAN

BI-SX8

company network PC

LAN

LAN or WLAN

network printer

local printer

BI-SX8

company network PC

LAN or WLAN

LAN or WLAN

network printer

BI-SX8

company network PC

local printer
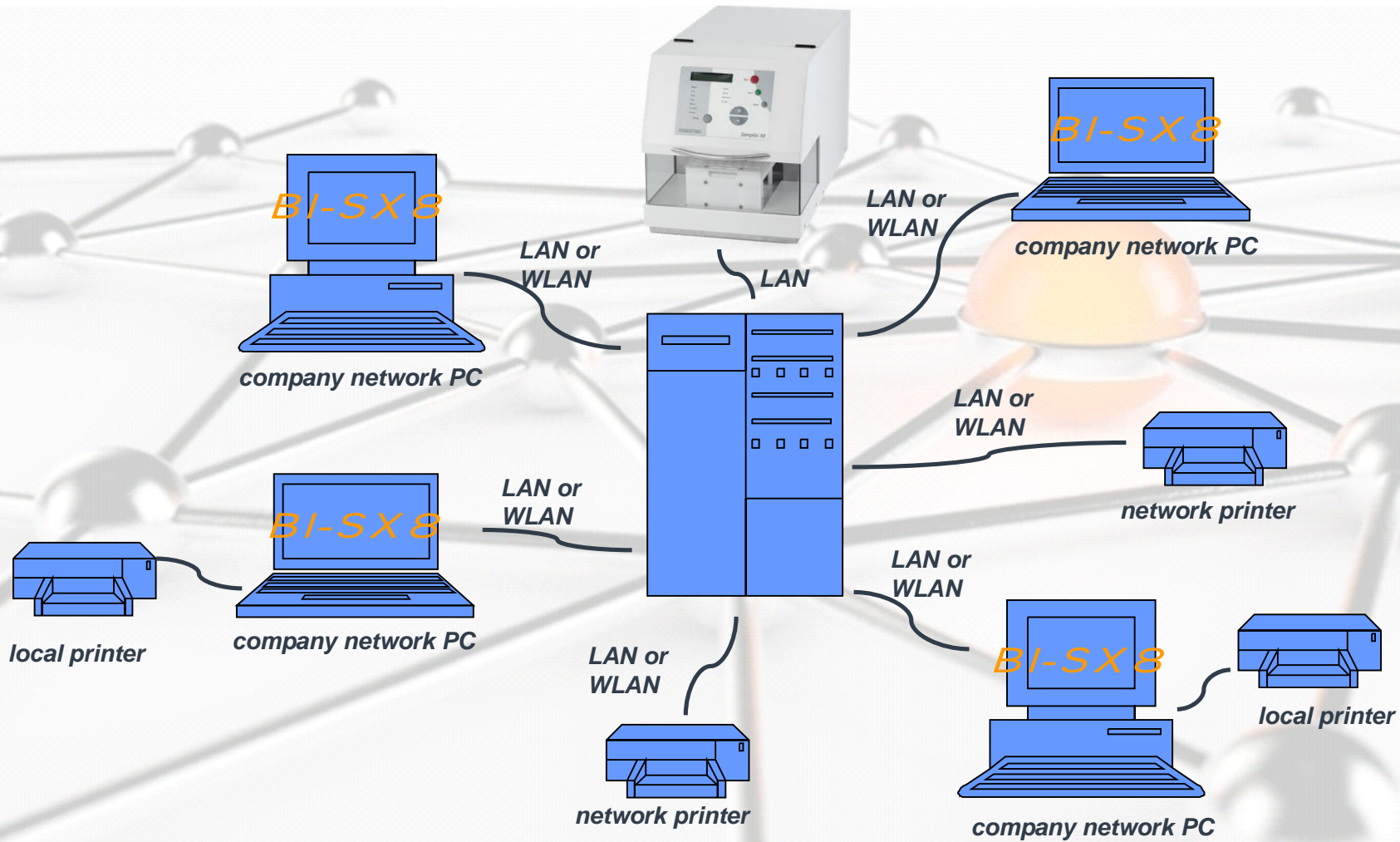
connection via company network

Browser-Interface for Sampilio X8

Data Integrity

The Browser-Interface is installed and running on the Sampilio X8, so NO more software-installation on any external PC is necessary. That´s why there is NO data exchange of test results between the Sampilio X8 and the Browser-Interface, so one single place where the data is saved.

The Sampilio X8 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 Sampilio X8, it is just an interface to administrate methods, reports, etc. on the Sampilio X8 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!

Browser-Interface for Sampilio X8

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 Sampilio X8 21 CFR Part 11 compliant.

Browser-Interface for Sampilio X8

Login

If the Sampilio X8 is connected to your local PC or your company network, you only have to enter the IP-address of your Sampilio X8 in your (Internet)-Browser to reach the Login-Screen – as shown above.

Browser-Interface for Sampilio X8
Navigation Bar and Method List

Navigation Bar

Action Buttons of a method

After the succesful 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).

Browser-Interface for Sampilio X8
editing methods

When editing a method, all shown parameters can be changed easily (depending on some general settings and whether a Dissolution Tester is connected or not).

If applicable interdependent parameters as Sample Timepoint and Sample Volume per Sample Step will be adapted automatically to possible values only.

The list of sample steps is ensuring a quick overview about all sample times. Each sample step can be edited separately.

Browser-Interface for Sampilio X8
viewing, printing and saving of reports

Table 1:

Show 10 entries   Search: [   ]

ID	Status	Report	Created	Printed	Actions
2	Unsigned	Method ID 5	00:07 12.01.2000	1	Print Sign
1	Unsigned	Method ID 4	23:48 11.01.2000	1	Print Sign

Showing 1 to 2 of 2 entries   Previous 1 Next

Table 2:

Show 10 entries   Search: [   ]

ID	Status	Report	Created	Printed	Actions
1	Unsigned	Calibration Flow Rates at 10 mL/min with 5.0 mL	13:24 29.08.2018	1	Print Sign

Showing 1 to 1 of 1 entries   Previous 1 Next

Table 3:

Show 10 entries   Search: [   ]

ID	Status	Report	Created	Printed	Actions
3	Unsigned	PQ-Test 5mL all Rates	11:57 17.07.2019	1	Print Sign
2	Unsigned	PQ-Test 5mL all Rates	01:26 11.01.2000	1	Print Sign
1	Unsigned	PQ-Test 5mL all Rates	23:51 10.01.2000	1	Print Sign

Showing 1 to 3 of 3 entries   Previous 1 Next

Report printout:

```
DISSOLUTION SAMPLING REPORT
No: 1

Dissolution Sampler
Sampilio X8 8 Channels

Instrument ID:
Serial Number: R00000003
Firmware Version: 1.30

General Data:
Sampling Counter: 25
Last Calibration Date: 00:33 05.01.2000
Samples since last calibration: 5

Method Parameter:
          Method ID: 2
       Used Channels: 8
             Version: 12
         Description: Method ID 2
           Used Rack: Test Tubes
     Collect Flow Rate: 20 mL/min
   Flush/Purge Volume: 9.5 mL
      Purge Flow Rate: 20 mL/min
     Stagger Interval: 0 sec
          Replacement: No
      Double Sampling: No

RIGGTEK DissoPrep:
          Serial Number: R40000003
          Report Number: 1

Start Time/Date: 01:01 05.01.2000

STEP NO. ELAPSED TIME VOLUME
         hh:mm:ss        mL
001      00:02:00       5.00

End Time/Date: 01:14 05.01.2000

Method finished successfully

Lot Number:    _____

Batch Number:  _____

Comments:      _____

Dates/Times are from device

Generated at: 01:14 05.01.2000
Printed (#4) at: 10:07 07.08.2019 by root

Electronic Signatures:
Submitted at: 10:06 07.08.2019 by root
Reviewed at: 10:07 07.08.2019 by root
Approved at: 10:07 07.08.2019 by root

------------ End of Report ------------
```

Electronic Signature Informations *

The Sampilio X8 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 Sampilio X8 and can´t be deleted or changed in any way.

Browser-Interface for Sampilio X8
Usermanager

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

- Realname
- Role – user roles can be defined individually (see „Rolemanager")
- Responsibility for the device
- password

Browser-Interface for Sampilio X8
Rolemanager

Edit Role ID: 0

Role Name: Admin
Role Rights:

Methods
- ☑ Add Method
- ☑ Archive Methods
- ☑ Import Methods
- ☑ Edit Method
- ☑ Delete Method
- ☑ Empty and Import Methods

Users
- ☑ View Users
- ☑ Edit User
- ☐ Unlock User
- ☑ Add User
- ☑ Archive User

Roles
- ☑ View Roles
- ☑ Edit Role
- ☑ Add Role
- ☑ Archive Role

Audittrail
- ☑ View Auditrail
- ☑ Update Auditrail
- ☑ Archive Audit Entries
- ☑ Download Auditrail

Setup
- ☑ View Setup
- ☑ Upload Product Key
- ☑ Update Setup
- ☐ Download Backup

Signature
- ☑ Submit Report & Methods
- ☑ Approve Report & Methods
- ☑ Same user Unsign & Submit Report & Methods
- ☑ Same user Review & Approve Report & Methods
- ☑ Review Report & Methods
- ☑ Unsign Report & Methods
- ☑ Same user Submit & Review Report & Methods
- ☑ Same user Approve & Unsign Report & Methods

Cancel   Update

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

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.

Browser-Interface for Sampilio X8

Setup

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).

Browser-Interface for Sampilio X8
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.

Browser-Interface for Sampilio X8
Electronic Signature

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.

Browser-Interface for Sampilio X8

Backup

Home	Methods	Reports	Calibrations	Performance	Rolemanager	Usermanager	Auditrail	Setup	Logout

General   Date / Time   Network   Printer   Security   Electronic Signature   **Backup**   System

Generate Backup: [Download]

Backup to: [FTP ▾]   **Backup Frequency in days:** [0]

FTP-Server and Path: [ ]

FTP-Username: [ ]

FTP-Password: [ ]

[Update]

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

Browser-Interface for Sampilio X8
System

The System Settings allow to edit some general settings of the Sampilio.
Additionally it is possible to add connected Dissolution-Testers* (optional Dissolution
Tester Driver) to control the Dissolution-Tester with the Sampilio and show all method
data on the common report of the Sampilio.

Browser-Interface for Sampilio X8
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
- Commenting of the Audittrail

Backup-Package:
This feature enables to make manual or automatic backups to USB or FTP.

Driver for Dissolution-Testers:
With the individual drivers for different Dissolution-Testers, it is possible to control the Dissolution-Testers and show all their method data on the common report of the Sampilio.

Browser-Interface for Sampilio X8
summary

- easy

- without software-
  installation /-validation

Browser-Interface for Sampilio X8

B I - S X 8

- 21 CFR Part 11
  compliant

- powerful

- standard feature

B I - S X 8

RIGGTEK
we are available!

Do you have any further questions?

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

We are available!
your RIGGTEK-Team