



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



Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure



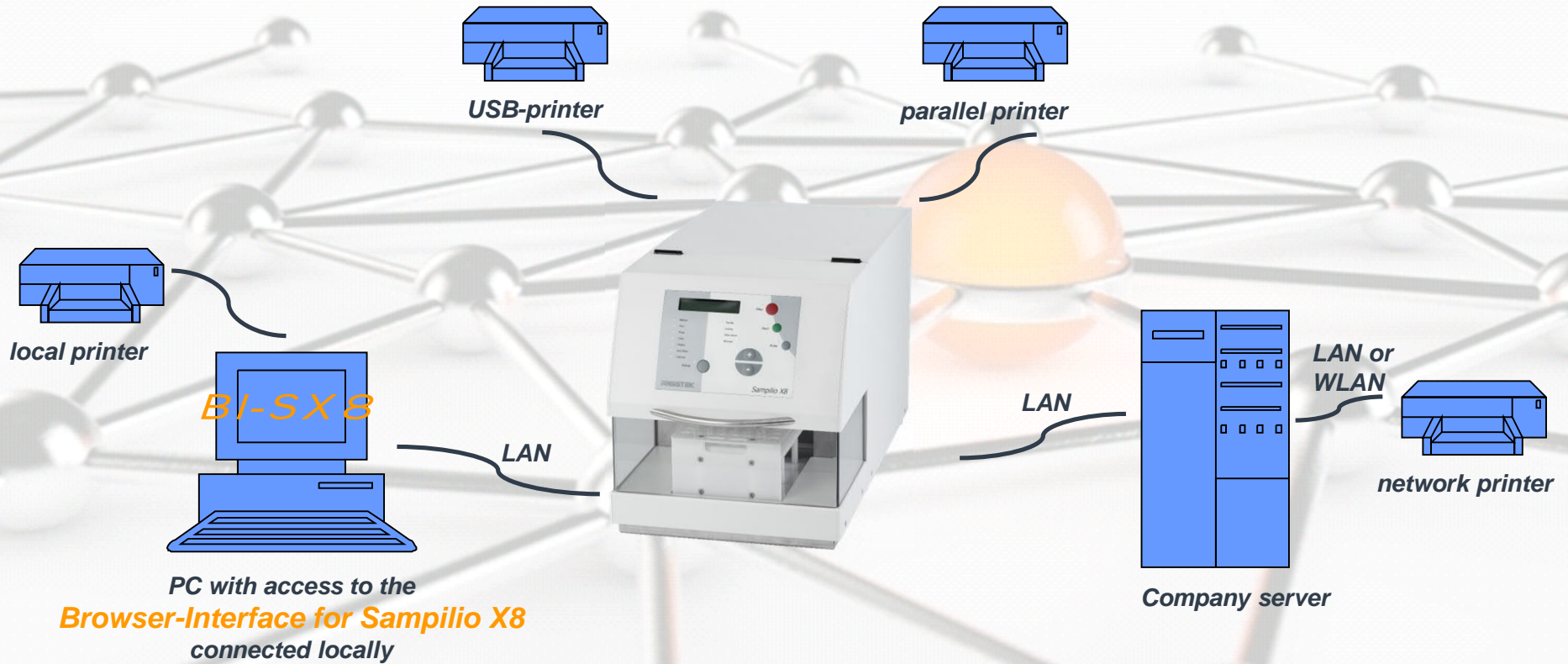
Administrate via the Browser-Interface:

- methods
- user permissions
- security settings*
- reports
- audit trail
- electronic signature*
- users
- Backup*
- system settings



Browser-Interface for Sampilio X8

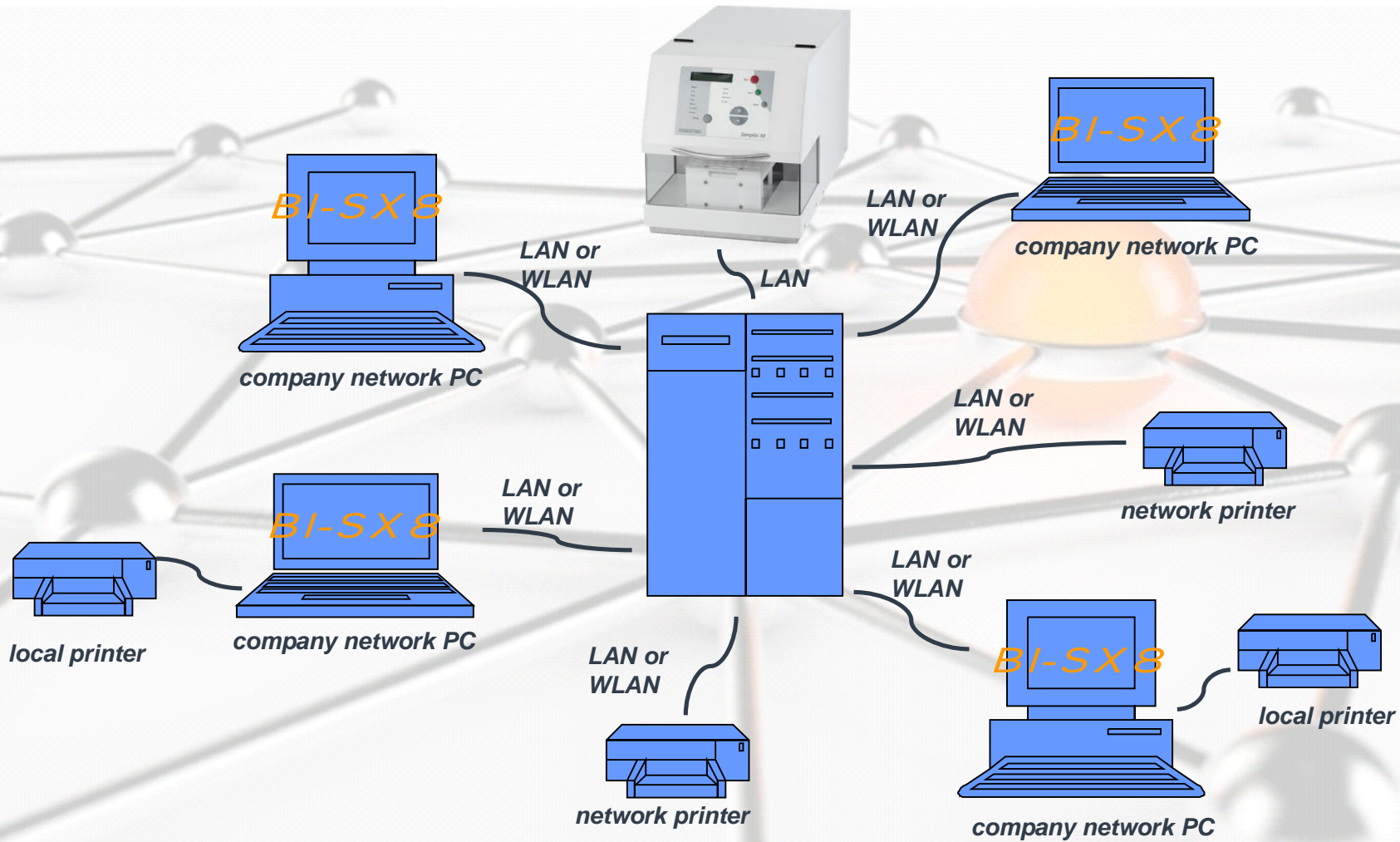
integrate your Sampilio X8 into your IT-infrastructure



direct / local connection

Browser-Interface for Sampilio X8

integrate your Sampilio X8 into your IT-infrastructure



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



Sampilio X8 Browser Interface (S/NR00000003)

[Home](#)

[Login](#)

```
Methods? START/SETUP
Functions? ENTER
```

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*

Update Method ID '3' successful!

Show entries

Search:

Show

Add new

ID	Method	Status	Parameter	Updated	Actions
3	Paracetamol 500	Unsigned	Vials Rack, 6 Lines, 4 Steps	12:17 06.08.2019	Print Edit Sign Archive Delete
4	Method ID 4	Unsigned	Tubes Rack, 6 Lines, 2 Steps	08:38 24.07.2019	Print Edit Sign Archive Delete
6	Method ID 6	Unsigned	Tubes Rack, 6 Lines, 3 Steps	05:44 13.01.2000	Print Edit Sign Archive Delete
7	Method ID 7	Unsigned	Tubes Rack, 6 Lines, 7 Steps	15:24 05.07.2019	Print Edit Sign Archive Delete
8	Method ID 8	Unsigned	Tubes Rack, 6 Lines, 0 Step	11:59 06.08.2019	Print Edit Sign Archive Delete
9	Method ID 9	Unsigned	Tubes Rack, 6 Lines, 2 Steps	15:18 10.07.2019	Print Edit Sign Archive Delete
10	Method ID 10	Unsigned	Tubes Rack, 6 Lines, 0 Step	11:59 06.08.2019	Print Edit Sign Archive Delete
11	Method ID 11	Unsigned	Tubes Rack, 6 Lines, 0 Step	11:59 06.08.2019	Print Edit Sign Archive Delete
12	Method ID 12	Unsigned	Tubes Rack, 6 Lines, 0 Step	11:59 06.08.2019	Print Edit Sign Archive Delete
13	Method ID 13	Unsigned	Tubes Rack, 6 Lines, 0 Step	11:59 06.08.2019	Print Edit Sign Archive Delete

Showing 1 to 10 of 16 entries

Previous 2 Next

← *Action Buttons of a method*

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).

Browser-Interface for Sampilio X8

editing methods



Home Methods Reports Calibrations Performance Rolemanager Usermanager Audittrail Setup Logout

Edit Method ID: 3

Description:

Rack: Test Tubes Test Vial

Lines:

Collection Flow Rate:

Flush Volume:

Purge Flow Rate:

Staggered Interval:

Use Double sampling: No Yes

Use Replacement: No Yes

Wetting Cycle:

Dissolution USP Method:

Dissolution Tester Volume:

Dissolution Tester Temperature:

Dissolution Tester Speed:

Dissolution Tester Infinity Duration:

Dissolution Tester infinity Speed:

Can be edited at Device: No Yes

Show entries

#	Type	Absolute Timepoint (hh:mm:ss)	Volume	Actions
Step 001	Sample	00:02:00	2.00 mL	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
Step 002	Sample	00:07:45	2.00 mL	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
Step 003	Sample	00:13:30	2.00 mL	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
Step 004	Sample	00:19:15	2.00 mL	<input type="button" value="Edit"/> <input type="button" value="Delete"/>

Showing 1 to 4 of 4 entries

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



Show 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 Next

Show 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 Next

Show 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 Next

```

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



Home Methods Reports Calibrations Performance Rolemanager **Usermanager** Audittrail Setup Logout

Show entries Search:

Show

Username	Realname	Role	Device responsible	Actions
testuser2	Test User 2	User	Yes	<input type="button" value="Edit"/> <input type="button" value="Archive"/>
test	Test User3	User	Yes	<input type="button" value="Edit"/> <input type="button" value="Archive"/>
root	RIGGTEK GmbH	Admin	No	
riggtek	Administrator	Admin	No	<input type="button" value="Edit"/>

Showing 1 to 4 of 4 entries Previous Next

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

Edit User ID: testuser2

Realname:

Role:

Responsible for the device:

Password:

Confirm password:

Browser-Interface for Sampilio X8

Rolemanager



Edit Role ID: 0

Role Name: Admin

Role Rights:

Methods

- | | |
|---|--|
| <input checked="" type="checkbox"/> Add Method | <input checked="" type="checkbox"/> Edit Method |
| <input checked="" type="checkbox"/> Archive Methods | <input checked="" type="checkbox"/> Delete Method |
| <input checked="" type="checkbox"/> Import Methods | <input checked="" type="checkbox"/> Empty and Import Methods |

Users

- | | |
|--|--|
| <input checked="" type="checkbox"/> View Users | <input checked="" type="checkbox"/> Add User |
| <input checked="" type="checkbox"/> Edit User | <input checked="" type="checkbox"/> Archive User |
| <input type="checkbox"/> Unlock User | |

Roles

- | | |
|--|--|
| <input checked="" type="checkbox"/> View Roles | <input checked="" type="checkbox"/> Add Role |
| <input checked="" type="checkbox"/> Edit Role | <input checked="" type="checkbox"/> Archive Role |

Audittrail

- | | |
|---|---|
| <input checked="" type="checkbox"/> View Audittrail | <input checked="" type="checkbox"/> Archive Audit Entries |
| <input checked="" type="checkbox"/> Update Audittrail | <input checked="" type="checkbox"/> Download Audittrail |

Setup

- | | |
|--|--|
| <input checked="" type="checkbox"/> View Setup | <input checked="" type="checkbox"/> Update Setup |
| <input checked="" type="checkbox"/> Upload Product Key | <input type="checkbox"/> Download Backup |

Signature

- | | |
|---|---|
| <input checked="" type="checkbox"/> Submit Report & Methods | <input checked="" type="checkbox"/> Review Report & Methods |
| <input checked="" type="checkbox"/> Approve Report & Methods | <input checked="" type="checkbox"/> Unsign Report & Methods |
| <input checked="" type="checkbox"/> Same user Unsign & Submit Report & Methods | <input checked="" type="checkbox"/> Same user Submit & Review Report & Methods |
| <input checked="" type="checkbox"/> Same user Review & Approve Report & Methods | <input checked="" type="checkbox"/> 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.

Browser-Interface for Sampilio X8

Audit-Trail



Show entries Search:

Show

Archived	Created	Entry	Actions
<input type="checkbox"/>	14:59 29.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	09:36 24.07.2019	BI2.00: User riggtek logged out!	Comment
<input type="checkbox"/>	08:55 24.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	08:38 24.07.2019	BI2.00: User riggtek updated Method ID 4: RowId, Version, Description, Rack, Lines, CollectFlowRate, FlushVolume, FlushFlowRate, PurgeFlowRate, StaggeredTime, UseDouble, WaitTime, WettingPeriod, DtsUspMethod, DtsTemperature, DtsRPM, DtsVolume, DtsInfinityDuration, DtsInfinityRPM, Cooling, UseReplacement, MethodEnable Old: 4, 19, , 0, 6, 5, 4.0, 5, 5, 0, 1, 0, 0, USP1,Baskets, 37.0, 100, 900, 0, 100, 20, 0, 0 New: 4, 19, Method ID 4, 0, 6, 5, 4.0, 5, 5, 0, 1, 0, 0, USP1,Baskets, 37.0, 100, 900, 0, 100, 20, 0, 1	Comment
<input type="checkbox"/>	08:37 24.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	13:14 19.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	11:41 18.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	11:17 18.07.2019	BI2.00: User riggtek logged out!	Comment
<input type="checkbox"/>	11:10 18.07.2019	BI2.00: User riggtek logged in!	Comment
<input type="checkbox"/>	11:04 18.07.2019	BI2.00: User riggtek logged in!	Comment

Showing 1 to 10 of 370 entries Previous ... Next

[Download Audittrail](#) [Archive Audittrail](#)

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



Home Methods Reports Calibrations Performance Rolemanager Usermanager Audittrail Setup Logout

General Date / Time Network Printer Security Electronic Signature Backup System

Upload Product Key: Keine Datei ausgewählt.

Device ID:

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



Home Methods Reports Calibrations Performance Rolemanager Usermanager Audittrail Setup Logout

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

Username minimum length:

Password Durability: Durability period in days:

Password Conditions: Special Character Lower Case Upper Case Number

Password Repetition: Password min. length:

Lock account after many Login attempts:

Logout after inactivity:

Can edit Setup at Device:

Can add Methods at Device: Can edit Methods at Device:

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



Home Methods Reports Calibrations Performance Rolemanager Usermanager Audittrail Setup Logout

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

Method Using Level: Unsigned

Electronic Signature Conditions: Submit Comment Review Comment Approve Comment Unsign Comment

Update

Sign the Method

Please insert a comment:

History:

Unsigned at: 17:13 12.07.2019 by
Comment: Method updated, Method unsigned!

Reviewed at: 17:13 11.07.2019 by rigtek

Cancel Submit Review Approve UnSign

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 Audittrail Setup Logout

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

Generate Backup:

Backup to: Backup Frequency in days:

FTP-Server and Path:

FTP-Username:

FTP-Password:

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



Home Methods Reports Calibrations Performance Rolemanager Usermanager Audittrail Setup Tini Logout

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

Upload DTS Driver: Keine ausgewählt

Connected Dissolution Tester:

DissoPreps S/N:

Max Tube Volume:

Flush Volume:

Flush Flow Rate:

Purge Flow Rate:

Max Racks:

Light Intensity:

Stepprocess:

HiFlow Tubings:

Saftey Switch:

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

Browser-Interface for Sampilio X8

- powerful

- without software-
installation /-validation

BI-SX8

- standard feature

- 21 CFR Part 11
compliant



BI-SX8

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

