



DropQuant CFR21p11 v1.4

User manual

December 2014

Contents

Contents	2
Chapter 1: DropQuant CFR21p11 at a glance	5
DropQuant CFR21p11 Overview	5
Basic terminology	6
Chapter 2: Getting started	7
Before installing	7
Installation	7
Before using it for the first time	13
Settings and tools	14
Users	20
Setting up a new experiment	22
Chapter 3: Using DropQuant CFR21p1123	
DataViewer (Measurement Database)	23
Detailed terminology	24
Annex I	28
Glossary	28
Annex II	29
Extra installation information	29

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DropQuant CFR21p11 at a glance

1

DropQuant CFR21p11 Overview

Before using the DropQuant CFR21 part11 software v1.4, we strongly recommend reading the following manuals/websites:

- DropQuant v1.4 User Manual
- Annex I - Part 11, Electronic Records, Electronic Signatures — Scope and Application
- CFR - Code of Federal Regulations Title 21 -
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1>
- CFR21 Part 11 FAQs - <http://www.21cfrpart11.com/pages/faq/>

DropQuant is the software part of the DropSense 96 product, including the user interface software to define experiments, to perform the measurements and to analyze and report the results. DropQuant CFR21p11 is a special version of this same software, including features that allow the customer to make his system compliant with the CFR21p11 regulations. Essentially CFR21p11 guarantees the integrity and traceability of DropQuant related data/measurements.

Compliance with CFR21p11 is not guaranteed by this software only. It also requires a number of procedures to be implemented in the laboratory. For more detailed procedures on how to implement the CFR21p11 compliance please read the recommended literature at the beginning of this chapter. This document is meant to guide the user through the system's process of installation and functionalities.

Basic terminology

Electronic record - CFR21p11 guarantees the integrity of electronic records. On the DropQuant software, the electronic record is called DropFile.

The **DropFile** contains the binary data file with all information from each measurement. This includes measurements' raw data, settings and parameters for doing the calculations, and intermediate and final results. When a user changes the parameters for analyzing the raw data, the DropFile will be saved as a new revision.

From this electronic record the user can create reports in various formats (pdf,xls, etc).

The **report** is the 'readable format' of the 'electronic record'. The same report structure as the default DropQuant is used, with an extra page containing the revisions and signatures information. All reports include the revision of the experiment from which the report is created.

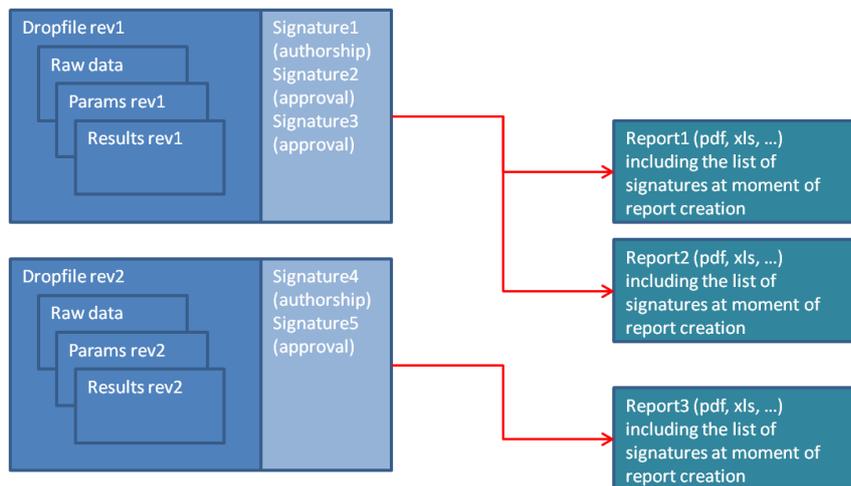


Figure 1: the electronic record (the DropFile) and the reports derived from the electronic record.

Audit trail - The audit trail is a database containing all events (actions) performed by a user on the system. This allows tracking the historic of an experiment or a report. The database is implemented as an SQL database, where each record describes the details of the event.

Signature – Any user can add an electronic signature to a revision of a DropFile. The electronic signature is a combination of the login name and the password. The signature information is stored on a database, including next fields:

- Username
- Timestamp
- Revision number of the measurement
- Reason (review, approval, responsibility, authorship)
- Information (a text field)

Getting started

2

Before installing

There are a couple of crucial steps to follow before installing the CFR21p11 version. Most of them due to their complexity will require Trinean's intervention.

- 1- Verify if there is a previous installation of PostgreSQL. Start Button > Control Panel > Programs and Features > PostgreSQL. If there is already a version installed, please contact Trinean Support.
- 2- Verify if DropQuant CFR21p11 is already installed. Start Button > All Programs > Trinean > DropQuant CFR21p11. If there is already a version installed, please contact Trinean Support.

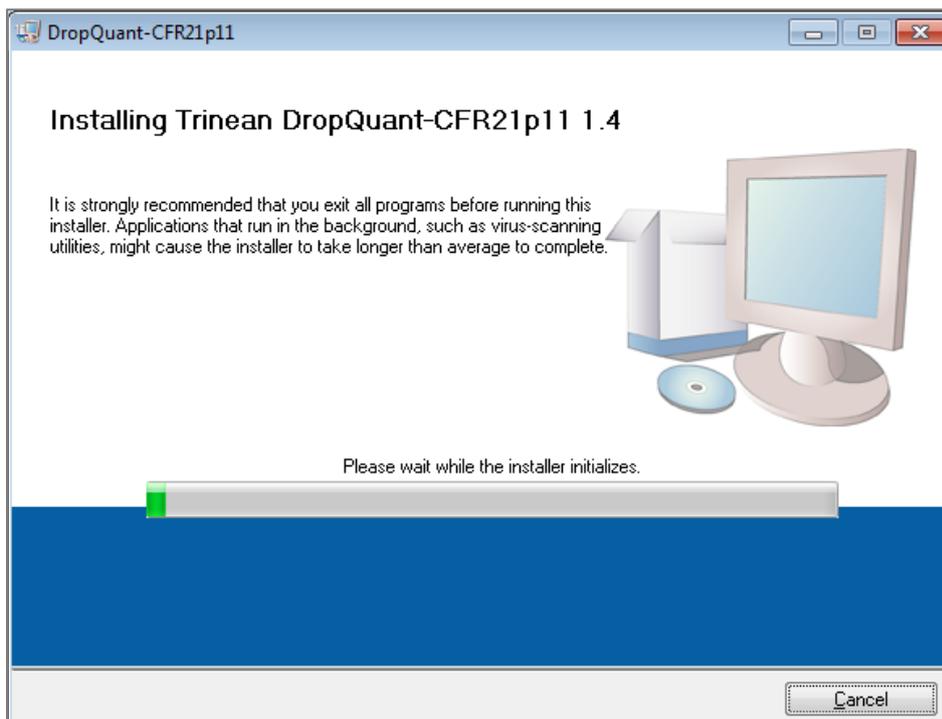
It is important to contact Trinean in case of having any of these previously mentioned programs installed, to avoid any compatibility issues from appearing and to assure a proper installation.

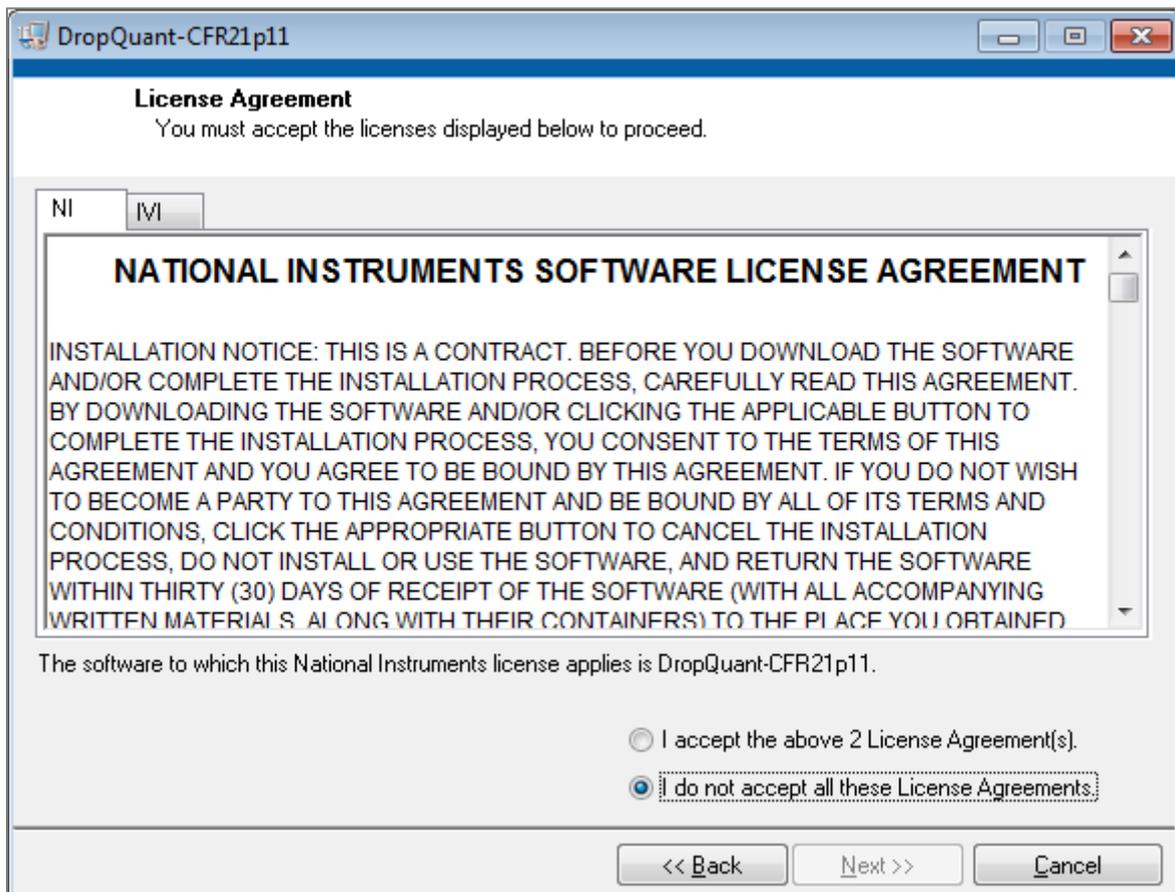
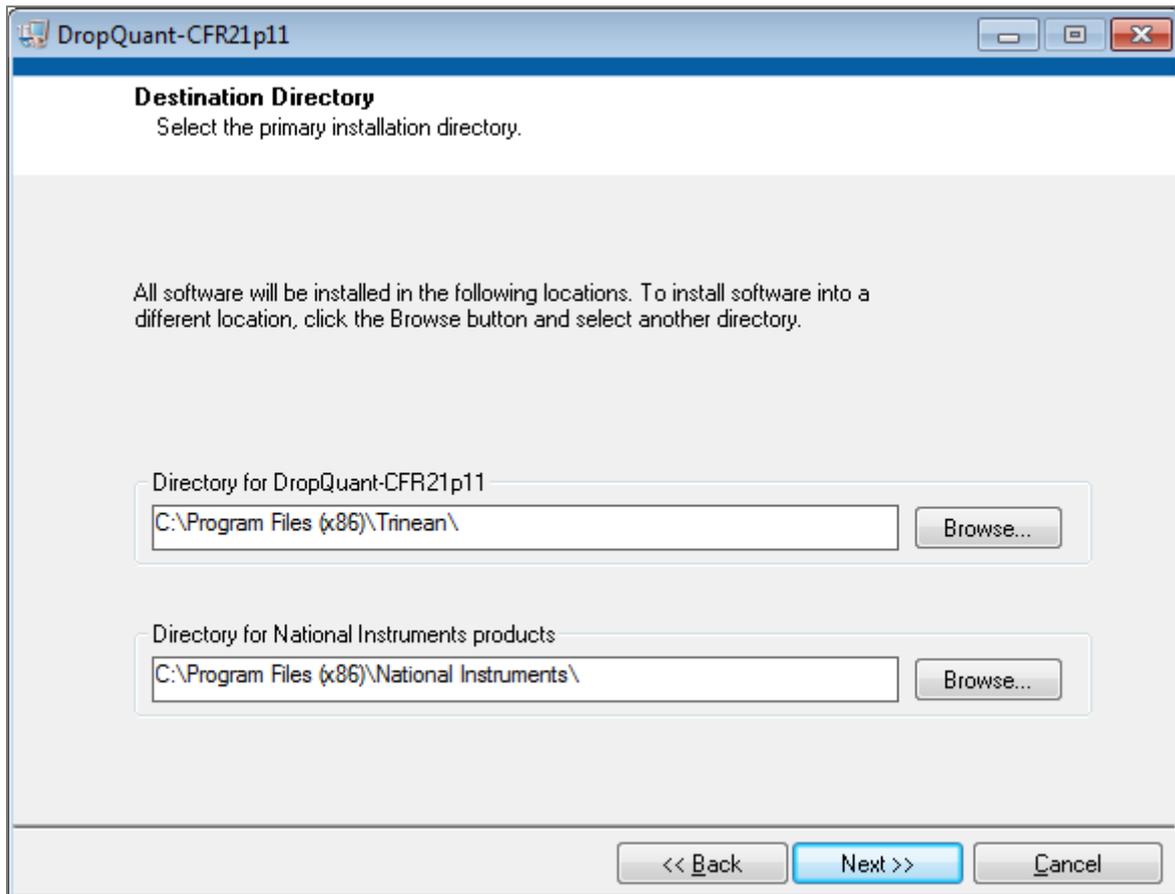
Installation

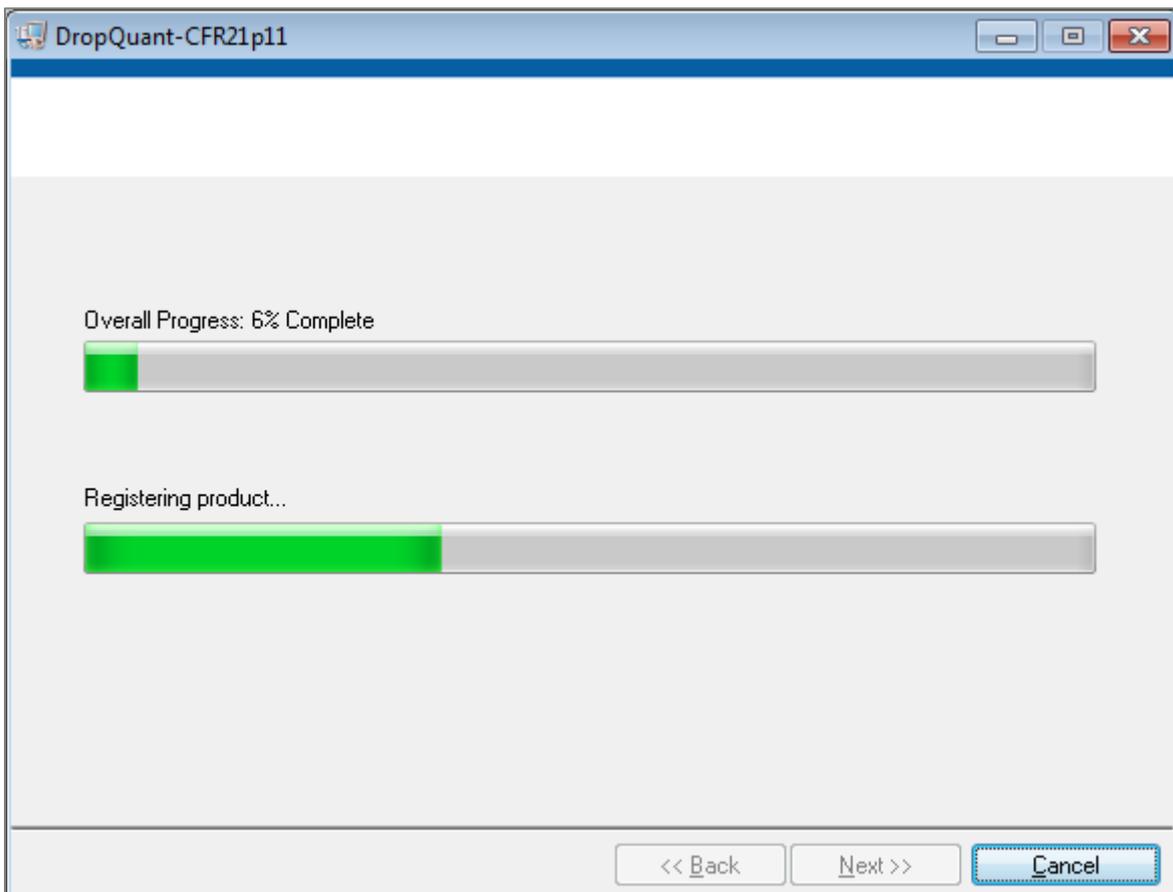
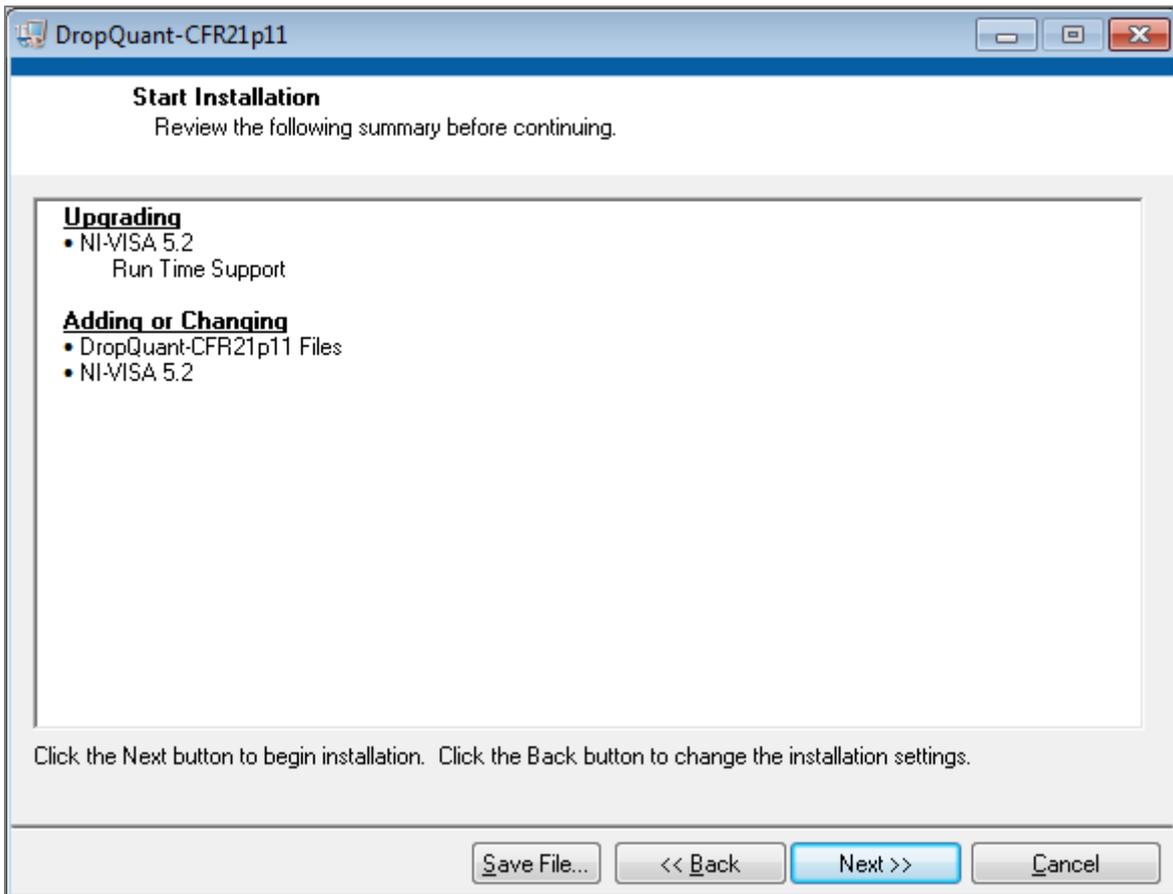
The DropQuant CFR21p11 installation, works the same way as any other kind of software package designed for Windows systems.

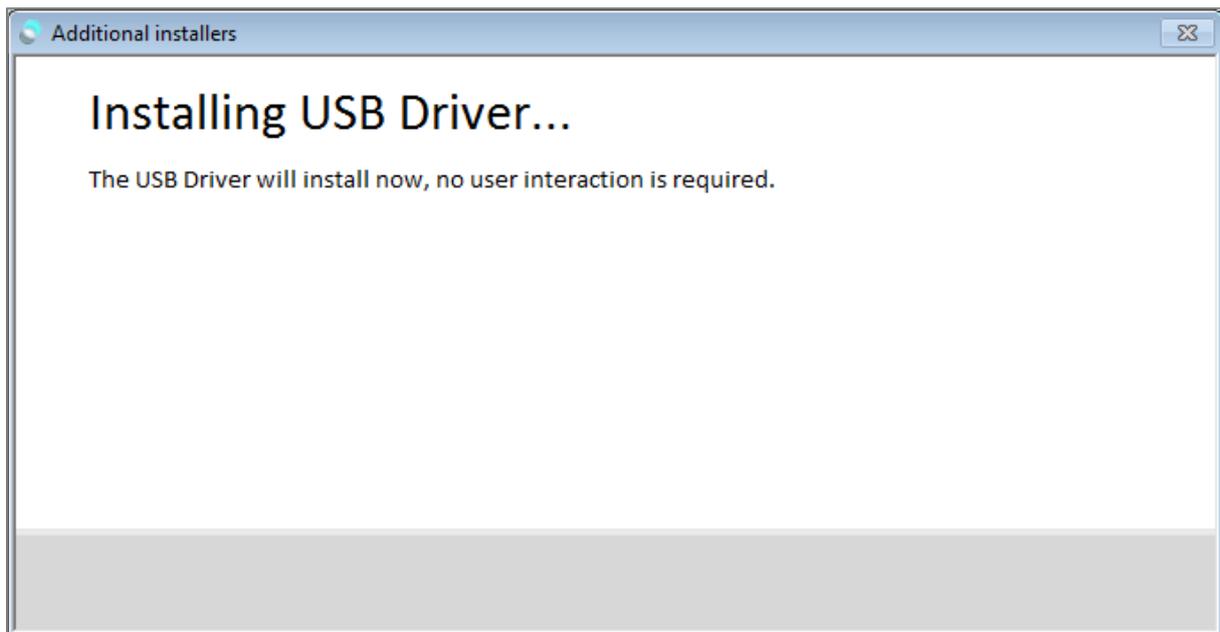
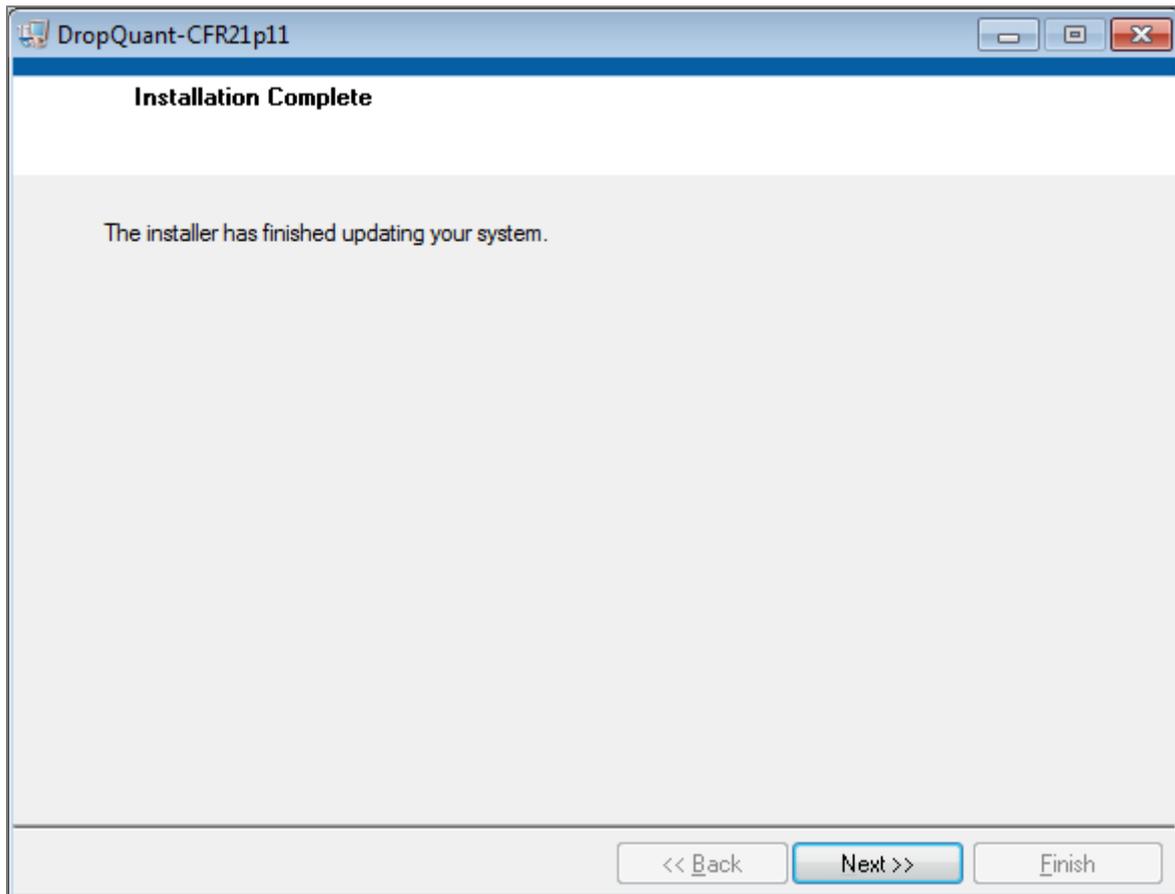
Start by double clicking on the installation file and follow the onscreen instructions.

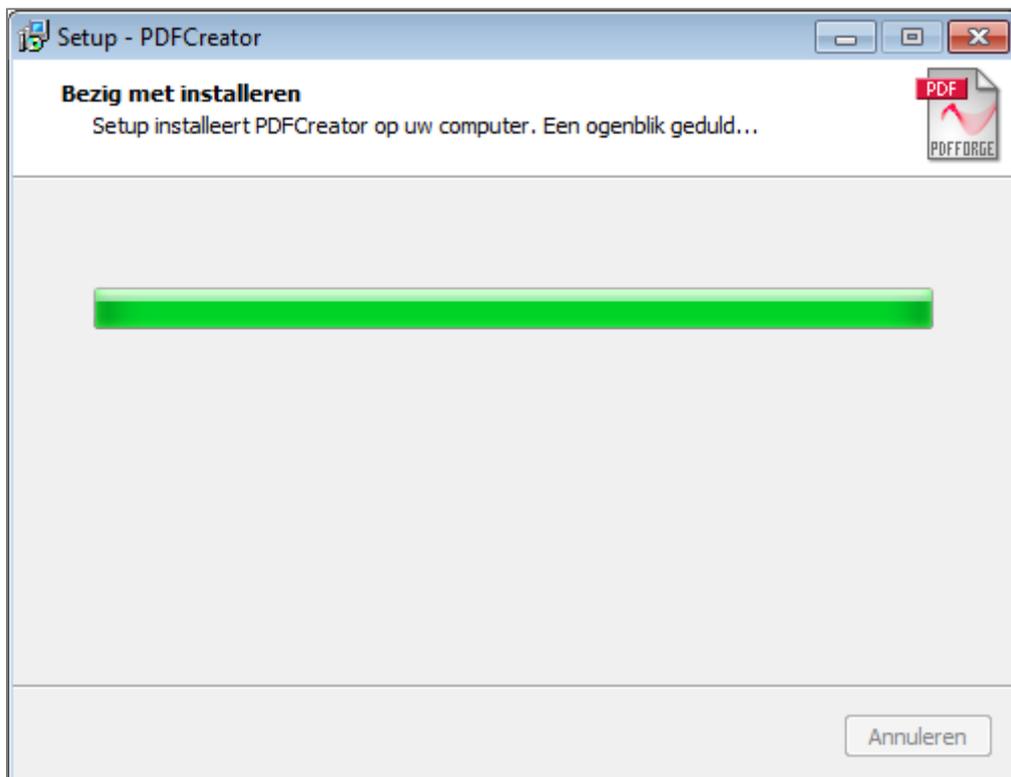
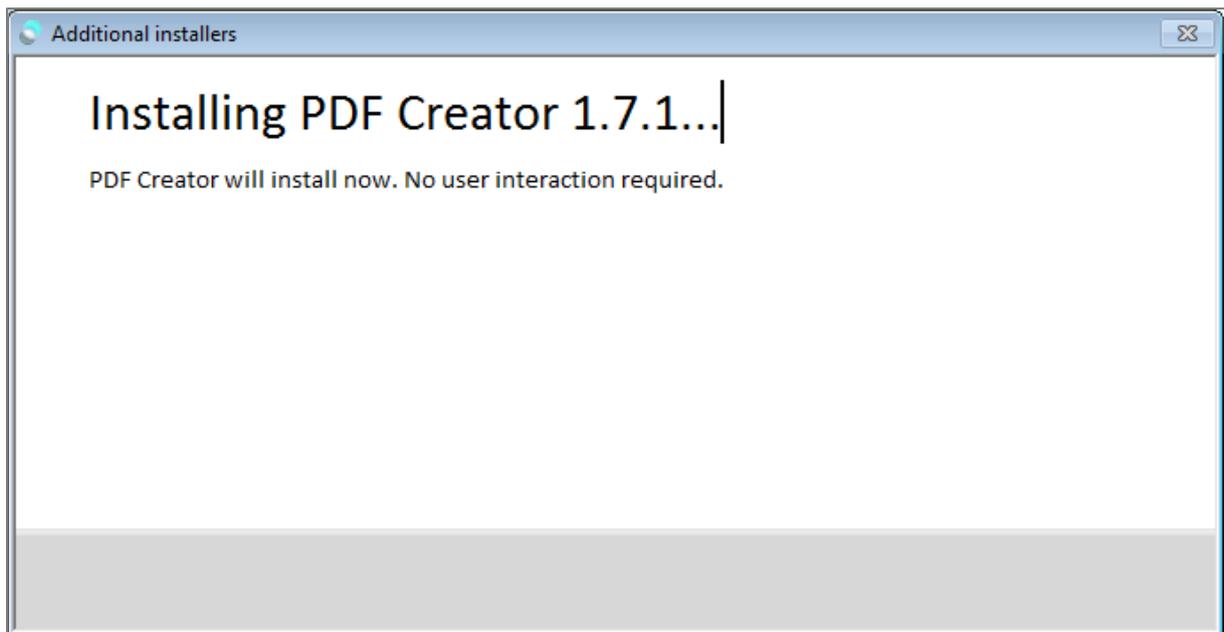
There isn't much intervention from the user's part while installing this software. The only thing possible to be changed is the installation location, but we recommend the default one.

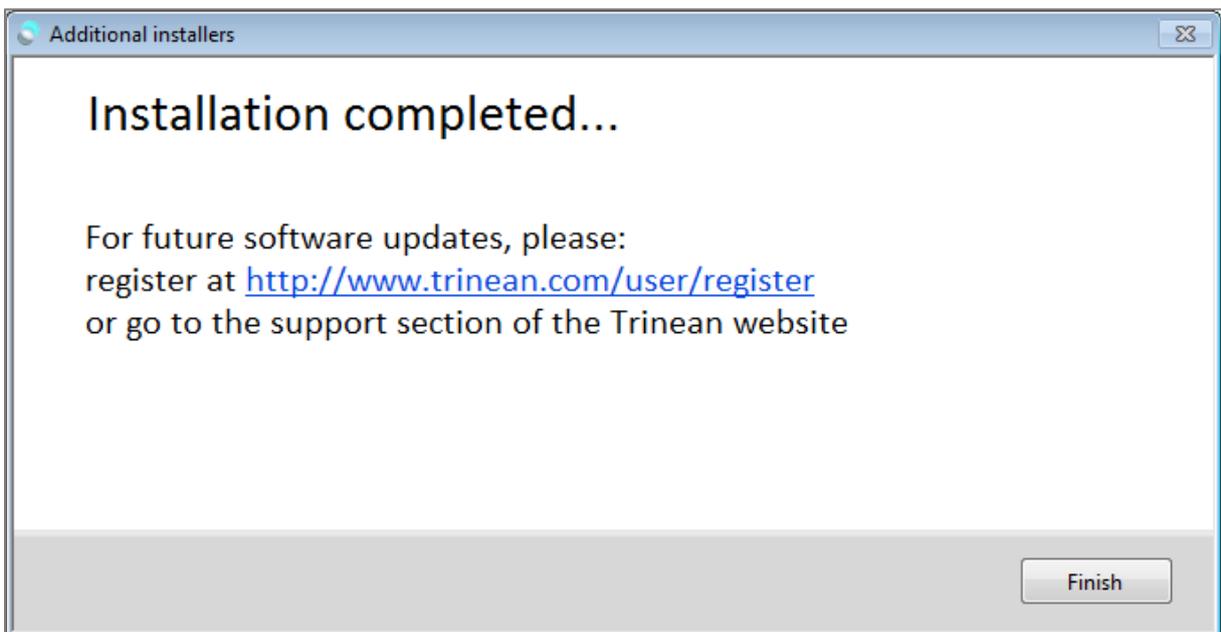
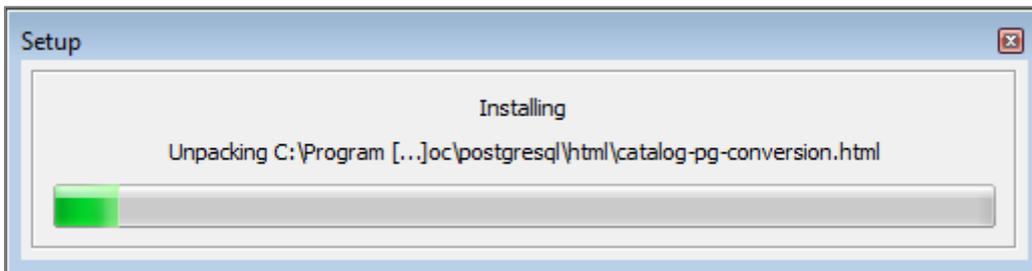
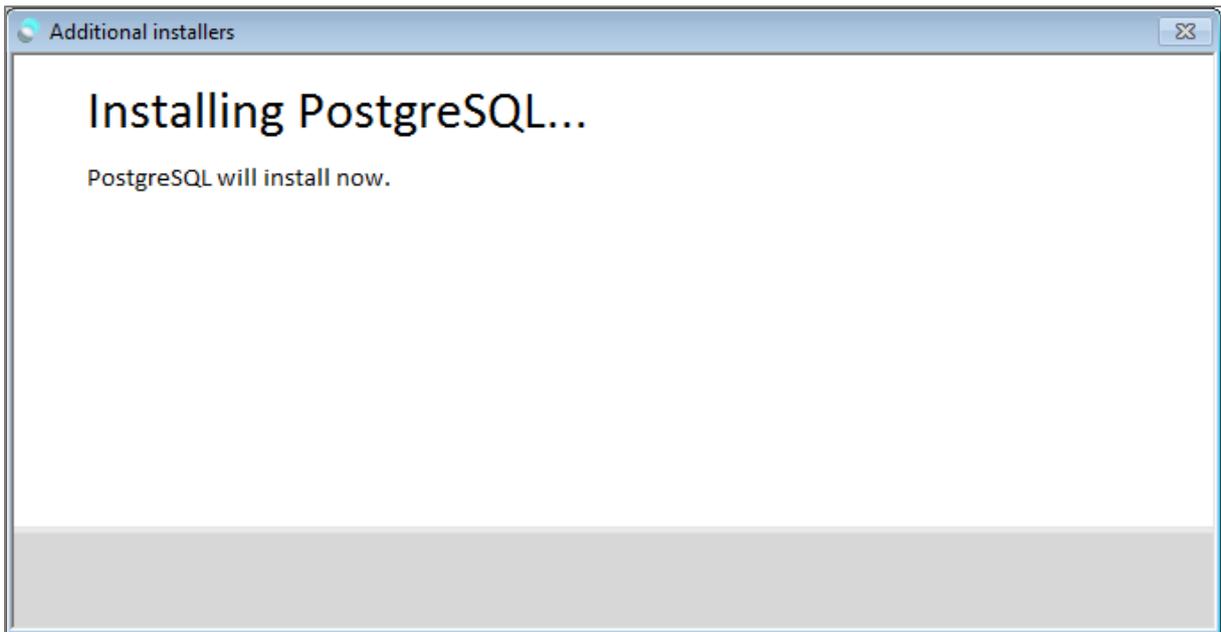


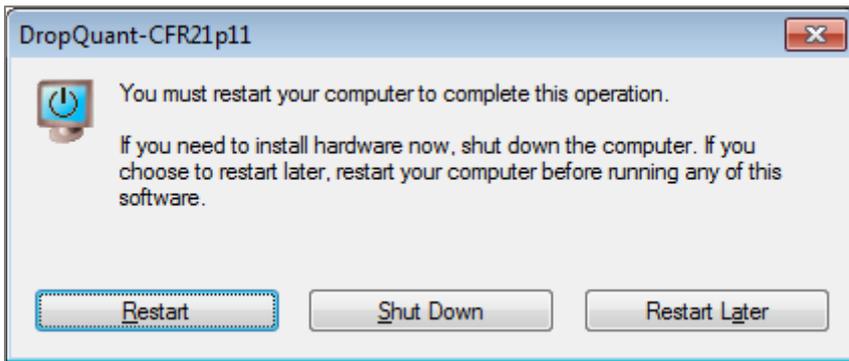






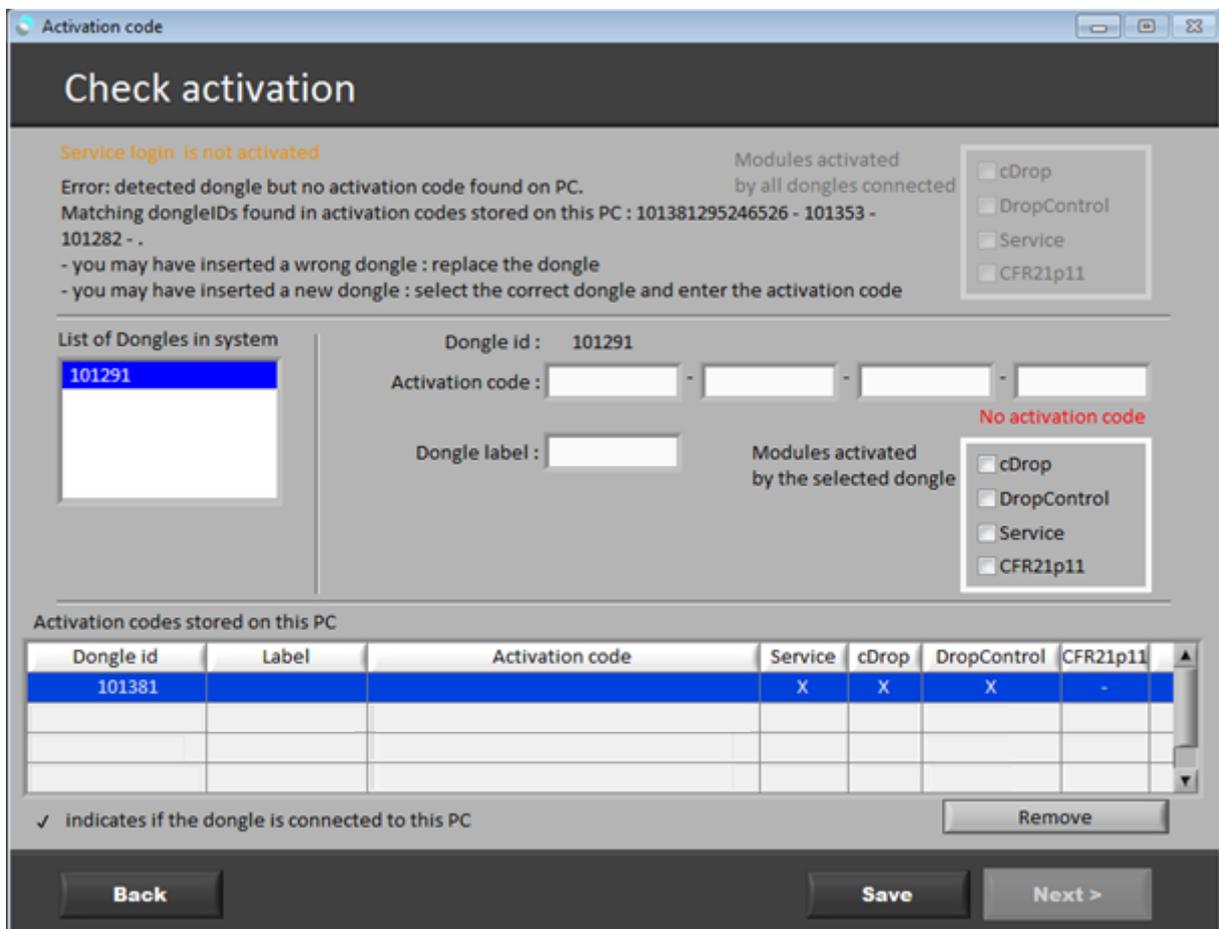






Note: It is important that a proper restart is performed before using the software.

Before using it for the first time



Once starting the software for the first time, the screen above will show up, asking for an activation code. Such activation code is associated to a dongle that can be purchased at your local distributor.

Before starting to use the software for the first time, a trained service engineer has to create an administrator account on DropQuant CFR21p11. If an authorized service engineer is not present, it will be impossible to create an administrator or simply a user account.

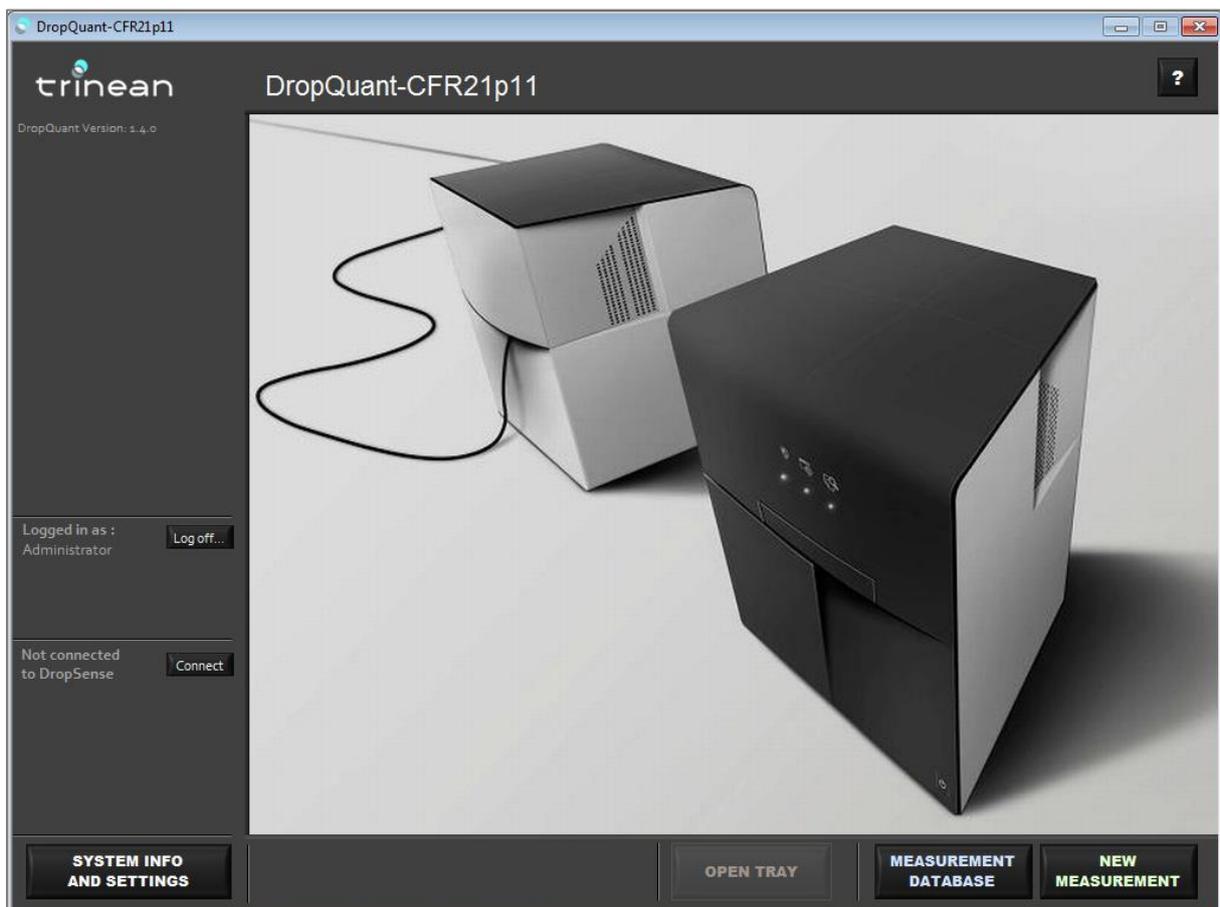
Advanced: This procedure is meant to be performed only by a trained service engineer.

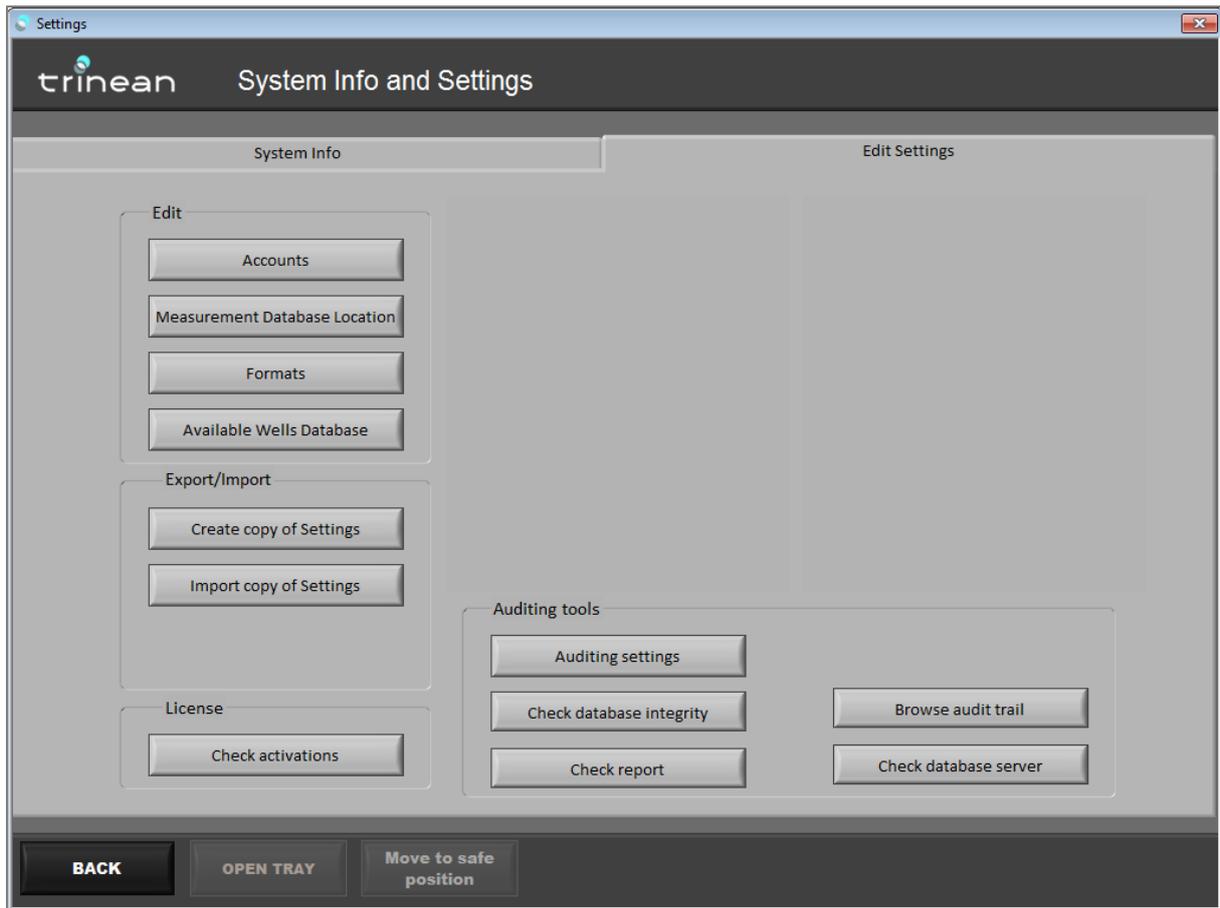
- Log in using the service account.
- Settings and tools> Edit Settings> Accounts
- Add new user
- Fill in all the required fields
- Level – Administrator
- Read rights - Read all meas of everyone (recommended)
- Save new
- Log off and log in again using the newly created Administrator account

Settings and tools

Before starting to use the DropQuant CFR21p11 software, it is important to understand the available CFR21p11 tools and settings we have designed specifically for this package.

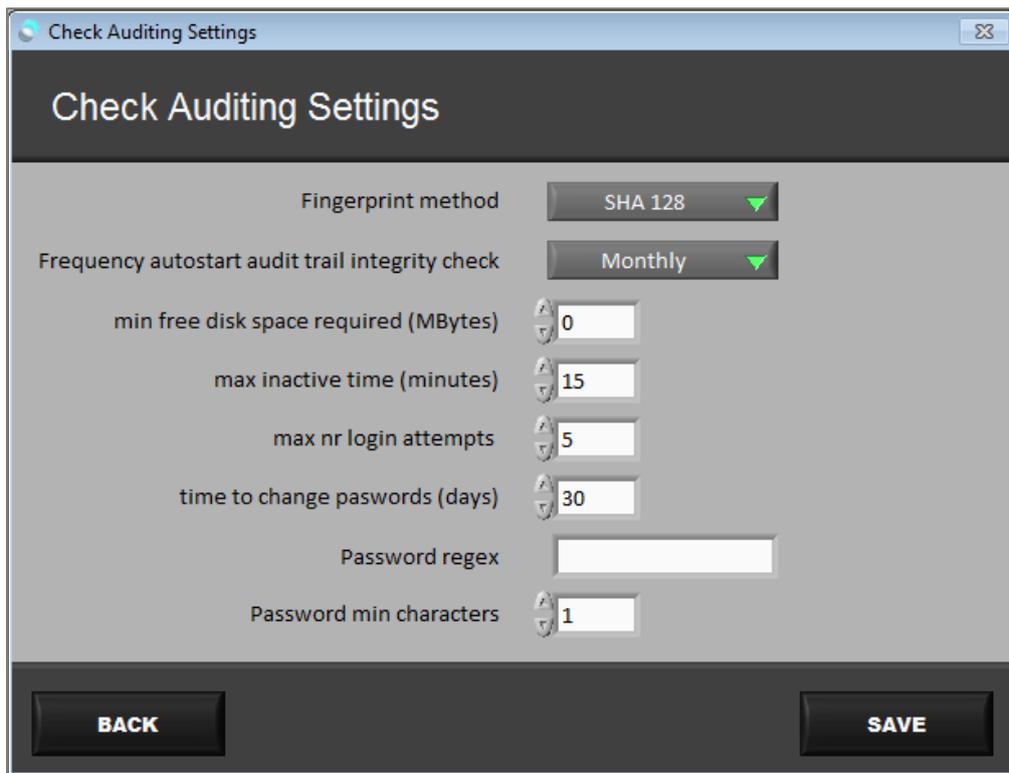
On the DropQuant CFR21p11 main screen, go to Settings and Tools>Edit Settings>Auditing tools.





Auditing settings

Setting	Options	Extra notes
Fingerprint method	SHA 128 (default)	
Audit trail integrity check frequency	Monthly/Weekly/Daily/ Never (not recommended)	
Maximum inactive time	User defined (minutes)	
Maximum number login attempts	User defined	
Time to change passwords	User defined (days)	
Password regex	Requires string (consult table below)	Password characters requirements
Password minimum characters	User defined	

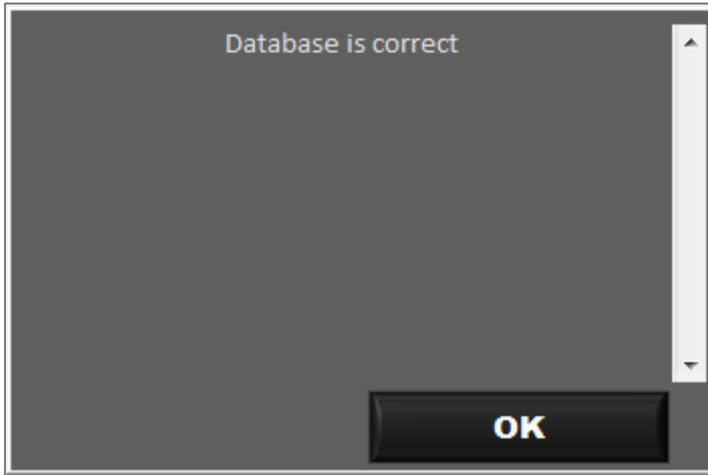


For the **password regex** settings, please use the table below as a reference.

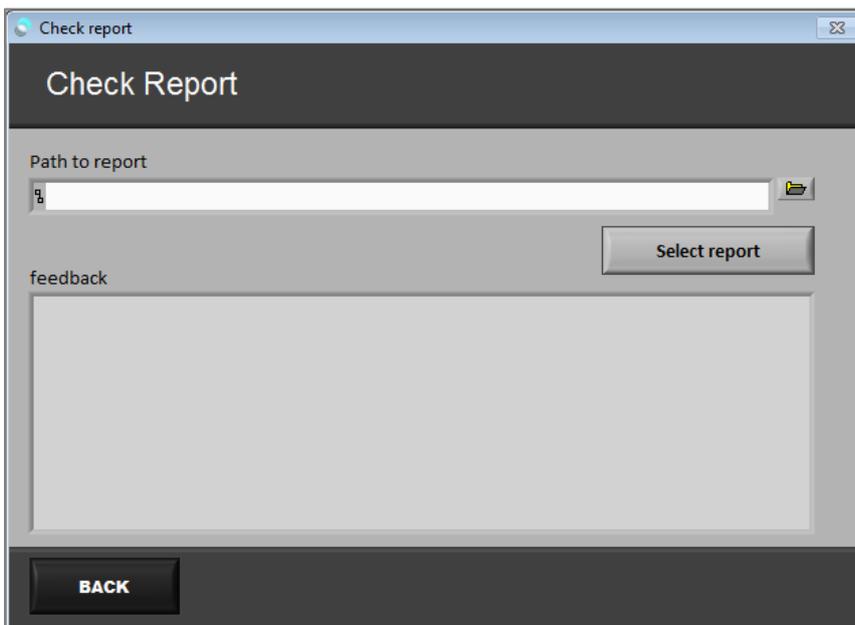
regex	meaning
(?=.*\d)	At least 1 number
(?=.*\W+)	At least one special character (not including [a-z; A-Z; 0-9])
(?![.\\n])	String cannot contain enter
(?=.*[A-Z])	At least one uppercase letter
(?=.*[a-z])	At least one lowercase letter
.*	All characters are allowed
\$	End of string
.*\$	Every possible string
(?=.*\d).*\$	String with at least one number
(?=.*[A-Z])(?=.*[a-z]).*\$	String with at least one uppercase and a lowercase letter.

Check database integrity – this tool runs over the experiments saved on the database and checks for the integrity of each DropFile there saved. In parallel the file access parameters are also checked.

Note: This procedure might take longer on large databases.



Check report – this tool allows the user to check the integrity of a previously generated report (pdf, xls, txt and csv).



Browse audit trail– this tool allows the access to the audit trail log database. Here the user will have access to a fair amount of information related to changes and operations performed on the software. This functionality is required in case the user wants to check what happened in the past.

Note: this contains the actions of all PCs in the network, running under the same CFR region.

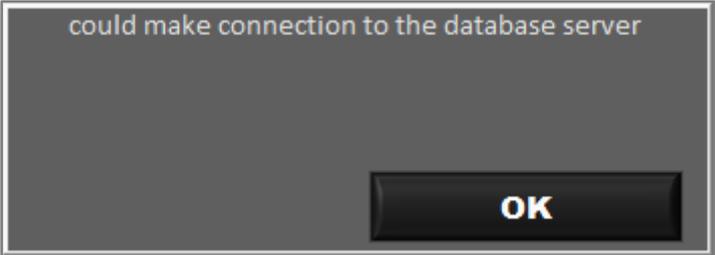
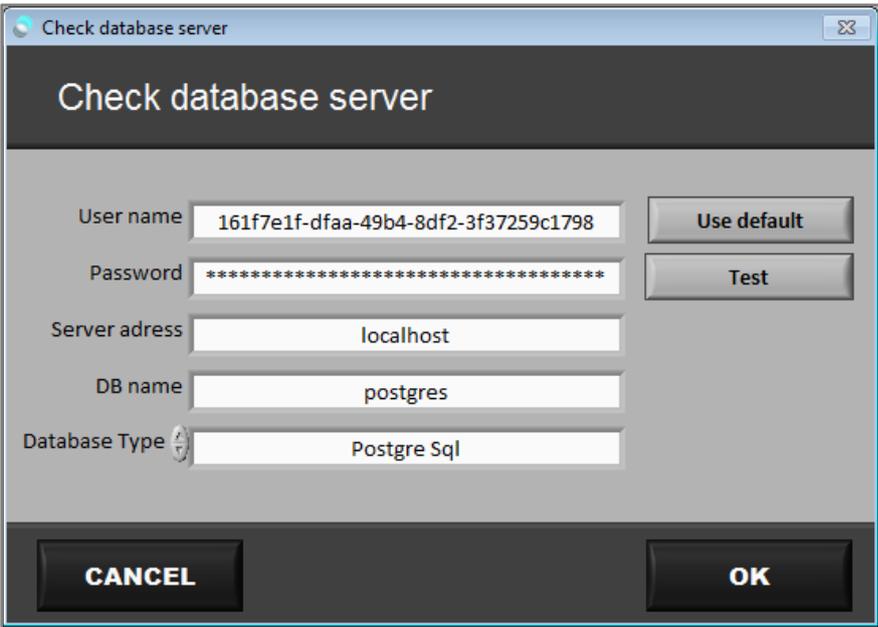
Setting	Options	Extra notes
Trail ID	Follow up number	
Experiment number		
Revision		
Timestamp		
Operator		Username linked to that action
Group	User/System/Error/Data	User group level
Type		Type of action
Information		Extra information

The screenshot shows the 'Browse Audit Trail' application window. At the top, there is a title bar and a header area with 'Browse Audit Trail' and a 'Status: OK' indicator. Below the header, there is a 'Select Group:' dropdown menu set to 'All'. The main area contains a table with the following columns: Trail ID, Exp nr, Rev, Timestamp, Operator, Group, Type, and Information. The table lists various system events, including integrity checks, settings changes, user logins, and user modifications. At the bottom of the window, there is a 'BACK' button and a printer icon.

Trail ID	Exp nr	Rev	Timestamp	Operator	Group	Type	Information
123			2013/12/17 16:04:56	Administrato	System	Integrity check	All files are correct
122			2013/12/17 16:04:56	Administrato	System	Change Settings	date latest validation Changed to [0]
121			2013/12/17 16:04:44	Administrato	User	User log in	login OK
120			2013/12/17 16:04:44		User	Change user	updated user admin
119			2013/12/17 16:04:39		System	Get Settings	Read CFR settings
118			2013/12/17 16:04:39		User	Get userinfo	read user data from user database
117			2013/12/13 14:48:34	Administrato	User	Change user	updated user test
116			2013/12/13 14:48:08	Administrato	User	Change user	updated user test
115			2013/12/13 14:47:27	Administrato	User	User log in	login OK
114			2013/12/13 14:47:27	service	User	Change user	updated user admin
113			2013/12/13 14:47:22	service	User	User log in	Login name not in user database
112			2013/12/13 14:47:20	service	User	User log in	Intrusion alert : maximum number of
111			2013/12/13 14:47:19	service	User	Change user	updated user test
110			2013/12/13 14:47:18	service	User	Change user	updated user test
109			2013/12/13 14:47:17	service	User	Change user	updated user test
108			2013/12/13 14:47:15	service	User	Change user	updated user test
107			2013/12/13 14:47:14	service	User	Change user	updated user test
106			2013/12/13 14:47:02	service	User	Get userinfo	read user data from user database
105			2013/12/13 14:47:02	service	User	Add user	added user test
104			2013/12/13 14:47:02	service	User	User log in	login OK
103			2013/12/13 14:47:02	service	User	Change user	updated user generic service
102			2013/12/13 14:18:45	service	User	User log out	Inactivity Timeout
101			2013/12/13 14:03:45	service	User	User log in	login OK
100			2013/12/13 14:03:45		User	Change user	updated user generic service
99			2013/12/13 14:03:24		System	reset time-out	startup proces : initialisation of the CFR manager fini

Check database server – the user can use this tool to check if the communications between the DropQuant CFR21P11program and the postgresQL server are successful.

Setting	Options	Extra notes
User name	User defined	
Password	User defined	
Server address	Do not change unless needed	
DB name	Do not change unless needed	
Database Type	Do not change unless needed	
Time to change passwords	User defined (days)	
Use Default		Reset to default settings
Test		Test connection with database



Users

On Settings and Tools>Edit>Accounts it is possible to find all the required information to add and edit users. Due to CFR21p11 regulations, a user cannot be deleted after being created. User database now includes more input fields:

User identification

- Login name
- Full name
- Company
- Department
- Function
- Email

The password and password lifetime – (setting password to -1 means no expiry date for the password. Please be aware that this action will not comply with the CFR21p11 rules.)

Status – defines if a user is active or not.

The administrator can set the status to inactive in case the user is not allowed to login to the system anymore, and the system sets the status to intrusion in case there is an intrusion event detected (too many successive errors in password). Resetting intrusion status can be done by the Administrator only.

User level – The user level defines its privileges.

- Administrator
- User

Read rights – defines the reading rights for each user.

- “read only own measurements”
- “read all measurements of own level” (if logged in as a user, you have access to all measurements done by someone of that user level).
- “read all measurement up to level admin”
- “read all measurements of everyone” (has also access to the measurements done by service engineers or users from a higher level)

Note: users cannot be deleted. Status can be set inactive, but once inactive they won't be able to login.

There are 4 actions possible within the user management window.

- Edit the user settings
- Change the password
- Add a new user
- Export the user data

Accounts

select user (click to view)

- trinean
- service
- Administrator**
- test

Login name: Administrator
 Full name: admin
 Company: test
 Department: test
 Function: beta tester
 E-mail: admin@trinean.com
 Password: *****

Level: Administrator
 Status: Active
 Read rights: Read only own measurements
 Publish rights: Visible for self and admin
 Date last login: 2013/12/17 16:04:44
 Date last password change: 2013/12/10 16:17:11
 Access to all meas: No
 Number of wrong attempts: 0
 Password lifetime: 30 days
 ID: 3

Add new user View user settings Edit Change password

BACK **EXPORT USER DATA** **VIEW LOG** login info **Logged in as service**

Accounts

select user (click to view)

- trinean
- service
- Administrator**
- test

Login name: Administrator
 Full name: admin
 Company: test
 Department: test
 Function: beta tester
 E-mail: admin@trinean.com

Read rights: Read only own measurements
 Status: Active
 Level: Administrator
 Password lifetime: 30 days

edit user cluster

Add new user Save Changes

BACK **EXPORT USER DATA** **VIEW LOG** login info **Logged in as service**

Setting up a new experiment

New Measurement – In order to set a new experiment, please refer to the DropQuant manual. On that screen, there are no DropQuant CFR21p11 related settings or options that will need the user intervention.

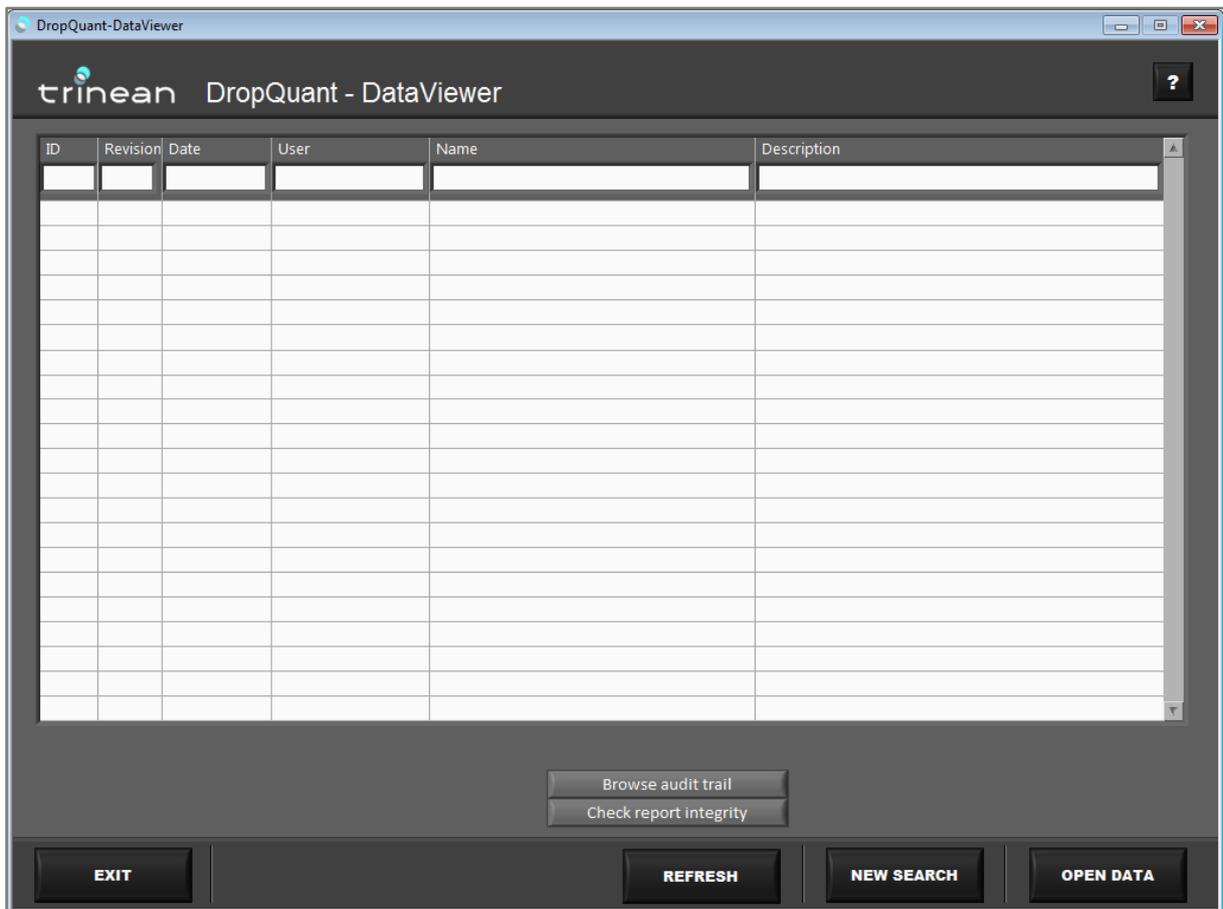
Using DropQuant CFR21p11

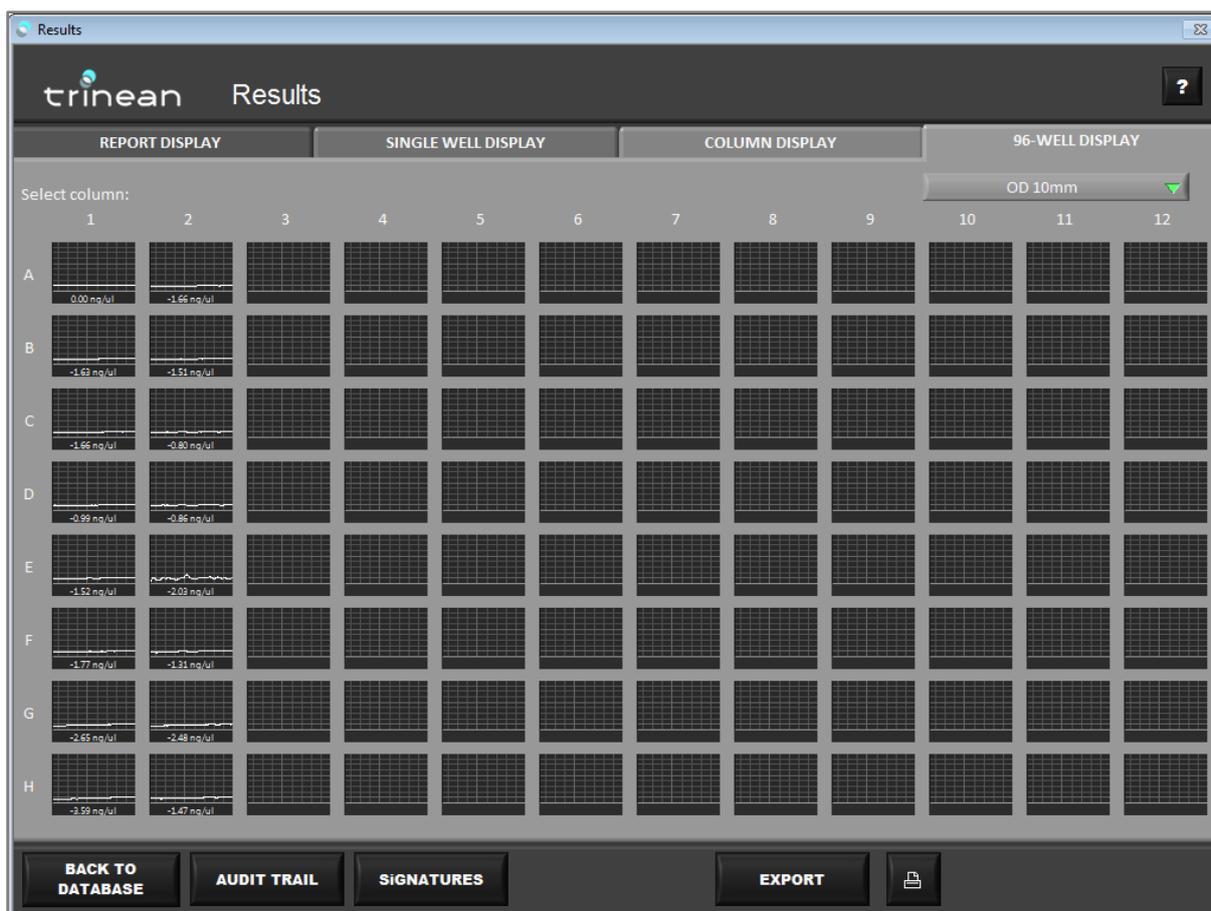
3

DataViewer (Measurement Database)

DropQuant CFR21p11 uses similarly to the standard DropQuant, DataViewer, as a tool to access and analyze all the DropQuant experiments.

Due to the specificity of the CFR21p11 version, some extra features can be accessed here. This chapter fully explains what is possible to access and change here.





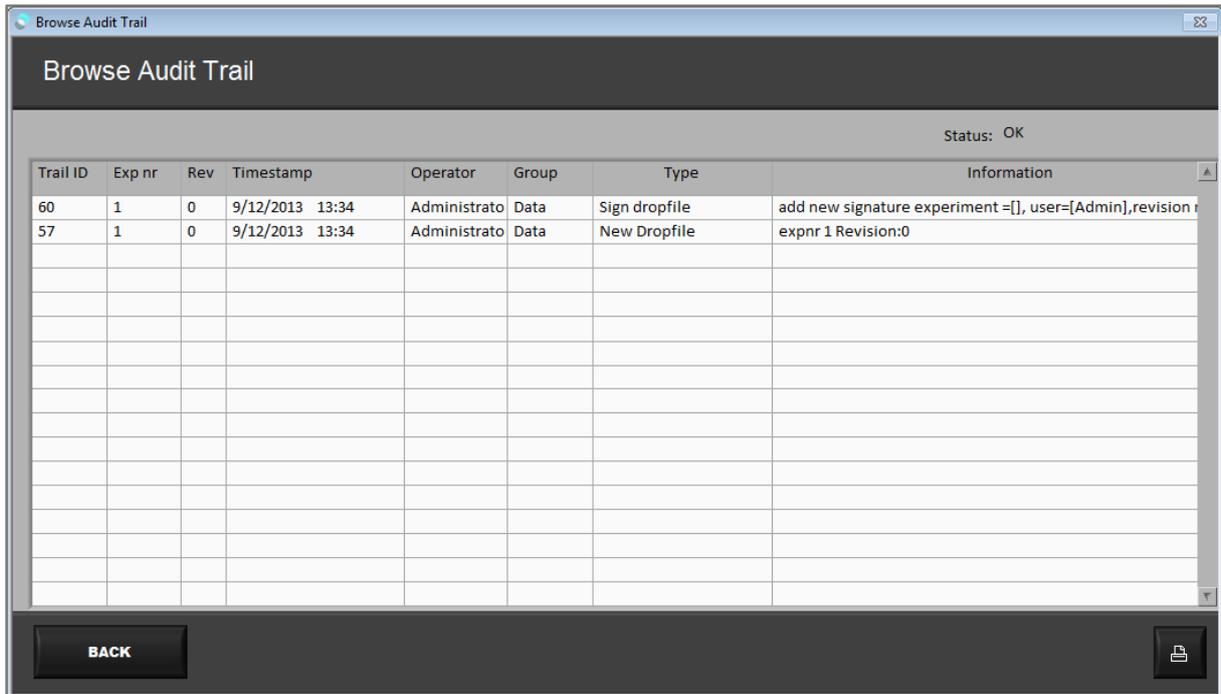
Detailed terminology

Audit trail – is a database containing all events (actions) performed by a logged user, in the system. This allows tracing the history of an experiment or report. The database is implemented as an SQL database, where each record describes the details of the event.

Type trail event	Group	Extra notes
Log in events	USER	
Log out events	USER	
Changes to the user database	USER	
Creation new dropfile	DATA	
Creation new revision	DATA	
Creation reports	DATA	
Applying signatures	DATA	
Change settings	SYSTEM	
Install	SYSTEM	
Error	ERROR	

The audit trail record contains next fields:

- Timestamp (recorded when saving the file, at the end of the measurement)
- User login name
- User level
- Type of event
- Measurement ID: unique ID
- Revision
- Information field: content depends on the type of the event.



The screenshot shows a window titled "Browse Audit Trail" with a status bar indicating "Status: OK". The main content is a table with the following columns: Trail ID, Exp nr, Rev, Timestamp, Operator, Group, Type, and Information. The table contains two rows of data:

Trail ID	Exp nr	Rev	Timestamp	Operator	Group	Type	Information
60	1	0	9/12/2013 13:34	Administrato	Data	Sign dropfile	add new signature experiment =[], user=[Admin],revision r
57	1	0	9/12/2013 13:34	Administrato	Data	New Dropfile	expnr 1 Revision:0

At the bottom of the window, there is a "BACK" button on the left and a print icon on the right.

Signatures – As required for CFR21p11, this software includes a unique signature, corresponding to the user logged on that session.

- Signing means password input
- First signature “authorship” is automatically generated during the measurement
- To add a signature: Open measurement>Signatures>Add New Signature (extra details explained bellow)>Sign
- It is not possible to remove signatures. User can re-sign an electronic record and use the “comment field” to re-sign.
- Signatures’ overview is in pop-up window that can be started from the post-processing window.

The signature includes:

- Username
- Timestamp
- Revision number of the measurement
- Reason (review, approval, responsibility, authorship)
- Information (a text field)

Add signature

User:

Measurement
Revision Nr:

Reason:

Info:

It is important to know that when an experiment has multiple revisions and an old revision is opened, it will be saved as the newest revision when it is changed by the user. On DataViewer, the revisions can be accessed simply by right clicking on the desired experiment, and by selecting open revision. On this screen, it is possible to track all the different revisions, as well as more information.

Annex



Glossary

Accounts	19	DropQuant CFR21p11 Overview	5
audit trail	6, 17, 24	Electronic record	6
Audit trail	6, 15, 23	Installation	2, 7
Auditing settings	15	new experiment	2, 21
Before installing	2, 7	password regex	16
Before using	2, 5, 13	PostgreSQL	7
Browse audit trail	17	report	5, 6, 17, 23
database integrity	16	Revisions	25
database server	18	Settings and tools	2, 13
DataViewer	2, 22, 26	Signature	6, 24
Detailed terminology	23	terminology	6
DropFile	6	Users	2, 19

Extra installation information

In case of having a previous DropQuant CFR21p11 already installed, there are a couple of important steps to follow.

Please bear in mind that Trinean is not responsible for any issues resultant of not following these steps properly. In case of any questions please contact the technical support team.

When following these steps we first assume that DropQuant CFR21p11 is installed.

IMPORTANT: Always restart your computer when asked to even on later steps.

- 1- Please go to Start > Control Panel > Programs and Features > DropQuant CFR21p11 > Uninstall/Change. And remove the selected software.

IMPORTANT: It is extremely important to confirm if there is any other application using the PostgreSQL software. In case there is, Trinean should be contacted before following any further steps. In case this measure is not followed, Trinean is not responsible for any damage created to 3rd party software.

- 2- Follow the same path to uninstall the PostgreSQL software and restart the computer if asked to.
- 3- Follow the same path to uninstall the ODBC software and restart the computer if asked to.
- 4- Navigate to C:\ProgramData\Trinean (**mind that this folder might be hidden**), and delete the folder Postgresql
- 5- Go to Start > Search Programs and files > cmd
- 6- On the new window type: net user postgres /delete
- 7- Restart your computer, and start the installation provided with the DropQuant CFR21p11 v1.4 software.