

4D-Nucleofector[®] LogWare Gen 2 Manual



Username

Password

Login 

Inactive users: 0

Locked users: 0

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1 Introduction

In addition to the standard software which is automatically implemented on each 4D-Nucleofector® System, Lonza offers the 4D-Nucleofector® LogWare suited for use in regulatory environments (Table 1). The 4D-Nucleofector® LogWare comprises specific features required for the compliance with Title 21 CFR part 11. These features ensure data consistency, enable electronic signatures and create electronic records of the systems usage.

Features comprise:

- User administration rights to create and manage users and allow data export according to Title 21 CFR part 11
- Generation of audit trails
- User login and re-authentication before conducting an experiment
- Logging of every data creation or modification (e.g. creating an experiment) as a specific user activity together with user information and a time stamp
- Logging of experiments with an enhanced result data set containing serial numbers, time stamps and user information
- Reporting of results, failure reporting and detailed failure description. Format of result file allows seamless export into standard office programs (Word, Excel)
- Generation of encrypted data and reports which are safely stored on the device (deletion is not possible)

Table 1: Overview of differences between standard 4D-Nucleofector® Software Gen 2 and 4D-Nucleofector® LogWare Gen 2

Feature	4D-Nucleofector® Software Gen 2	4D-Nucleofector® LogWare Gen 2
Cell Type Programs, representing the optimal settings	+	+
Free program choice	+	+
Condition transfer from 20 µL to 100 µL, 1 mL or 20 mL	+	+
Custom program generation and modification	+	+
Administration mode	-	+
User login	-	+
Activity logging	-	+
Data encryption	-	+
Audit trail generation and export	-	+
Data corruption detection	-	+
Data handling according Title 21 CFR part 11	-	+

2 Product Components

The 4D-Nucleofector® LogWare and additional facilitating PC software is provided on a USB memory stick and comes with further accessories for convenient use.

1. 4D-Nucleofector® LogWare Gen 2 USB Stick containing:
 - 4D-Nucleofector® LogWare Gen 2 (serial number locked)
 - 4D-Nucleofector® PC Editor Gen 2 (PC Software)
 - 4D-Nucleofector® Audit Viewer Gen 2 (PC Software)
 - Software manual

NOTE: We strongly recommend to store the original 4D-Nucleofector® LogWare USB stick in a safe place and not to use it for regular data transfer to or from the 4D-Nucleofector® System to have it available in case a system reset is required (see chapter 7)

2. 4D-Nucleofector® LogWare Gen 2 Admin Recovery (USB stick)
3. Flexible silicone QWERTY keyboard
4. Software manual (hard copy)

3 Software Features

In this chapter the general software features are described. For software handling, please refer to chapter 4 – 10.

3.1 User Levels and Rights

Following the Title 21 CFR part 11 guidelines users shall not be able to change system settings or alter the system in a way that influences the data created or the performance. Therefore, in the 4D-Nucleofector® LogWare all adjustable settings have been assigned to the administration dialog to be handled by an administrator only.

There are three different user levels:

- Device administrator
- User with standard access
- User with limited access

The administrator level is required to configure the system. An administrator is not able to act as a user and vice versa. A user is allowed to perform the standard operational functions of the 4D-Nucleofector® System. Neither a device administrator nor a user has the right to delete data such as results, experiments or programs. Table 2 provides an overview on user levels and rights.

3.2 Login, Log Out and Lockout

3.2.1 Login

The maximum number of login attempts is set to three by default, but can be adjusted by an administrator. In case the number of allowed attempts is reached without success, the user is locked out from the system and only an administrator is able to reactivate this user (see chapter 3.2.4).

Table 2: Overview of device administrator and user rights

Feature	Chapter	Device Administrator	User with Standard Access	User with Limited Access
User management <ul style="list-style-type: none"> – Create user accounts – Create further administrators – Lock or unlock user accounts – Activate and deactivate accounts – Generate new temporary passwords 	6.1	+	–	–
Perform a system backup	6.2	+	–	–
Perform a firmware, software or Lonza programs list update	6.3	+	–	–
Export audit trails (unfiltered or filtered by time period)	6.4	+	–	–
Adjust default LogWare settings (password length, inactivity duration, etc.)	6.5	+	–	–
Allow PIN instead of password	6.5	+	–	–
Activate/De-activate Password or PIN requirement prior to experiment execution	6.5	+	–	–
Activate/De-activate LogWare functionality	6.5	+	–	–
Reset of default administrator account	7	+	–	–
Add/edit custom cell type codes	8	–	+	–
View custom cell type codes	8	–	+	+
Export / view result files	8.1	+	+	+
Set or change date and time	9	+	–	–
View firmware version and serial number of all attached 4D-Nucleofector® Units	9	+	+	+
Adjust display brightness	9	+	+	+
Adjust volume	9	+	+	+
Perform a device cleaning	9	+	+	+
System shutdown	9	+	+	+
Generation and import of experiments	10	–	+	–
Run experiments	10	–	+	+
Change of volume (LV Unit)	10	–	+	+
De-/activation of bubble detection (LV Unit)	10	–	+	+

3.2.2 Log Out

A user or device administrator can actively log out by pressing the gear icon in the upper right corner of the software and selecting “Logout” (see chapter 9, Figure 15A).

Users or device administrators are automatically logged out after 30 minutes of inactivity by default. The time of inactivity can be adjusted by an administrator within the “LogWare Settings” menu via “active time” (see chapter 6.5, Figure 11B).

3.2.3 Inactivity (User Only)

A user who is inactive for more than 60 days will be set to “inactive”. In order to be able to access the software again an administrator needs to activate the user again by removing the “inactive” checkbox for the corresponding user in the “User Management” section (see chapter 6.1.3). The time of inactivity can be adjusted by an administrator within the “LogWare Settings” menu via “max inactive” (see chapter 6.5).

3.2.4 Lockout

In the event of repeatedly entering a wrong password (default: 3 times), the user or device administrator will be locked out of the system. At each login, the user will be informed about the last unsuccessful login (if such happened), including time and date of attempt.

If a locked user tries to log in a notification is shown that the user is locked out and a device administrator needs to be contacted to reactivate the user account.

In order to be able to access the software again, an administrator needs to unlock the user. Unlocking a user automatically generates a new temporary password (to be provided to the user by the administrator) that has to be changed by the user within one day and can only be used once.

For resetting the default administrator account in case of a lockout, see chapter 7.

3.3 Data Handling

3.3.1 Data Logging

The 4D-Nucleofactor® LogWare logs all user activities relevant for the system use together with a time and date stamp, the operator’s user name, user level and serial numbers of 4D-Nucleofactor® Units connected:

- User creation or edits
- User login successful
- User log out
- User lock out
- Experiment saving, run, abortion, finish
- Result saving
- Password change
- Time/date change
- Standby
- System check
- System backup
- Use of device cleaning mode
- Firmware update (only Core Unit)
- Lonza programs list update
- LogWare deactivation
- Shutdown via menu or power button on the front - A hard switch or crash is not logged

3.3.2 Data Storage

The system stores all data generated without allowing the user to delete specific data. In case of low system memory (<500 MB), the user will be notified to contact the system administrator. Under typical operating conditions, even with every day usage, this limit won’t be reached before a minimum of 10 years of use. In case the low system memory status is reached, please contact Lonza for help to free up memory.

To avoid the loss of data, it is recommended to regularly create a system backup as described in section 6.2. Store the backup files on a secured hard disk drive or server network. In case of system damage, Lonza can restore the system with the data from the most recent backup.

4 Quick Start Guide

Table 3 below provides a quick start guide describing the required steps to set up the system. For more details on the single steps, please refer to the indicated chapters of this manual or the general 4D-Nucleofector® System Gen 2 Manual (CD-MN050).

Table 3: Quick start guide

Step	Description	More Details See Chapter
1	Turn on 4D-Nucleofector® System on the rear side of the Core Unit and press the "Power" button on the front. A system check will be performed after every 10 th start.	4D-Nucleofector® Manual, 2.7.1
2	Install the 4D-Nucleofector® LogWare Gen 2 using provided USB stick.	5
3	Login as administrator using first login settings. User: administrator Password: PASSWORD1 Press "Sign in"	Figure 1
4	At your first login as administrator the system asks to change the password. Change your administrator password according to password rules. The initial administrator password is invalid after being changed to the individual administrator password.	6.1.1, Table 4
5	Login with the new administrator password. The number of inactive or locked users will be displayed, and there will be a warning if memory is low.	
6	Check/Adjust LogWare settings (e.g. setup date and time).	6.5
7	Enter users and note user name and temporary password.	6.1.1, Table 4
8	Log in as user with your temporary password. Acknowledge the message about password expiry by "OK".	
9	Change your user password according to password rules. The number of inactive or locked users will be displayed, and there will be a warning if memory is low.	6.1.1, Table 4
10	After changing the password and logging in you can now access the standard operational functions as described in the 4D-Nucleofector® Manual, i.e. <ul style="list-style-type: none"> - Define an experiment - Execute an experiment (requires user re-authentication) , unless de-activated by administrator - View results 	4D-Nucleofector® Manual, 2.9 – 2.12
11	Turn off system when not in use anymore.	4D-Nucleofector® Manual, 2.7.3

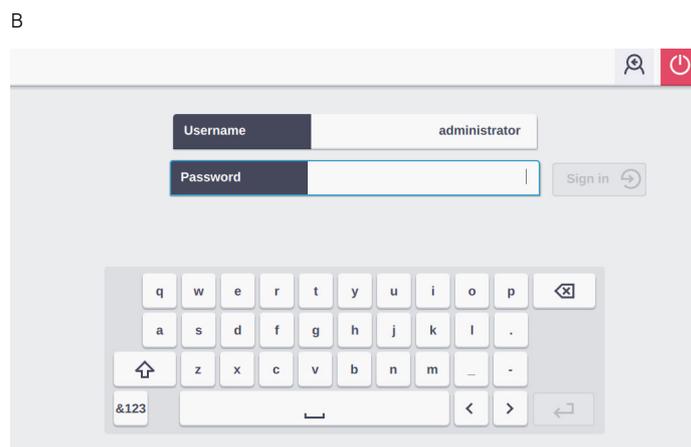
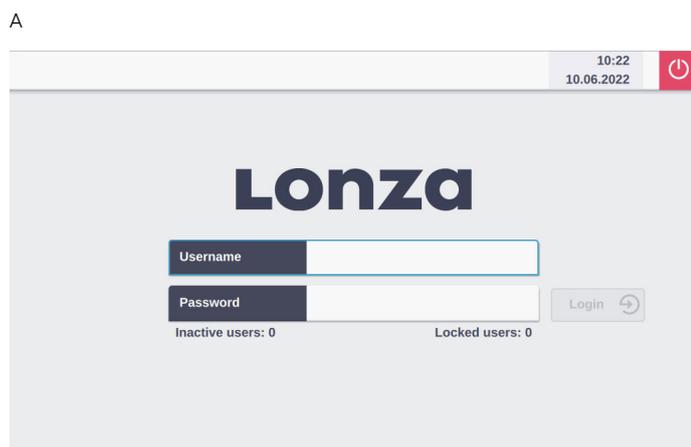


Figure 1: Login screen (V05.10)

5 Installation of the 4D-Nucleofector® LogWare

The 4D-Nucleofector® LogWare Gen 2 can be installed on any 4D-Nucleofector® System Gen 2 comprising of Core, X and/or Y Unit and/or LV Unit and will replace the standard software which is installed by default. Existing experiment or result files will not be overwritten and are still valid.

NOTE: The 4D-Nucleofector® LogWare is serial number locked, thus it will only work with the specific Core Unit serial number that needs to be provided during the ordering process.

To install the 4D-Nucleofector® LogWare the following steps are required:

- Start the 4D-Nucleofector® System. The home screen will appear
- Plug in the USB stick containing the 4D-Nucleofector® LogWare (as provided by Lonza)
- A message will appear asking to confirm installation

- Once installation is done the 4D-Nucleofector® System will shut down
- Upon re-start by the user, the system will show the login screen
- Login as administrator using first login settings:
User: administrator
Password: PASSWORD1 (temporary)
- At your first login as administrator the system asks to change the password
- Change your administrator password according to password rules (see chapter 6.1.1, Table 4)
- The initial administrator password is invalid after change to the individual administrator password

For future firmware updates of the 4D-Nucleofector® LogWare see chapter 6.3.

6 Administrator Settings

After login as administrator an administration tools menu is displayed which contains all tasks related to user management and system settings (Figure 2).

The menu items can be either accessed via the touchscreen or a mouse (if attached). To leave a submenu press “Back”. If text entry is required this can be either done via the touchscreen or the keyboard. The tab key can be used to walk through the fields or buttons.

6.1 User Management

Upon entering the user management a list of available users and their activity state will be shown (Figure 3).

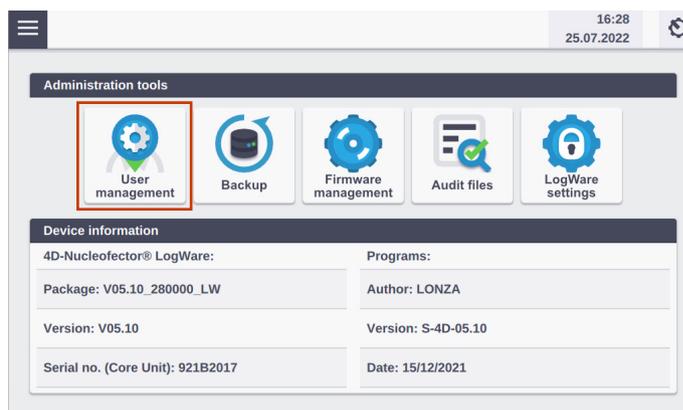


Figure 2: Home screen “Administration tools”, (V05.10)

6.1.1 Creation of a New Account

Users with administrator rights have the ability to create new user accounts and assign a user level. For adding a new user (Figure 4 and 5), press the “Add user” button.

- User name: For defining a user name, please refer to table 4 for guidelines. A user name is unique and can only exist once
- First name
- Last name

Note: Once a user has been saved, selected user name, first and last name cannot be edited anymore. If a change is required, a new user has to be created. Existing users cannot be deleted, only locked.

- User level: Define the user level using the drop-down list (for further information on user rights see 3.1, Table 2):

Limited access: Users with this access level are only allowed to execute predefined experiments, export and view results and view software versions.

Standard access: These users are allowed to setup and run experiments, export and view results and view software versions.

Administrator: Users with administrator rights are allowed to execute all tasks described in chapter 6.

- Press “Save”
- A temporary password is displayed. Note that password and provide it to the new user. Confirm message by “OK”.

The successful creation is acknowledged with a message. The temporary password is again displayed.

After pressing “OK” one can continue creating further users by repeating the steps described above or leave the menu by pressing “Back”.

6.1.2 Export/Import of users

A user who has been generated on one system can be copied to another system by using the export/import functionality. This enables the use of the same account on multiple systems.

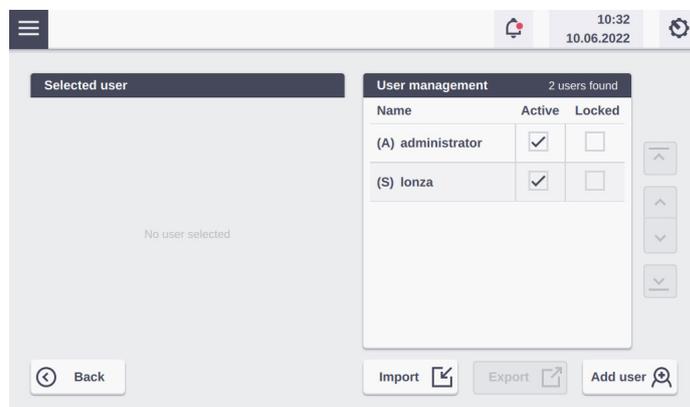


Figure 3: Menu “User Management”, (V05.10)

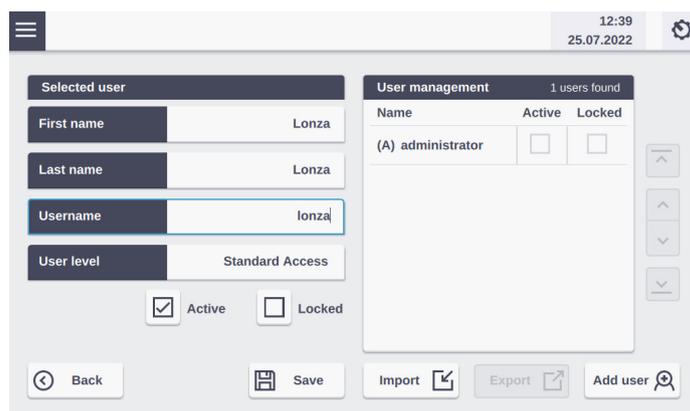


Figure 4: Generating a new user, (V05.10)

Table 4: Guidelines for user names, passwords and PIN

Definition of user name	User names should be unique on the system and identify a person, not being generic for multiple users. The length should be between minimum 3 to maximum 20 characters. The default under “LogWare settings” is set to minimum 3 and maximum 12. Settings can be adjusted by an administrator (see chapter 6.5). A user name can only contain letters (a-z,) and numbers (0-9), but no special characters. The user name can only use lower cases
Temporary passwords	Upon generation of a new account or release of a locked account a temporary password is automatically generated by the software. This password should be noted and used for the first login. Temporary passwords must be changed upon the first login, they cannot be kept for future logins. A temporary password has a limited validity of 1 day only. Settings can be adjusted by an administrator (see chapter 6.5)
Individual passwords	Each user will be asked to define his individual password after first login using the temporary password. The individual password must have <ul style="list-style-type: none"> - a minimum length of 3 and a maximum length of 20 characters. The default under “LogWare settings” is set to minimum 8 and maximum 12. Settings can be adjusted by an administrator (see chapter 6.5). - upper and lower case letters - numeric characters - special characters (for example: . " £ ^ * & !). <p>Important: Characters “;” and “\” are not allowed. If such characters are part of a password this either leads to a manifold multiplication of the user entry and will swamp the system or it will lead to a deletion of the user database. In both cases the system may be unable to read the user database and start, when the user logs in the next time. The system would have to be returned to Lonza for fixing the issue.</p> <p>Words from English dictionaries and combinations like 12345678, 00000000, abcdefgh, aaaaaaaa etc. are NOT allowed. The software contains a library of prohibited terms, names, words and combinations to check conformity of the password selected with the rules described above.</p> <p>Each password has a default validity period of 90 days after which the password has to be changed. Settings can be adjusted by an administrator (see chapter 6.5). If a password is expired the user has to change the password upon next login. There is no advance notice on expiry. The user does not get locked if the password is expired.</p> <p>Re-use of the same password is prohibited for a period of 365 days. Settings can be adjusted by an administrator (see chapter 6.5).</p> <p>Passwords characters are displayed as dots only.</p>
PIN instead of password	In the LogWare settings (see chapter 6.5) an administrator can allow use of PIN instead of password. That means in addition to a password and its rules described above it is also possible to use numbers only.

6.1.3 Editing a User

For editing a user select the user in the list on the right (Figure 5). Editing a user account might be required for

- Activating or deactivating users (users who have been inactive for more than 60 days are set to inactive and they are not able to log into the system without an administrator having them activated again)
- Re-activating locked users after repeated unsuccessful login attempts (in this case a new temporary password is generated that has to be changed by the user within the next 1 day)
- Assigning a new temporary password

User name, first and last name cannot be edited anymore.

Press “Save” to save changes.

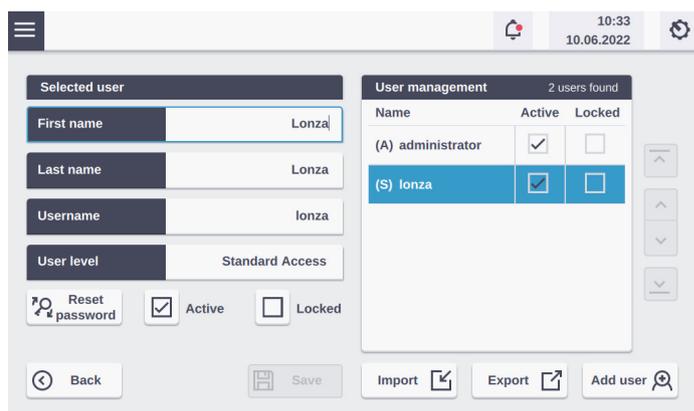


Figure 5: Editing a user, (V05.10)

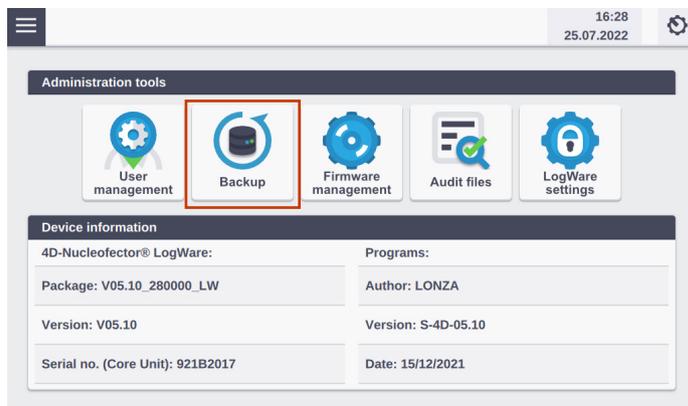
6.2 Backup

A complete data backup containing all experiments, results, logs and system files required to restore the system can be stored as an encrypted package onto a USB stick. To create a backup select “Backup” from the administration tools menu and press “Create backup” (Figure 6A and B). The system will save an encrypted file which can be exported to a USB stick via the “Export” button.

Note: Do not use encrypted USB sticks for exporting or importing files. The 4D-Nucleofector® System may not be able to write/read files properly on/from encrypted USB sticks.

Restoring the system can only be done by Lonza.

A



B

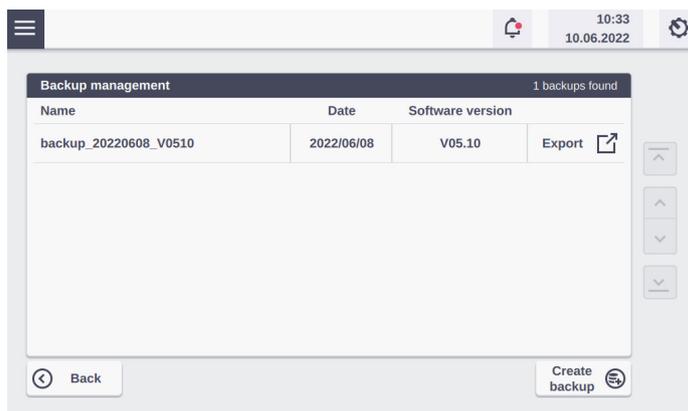
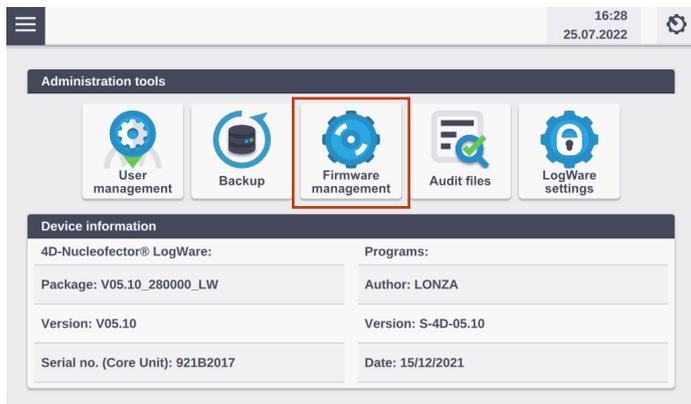
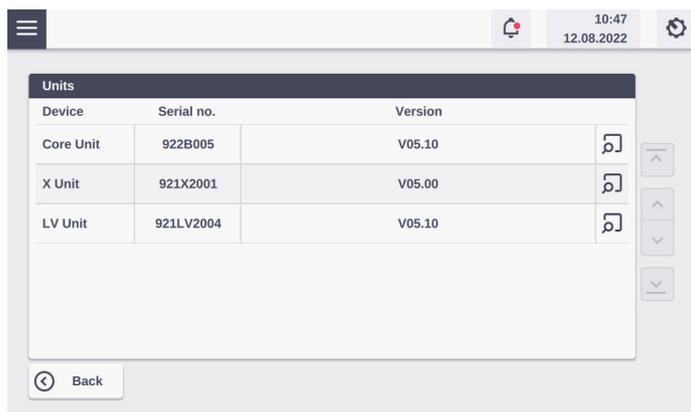


Figure 6: Admin tools - Backup, (V05.10)

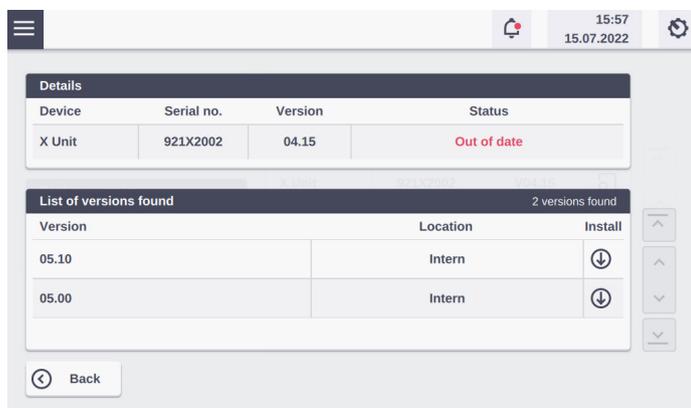
A



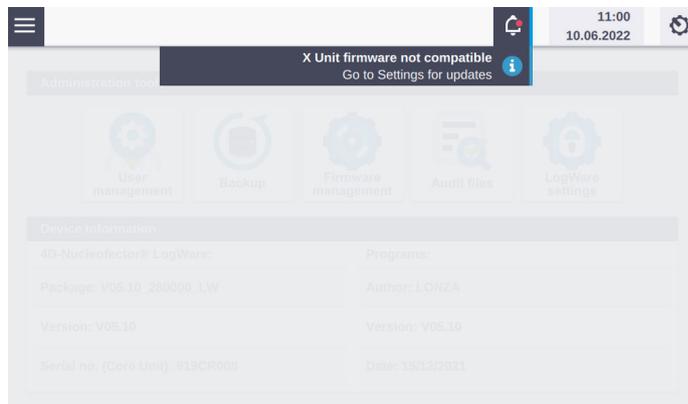
B



C



D



E

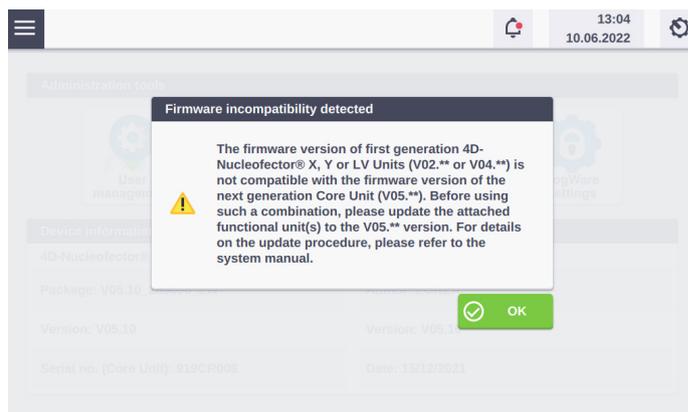


Figure 7: Admin tools - Firmware management, (V05.10)

6.3 Firmware Management

In the firmware management (Figure 7A) the administrator can check for serial numbers and software version status of all units (Figure 7B). By pressing on the magnifier icon further unit details and available updates are displayed (Figure 7C). Each unit has to be updated separately.

6.3.1 Firmware update of the Core Unit

The 4D-Nucleofector® System may require an update of its firmware due to new optimized protocols added to the Lonza programs list or technical improvement of the operation software. A new firmware will be provided by Lonza on a USB stick. To update the firmware proceed as follows:

- Start the 4D-Nucleofector® System and login as administrator. The home screen will appear
- Plug in the USB stick containing the new 4D-Nucleofector® Software (as provided by Lonza)

- The bell icon at the top of the screen shows a notification (red dot). Tapping on the bell icon shows further information
- By clicking on the information, a message will appear showing current version and available update
- Press “Update” to load the update
- Once ready the 4D-Nucleofector® System will shut down and needs to be restarted by the user

Note: If a LogWare version was pre-installed before, the system will show the login screen upon re-start. Administrators and user can log in using the established user name and password.

6.3.2 Software update of functional units

The firmware of the system and the software of the functional units may differ in case newer and older units are mixed. Depending on the constellation different procedures are recommended.

- a) **Software version of functional units is lower than firmware version of Core Unit:** The bell icon at the top of the screen shows a notification (red dot).
- Tapping on the bell icon shows further information (Figure 7D)
 - Go to the gear menu and select “Version”
 - Update each functional unit by selecting the magnifier icon (Figure 7B). Select available upgrade and press install (Figure 7C).

During the update the screen turns black for about 15 seconds until the Lonza logo is shown. It takes another 30 seconds for the login screen to appear.

Note: In case of connecting a functional unit running under a Gen 1 software version 2.** or 4.** an update to the Gen 2 software version (5.***) must be done for proper function (Figure 7E)

- b) **Software version of functional units higher than firmware version of Core Unit:** Update the Core Unit to the most recent firmware version (see 6.3.1) or downgrade the functional units.

6.3.3 Update of the Lonza programs list

The Lonza programs list, comprising all pulse codes, solutions and cell type codes, can be exchanged independently from a firmware or software update. For uploading a new Lonza programs list follow instructions below:

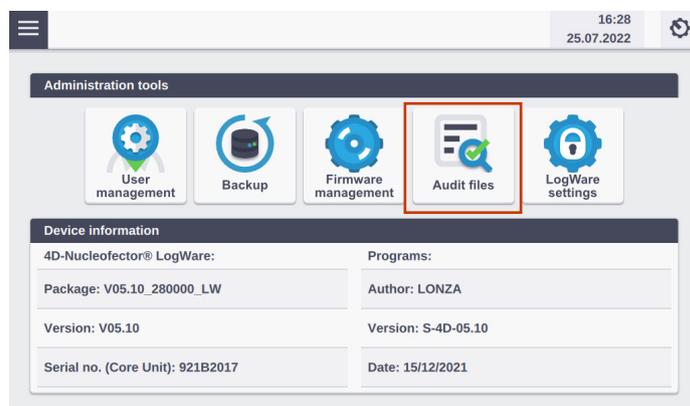
- Insert a USB stick comprising the file you want to upload (*.pd) at the front or the rear of the 4D-Nucleofector® Core Unit

- The bell icon at the top of the screen shows a notification
- Choose “Program updates available” by tapping in the field
- Tap on “Update”
- The new program files will be updated and the 4D-Nucleofector® Core Unit will restart

6.4 Audit File Export

In addition to experiment and result files, the system generates log files for audit trails. These log files are chronological records of all relevant user interactions with time stamp, device information and reference to the user involved in that action (for interaction types that are logged, please refer to 3.3.1).

A



B

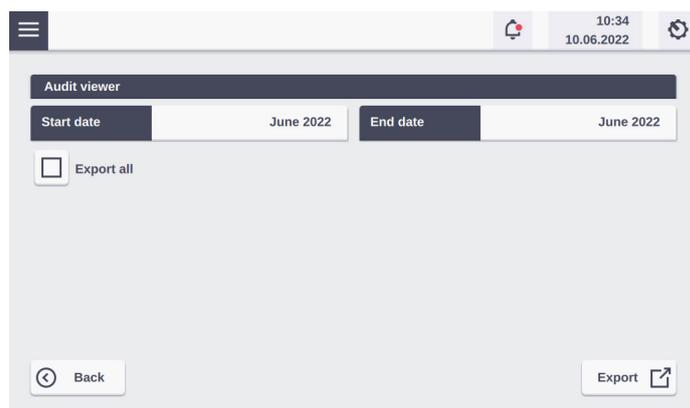


Figure 8: Admin tools - Audit files, (V05.10)

A log file can be exported from the 4D-Nucleofector® System to a USB stick in order to view or print it with help of the PC-based **4D-Nucleofector® Audit Viewer**, which is provided on the original 4D-Nucleofector® LogWare USB Stick.

Note: Do not use encrypted USB sticks for exporting or importing files. The 4D-Nucleofector® System may not be able to write/read files properly on/from encrypted USB sticks.

6.4.1 Installation of the 4D-Nucleofector® Audit Viewer

It is not required to run an installation routine to install the 4D-Nucleofector® Audit Viewer on a PC. Just follow the steps below to copy the software onto the hard disk drive:

- Insert 4D-Nucleofector® LogWare USB Stick into a PC
- Copy the folder called **“4D-Nucleofector® Audit Viewer”** onto the PC hard disk
- Open the folder, search the file called **“4D-Audit-Viewer.exe”** and double click on it to start the software

6.4.2 Export and Printing of Log Files

For exporting and printing log files enter the “Audit files” menu (Figure 8A). One can either export all logged events or events within a defined time frame (Figure 8B). For exporting the log files insert a USB stick into the USB port of the 4D-Nucleofector® Core Unit and press “Export”. Exported log files are named **“4DN-yyyy-MMM-dd.NAT”** where yyyy-MMM-dd is reflecting the industry standard for the date of the audit trail export (e.g. “4DN-2021-NOV-12.NAT”).

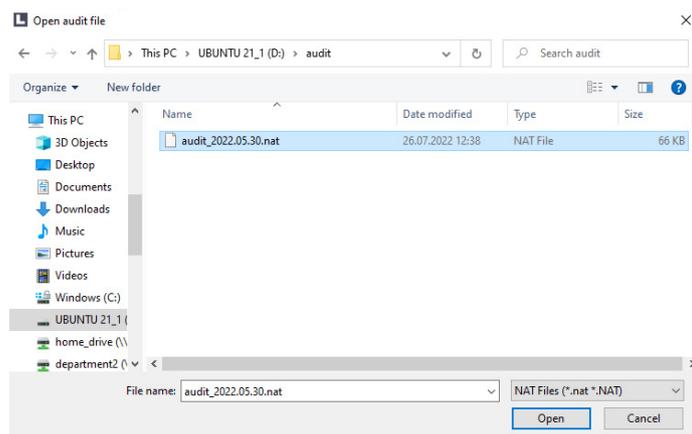
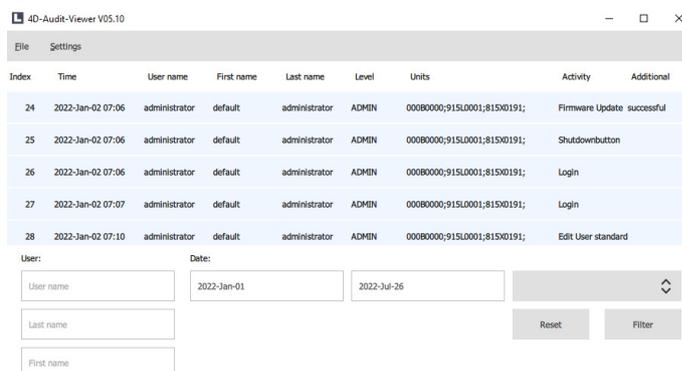


Figure 9: Open audit trail file



Index	Time	User name	First name	Last name	Level	Units	Activity	Additional
24	2022-Jan-02 07:06	administrator	default	administrator	ADMIN	00080000;915L0001;815X0191;	Firmware Update	successful
25	2022-Jan-02 07:06	administrator	default	administrator	ADMIN	00080000;915L0001;815X0191;	Shutdownbutton	
26	2022-Jan-02 07:06	administrator	default	administrator	ADMIN	00080000;915L0001;815X0191;	Login	
27	2022-Jan-02 07:07	administrator	default	administrator	ADMIN	00080000;915L0001;815X0191;	Login	
28	2022-Jan-02 07:10	administrator	default	administrator	ADMIN	00080000;915L0001;815X0191;	Edit User standard	

Figure 10: Log file report, (V05.10)

For viewing or printing the log file

- Start the Audit Software
- Select “File” → “Open” in the upper left corner of the software
- Navigate to the respective folder on the USB stick and select the previously exported audit trail file (Figure 9)
- In the bottom section of the software window the report can be filtered by time period, activity and user
- To print the report press “File” → “Print” in the upper right corner of the software window (Figure 10).

6.5 LogWare Settings

In the LogWare settings menu (Figure 11A) the administrator can modify the LogWare specific settings of the system (Figure 11B):

User settings	Default
Active time: After the selected time of inactivity the user will be logged out	30 minutes
Minimum user name length	3 characters
Maximum user name length	12 characters
Password settings	Default
Maximum login attempts	3
Maximum inactive: After this inactivity time user will be locked	60 days
Minimum password or PIN length	8 characters
Maximum password or PIN length	12 characters
Time frame for re-use of the same password	365 days
Time frame for effectiveness of temporary passwords	1 day
Expiry duration for password or PIN	90 days
Allowing PIN use instead of passwords	Not enabled
Activating or de-activating the requirement for re-authentication prior to experiment execution	Active

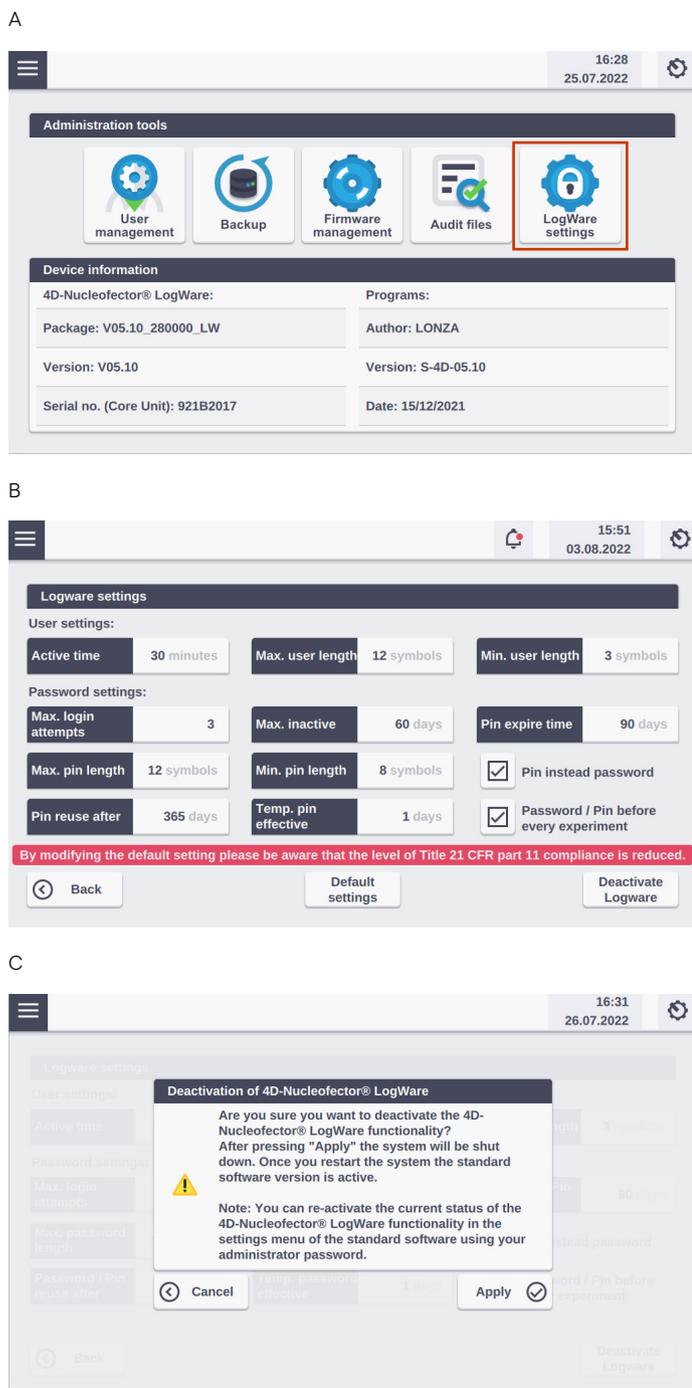


Figure 11: Admin tools - LogWare settings, (V05.10)

6.5.1 LogWare de-activation/re-activation

The administrator can de-activate the LogWare functionalities by pressing the "Deactivate Logware" button (Figure 11B). A message will appear (Figure 11C) that needs to be acknowledged by "Apply" to finalize the deactivation by a system shutdown. De-activation can be cancelled by pressing "Cancel". After restart, the system will start in the standard software version. In case the LogWare has been installed before, the version information of the standard software also shows the suffix "_LW" for the software package.

The LogWare functionality can be re-activated by the administrator in the settings menu of the standard software. By pressing the "LogWare on" button (Figure 12) a message will appear that needs to be acknowledged by "Shutdown" to initiate a system shutdown. Re-activation can be cancelled by pressing "Cancel". After restart, the system will require the administrator to login. In case the administrator login details are lost, the administrator account can be reset as described in chapter 7.

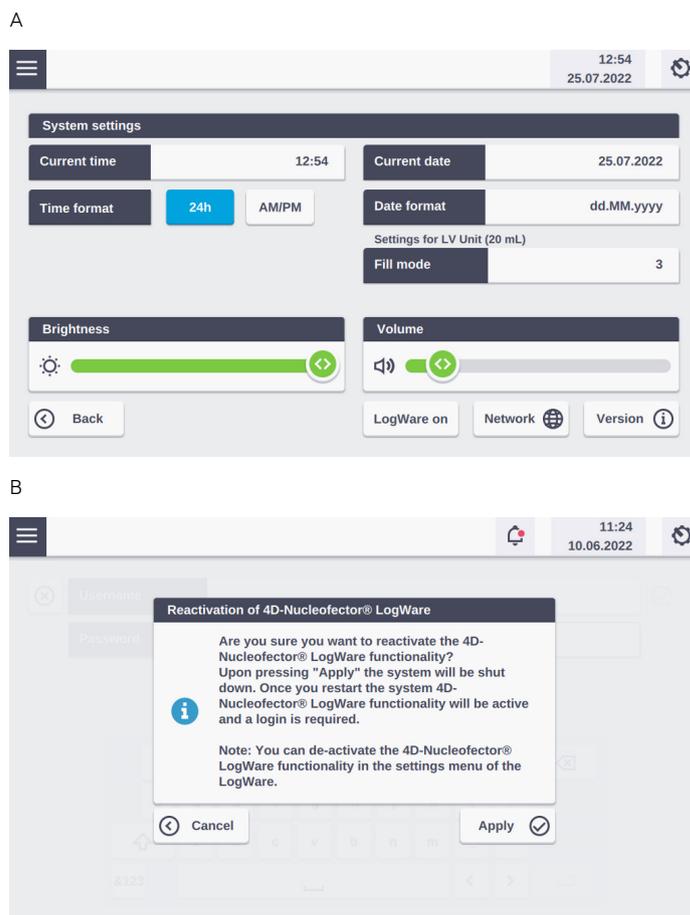


Figure 12: LogWare reactivation in standard software, (V05.10)

7 Reset of Administrator Account

In case the default administrator has been locked out, the administrator account can be reset by starting the 4D-Nucleofector® System with the **4D-Nucleofector® LogWare Admin Recovery** USB stick.

- Enter the USB stick (this can be done any time)
- The application recognizes the update files and the serial number and prompts Reset “administrator” password to default?” (Figure 13)
- When the operator selects “OK” the password for “administrator” is reset to the temporary password PASSWORD1.

NOTE: The 4D-Nucleofector® LogWare Admin Recovery USB stick should remain with a device administrator to be available in case the device administrator has been locked out or forgot the password.

Existing user accounts are not affected when resetting the default administrator.

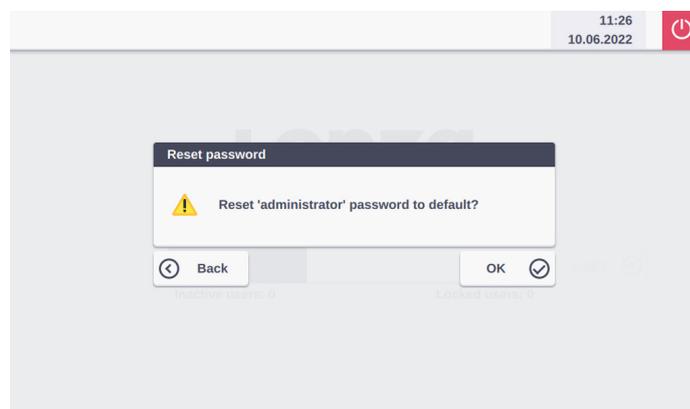


Figure 13: Reset of administrator account, (V05.10)

8 Left Menu

The left menu comprises following selections:

- **Home (administrators and users):** For getting back to the home screen
- **Experiments (users only):** A list of past experiments can be viewed and loaded. A user can see all experiments including author information. An experiment is only shown once it has been executed or actively saved.
- **Results (administrators and users):** A list of past results can be viewed, exported and printed (see 8.1). A user will only see and can only export the result files that were generated by the user
- **Custom cell type codes (users only):** Custom cell type codes, i.e. a specific combination of pulse code and solution entered by a user, can be viewed, edited or added depending on user access level.

8.1 Result Export

Via this menu administrators and users are able to view results and export them to a USB stick for the transfer to the PC Editor (see chapter 11) in order to print them. To generate a printable result report with the PC Editor the following steps are required:

Note: Do not use encrypted USB sticks for exporting or importing files. The 4D-Nucleofector® System may not be able to write/read files properly on/from encrypted USB sticks.

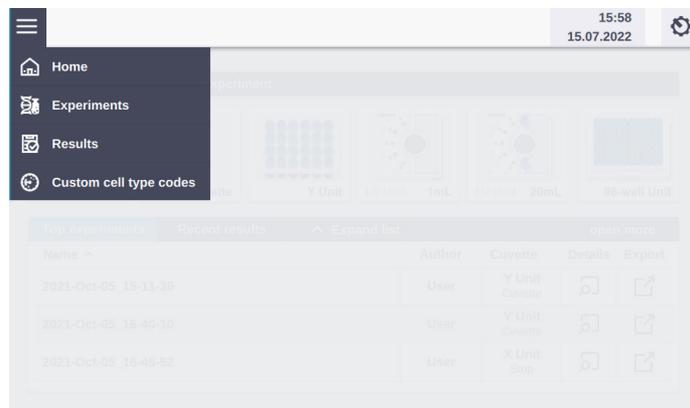
a) Export from 4D-Nucleofector® System

- Start the 4D-Nucleofector® System and login as user or administrator
- Plug in a USB stick
- Open the left menu and select “Results”
- Select the result to be printed (Figure 14) and press “Export”
- Navigate to the desired folder on the USB stick and press “Export”

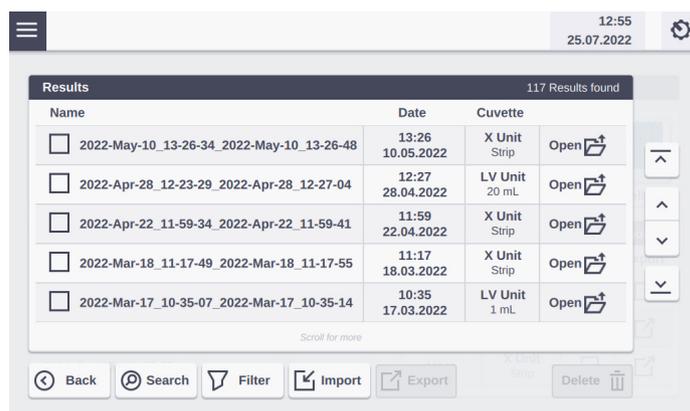
b) Import into PC Editor

- Start the 4D-Nucleofector® PC Editor
- The “Home” screen will appear
- Open the left menu and select “Results”
- Select “Import” and navigate to the directory where the desired result file has been stored
- Select the desired result and press “Open”.
- The encrypted result file is now copied to the PC editor
- Select
 - “View” to view the result
 - “Print” to print the result
 - “Load” to load another exported result file from the USB stick

A



B



C

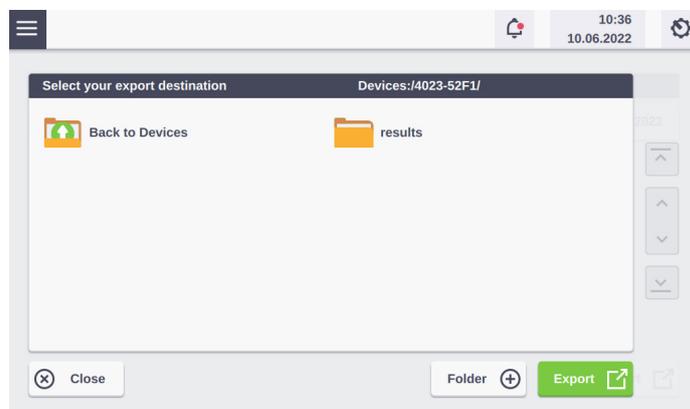


Figure 14: Result file export, (V05.10)

9 Gear Menu

The gear menu, (on the far right), the administrator and the user can access the standard system settings and functionalities (Figure 15). For some settings a user may only be able to view these, but adjustments can only be done by an administrator.

- **Settings:**
 - Time and time format (administrator only)
 - Date and date format (administrator only)
 - Brightness
 - Volume
 - Fill mode (administrator and standard user)
 - Change password
 - Network
 - Version: Provides information on the installed firmware version and serial number of each connected unit as well as the version of the Lonza programs list containing the Lonza Optimized Protocols
- **Cleaning mode**
- **Lock screen:** Select to lock the screen
- **Logout:** For active logout
- **Version**
- **Shutdown:** Shuts down the system

Additional unit-specific menu items may appear when menu is opened after selection of a specific vessel type.

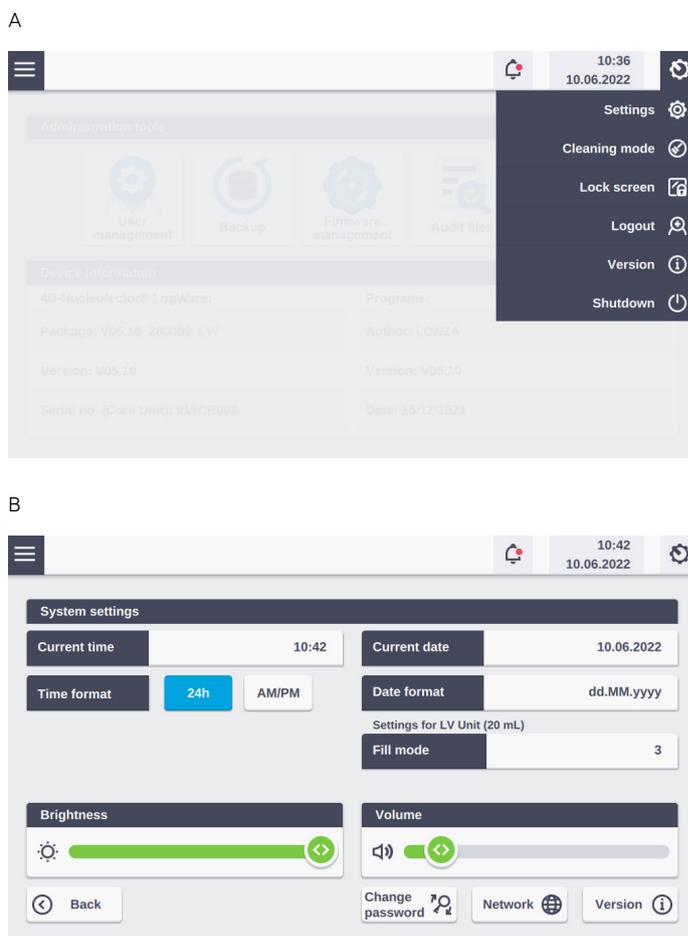


Figure 15: Settings menu, (V05.10)

10 Operating the System (Users)

For defining and running Nucleofection® Experiments on the 4D-Nucleofector® System, please refer to the 4D-Nucleofector® System Manual Gen 2; CD-MN050).

The handling of the system as a user is identical when using the 4D-Nucleofector® LogWare with few exceptions related to user rights (for overview, also see 3.1, Table 2):

- Starting an experiment requires user re-authentication (if not changed by the administrator)
- Setting up and saving experiments is only allowed for users with standard access level
- Settings do not allow for
 - Changing date and time
 - Firmware update

11 PC Editor Software

The 4D-Nucleofector® LogWare is accompanied by a dedicated PC Editor version which is also provided on the original 4D-Nucleofector® LogWare USB Stick. This PC editor can be used to:

- Conveniently program experiments for subsequent upload to the 4D-Nucleofector® LogWare (allowed for standard user only)
- Print result files that have been exported from the 4D-Nucleofector® LogWare as a table including date and time of the experiment, user, additional information and individual results per well

The PC Editor has been adapted to the changes made to the standard 4D-Nucleofector® Software in order to be compatible to the Title 21 CFR part 11 implications in the 4D-Nucleofector® LogWare. These changes do not include the need to login into the software, since the generation of experiments or printing of results does not have to be linked to a specific user.

11.1 Installation of the PC Editor

It is not required to run an installation routine to install the 4D-Nucleofector® LogWare PC Editor on a PC. Just follow the steps below to copy the software onto the hard disk drive:

- Insert 4D-Nucleofector® LogWare USB Stick into a PC
- Copy the folder called “4D-Nucleofector® PC Editor” onto the PC hard disk
- Open the folder, search the file called “4D-Nucleofector_Editor.exe” and double click on it to start the software
- A window will appear displaying a graphical user interface of the 4D-Nucleofector® LogWare that allows to:
 - Set up, store and export experiments to a USB drive
 - Load, view and print result files from a USB drive

11.2 Generating a Printable Result Report

To generate a printable result report with the PC Editor, please refer to chapter 8.1.

12 Troubleshooting

For transfection results troubleshooting, sample rescue and error codes please refer to 4D-Nucleofector® System Manual (CD-MN050). Here only potential issues specific to the 4D-Nucleofector® LogWare are described.

What Happened?	Procedure
I am locked out	Contact your administrator to unlock you.
I lost my user password	Contact your administrator to generate a new password.
I lost my administrator password	Reset the administrator account as described in chapter 7.
I want to change my password	Contact your administrator to generate a new password.
The system does not start because a user has entered a password containing not allowed characters (“;” or “\”). See table 4 for more information.	Return the system to Lonza for fixing the issue.
System cannot read the inserted USB stick.	Make sure to store the files on a non-encrypted USB stick.

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