uniogen

CE IVD

# GenomEra® CDX System

## User Manual

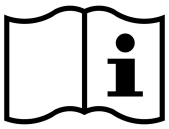
For *In Vitro* Diagnostic Use

REF

**CDX-10-020**
**RD-10-CDX 10-0010**

# CONTENTS

# PRECAUTIONS AND WARNINGS



Read the user manual completely before using the GenomEra CDX Instrument. This user manual is **not valid for GenomEra CDX software versions prior to 1.3.0.** If you have prior versions (1.2.X), refer to the manual version 2.9 and contact the authorized distributor for a software update.

**Caution:** Hot surfaces. There are heated parts inside the Instrument. To avoid burns, do not reach beyond the sample holder sled.

**Caution:** Upon receiving of the device, it is necessary to carefully examine the integrity of the shipping package and the product. Check additional instructions printed on the shipping package. If there are any traces of maloperation or damage, contact the authorized distributor or the manufacturer immediately.

**Caution:** When unpacking, lifting, or moving the Instrument, place your hands underneath it. The plastic top cover should never be used for lifting. Because of the GenomEra Instrument's weight, the Instrument should not be carried by one person alone.

**Caution:** The Instrument contains moving parts. The lid of the Instrument is kept locked while performing assay runs or service runs. Do not try to open the lid when the Instrument is not on standby.

**Caution:** Do not remove the Instrument cover under any circumstances. This is important to prevent device breakdown and to protect users.

**Caution:** There is a UV lamp producing non-ionizing UV radiation inside the Instrument, covered with an additional protective casing including a warning sticker.

**Caution:** Do not connect the System to the Internet without proper precautions. Connecting the System to the Internet contains an inherent risk of infection by malicious software.

**Caution:** It is not permitted to update the operating system of the computer, and additional software must not be uploaded or installed on the computer without consulting the manufacturer.

**Caution:** Do not manipulate or attempt to repair the GenomEra CDX Instrument or Software. Contact Technical Support for all issues concerning the functionality of the System.

**Caution:** Connect the System and all accompanying devices to grounded power outlets. Any damaged cables or power cords must be immediately replaced; contact Technical Support in such case. Do not replace mains supply cords with inadequately rated cords.

**Caution:** Wear protective clothing and disposable gloves while handling the Instrument especially when working with Assay Kits and potentially infectious specimens. While the Instrument and the GenomEra Assay Kits are not biohazardous by themselves, it is good laboratory practice to handle all waste materials as potentially biohazardous material.

**Caution:** In case of error or malfunction, please contact Technical Support immediately even if the Instrument is able to recover. Create and attach a Technical Support report from the Log menu (see Section 7.3) for Technical Support.

**Caution:** In case of a failed run due to a malfunction in the System, it is advisable to shut down and restart the entire System (Instrument, Software and computer) and contact Technical Support. This is also the case if the System does not respond.

**Caution:** If any defect is detected, for example abnormal noise or smell coming from the Instrument or any abnormal appearance or positioning of the sealing imprint on the Test Chips, **halt the use of the System immediately and contact Technical Support.**

**Caution:** Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the operation of the System. The GenomEra System complies with the emission and immunity requirements of EN 61326-1 and EN 61326-2-6.

***CAUTION: DO NOT USE THE INSTRUMENT FOR PURPOSES NOT SPECIFIED BY THE MANUFACTURER, AS THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.***

- **Note: This document (original instructions) is to be used solely for the purpose of operating the instrument. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of the manufacturer. Upon request, additional copies of this document in paper format will be provided free of charge to the customers.**
- **Note: Note for customers within the European Union (EU): Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established. Note for customers outside the European Union (EU): Any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the local regulatory authorities according to applicable regulation.**
- **Note: This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference. It is advised to evaluate the electromagnetic environment prior to operating the device.**
- **Note: The Software is not intended to handle or store patients' personal information. Do not use any personal information in sample identification.**
- **Note: Keep the lid closed when the Instrument is not in operation to avoid dust particles entering the device.**
- **Note: When stored for a long time, keep the Instrument indoors and protected from moisture and dust. During transport, moving and installation, the Instrument must be handled with care, and kept upright and dry.**
- **Note: Store the shipping package, paddings, plastic pouch, and the Locking Pin in case the instrument needs to be shipped for service. The instrument should not be transported without the Locking Pin being properly installed.**
- **Note: The GenomEra CDX System complies with the applicable EU legislation. The EU Declaration of Conformity is available upon request, please contact the authorized distributor.**

# 1 Intended use

The GenomEra® CDX System is an automated *in vitro* diagnostic (IVD) medical device used to run the GenomEra Assay Kits that have been developed for the qualitative detection of specific DNA or RNA in various direct clinical or cultured sample matrices. The GenomEra CDX System is composed of one to eight molecular analyzers (here referred to as the Instrument) connected to a personal computer and operated via the GenomEra CDX Software. The Instrument consists of an integrated thermal cycler and a fluorometer capable of time-resolved and prompt measurement. The GenomEra CDX Software controls the function of each Instrument and collects, analyzes, and stores data generated by each Instrument.

# 2 Intended user and use environment

The intended use environment is a clinical laboratory or healthcare unit not necessarily having a specialist in molecular biology but rather personnel who routinely perform assays and analyses in the field of infectious diseases diagnostics. The GenomEra CDX System is intended to be used in a laboratory environment by professional personnel, e.g., laboratory technicians, or personnel qualified by training, accustomed to routine laboratory methods and using equipment for general laboratory use such as pipets, vortex mixing, thermal blocks, and centrifuges. The GenomEra CDX System is NOT intended for self-testing or near-patient testing.

# 3 Principle of operation

The GenomEra CDX testing platform utilizes dry-reagent assay chemistry in conjunction with automated homogeneous close-tube assay format. All reagents required for performing the homogeneous amplification and detection steps are contained in dry form in the Test Chips provided within the GenomEra Assay Kits. The Instrument contains a multi-block thermocycler and fluorometer capable of time-resolved fluorometry (TRF) and prompt fluorescence measurements.

The conventional approach to thermocycling in traditional polymerase chain reaction (PCR) instruments consists of a single thermal block which manages both cooling and heating of the PCR reaction chamber. This usually leads to longer ramping times. To achieve faster ramping times, the GenomEra CDX Instrument has an array of thermostabilized blocks with a total of five thermal blocks adjusted to a constant temperature (Figure 1). The rapid thermocycling is performed by moving the chips between the metal surfaces of the thermal blocks.

In addition to the denaturation (Den), annealing/extension (Ann/Ext) and measurement blocks, there are blocks that are set to more extreme temperatures. The extreme-temperature blocks are used to further increase the speed of temperature change and to create a sharp thermocycling profile.

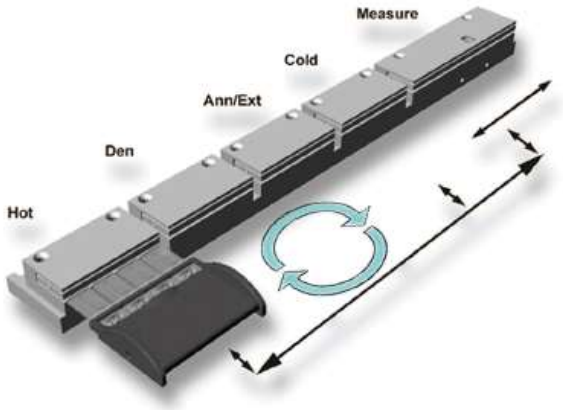



**Figure 1. Thermal blocks of the GenomEra Instrument. Each block serves a specific function in the PCR thermocycling sequence: Hot, Denaturation (Den), Annealing/Extension (Ann/Ext), Cold and Measure.**

# 4 Limitations of use

- The GenomEra CDX System is intended to be used in combination with *in vitro* diagnostic GenomEra Assay Kits designed and manufactured for use on the GenomEra CDX System by Uniogen Oy.
- For professional use only.
- The GenomEra CDX System must be installed by a specialist from Uniogen Oy or an authorized distributor.
- Only authorized service personnel should perform service or maintenance on the System. Contact Technical Support for information about System service.

# 5 GenomEra CDX System setup

## 5.1 GenomEra CDX System package contents

The GenomEra CDX System package comprises the following components:

| | |
|---|---|
| • GenomEra CDX Instrument<br>• Power supply<br>• Power cord<br>• USB cable |  |
| • Computer (models may vary) with GenomEra CDX Software installed<br>• Power adapter<br>• Power cord |  |
| Accompanying devices<br>(models may vary):<br>• Hand-held barcode reader<br>• USB hub<br>• Optical mouse and mouse pad |  |

Printer package:

- Laser printer (the model of the printer varies upon availability)
- Power cord
- USB cable (A-to-B)

Additional items:

- 1 x GenomEra Cleaning Kit
- 2 x Dummy Chips – 4 pcs
- 40 x Rehearsal Chips
- 2 x Rehearsal solution tubes
- 2 x Cord stackers
- 1 x Locking Pin (for transportation)

Documents:

- 1 x GenomEra CDX System – User Manual
- 1 x GenomEra CDX System – Notice for Lifting
- 1 x GenomEra CDX System – Software installation qualification
- 2 x GenomEra CDX System – System installation qualification
- 2 x GenomEra CDX System – Usernames and passwords

## 5.2 Materials required but not provided

See applicable Assay Kit Instructions for Use for the materials and equipment required but not provided. Independent of the kit, the following materials are required:

- Disposable powderless gloves (required when handling potentially infectious material i.e. placement of the chip holder into the instrument).
- Micropipette (middle-range including 35 µL)
- Sterile filter-blocked tips (e.g. range of 10–100 µL)

**Note: All electrical cords / plugs must correspond to the local electrotechnical requirements of the installation site. Power cords for the GenomEra CDX System (Instrument, computer, and printer) come with type F plugs (a Schuko plug) compatible with socket types E and F.**

## 5.3 System installation

The GenomEra CDX System must be installed by a specialist from Uniogen Oy or an authorized distributor.

### 5.3.1 Assembly recommendations

Please adhere to the following recommendations for the assembly of the GenomEra CDX System:

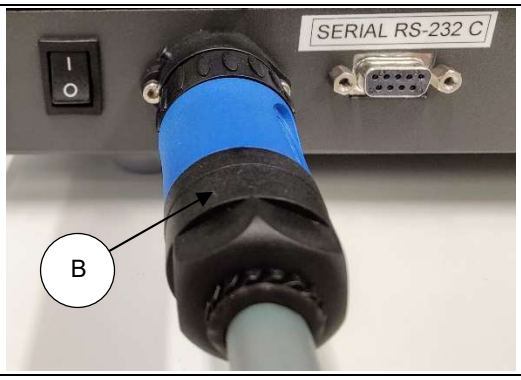
- Select a clean, well-ventilated area for the System that is large enough to fit the instrument(s), computer, external power supply, barcode reader and a printer.
- It is recommended that the System is mounted on a table surface of a standard height to allow safe operation.
- The table surface should be stable enough to prevent components moving during operation and to hold the weight of all the System components. The total weight of the Instrument, computer and printer is approximately 45 kg.
- Reserve enough space around the System for safe operation and ventilation. The operator must have unblocked access from the instrument to the computer.
- To avoid overheating, make sure that the instruments are not in direct sunlight and position all the System components in a way that air circulation is not negatively affected. Ventilation openings of the System components must not be blocked or covered.
- The depth of the surface space should be at least 70 cm. The external power unit can be located behind the Instrument, and the Printer behind the computer, especially when the amount of space is limited.
- Ensure that all four legs of the Instrument are firmly and completely on the table surface.
- Ensure unrestricted access to the ON/OFF switches on all components and to the plug connected to the power outlet.
- Position the Instrument in such a way that the lid opens directly towards the operator. The operator must have good visibility into the Instrument when the lid is open.
- Install the Instrument into the same space (room) as the computer used to operate the System.
- Only use the cables supplied when connecting the Instrument to the computer.
- Never mount the System in close proximity to water sources or anywhere the System might be exposed to liquid spills.
- Do not run other software programs when running the GenomEra CDX Software.
- It is not permitted to modify the GenomEra CDX Software or configuration settings.
- Do not adjust the System settings while the Instrument is running.
- Never adjust the date or time on the computer.
- Do not move or reposition any parts of the System while the Instrument is running.

### 5.3.2 System configuration

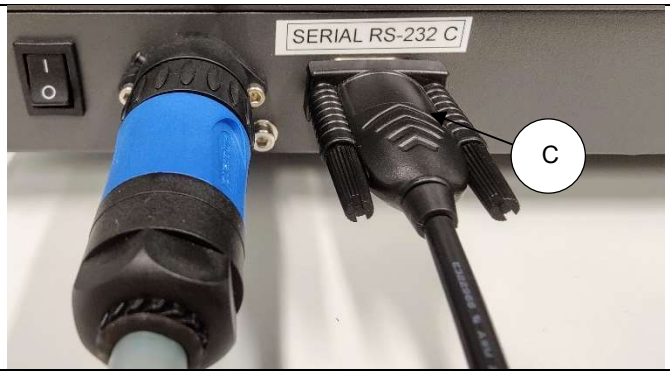
For relocating the System within the laboratory, follow the System configuration steps described below. For long-distance transport, please consult Technical Support before relocation and see additional instructions in Section 10.5.

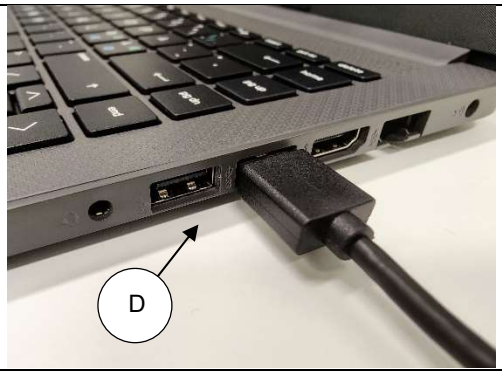
1. If present, remove the Locking Pin from the Instrument. Check that the power switches for the Instrument and the external power supply are off (”0”). Remove the tape from the warning label (A). Open the lid and remove the Locking Pin by screwing it counterclockwise until it can be pulled out. Store the Locking Pin and the attached warning label; these parts must be used if the Instrument is shipped for service (see Section 10.5).

2. Connect the external power supply to a **grounded** power outlet with the power cord and to the Instrument with the gray power cord (B) that is permanently connected to the power supply.




3. Connect the Serial-to-USB adapter cable (C) to the Instrument and tighten the screws. Connect the other end of the cable to a USB port on the computer or a USB hub connected to the computer.
4. Connect the USB hub to a USB port (D) on the computer.




5. Connect the printer to the USB hub using the USB A-to-B cable. Also connect the printer to a power outlet.

6. Connect the mouse to the USB hub. Now the following devices are connected to the computer via the USB hub:
   - the printer
   - the mouse
   - the Instrument (if not connected to the USB port)

7. Connect the hand-held barcode reader to a free **USB port on the computer**.

**Caution:** Do not connect the hand-held barcode reader to the USB hub. The barcode reader may interfere, or interrupt assay run if connected to the USB hub due to the high-power consumption of the reader. Use the USB port on the computer instead.

**Note: When connecting two or more Instruments to one computer via USB cables, use the supplied USB hub and free USB ports on the computer for the additional Instruments. If an additional USB hub is required to connect more Instruments, contact the authorized distributor.**

**Note: Each computer and external power supply require a grounded power outlet. A full eight-instrument setup requires 10 electrical/power outlets.**

# 6 Running an assay

## 6.1 Starting the System

1. Switch on the GenomEra CDX Instrument and the external power supply from their respective power switches. The power switch on the Instrument is located on the back, at the right-hand side.
2. Switch on the computer and login to Windows as a GenomEra user (password is not required).
3. Start GenomEra CDX Software by double clicking the GenomEra CDX application on the desktop. Login to the Software using your username and password.
4. Allow the Instrument to heat to Standby. The Instrument status is shown by an LED indicator located on the top cover of the Instrument. The color codes for the LED indicator are:

   **Orange**: Initializing, Heating, Starting, Stopping, Cancelled or Running

   **Green**: Standby, Idle

   **Red**: Error

5. The 'Start assay with [Instrument name]' button will then appear in the Instrument tab and the LED indicator on the top cover of the Instrument will turn from orange to green. This will take approximately 20 to 25 minutes depending on the ambient room temperature. An estimate of the heating time is shown on the screen.

**Note: The Instrument starts to heat only once a connection with the computer and the GenomEra CDX Software has been established. The LED indicator on the top cover of the Instrument will light up and turn orange when the Instrument is heating, not before.**

**Note: The System automatically monitors the internal temperature of the Instrument and provides an error code if the Instrument overheats or if the room temperature is too high (operating temperature should not exceed +28°C).**

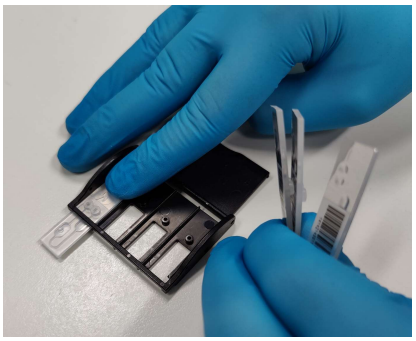
## 6.2 Preparation of Test Chips

1. Prepare samples as instructed in the relevant Assay Kit Instructions for Use.
   Handle all biological specimens as potentially infectious using microbiology laboratory safety procedures.

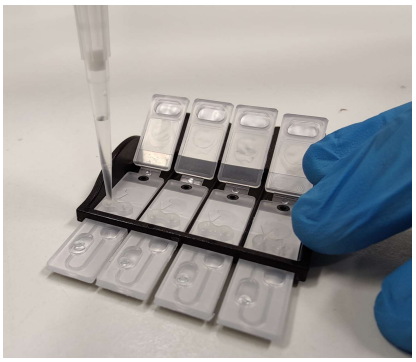
2. Ensure that the Instrument is on Standby (LED indicator is **GREEN** and 'Start assay' button is visible in the Software).

3. Ensure that the lot code of each Assay Kit has been downloaded to the Software (see section 7.2).

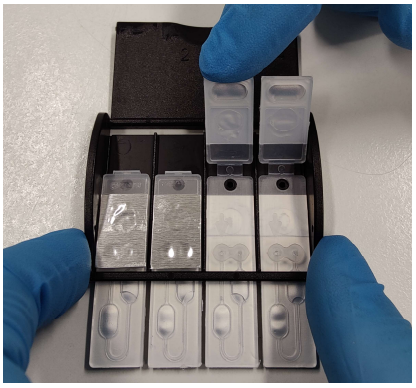
4. Place the Test Chips into the chip holder. **Note the order of the Test Chips in the chip holder!** All four positions in the chip holder must be filled with a Test Chip. Use Dummy chips to fill empty slots when necessary.



5. Add 35 µL of prepared sample per Test Chip. Insert the pipette tip into the sample opening in an upright position and ensure that the tip is firmly in place in the opening. Take care to avoid bubbles forming.



6. Close the lid of each Test Chip **individually** by pressing the lids firmly over the sample openings.

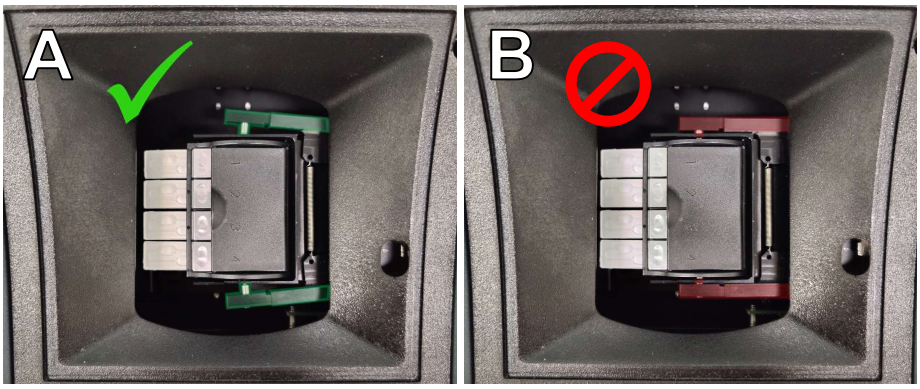


7. Close the lid of the Test Chip holder and insert the chips into the Instrument.

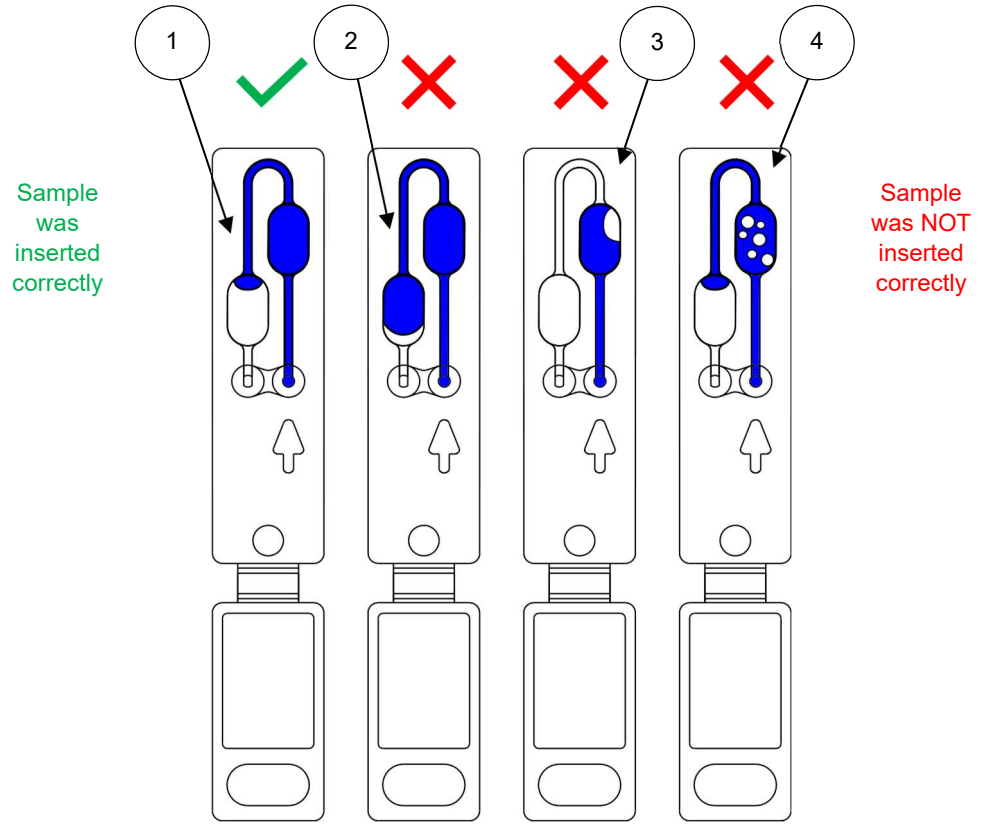
   **A) Ensure that the chip holder is properly placed**.

   **B) Do not push spring loaded shafts inwards.**

8. Close the lid of the Instrument.



**Important:** A correct sample volume of 35 µL will leave the second (expansion) chamber mostly empty of liquid (1). A sample volume above ca. 37 µL will overly dilute the reagents and can be identified from an overfilled second chamber (2). A sample volume below ca. 33 µL (3) will cause bubbles to form during the reaction. Any sized air bubbles (3, 4) visible in the reaction chamber will compromise the integrity of the assay results due to excessive light scattering.



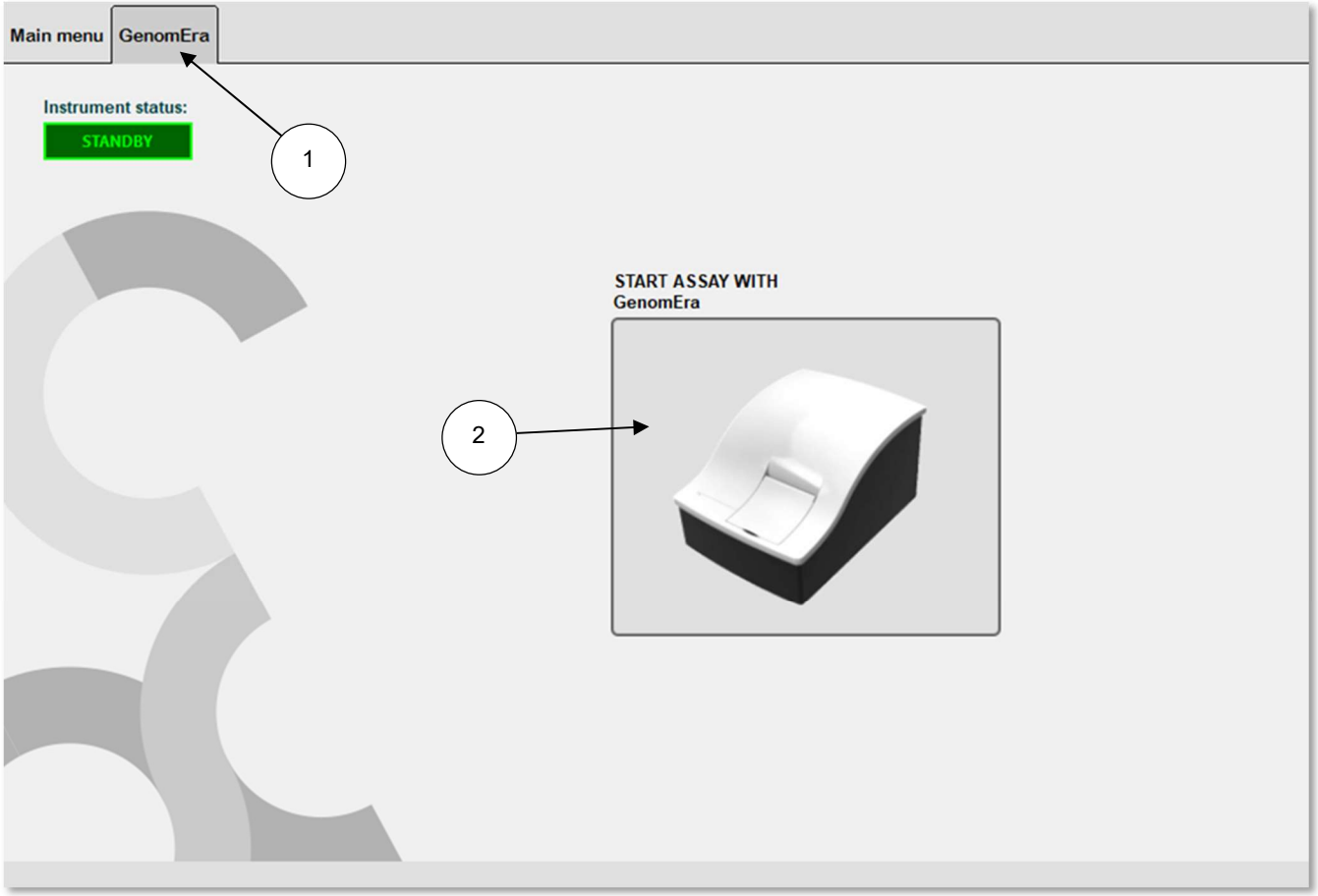

Always discard a Test Chip with excess sample volume (2), insufficient sample volume (3) or visible air bubbles (3, 4) and restart Test Chip preparation with a new aliquot of sample. The Rehearsal Chips provided with the System can be used for pipetting rehearsal.

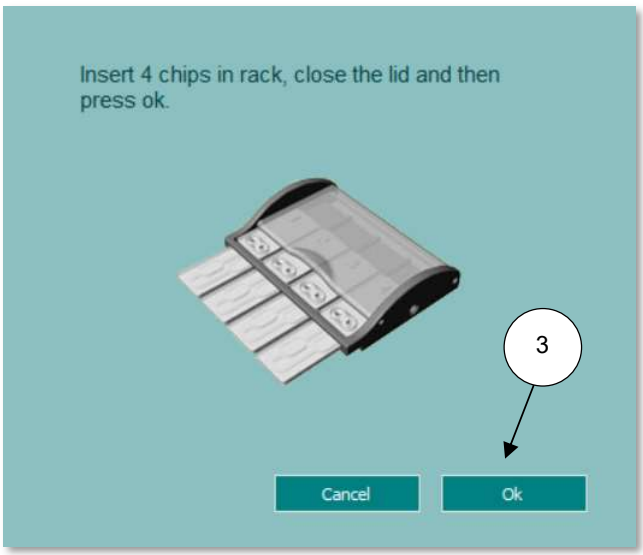
- **Note: The dried reagents start to dissolve rapidly once the sample is added. Pipette samples in the Test Chips immediately before starting the assay run. Start the assay within 3 minutes from pipetting the first Test Chip.**
- **Note: Pay attention to the order of the samples in the chip holder. Chip #1 refers to the chip furthest away from the user when the chips are placed into the instrument. The numbering is shown on the chip holder. For assistance in sample identification, a Sample-ID sheet is provided for printing (see the Manuals folder on the computer desktop).**
- **Note: Test Chips from different GenomEra Assay Kits can be analyzed within the same assay run depending on the Assay Kits used. Check PCR protocol compatibility from GenomEra Assay Kit Compatibility Sheet (available upon request).**
- **Note: Only use consumables related to GenomEra Assay Kits within their expiration date.**
- **Note: Follow standard laboratory safety procedures for working with chemicals.**
- **Note: If a Dummy chip is used at all four positions of the chip holder, the Instrument reports two positive and two negative results.**

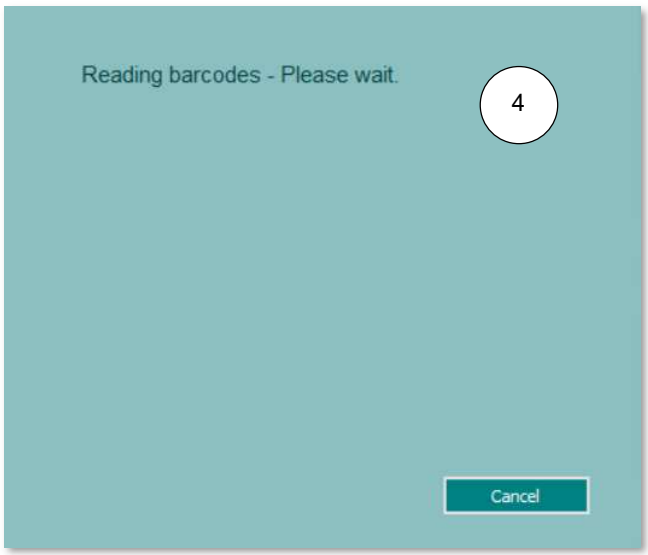
## 6.3 Starting the assay run

Follow these steps after you have inserted the Test Chip holder into the Instrument and closed the Instrument lid:

1. Select the [Instrument name] Instrument tab on the tab row on the right side of ‘Main Menu’.
2. Click the ‘Start assay with [Instrument name]’ button.
3. Proceed to the automatic reading of the chip barcodes by clicking ‘Ok’.
4. The Instrument will read the barcodes and start the assay automatically.



**Note: If the lot information (lot code) of any of the Test Chips has not been provided to the Software before starting the assay, the user will be requested to provide the lot code at this stage (for detailed instructions, see section 7.2). If the lot code is not provided within 3 minutes, the assay is cancelled automatically, and the Test Chips are considered invalid. In these cases, discard the Test Chips and prepare a new set after providing the lot code through 'Main menu' → 'Lot Codes'.**

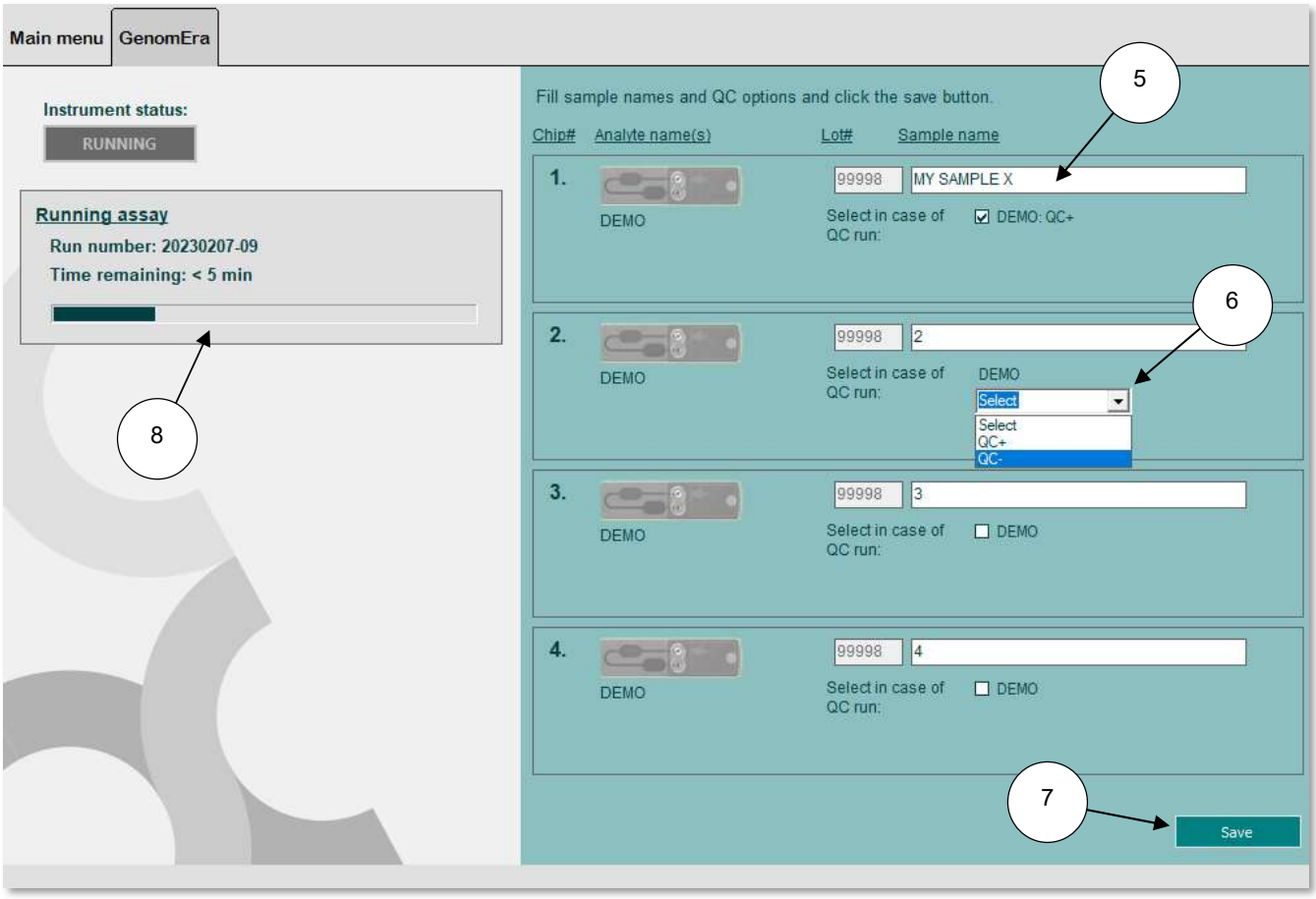
5. Enter the sample names or numbers (max 50 characters) manually or using the hand-held barcode reader for each Test Chip.

6. If applicable, identify quality control (QC) samples using the checkboxes below the sample names. Each analyte can be flagged as a) non-QC, b) QC positive or c) QC negative. QC results are displayed in reports next to the analyte results with flags +/-QC PASS or +/-QC FAIL. Flagging QC samples does not affect the calculation or reporting of results but allows exporting QC results via the 'Archives and Quality Control' view of the GenomEra CDX Software.

7. Click the 'Save' button to lock the sample names (optional).

**Note: After saving, the sample names and QC flags cannot be changed. The 'Save' button will change to 'Interrupt' button after it has been clicked once and can then be used to stop the assay (see section 6.4).**

8. The remaining assay time is displayed together with the run number. The Instrument can be left running unattended.




**Note: The chip holders can be re-used approximately 25 times. Discard old chip holders when opening a new kit package, or sooner if damage or maloperation is detected. Upon long-term use, the chip holders may become bent and/or the narrow plastic support structures may break.**

## 6.4 Interrupting an assay

To stop / abort / interrupt an assay, click the 'Save' button in the righthand corner of the running assay view (see the figure above), and an 'Interrupt run' button will appear. Clicking the 'Interrupt run' button will open a confirmation dialog box, and by clicking 'Yes' the assay is stopped.

After the assay is stopped, the Software shows a notification message for an interrupted run. After 'Ok' is clicked, the Instrument returns automatically to the initial position. The run data is automatically saved, and an Error run log is created. The green light next to the Instrument lid informs the operator that the lid can be opened to remove the chip holder. Once the

'Standby' status is visible in the Instrument tab and the ''Start assay with [Instrument name]' button becomes active, the System is ready for the next assay run.

The Test Chips need to be replaced (follow the Instructions for Use of the Assay Kit) after which the operator can proceed according to section 6.2 of this manual to reanalyze the samples. If the assay was stopped due to a suspected system malfunction, please see section 11.6 of this manual or contact the authorized distributor for Technical Support.

**Note: In an emergency or an accidental breakdown situation the Instrument can be stopped by using one of the following protocols:**

1. **Click SAVE button -->Then click INTERRUPT RUN**
2. **Turn the Instrument or the power supply off from the ON/OFF switch**
3. **Unplug the power supply from the power outlet.**

**Note: If the System shut down is carried out by unplugging or using the ON/OFF switch without interrupting the assay first from the Software, the Software creates an Error run log. The run data is lost, and samples must be run again. In this case, follow the instructions given in section 6.2.**

## 6.5 Interpretating and reporting results

Test results are automatically calculated, shown and saved by the GenomEra CDX Software at the end of each assay. The result interpretation is based on the measurement of the fluorescently labelled, target-specific oligonucleotide probes at different stages. The results obtained are automatically compared to the lot- and label-specific cut-off values specified in the lot code of the Assay Kit.

The result interpretation is dependent on the Assay Kit. See the relevant Assay Kit Instructions for Use for different result interpretation alternatives, additional info on the LIS text format and recommended troubleshooting steps. The possible result interpretation alternatives of GenomEra CDX Software are listed in the table below.

| Result interpretation | Explanation |
|---|---|
| **+ POSITIVE** | The analysis was successful, and the target sequence was present in the sample. |
| **- NEGATIVE** | The analysis was successful, and the target sequence was not present in the sample. |
| **? BORDERLINE** | Inconclusive assay result. The result value obtained was too close to the decision (cut-off) limit and no definitive result can be deduced. |
| **! PCR INHIBITION** | The reaction was inhibited. Neither the target sequence nor the internal amplification control (IAC) has been detected. No results are available. |
| **! FAILED** | The dry chemistry of the Test Chip failed, or the sample was not compatible with the System. |
| Run failed | Run failed is not a result interpretation per se because no results are available for any of the Test Chips in the assay run. The entire run can fail only in case of a malfunction of the instrument. In such cases, please contact Technical Support. |
| (+/-) QCPASS | The obtained result **corresponded** to the QC sample type. E.g. a negative result was obtained for a negative control sample. |
| (+/-) QCFAIL | The obtained result **did not correspond** to the expected value. E.g. a positive result was obtained for a negative control sample or the result was not available. |

The results are displayed on the 'Instrument tab' and they are also saved automatically in PDF and text formatted (LIS) reports. Saved reports can be accessed through 'Main menu' → 'LOG' → 'SHOW REPORT FILES' which will open a '*GenomEra CDX Reports*' folder. The automatically saved PDF reports and text formatted (LIS) reports are available in the subfolders '*Automatic Reports*' and '*Automatic LIS Reports*', respectively.

Results are reported on the screen and in PDF files in the following format:

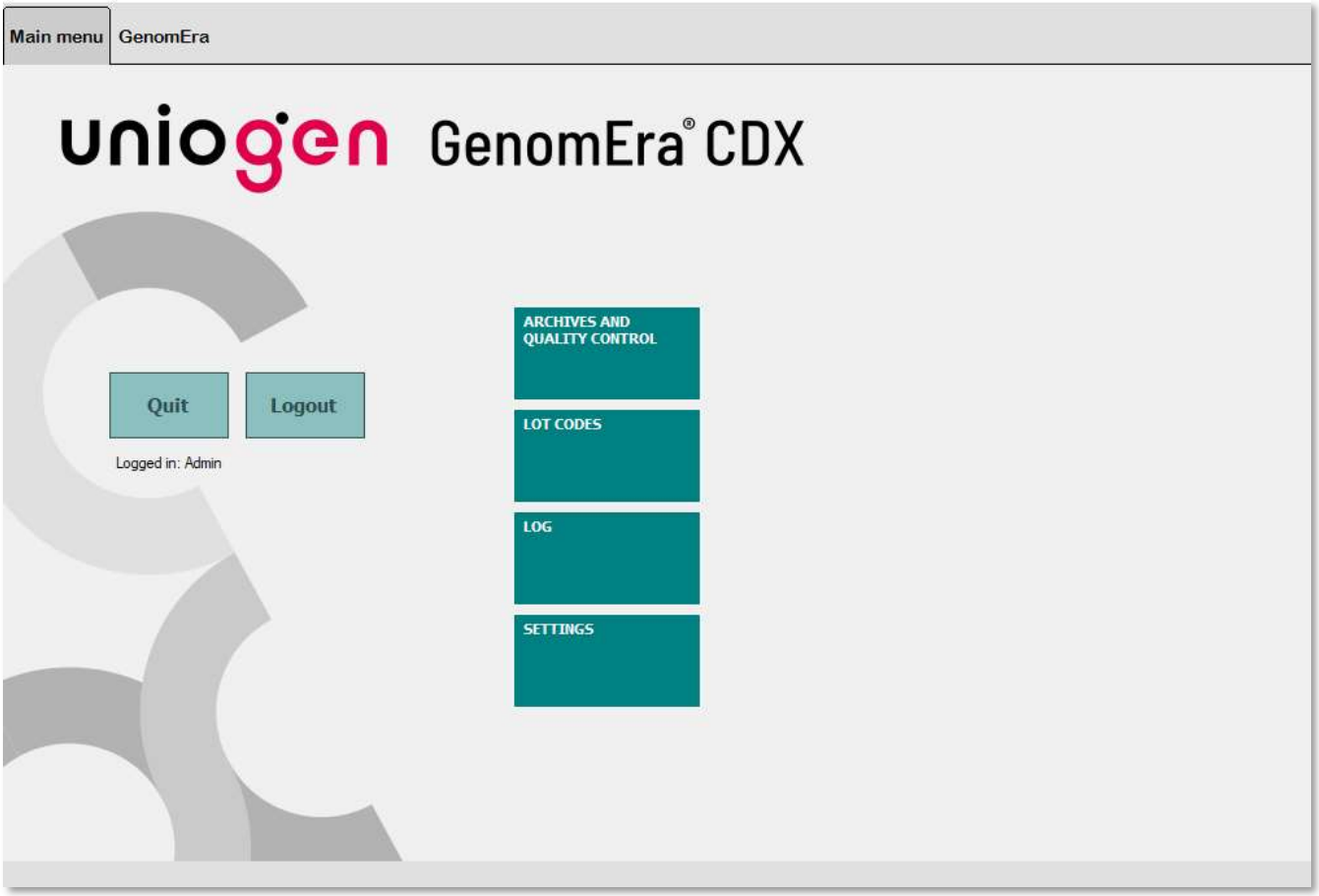
```
================================================================================
               *** UNIOGEN - GENOMERA CDX - PCR RESULTS ***
================================================================================

Date:                15.04.2022 12:34
Run number:          20220414-03
Operator:            Admin
Instrument name:     GenomEra
Instrument serial:   20200172

================================================================================
Chip position:         1
Sample name:           1
Chip serial:           00870
Lot number:            30001
Analytes               Results              Values               QC-results
SARS-CoV-2             + POSITIVE           33.1                 +QCPASS
Influenza A            - NEGATIVE           0.0
Influenza B            - NEGATIVE           0.0
RSV                    - NEGATIVE           0.0
================================================================================
Chip position:         2
Sample name:           2
Chip serial:           00893
Lot number:            30001
Analytes               Results              Values               QC-results
SARS-CoV-2             + POSITIVE           31.8
Influenza A            - NEGATIVE           0.0                  +QCFAIL
Influenza B            - NEGATIVE           0.0
RSV                    - NEGATIVE           0.0
================================================================================
Chip position:         3
Sample name:           3
Chip serial:           00785
Lot number:            30001
Analytes               Results              Values               QC-results
SARS-CoV-2             + POSITIVE           33.5
Influenza A            - NEGATIVE           0.0
Influenza B            - NEGATIVE           0.0                  +QCFAIL
RSV                    - NEGATIVE           0.0
================================================================================
Chip position:         4
Sample name:           4
Chip serial:           00837
Lot number:            30001
Analytes               Results              Values               QC-results
SARS-CoV-2             + POSITIVE           32.7
Influenza A            - NEGATIVE           0.0
Influenza B            - NEGATIVE           0.0
RSV                    - NEGATIVE           0.0                  +QCFAIL
================================================================================
```

## 6.6 Discarding the used Test Chips

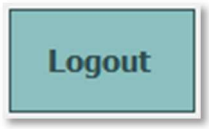
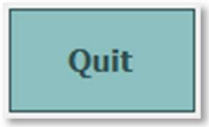
Push chip holder sides outwards to release the lid. Detach the used Test Chips from the chip holder one by one by pressing from below (at the barcode area). It is important not to detach the Test Chips all at once because it may bend and break the reusable chip holder. Dispose of the used Test Chips as potentially biohazardous material in accordance with the local and laboratory regulations.

# 7 Main menu

After a successful login, the ‘Main menu’ tab is displayed.

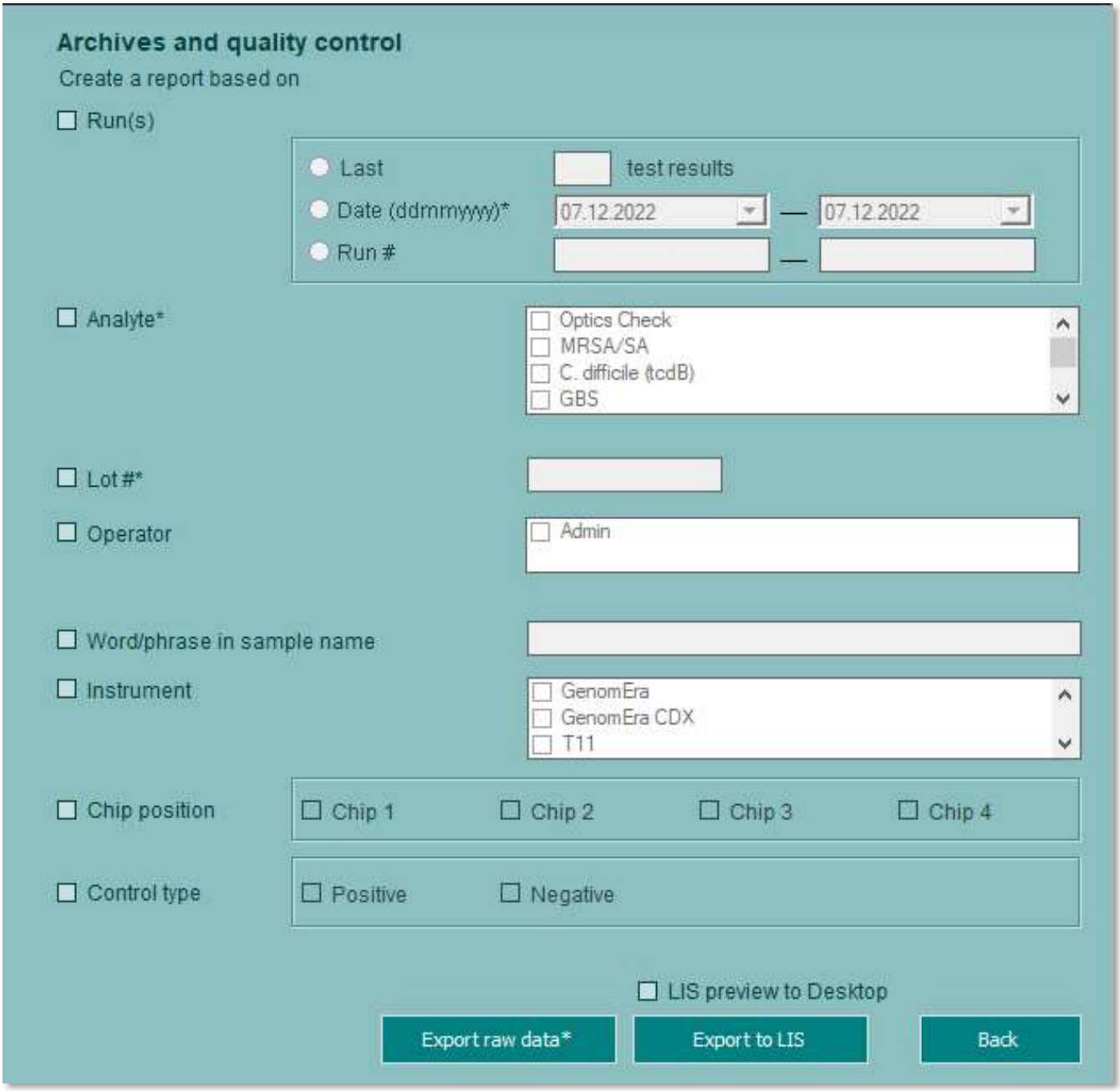


The functions available in the main menu tab are dependent on the user level (User or Administrator) and can be accessed with the following buttons:

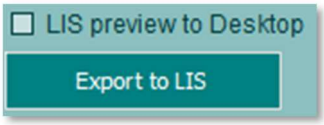
| | |
|---|---|
|  | • Exporting result history with several user selectable search options. |
|  | • Providing lot information for new Assay Kit lots. Must be performed **each time a new lot is used for the first time.**<br>• List of previously downloaded lots. |
|  | • Browsing of reports created by the Software or the user.<br>• Creating reports for Technical Support.<br>• Making backup copies of the database (recommended at least every 6 months).<br>• Viewing the audit trail (Administrator level users only). |
|  | This button is visible to Administrator level users only.<br>• Managing user accounts.<br>• Selecting language.<br>• Setting automatic printing option ON or OFF.<br>• Setting LIS options.<br>• Changing name of the Instrument. |
|  | • Logout from the Software or changing the user (allowed also during assay runs). |
|  | • Closing the GenomEra CDX Software (not allowed during assay runs). |

## 7.1 Archives and Quality Control


All the assay results calculated and reported by the Software are saved into a database. The Archives and Quality Control window can be used to view and create reports from completed assay runs.



The buttons below have the following functionalities:

| | |
|---|---|
|  | Creates a password-protected zip file to be sent to Uniogen Oy for test result and performance analysis. Only the search options marked with * can be applied. |
|  | Creates a text file in LIS format in a preselected location. Checking the check box will save the file on the desktop and show the contents automatically. See section 9 for more details. |
|  | Closes the 'Archives' view and takes the user back to the 'Main menu'. |

Available search parameters:

| **Desired results** | **Selections** |
|---|---|
| All results | Do not check any boxes. |
| Last run | Check the 'Run(s)' box and select 'Latest run'. |
| Assays run in a specific time frame | Check the 'Run(s)' box and select 'Date'. Enter the date interval. |
| Run numbers in a specific range | Check the 'Run(s)' box and select 'Run #'. Enter the run numbers. |
| Results for specific analytes | Check the 'Analyte' box and then select the analyte. |
| Results for specific lots | Check the 'LOT #' box and enter the lot number. |
| Results for a specific user | Check the 'Operator' box and select the operator. |
| Free text search for specific sample names | Check the 'Word/phrase in sample name' box and enter the keyword(s). |
| Results for a specific Instrument | Check the 'Instrument' box and select the Instrument. |
| Results based on the Test Chip position | Check the 'Chip position' box and select the chips (positions 1 to 4). |
| Results based on quality control samples | Check the 'Control type' box and select the QC sample type (positive / negative / both). |

All the search options can be combined. For example, to search results for a certain test analyte in a certain sample, check the box 'Analyte' and select the required analyte; then check the box 'Word/phrase in sample name' and fill in a preferably anonymized sample/patient code. If only one type of test (analyte) has been run with the relevant patient sample, it is only necessary to check the box 'Word/phrase in sample name' and use the patient code to start the search.

## 7.2 Lot codes


**Before running assays with a new Assay Kit lot, a Lot code must be downloaded into the Software using the hand-held barcode reader provided.** Lot codes are printed on the label (see below) of the kit box as barcodes. The Lot code of each Assay Kit lot must be downloaded only once. Several Assay Kits can have the same Lot code but providing the same Lot code again is allowed and will not cause any error messages.

A **Lot code** is different from a **Lot ID** which is a **five-digit lot identification number**. The Lot ID is always indicated with the LOT symbol on the kit box. The Lot ID can also be found in the beginning of the barcode of each Test Chip.

Follow these steps to download a new Lot code into the Software:

1. Click the ‘Lot codes’ in the ‘Main menu’ tab. This will open a window showing the Lot IDs (A) for which the Lot codes have already been downloaded.

2. Use the hand-held barcode reader provided to download the new Lot code (see further instructions below the figure).

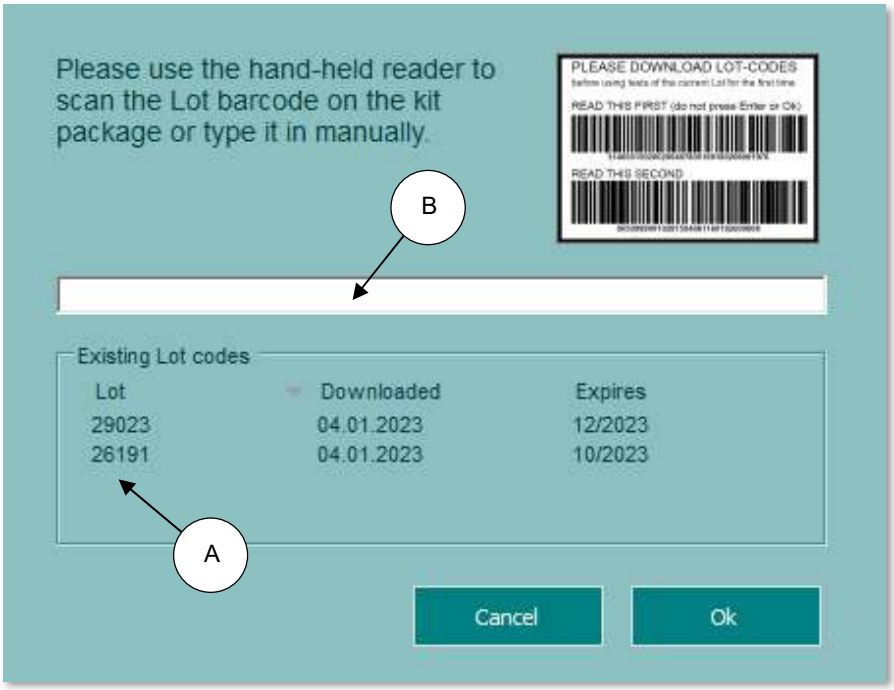
The Lot code is separated into two barcodes:


3. Read the first part of the barcode (1) by moving the barcode reader from top-to-bottom.

4. Read the second part of the barcode (2) by moving the barcode reader from bottom-to-top (to avoid reading the same barcode twice).

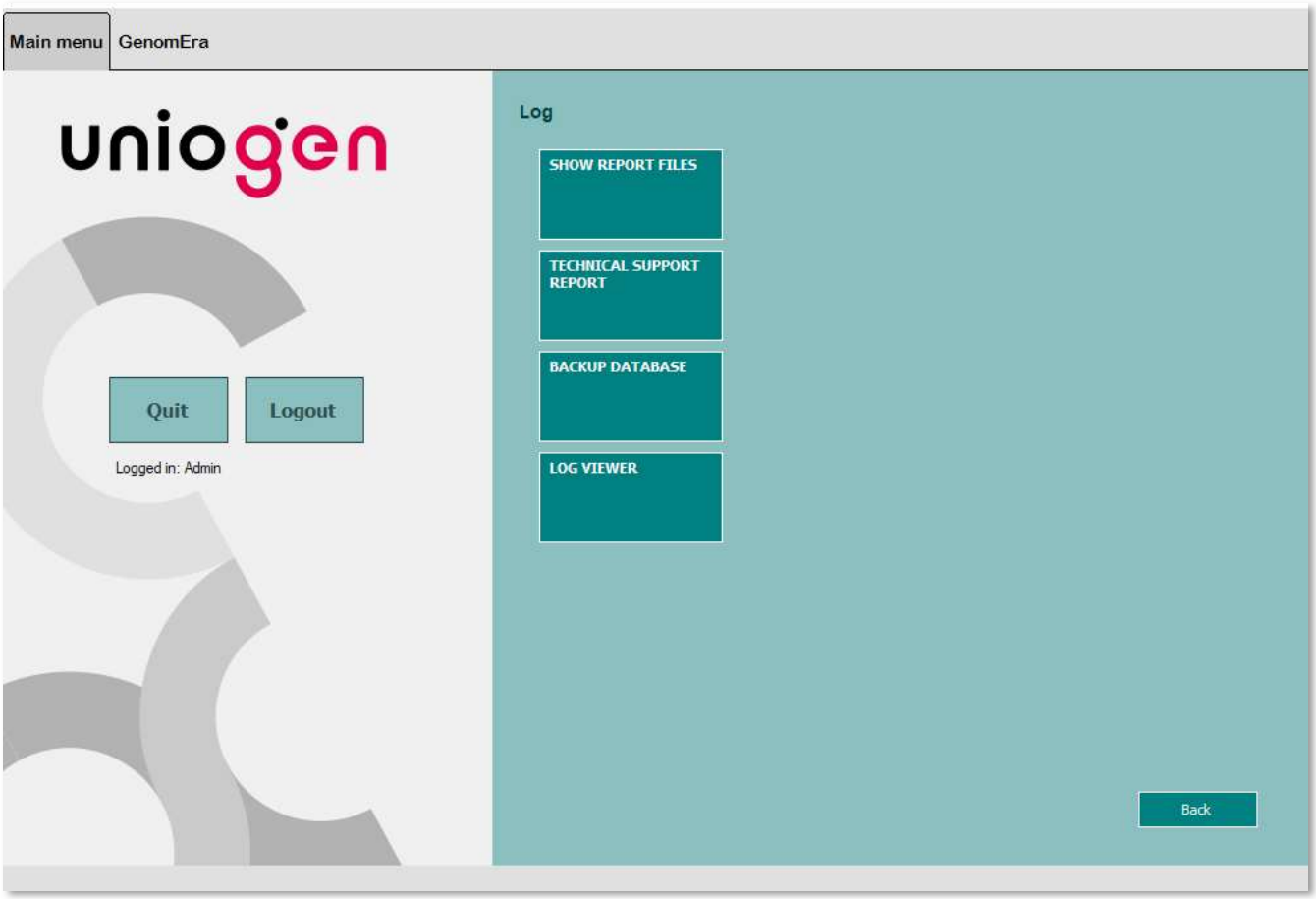
5. The Lot code is automatically downloaded and saved.

It is also possible to type the Lot code manually into the text box (B). Click ‘Ok’.



## 7.3 Log

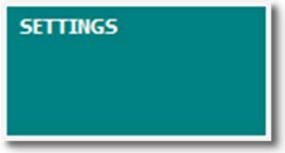

The ‘Log’ menu contains functions for accessing report folders, creating Technical Support reports and backup copies of the database and for viewing the audit trail (administrator level users only).



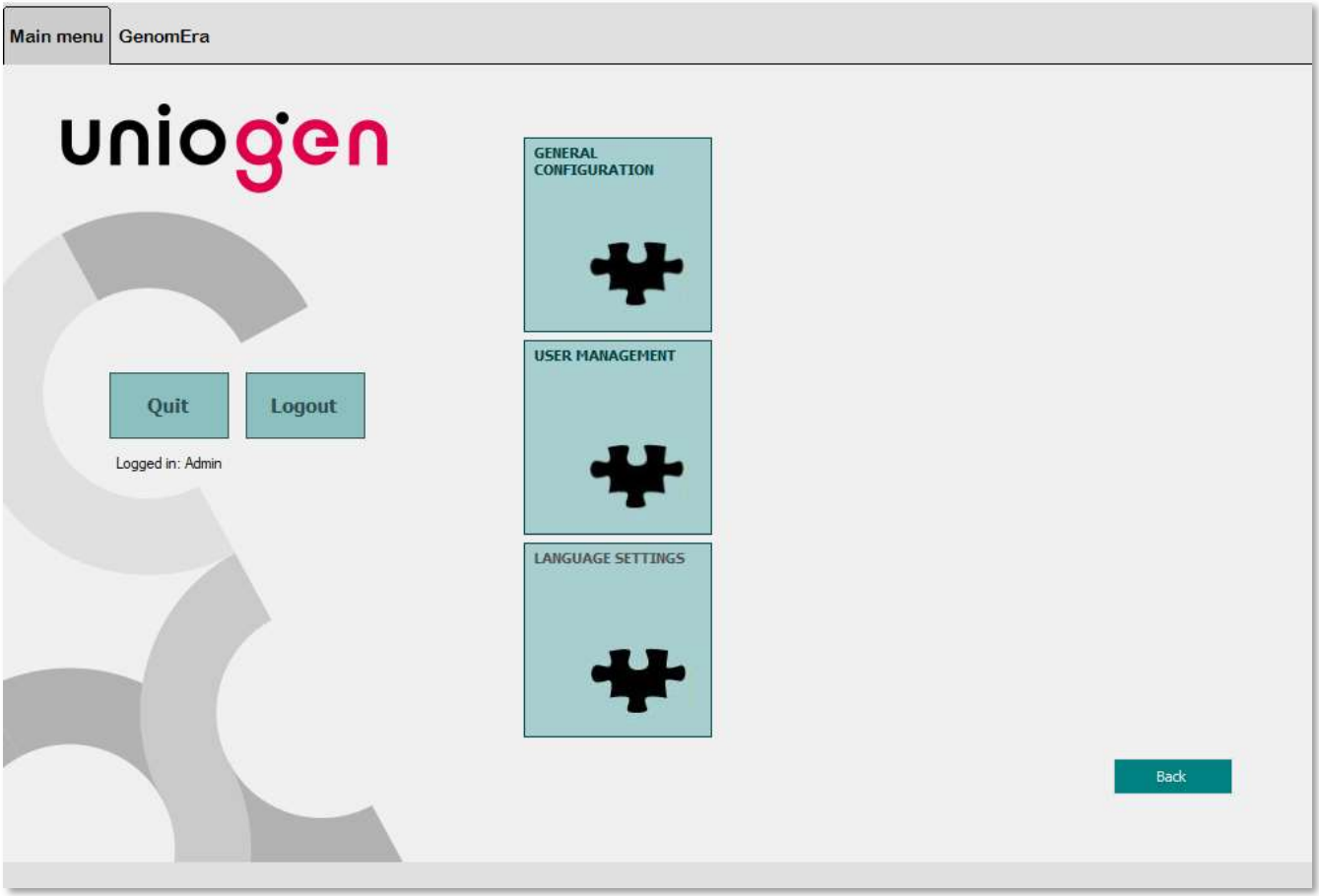

The buttons have the following functionality:

| | |
|---|---|
| SHOW REPORT FILES | Opens ‘GenomEra CDX Reports’ folder which contains all report files created by the Software and users. |
| TECHICAL SUPPORT REPORT | Creates Technical Support Report to be sent to Uniogen Oy for troubleshooting in case of Instrument malfunction or other problems with the System. The name and location of the report is given in a separate information window. |
| BACKUP DATABASE | Creates a backup copy of the database. See section 10.3 Backups of the database for additional information. |
| LOG VIEWER | Opens the event log to view the audit trail (administrator level users only). To view the audit trail, click ‘LOG VIEWER’ and then click ‘Update’. |

## 7.4 Settings

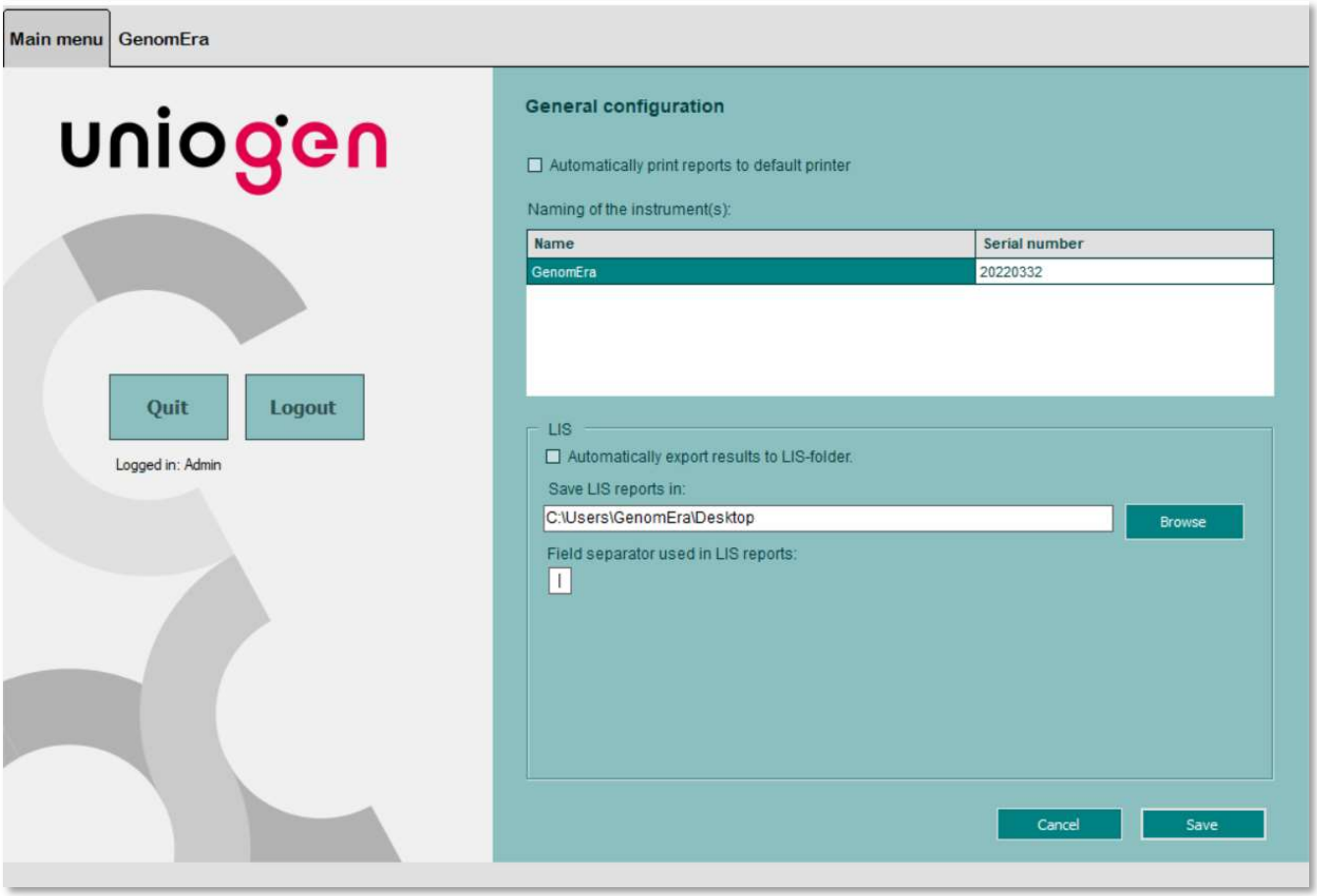



The ‘Settings’ view displays options for configuring the Software. Only the local administrator (admin user) can customize the settings to meet the user laboratory policies. The functionalities of the buttons are described in the following subsections.



### 7.4.1 General configuration

This section describes the general settings of the Software. To open the screen, click ‘General configuration’. All changes made to the settings are accepted by clicking ‘Save’. To exit without saving, click ‘Cancel’.




***Automatically print reports to default printer***

Checking the box enables automatic printing of PDF reports after successful assay runs. The reports are always saved (in both PDF and LIS text format) and can be printed manually from the *‘GenomEra CDX Reports’* folder at any time.

***Naming of the instrument(s)***

All connected GenomEra CDX Instruments are listed here. The recognition of individual Instruments is based on their serial numbers. For easier identification of multiple Instruments, the names of the Instruments can be changed. This must be done while the instrument is on STANDBY.

***LIS options***

For a complete description of LIS functionality and options, see section 9.

### 7.4.2 Language settings

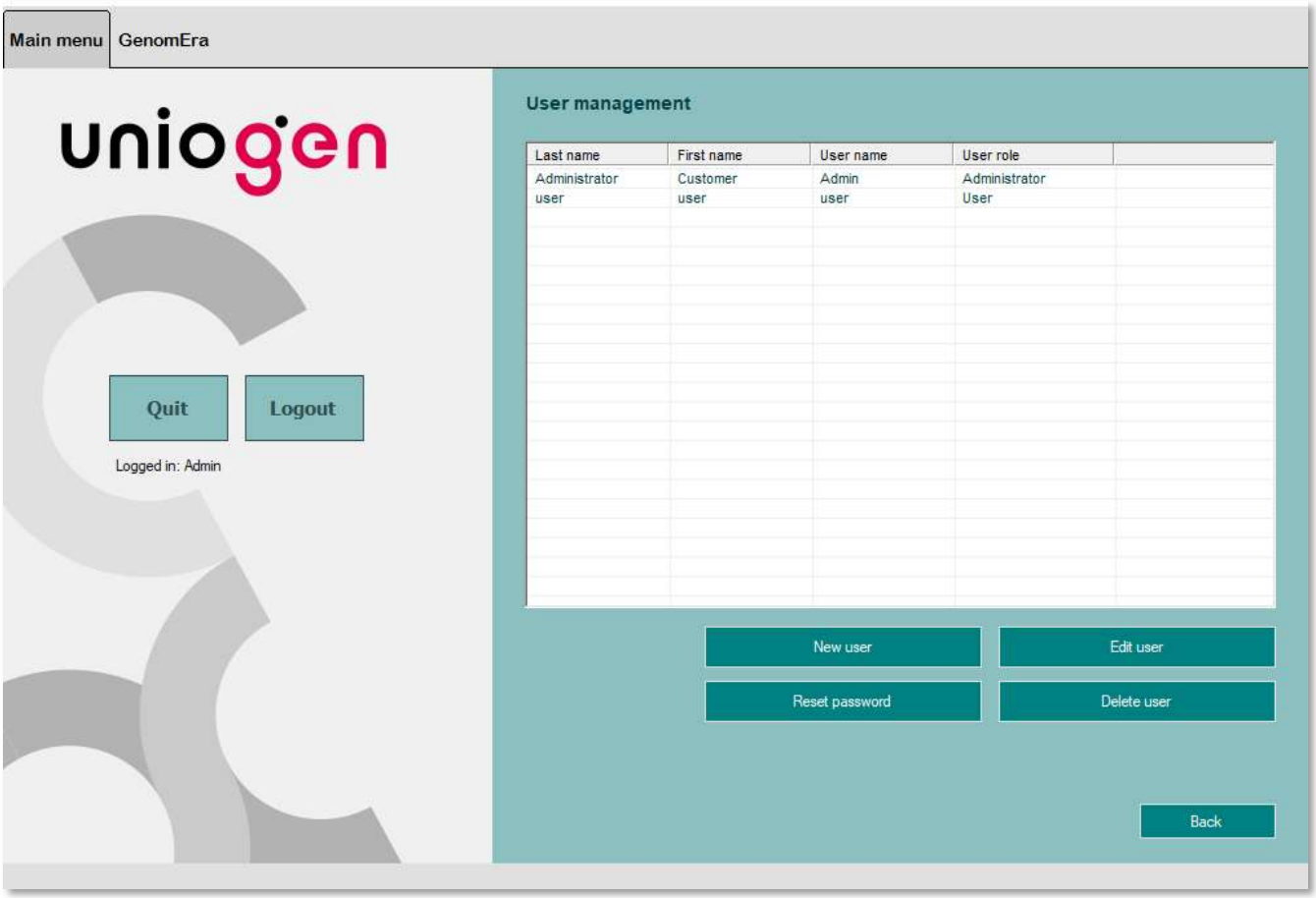
Change the language of the GenomEra CDX Software by clicking the ‘Language Settings’ button. This will open a view where the language options are listed. Select the language from the list and confirm the choice by clicking ‘Ok’. Exit without saving by clicking ‘Cancel’.

If the ‘Language Settings’ button is disabled, no other languages are available.

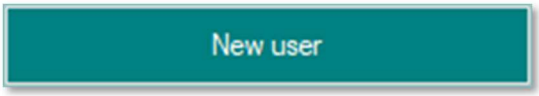
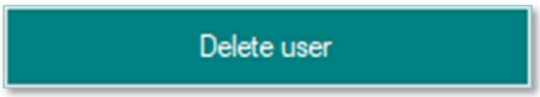
### 7.4.3 User management

A default Administrator username and password is provided with the System (a paper print provided together with the User Manual). The default Administrator can create additional user accounts with either User or Administrator level rights.

To create a new user account or to make changes to existing user accounts, select ‘User management’.




The buttons have the following functionality:

| | |
|---|---|
|  | Create new user account. |
|  | Edit an existing user account. |
|  | Delete an existing user account. |
|  | Change the password of an existing account. |

### 7.4.4 Managing user accounts

1. By clicking the ‘New user/Edit user/Delete user/Reset Password’’, the Software opens a dialogue box to manage user accounts.

2. User accounts can be customized with following fields:
   - User name: *the user name for logging in*, e.g. the first name of the user
   - Last and first names of the user (not shown elsewhere in the Software)
   - User role: User (routine users) or Administrator
   - Password: *the password for logging in*

3. You may also enter specific notes for the account (e.g. a reminder about the user account termination)

4. Save changes to user account by clicking ‘Ok’. The ‘Cancel’ button returns the user to the previous dialogue box without saving the changes.

**Note: Successful creation of a new user account will be notified in a separate message window. Click ‘Ok’ to close the window.**

**Note: Deletion of a user account will be notified in a separate message window. To permanently delete a user account, click ‘Yes’. Clicking ‘No’ cancels the action and returns the user to the previous window.**

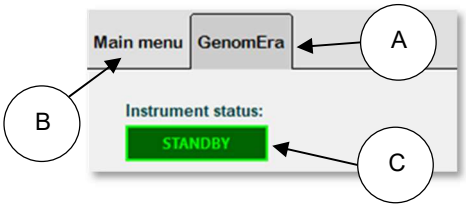
**Note: For security reasons, changing the password of the default Administrator account is not allowed. However, additional administrator level user accounts with an ability to change the password can be created in the user management section.**

**Note: Password restrictions: The Software only accepts passwords of 6 to 30 characters long and containing upper- and lower-case letters, numbers and special characters (!*|,\":<>[]{}`\';()@&$#%).**

The availability of functionalities at different user account levels:

| **Functionality** | **User level** | |
|---|---|---|
| | **Administrator** | **User** |
| Run assays | Yes | Yes |
| Create reports using the Archives function | Yes | Yes |
| Download Lot codes | Yes | Yes |
| Backup database | Yes | Yes |
| Create error report for Technical Support | Yes | Yes |
| General configuration | Yes | No |
| Language settings | No | No |
| User management | Yes | No |
| View audit trail | Yes | No |

# 8 Instrument tab




The Instrument specific USB cables that are connected to the computer are shown as ‘Instrument tabs’ (A, here ‘GenomEra’) next to the ‘Main menu’ tab (B).

When the instrument end of a USB cable is not connected to an Instrument OR the Instrument connected to the cable is switched off, the Instrument tab will be shown as ‘Device N’, where ‘N’ is the tab index ranging from 1 to 8 from left to right depending on the number of Instruments connected to the computer.

The Instrument tabs are named based on the names set for the Instrument(s). To change the Instrument name, please see section 7.4.1.

Up to *eight* Instruments can be operated from one computer.

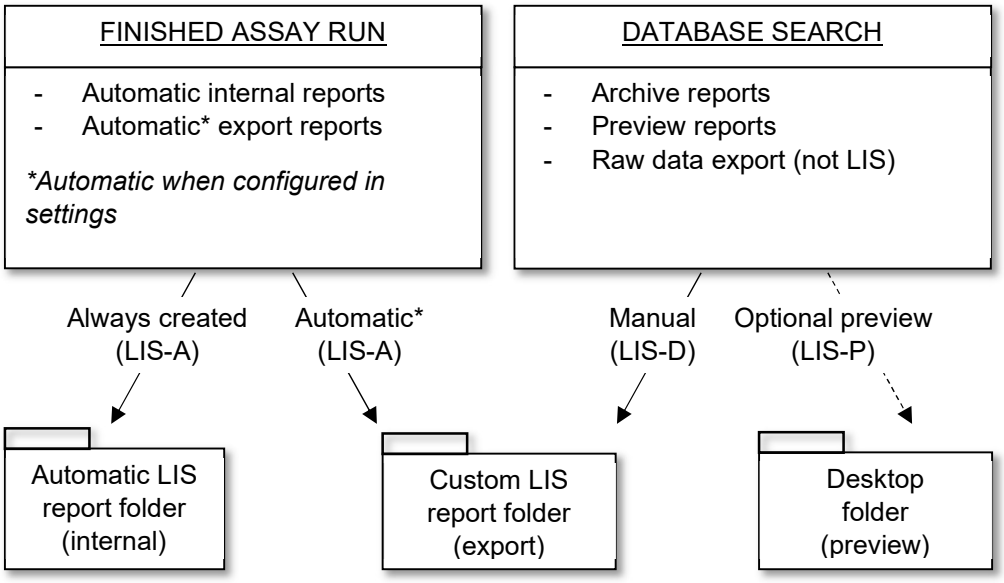
## 8.1 Instrument status indicator

The status of the GenomEra CDX Instrument is displayed in the Instrument tab (C). There are 11 possible statuses:

1. Unconnected: The Instrument is switched off or not present.
2. Initializing: The Instrument is performing initial start-up checks.
3. Heating (XX min remaining): The Instrument is heating up to Standby state.
4. Standby: The Instrument is ready for an assay or cleaning run.
5. Starting: The Instrument is performing assay start-up procedures.
6. Running: An assay run is in progress.
7. Idle: An assay run has ended, and the results are calculated / shown.
8. Stopping: The Software is waiting for an on-going assay run to stop.
9. Cancelled: An assay run has been cancelled by user of a failed start-up check.
10. Error: The Instrument has malfunctioned.
11. Cleaning: A cleaning run is in progress.

# 9 Laboratory Information System (LIS) export functionality

The assay run results can be exported in LIS data format to several folders either directly after an assay run or later from the database. The different options and report types are shown in the chart and explained further in the sections below.

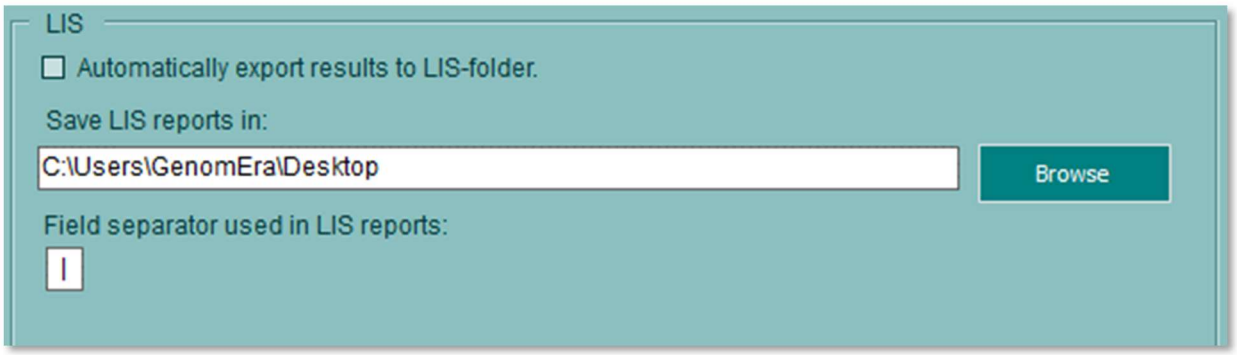



## 9.1 Automatic internal reports

The assay run results are automatically saved to an internal LIS report folder ‘GenomEra CDX Reports/Automatic LIS reports’ in LIS format. The reports can be accessed through ‘Main menu’ → ‘LOG’ → ‘SHOW REPORT FILES’ button which will open a folder named ‘GenomEra CDX Reports’.

## 9.2 Customized LIS reports

LIS reporting can be customized from the ‘General configuration’ window by the administrator user (see section 7.4.1):




### 9.2.1 Automatically export results to LIS-folder

If the option ‘Automatically export results to LIS-folder’ is selected, all assay runs will produce a LIS report file into a custom folder in addition to the internal report folder. A disclaimer is shown when the automatic option is selected which must be accepted by clicking ‘Ok’ before the automatic option is enabled.

### 9.2.2 Setting the location of the custom folder

The location of the custom folder can be determined by clicking ‘Browse’ or typing the folder path directly in the ‘Save LIS reports in’ text box. As a default, the path is set to the laptop’s desktop. The folder must always be accessible for LIS reporting to operate correctly - especially if the folder is located on a network.

### 9.2.3 Setting the field separator

By changing the 'Field separator used in LIS reports', the user can define which character will act as a field separator between individual test data fields in the report (see report examples in section 9.5). The use of letters, numbers, slash, or mathematical signs is **not** recommended. If possible, the character should be left to its default value, |.

## 9.3 Manual export of results to LIS after database search

The LIS reports can also be produced from the database. The database LIS reports are created from the 'Archives and Quality Control' view (see section 7.1) by clicking 'Export to LIS'. These reports are always saved into the administrator defined custom folder.

The user can also **preview** the report by selecting the 'LIS preview to Desktop' check box before clicking the 'Export to LIS'. This action will save a file named 'LIS-P.txt' to the Desktop and the file will be automatically opened in the Notepad application. If the result listing is as expected, exporting to the custom LIS folder can be performed by clearing the check box and clicking the 'Export to LIS' again.

## 9.4 Report file naming

The names of the LIS report files are generated as follows:

- **LIS–**
- **A** (automatic), **M** (manual) or **D** (database archives) **–**
- **XXXX–** 4 last digits of an instrument's serial number (only A/M reports)
- **YYYYMMDD-NN** run number (A/M reports) or report number (D report)
- **.txt**

Examples:

`LIS-A-0044-20111204-01.txt`
`LIS-M-0044-20111204-01.txt`
`LIS-D-20111204-01.txt`

**Note: In the database reports (generated from the 'Archives and Quality Control' window), the last two digits (NN) of the report number constitute a running number that is determined by the number of files with the prefix `LIS-D-YYYYMMDD` in the custom folder at the time the report is saved. If database generated files are deleted from the custom folder, it is possible that subsequent database files (generated after deletion) will have the same file names as some of the deleted files. Therefore, it is not recommended to delete these files on the day they are created.**

As an alternative for deletion, the files can be renamed (e.g. after any upload or logging operations) by preserving the prefix.

Example:

`LIS-D-20111204-01.txt` → `LIS-D-20111204-01-UPLOADED.txt`

The preview file name is always `LIS-P.txt`; it is saved temporarily on the desktop and overwritten when a new preview is generated.

## 9.5 Data structure

The LIS text format is dependent on the GenomEra Assay Kit used. See relevant Assay Kit Instructions for Use for additional information.

The LIS text file contains one row for each Test Chip. Each row contains data fields without field numbers, separated by a user configurable LIS separator character (| in the example). If all fields are not used for the specific analyte/result, the unused fields are automatically marked with "". If results are not available (e.g. in case of PCR inhibition), a row for that Test Chip is not produced at all. The file does NOT contain empty lines.

Example:

|"Patient 1"|"20120903-10"|"20120046"|"14001"|"1"|"C. difficile (tcdB)"|""|"+ Positive"|""|"POS"|""|""|""|"15"|""|""|""|""|

# 10 Service and maintenance

The Instrument does not require daily maintenance. It is recommended to turn the Instrument and the computer OFF for a downtime of 8 hours or longer, e.g., during nights and weekends. However, this is not a prerequisite in time critical laboratories where the System can be kept ON continuously.

It is recommended that the System should be serviced by authorized service personnel after every 3000 runs or 5 years of use. Contact Technical Support for information about System service. GenomEra CDX System's Preventive Maintenance procedure is recommended to be performed annually. For further information regarding Preventive Maintenance, please contact Technical Support.

## 10.1 Cleaning and decontamination

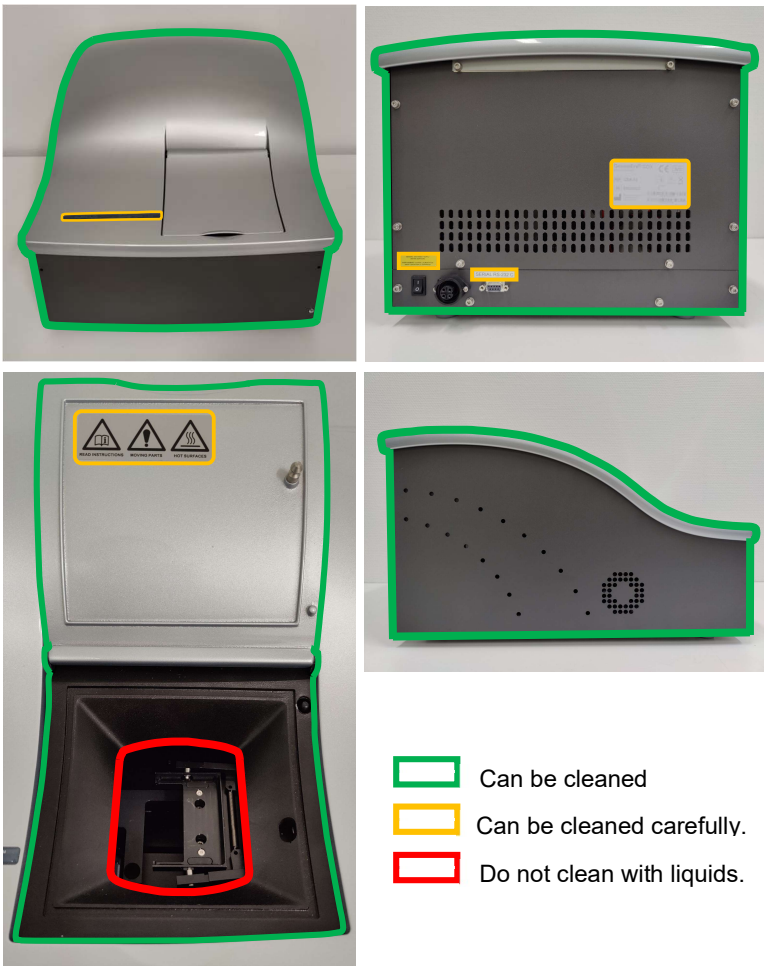
### 10.1.1 Cleaning the Instrument surface

Follow these instructions for cleaning and decontaminating the externally accessible parts of the Instrument. If it is suspected that a spill has ended up inside the instrument, please contact Technical Support before starting decontamination.

Make sure the Instrument is powered off when cleaning the instrument and only use lint-free wipes for the cleaning. If you need to wipe the labels (highlighted below in yellow), do this carefully to avoid them becoming detached. Do not clean the sled (highlighted below in red) with any liquids. Note that periodical cleaning is not required by the manufacturer – follow your local laboratory cleaning schedule.

The outer surfaces of the Instrument and the accompanying devices can be wiped clean with a soft cloth which is slightly moistened with a mild detergent. Extra care should be paid not to apply excess liquids when cleaning devices connected to electrical outlets as this may cause an electrical hazard. For general cleaning/decontaminating of the instrument, use 70 % ethanol. The following products are recommended for eliminating DNA, RNAses and DNAses from the surfaces:

- DNA AWAY™ Surface Decontaminant from Thermo Fisher
- RNase AWAY® from Sigma-Aldrich
- RNase AWAY™ Surface Decontaminant from Thermo Fisher



### 10.1.2 Cleaning the thermal blocks of the Instrument

A special Cleaning Cassette provided within the GenomEra Cleaning Kit should be used for cleaning the thermal blocks of the Instrument. The cassette removes the fine aluminum dust which is sometimes produced by the Test Chips. Dust can accumulate in the thermal blocks during routine use.

It is recommended to use the Cleaning Cassette after every 50–100 assay runs OR when notable aluminum dust can be seen on the used Test Chips. The cleaning strip of the Cleaning Cassette can be used multiple times but should be changed when it has collected a lot of dust or starts to show any signs of disintegration.

To start the cleaning assay, insert the Cleaning Cassette into the Instrument as you would usually insert the Test Chip and start the cleaning run using the ‘Start assay’ button. The cleaning sequence takes approximately 2 min. After successful cleaning, remove the Cleaning Cassette from the Instrument. Note that the Instrument automatically initializes after the cleaning run; this takes approximately 1 min.

- **Note: In the rare case where it is suspected that pathogen or DNA contamination originates from within the Instrument after use, contact Technical Support before initiating any cleaning process.**
- **Note: Do not use strong detergents or solvents such as isopropanol in cleaning as they deteriorate the Instrument materials. It is the user's responsibility not to use decontamination or cleaning agents that could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it. The authorized distributor must be consulted if there is any doubt about the compatibility of the decontamination or cleaning agents.**
- **Note: It is the user’s responsibility to perform appropriate decontamination if hazardous material is spilt on the equipment. If the spill ends up inside the Instrument, please contact Technical Support before beginning decontamination.**

## 10.2 Quality Control samples

The Instrument does not require any on-site calibration or quality control (QC) runs. Each Test Chip contains an internal amplification control (IAC) for monitoring the reagent integrity and PCR inhibition within each sample. The IAC results of a successful assay are not reported.

Positive and negative control samples can, however, be run at any time. Follow the local laboratory policy regarding the recommended frequency of QC runs. It is recommended that commercially available control materials are used for QC but well-characterized positive and negative samples are also suitable as controls.

Control samples can be included in a conventional assay run or in a separate assay run. Both positive and negative control samples can be run. However, if most patient samples typically yield negative results, it is good practice to run positive controls, and *vice versa*. Identifying the QC samples when starting the assay run allows exporting the QC results via the ‘Archives and Quality Control’ window of the GenomEra CDX Software.

Signal levels may drift, causing FAILED results. Contact Technical Support for instructions to verify causes for FAILED results. Signal levels can be adjusted with remote assistance.

## 10.3 Backups of the database

Regular back up of the entire database is recommended. The System will give a reminder message every 6 months. To make a backup copy of the database:

1. Click the ‘LOG’ button in the ‘Main menu’ and then click the ‘BACKUP DATABASE’ (see section 7.3).
2. When saving the backup file, select a location other than the computer to ensure that all results can be restored in case of a computer malfunction.
3. Click ‘Save’.
4. You will be notified of a successful backup. Exit by clicking ‘Ok’.

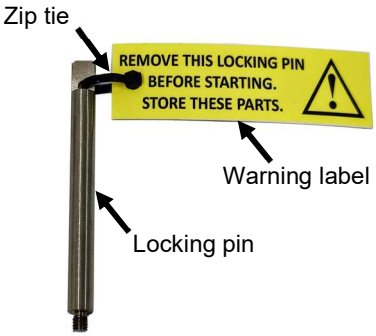
## 10.4 Other regular checks and visual checks


The Test Chips are permanently sealed with heat and pressure in the beginning of the assay run, which eliminates the possibility of amplicon contamination in the surroundings. The used Test Chips can be discarded safely. Dispose of infectious waste in accordance with the local and laboratory regulations. Do not open, pierce or grind used Test Chips.

**Note: Never cover the upfront part of the test chip (indicated by a red rectangle). It may affect the sealing process.**

Ensure that all cables and cords are tightly connected and all the accessories work as normal. Ensure that the chip holder (especially the narrow support structures in the front) is intact and is stable when put on a flat surface. Discard all old, bent, or broken chip holders.

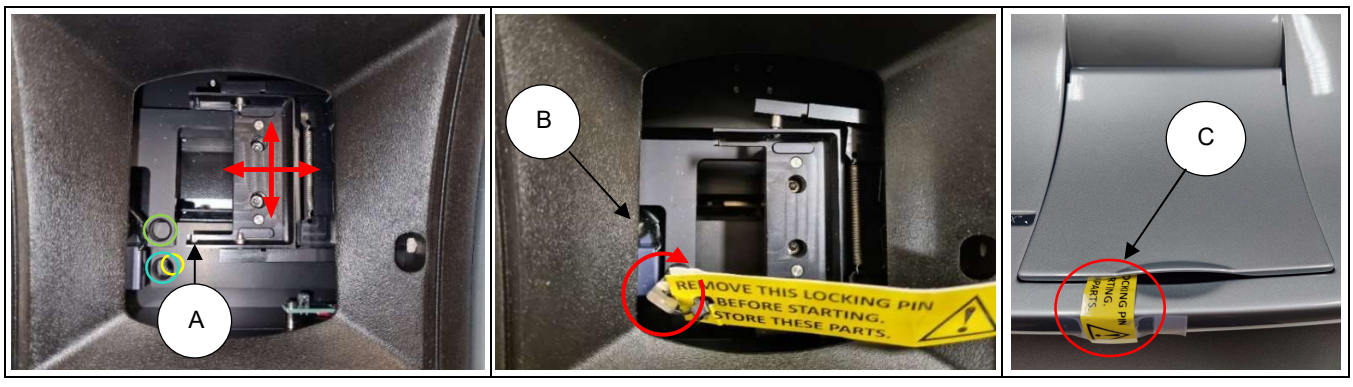
## 10.5 Transporting the Instrument




Please consult Technical Support before transporting the Instrument.

The Instrument should be transported in its shipping package, and the sled must be secured in place by a Locking Pin provided with the System. The Locking Pin includes a warning label that is attached to the pin with a zip tie. Besides being a visual reminder to remove the pin before System installation, the warning label acts as a cushion between the lid and the body of the Instrument during transportation. Follow the instructions below to pack the Instrument for transportation. Additional packing instructions are available upon request.

1. Check that the power switches for the Instrument and the external power supply are off (”0”).
2. Open the lid.
3. Align the holes for the Locking Pin (indicated with green, blue, and yellow circles) by moving the sled manually. When moving, hold the sled by the thickest parts, NOT on the narrow sides, which can bend (A).
4. Insert the Locking Pin into the holes and screw it firmly in place by turning it clockwise (B).
5. Tape the warning label to the cover (C).
6. Close the lid.
7. Place the Instrument inside the plastic pouch provided.
8. Pack the Instrument following the instructions printed on the shipping package. Note that two persons are needed to lift and place the Instrument into the box. If the Instrument is being shipped for service, there is no need to include the power supply.
9. Close the shipping package with tape and attach the necessary shipping documents to the box.




**Note: The Instrument should not be transported without the Locking Pin fastened. Contact Technical Support if the Locking Pin or the attached warning label is missing.**

**Note: The lid should not be forced open. If the Locking Pin is inside the Instrument and the lid is locked, please contact Technical Support for further assistance.**

# 11 Troubleshooting

## 11.1 General use of the GenomEra CDX System

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| The Software will present an error message after detecting that the sled cannot be moved. | The Instrument is turned on without removing the Locking Pin. | 1. Turn off the instrument and remove the Locking Pin.<br>2. Close the lid, turn the Instrument on and close the error message. The Instrument will then continue with the startup procedure. |
| The Instrument does not turn on; the green LED light in the front panel and the LED indicator light on the top cover of the Instrument are off. | The external power supply and/or the Instrument are switched **OFF**. | 1. Check that **both** switches (Instrument and the external power supply) are switched **ON**.<br>2. Check that the external power supply is plugged into a power outlet. |
| The Instrument is on (the green LED light in the front panel is on) but the Instrument is not visible in the GenomEra CDX Software and the LED indicator light is off. | 1. The Instrument tab is showing "Device N": The serial-to-USB-port adapter is connected to the computer but **not** to the Instrument.<br>2. No Instrument tab is shown: The serial-to-USB adapter is **disconnected** from the computer. | 1. Check the connections, especially the USB hub.<br>2. If checking the cables does not help, disconnect the serial-to-USB-port adapter from the computer and then reconnect it. Follow the instructions on the screen. |
| Heating the Instrument to standby takes much more than 20 minutes. | 1. Only the Instrument has been turned on during the initial startup, but the GenomEra CDX Software has not been started.<br>2. The room temperature is very low. | 1. The Instrument only starts to heat once the connection with the computer **and** the GenomEra CDX Software has been established. The LED indicator on the top cover will light up and turn orange when the Instrument is heating, not before.<br>2. The lowest operating temperature of the Instrument is 15 °C. At low room temperatures, the heating time may be slightly longer, but should not last more than 30 minutes. |
| The Instrument does not allow an assay run to start. | The Instrument is not yet on standby. | Always check that the LED indicator on the top cover of the Instrument is green and the 'Start assays…' button of the Software is visible before pipetting samples to the Test Chips. |

## 11.2 Login

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| Login is unsuccessful. | 1. No account has been created for the user.<br>2. The password is incorrect. | Administrator level users can create new user accounts and change passwords for existing accounts when necessary. |
| Password cannot be changed. | Changing the password of the **default** Administrator is not allowed. | Create additional administrator level accounts when necessary. |

## 11.3 Assay runs

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| Lot specific information is missing (assay run cannot be started). | The Lot code of the assay kit has not yet been downloaded into the GenomEra CDX Software. | Read the barcode from the label of the kit package using a barcode reader provided. Note that both parts of the barcode need to be read. |
| Downloading the lot information failed (assay run cannot be started). | The two-part Lot code has been downloaded in an incorrect order, or one part is missing. | Download both parts of the Lot code in a correct order. Make sure you are using a barcode reader supplied by the manufacturer. |
| Assay or analyte specific information cannot be found (assay run cannot be started). | The GenomEra CDX Software is not compatible with the assay or analyte in at least one of the Test Chips. | Please contact the authorized distributor for a software update. |
| Chips have already been used (assay run cannot be started). | The Test Chips have already been analyzed or barcodes on the Test Chips have already been read. The chemistry of the chips is no longer valid. | Prepare and run new Test Chips. |
| Chips have expired (assay run cannot be started). | The Test Chips have a limited shelf-life. Expired chips cannot be run. | Check the expiry date on the kit package. Start again with a new kit. |
| The ‘Start assay’ button is not visible (assay run cannot be started). | 1. ‘Start assay with button is not visible and the LED indicator light is yellow: The Instrument is heating/cooling (not on standby yet).<br>2. ‘Start assay with’ button is not visible and the LED indicator light is red: The Instrument is in error state. | 1. Wait until the Instrument is on standby. This will take a maximum of 30 minutes (the heat-up time upon cold-start). If the Instrument indicates overheating or the room temperature is high, check that there is unobstructed airflow for the fans on both sides of the Instrument. The highest operating temperature of the Instrument is 28°C.<br>2. Follow the instructions on the screen. If instructed, please create and send a report to Technical Support. Otherwise check the cables and connections and restart the entire System (Instrument, Software, and computer). |
| Chips are missing (assay run cannot be started). | The chip holder contains fewer than four Test Chips. | All four chip positions in the chip holder must be filled. Use Dummy chips to fill in empty positions when necessary. |
| The Instrument is disconnected from the computer (assay run cannot be started), or the connection is lost during an assay run (assay run failed/interrupted). | 1. Some USB ports may have faulty contacts, or the USB cable has been disconnected manually during the run.<br>2. Barcode reader is connected to the USB hub. | 1. Use a different USB port.<br>2. Connect barcode reader directly to computer.<br>If the connection is lost during an assay run, the assay will resume until finished despite of this. |
| The Instrument reports FAILED results repeatedly and replacing the sample or the Test Chip does not resolve the issue. | Signal levels may have drifted. | Contact Technical Support for instructions to verify causes for repeated FAILED results. Signal levels can be adjusted with remote assistance. |

## 11.4 Result reporting

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| Results are not sent to the default printer. | 1. Automatic printing is off.<br>2. The printer is not turned on or is not connected to the computer via the USB hub. | 1. Check the checkbox for automatic printing in settings/ general configuration (Administrator level option).<br>2. Check the printer connection and that the printer is on |
| No matching data was found (report could not be created). | The search parameters do not match with any of the results stored in the database. | Try different search criteria. |
| Exporting a LIS report failed. | The destination folder is not accessible. | Make sure that the custom LIS folder is accessible. |

## 11.5 User management

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| The Settings options cannot be accessed. | Settings are only available to Administrator level users. | Login as Administrator. |
| New user accounts cannot be created. | 1. Not all required information has been entered.<br>2. The password does not meet the requirements. | 1. Check that all the required information has been entered.<br>2. Check that the password meets specifications. |
| Editing or deleting a user account is not successful. | The default Administrator account cannot be altered. | Create new user accounts when necessary (Administrator level option). |

## 11.6 Malfunction

| ERROR OR MALFUNCTION | POSSIBLE REASON | RECOMMENDED ACTION |
|---|---|---|
| The lid cannot be opened. | The sled is not in the home position. | Shut down and restart the Instrument. If the Instrument does not initialize, please contact Technical Support. |
| Any detectable defect, e.g. abnormal noise or smell coming from the Instrument, or abnormal appearance of used Test Chips (e.g. depth or positioning of the sealing imprint). | Mechanical or electrical malfunction. | Halt the use of the System and immediately contact Technical Support. |
| The Instrument reports a mechanical malfunction immediately after starting an assay run. Possible crashing noise from the Instrument. | 1. The chip holder is not fully in place in the Instrument sled.<br>2. The lid of the chip holder is not closed.<br>3. The Test Chips are not fully in place in the chip holder.<br>4. The Test Chips are crooked/bent in the chip holder (e.g. due to collision). | 1. Ensure that the chip holder is fully in place in the Instrument sled. Some chip holders may be slightly wider than others. In this case, discard the chip holder and replace it with a new one.<br>2. Ensure that the lids of the Test Chips have been closed one by one before closing the lid of the chip holder.<br>3. Ensure that the Test Chips are snapped to the pins of the chip holder.<br>4. Straighten the Test Chips so that the tips are on the same level and point forward horizontally.<br>Immediately re-start the assay run. After a delay of 5 minutes, the Instrument reports the Test Chips invalid. In this case, prepare new Test Chip(s) and start a new assay run. You may use Dummy chips to fill in empty positions.<br>In all cases, ensure that no Test Chips or other objects are left **inside the Instrument**. Also, create and send a **Technical Support report**. |
| Reoccurring error messages. | Instrument or software malfunction. | Contact Technical Support and report the problem as soon as possible. |

# 12 Support information

## 12.1 Procedure for returning the Instrument

Contact the authorized distributor for detailed instructions for returning the Instrument.

## 12.2 Instructions for disposal

Components of the GenomEra CDX System marked with the crossed-out wheeled bin symbol must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your product or the components, please contact your city office or waste disposal service, or the authorized distributor.

## 12.3 Orders and Technical Support

Contact an authorized distributor for orders and Technical Support

# 13 Specifications

**Environmental**

| | |
|---|---|
| Operating temperature: | 15–28 °C |
| Ambient humidity: | 10–80% RH (non-condensing) |
| Altitude: | Max. 2000 m |
| Transport: | Ambient conditions |
| Storage: | Indoors, protected from moisture and dust |

**Electrical (power supply)**

| | |
|---|---|
| Input: | 100–240 VAC / 5A (Fuse 5A F) / 50/60 Hz |
| Output: | 13.0 VDC / 5 A & 24.8 VDC / 12 A |
| Peak power: | 365 W |
| Mains supply fluctuations: | Up to ± 10% of the nominal voltage |

**Physical**

| | |
|---|---|
| Dimensions: | 33 (H) x 40 (W) x 54 (D) cm<br>(power supply: 13 x 13 x 26 cm) |
| Weight: | 31.3 kg<br>(power supply: 3.4 kg) |
| Noise level: | < 60 dB |

**Sample capacity and test throughput**

| | |
|---|---|
| Sample capacity per run: | 4 |
| Assay time: | 50–70 min (assay specific) |
| Test throughput: | 96 in 24 hours |
| Cold-start heat-up time: | < 30 min |

**Supported barcode types**

| | |
|---|---|
| Instrument: | Code 128 c |
| Manual barcode reader: | UPC/EAN/JAN, UPC/EAN with supplementary, JAN 8 & JAN 13, ISBN/ISSN, Japanese Bookland EAN, Code 39, Code 39 with full ASCII, Codabar (NM7), Code 128, Code 128 with full ASCII, Code 93, Interleaved 2 of 5 (ITF), Addendum 2 of 5, IATA Code, MSI/Plessy, China Postal Code, Code 32 |

**IT hardware**

| | |
|---|---|
| Processor: | 64-bit, 2 gigahertz (GHz) processor or higher |
| Memory: | 4 gigabytes (GB) RAM or higher |
| Hard disk: | 100 gigabytes (GB) or higher |
| Operating system: | 64-bit Microsoft® Windows® 10 (Home/Professional)* |
| Language: | English |
| Format: | English (United Kingdom) |
| System locale: | English (United Kingdom) |
| USB ports: | 3 or more |
| Display Resolution: | 1024x768 or higher, screen size 15" or higher |

*Microsoft and Windows 10 are trademarks of the Microsoft group of companies.

**Software**

| | |
|---|---|
| Software package: | FTDI USB-cable driver (CDM20802_Setup.exe);<br>Microsoft SQL Server Compact Edition 3.5 SP2 (SSCERuntime_x86-ENU.msi,SSCERuntime_x64-ENU.msi);<br>Adobe Acrobat Reader 9 (AdbeRdr934_en_US.exe);<br>GenomEra CDX 1.4.X (GenomEra CDX 1.4.X.Y.msi) |

**Product codes**

| | |
|---|---|
| GenomEra CDX System (analyzer, computer, Software, accessories) | CDX-10-020 |
| GenomEra CDX Instrument (on an existing platform) | CDX-10-010 |
| GenomEra CDX Software | CDX-10-031 |
| GenomEra Cleaning Kit | CDX-20-620 |

# SYMBOLS

| | | | |
|---|---|---|---|
| IVD | **In vitro diagnostic medical device** |  | **Caution** |
| REF | **Catalogue number** |  | **Caution, hot surface** |
| SN | **Serial number** |  | **Consult instructions for use** |
| CE | **CE marking** |  | **Manufacturer and Date of manufacture (YYYY-MM)** |
|  | **Waste Electrical and Electronic Equipment** |  | **Biological risks** |

The GenomEra CDX System complies with the applicable EU legislation. The EU Declaration of Conformity is available upon request, please contact the local distributor.

For other language versions of the instructions for use, please contact your local distributor.

# REVISION HISTORY

| Revision | Description of changes | Effective date |
|---|---|---|
| 1.0-4.0 | Previous releases | 11/2010 - 12/2022 |
| 5.0-5.2 | Addition of:<br>• Document number on title page<br>• Precautions and warnings related to correct handling and storage of the Instrument, electromagnetic radiation, non-ionizing radiation from the UV lamp, keeping the lid closed also when not running an assay, checking the device visually during unpacking, notification of incidences, guidance on the use of personal protective equipment, connection of barcode reader, required amount of power outlets, and guidance on cleaning the Instrument<br>• Disclaimer and confirmation of this manual containing the original instructions<br>• Availability of DoC upon request<br>• Limitation of use<br>• List of materials required but not provided<br>• Recommendations for System assembly<br>• Information regarding System readiness for the next assay run after intentional run interruption<br>• Instructions for System shut down and information on consecutive saving of data<br>• Information on signal level drifting in the section Quality control samples<br>• Information on infectious waste management<br>• Troubleshooting related to repeated FAILED results and Locking Pin<br>• Instructions for Instrument transportation<br>• Instructions for disposal of the device<br>• Minimum requirements regarding IT hardware and details of software package in the Specifications section<br>• Special characters allowed in the Software password<br>• Transport and storage conditions<br>• Revision history<br><br>Updating of:<br>• Minor typographical edition to clarify the text<br>• Accessory devices are now called accompanying devices<br>• Intended user and use environment section<br>• Principle of operation section<br>• Images with the latest software version<br>• Precaution related to the maintaining patient privacy<br>• GenomEra System package content<br>• Note regarding PCR protocol compatibility<br>• Note regarding chip holder reuse<br>• Interrupting an assay section<br>• Instrument tab section<br>• Lot codes section<br>• Guidance on device cleaning<br>• Symbols<br><br>Removal of:<br>• Detailed principles of TRF measurement and label technologies<br>• Information that is more relevant for Assay Kits and can be found in the respective Instructions for Use | Not published |

| Revision | Description of changes | Effective date |
|---|---|---|
| 6.0 | Addition of:<br>• Recommendation for preventive maintenance<br>Updating of:<br>• Instrument weight<br>• Functionalities at different user account levels<br>• Manufacturer information changed from Abacus Diagnostica Oy to Uniogen Oy throughout the document<br>• Layout according to new company style<br>• Software screenshots updated to version 1.4.0 | 03/2023 |

Uniogen Oy
Tykistökatu 4
20520 Turku
Finland

Tel. +358 (0)207188380 • Email: info@uniogen.com
www.uniogen.com

uniogen