



DiagCORE[®] Analyzer

User manual

Software version 1.0
PL-009-05/2018-EN



REF 110001 AM

REF 110002 OM

This document is to be used solely for the purpose of operating the DiagCORE Analyzer. No part of this document may be reproduced or transmitted by any means, whether electronic or mechanical, or for any purpose, without the express written permission of STAT-Dx Life, S.L.

Always maintain the DiagCORE Analyzer in good working order. Using the DiagCORE Analyzer in a manner not specified by STAT-Dx Life, S.L. may impair protection provided by the equipment.

A printed version of this manual is available upon request.



STAT-Dx Life, S.L.
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08028 Barcelona, Spain

REF 110001 Analytical Module

REF 110002 Operational Module

Customer and technical support

If assistance is required, contact Technical Support using the contact information below.

- Website: <http://support.qiagen.com>

When calling Technical Support about errors, please have the following information ready:

- DiagCORE Analyzer serial number, type and version
- Error code (if applicable)
- Time point when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Photo of error, if possible
- Copy support package

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Table of symbols

The table below describes various symbols used throughout this user manual and on the DiagCORE Analyzer instrument and assay cartridges.

	Location	Description
	Type plate on the back of the instrument	CE marking for European Conformity
	Type plate on the back of the instrument	TÜV mark of the TÜV SÜD Product Service for testing.
	Type plate on the back of the instrument	Legal manufacturer
	Type plate on the back of the instrument	Caution HAZARD: Risk of personal injury and material damage
	Type plate on the back of the instrument	WEEE mark for Europe
	Type plate on the back of the instrument	FCC mark of the United States Federal Communications Commission
	Type plate on the back of the instrument	In vitro diagnostic medical device
	Type plate on the back of the instrument	Catalog number
	Type plate on the back of the instrument	Serial number

1 Information about this user manual

Read this user manual carefully and pay particular attention to the safety information before operating the DiagCORE Analyzer. The instructions and safety information in this user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

1.1 Revision

This is the DiagCORE Analyzer User Manual, version 1.0. This manual is for use with the DiagCORE Analyzer 1.0 and DiagCORE Application Software version 1.0.

1.2 Intended use of the DiagCORE Analyzer

The DiagCORE Analyzer is intended for in vitro diagnostic use and provides diagnostic results. All analytical steps are fully automated using molecular diagnostic DiagCORE application cartridges and real-time PCR detection.

The DiagCORE Analyzer system is intended for professional use only and is not intended for self-testing.

1.3 Limitations of use

- The DiagCORE Analyzer can only be used with DiagCORE cartridges according to the instructions contained in this user manual and in the DiagCORE cartridge instructions for use.
- When connecting the DiagCORE Analyzer, use only the cables supplied with the system.
- Any service or repairs should only be performed by personnel authorized by STAT-Dx Life, S.L.
- The DiagCORE Analyzer should only be operated if it is on a flat, horizontal surface with no angles or tilts.
- Do not re-run a DiagCORE assay cartridge if it has already been used successfully, or if it has been associated with an error or an incomplete run.
- Allow at least 10 cm clearance on each side of the DiagCORE Analyzer to ensure adequate ventilation.
- Make sure that the DiagCORE Analyzer is positioned away from any air conditioning outlets or heat exchangers.
- Do not move the instrument while a test is running.
- Do not change the system configuration during a run.
- Do not use the touchscreen to lift or move the DiagCORE Analyzer.

1.4 Sections of the user manual

This user manual provides information about the DiagCORE Analyzer in the following sections:

1. Information about this user manual
2. Safety information
3. General background
4. Installing the DiagCORE Analyzer
5. Running a test and viewing results
6. System reference
7. Maintenance
8. Troubleshooting
9. Appendices

The appendices include the following:

- Technical specifications
- Disposal information
- Declaration of Conformity
- Glossary
- Trademarks and copyright
- Copyright, disclaimer and warranty
- Patent statement
- Software License Agreement

2 Safety information

Before using the DiagCORE Analyzer, it is essential to read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout this manual.

⚠ WARNING The term **WARNING** is used when referring to situations that could result in personal injury to the operator or others.

Details about the circumstances are provided in a message like this one.

⚠ CAUTION The term **CAUTION** is used when referring to situations that could result in material damage to the DiagCORE Analyzer or other equipment.

Details about the circumstances are provided in a message like this one.

⚠ IMPORTANT The term **IMPORTANT** is used to highlight information that is critical for the completion of a task or optimal performance of the system.

NOTE The term **NOTE** is used for information that explains or clarifies a specific case or task.

The advice provided in this user manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1 General safety precautions

Use the DiagCORE Analyzer according to this manual. It is highly recommended to carefully read and become acquainted with the instructions for use before using the DiagCORE Analyzer.

- Follow all safety instructions printed on, or attached to, the DiagCORE Analyzer.
- Improper use of the DiagCORE Analyzer or failure to comply with its proper installation and maintenance may cause personal injuries or damage to the DiagCORE Analyzer.
- The DiagCORE Analyzer must only be operated by qualified and appropriately trained healthcare personnel.
- Servicing of the DiagCORE Analyzer must only be performed by Field Service Specialists authorized by STAT-Dx Life, S.L.
- Do not use the DiagCORE Analyzer in hazardous environments for which it has not been designed.

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Do not open the housing of the DiagCORE Analyzer. The housing of the DiagCORE Analyzer is designed to protect the operator and to ensure proper operation of the DiagCORE Analyzer. Using the DiagCORE Analyzer without the housing leads to electrical hazards and DiagCORE Analyzer malfunction.

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Use caution when the lid of the cartridge entrance port closes to avoid personal injury, such as pinched fingers.

2.2 DiagCORE Analyzer transport precautions

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

The DiagCORE Analyzer is a heavy instrument. To avoid personal injury or damage to the DiagCORE Analyzer, take care when lifting it and use appropriate lifting methods.

2.3 Electrical safety

Observe all general safety precautions that apply to electrical instruments.

Disconnect the line power cord from the power outlet before servicing.

⚠ WARNING

Electrical hazard

Lethal voltages inside the DiagCORE Analyzer. Do not open the housing of the DiagCORE Analyzer.

The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).

Do not touch any switches or power cords with wet hands.

Do not use the instrument outside of the specified power conditions.

2.4 Chemical safety

Material safety data sheets for the cartridge materials are available and can be requested from STAT-Dx Life, S.L.

Used cartridges must be disposed of in accordance with all national, state and local health and safety regulations and laws.

⚠ WARNING

Hazardous chemicals

Chemicals may leak from the cartridge in the event that the cartridge housing is damaged. Some chemicals used in DiagCORE cartridges may be hazardous or may become hazardous. Always wear eye protection, gloves and a lab coat.

⚠ CAUTION

Risk of damage to the DiagCORE Analyzer

Avoid spilling chemicals or other liquids into or out of the DiagCORE Analyzer. Damage caused by liquid spillage will void the warranty.

2.5 Biological safety

The DiagCORE Analyzer and cartridges do not themselves contain biohazardous materials, however, samples and reagents containing materials from biological sources should generally be handled and disposed of as potentially biohazardous. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, from the Centers for Disease Control and Prevention and the National Institutes of Health (www.cdc.gov/od/ohs/biosfty/biosfty.htm).

Samples tested on the DiagCORE Analyzer may contain infectious agents. Users should be aware of the health hazard presented by such agents and should use, store and dispose of such samples according to the required safety regulations. Wear personal protective equipment and disposable powder-free gloves when handling reagents or samples, and wash hands thoroughly thereafter.

Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guidelines M29, or other appropriate documents provided by:

- OSHA: Occupational Safety and Health Administration (United States of America)
- ACGIH: American Conference of Government Industrial Hygienists (United States of America)
- COSHH: Control of Substances Hazardous to Health (United Kingdom)

Avoid contamination of the DiagCORE Analyzer and workspace by handling samples and DiagCORE cartridges with care. In the event of contamination (e.g., a leak from a cartridge), clean and decontaminate the affected area and the DiagCORE Analyzer.

⚠ WARNING

Biological hazard

Use caution when loading or removing cartridges containing infectious samples into or from the DiagCORE Analyzer. A break in the cartridge could contaminate the DiagCORE Analyzer and the surrounding area.

All cartridges should be handled as if they contain potentially infectious agents.

⚠ CAUTION**Risk of contamination**

Contain and clean contamination from a broken or visibly damaged cartridge immediately. Contents, though not infectious, can be spread by normal activity and may contaminate further analytical results, leading to false positives.

For instructions on cleaning and decontaminating the DiagCORE Analyzer, refer to sections 7.2 Cleaning the DiagCORE Analyzer surface and 7.3 Decontaminating the DiagCORE Analyzer surface.

2.6 Waste disposal

Used cartridges and plasticware may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with all national, state and local health and safety regulations and laws.

3 General background

3.1 System description

The DiagCORE Analyzer, in combination with DiagCORE assay cartridges, uses real-time PCR to detect pathogen nucleic acids in human biological samples. The DiagCORE Analyzer and cartridges are designed as a closed system that enables hands-off sample preparation followed by detection and identification of pathogen nucleic acids. Samples are inserted into a DiagCORE cartridge, which carries on board all reagents necessary to isolate and amplify nucleic acids from the sample. Detected real-time amplification signals are interpreted by the integrated software and are reported via an intuitive user interface.

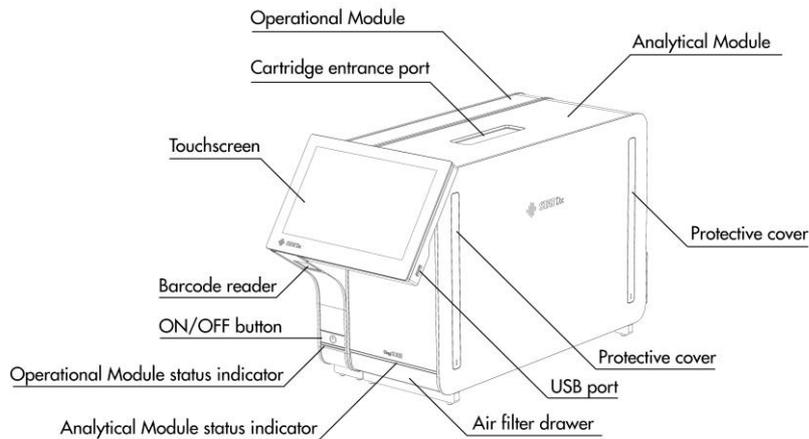
3.2 DiagCORE Analyzer description

The DiagCORE Analyzer consists of an Operational Module and an Analytical Module. The Operational Module includes elements that provide connectivity to the Analytical Module and enable user interaction with the DiagCORE Analyzer. The Analytical Module contains the hardware and software for sample testing and analysis.

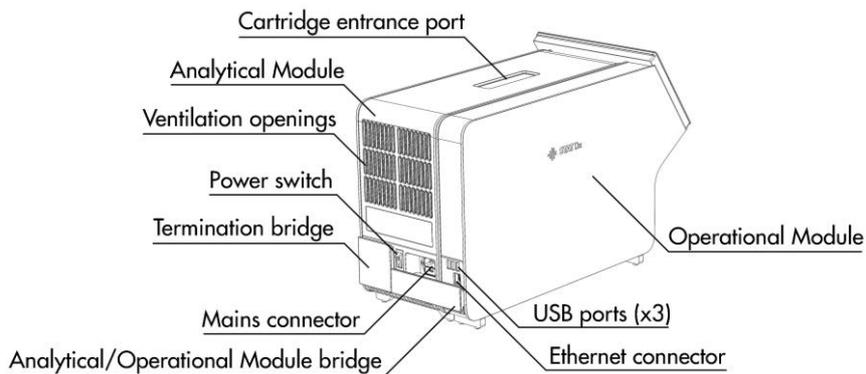
The DiagCORE Analyzer includes the following elements:

- Touchscreen for user interaction with the DiagCORE Analyzer
- Barcode reader for sample, patient and cartridge identification
- USB ports for assay and system upgrades, document export and printer connectivity (one in front, three in back)
- Cartridge entrance port for inserting DiagCORE cartridges into the DiagCORE Analyzer
- Ethernet connector for network connectivity

The following images show the locations of various DiagCORE Analyzer features.



Front view of the DiagCORE Analyzer. The Operational Module is on the left, and the Analytical Module is on the right.



Rear view of the DiagCORE Analyzer. The Operational Module is on the right, and the Analytical Module is on the left.

3.3 DiagCORE cartridge description

The DiagCORE qPCR cartridge is a disposable plastic device that allows performance of fully automated molecular assays. Main features of the DiagCORE qPCR cartridge include compatibility with various sample types (e.g., fluids, swabs), hermetical containment of all pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge.

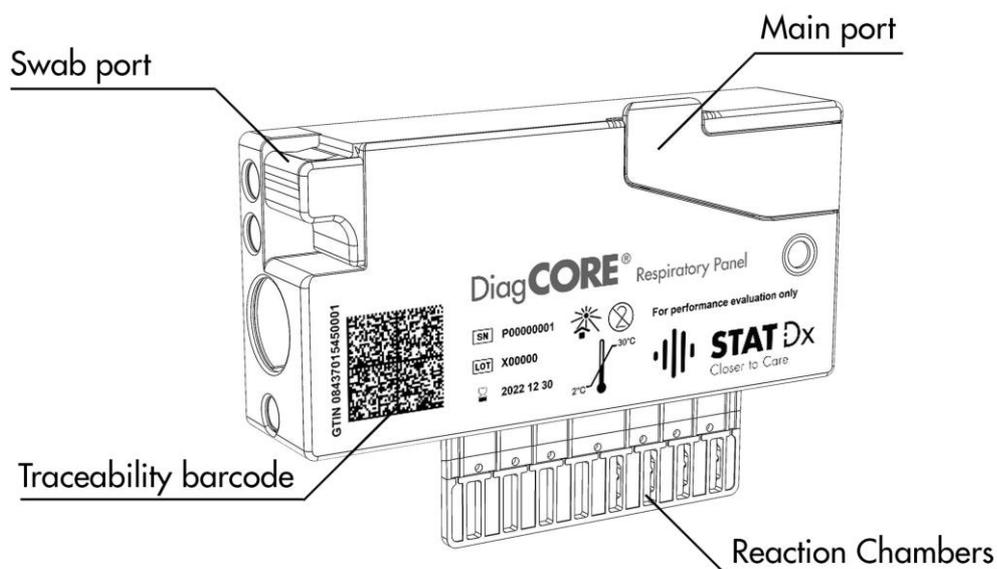
All reagents required for the complete execution of a test run are pre-loaded and self-contained in the DiagCORE cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled in the Analytical Module by pneumatically operated microfluidics and make no direct contact with the DiagCORE Analyzer actuators. The

DiagCORE Analyzer houses air filters for both incoming and outgoing air, further safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations. After the cartridge is introduced into the DiagCORE Analyzer, the following assay steps occur automatically:

- Resuspension of internal control
- Cell lysis using mechanical and/or chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized master mix reagents
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of real-time, multiplex PCR testing within each reaction chamber. An increase in fluorescence, indicating presence of the target analyte, is detected directly within each reaction chamber.

The general layout of the cartridge and its features are illustrated below.



DiagCORE cartridge.

4 Installing the DiagCORE Analyzer

4.1 Site requirements

Select a flat, dry and clean workbench space for the DiagCORE Analyzer. Ensure that the space is free of excessive drafts, moisture and dust, as well as protected from direct sunlight, large temperature fluctuations, heat sources, vibration and electrical interference. Refer to section 9.1 Technical specifications of the appendix for the weight and dimensions of the DiagCORE Analyzer and the correct operating conditions (temperature and humidity). The DiagCORE Analyzer should have sufficient clearance on all sides to enable proper ventilation, and to allow unimpeded access to the cartridge entrance port, the back of the DiagCORE Analyzer, the ON/OFF button, the barcode reader and the touchscreen.

CAUTION

Impeded ventilation

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the rear of the DiagCORE Analyzer and do not block airflow under the unit.

Slits and openings that ensure instrument ventilation must not be covered.

CAUTION

Electromagnetic interference

Do not place or use the DiagCORE Analyzer in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

NOTE

Before installing and using the DiagCORE Analyzer, refer to section 9.1 Technical specifications of the appendix to become familiar with the DiagCORE Analyzer operating conditions.

4.2 What is included with the DiagCORE Analyzer

The DiagCORE Analyzer is delivered in two separate boxes and includes all the necessary components for setting up and operating the system. The contents of the boxes are described below.

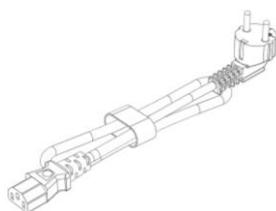
Box 1 contents:



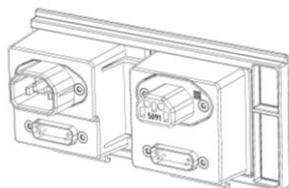
1x Analytical Module



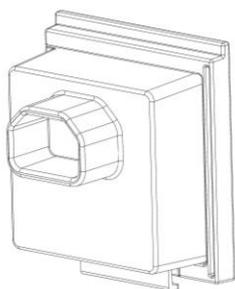
1x USB storage device containing the user manual and quick-start guide in multiple languages



1x Power cord



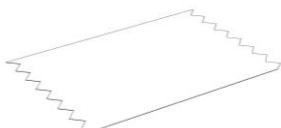
1x Analytical/Analytical Module bridge



1x Termination bridge



1x Analytical-Operational Module assembly tool

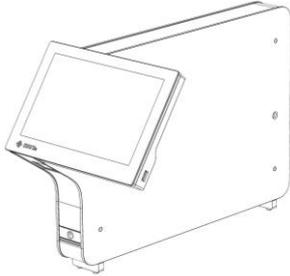


1x Screen suede

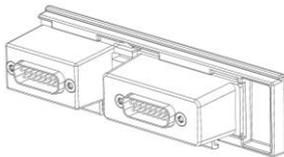


1x Protective cover removal tool

Box 2 contents:



1x Operational Module



1x Analytical/Operational Module bridge

4.3 Unpacking and installing the DiagCORE Analyzer

Carefully unpack the DiagCORE Analyzer according to the following steps:

1. Remove the Analytical Module from its box and place it on a level surface. Remove the foam pieces attached to the Analytical Module.

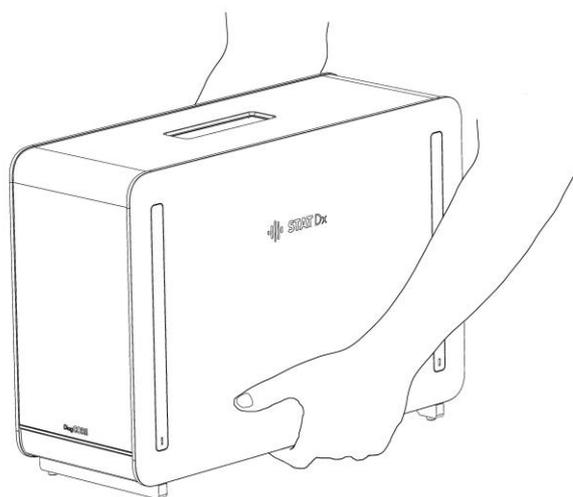
⚠ WARNING

Risk of personal injury and material damage

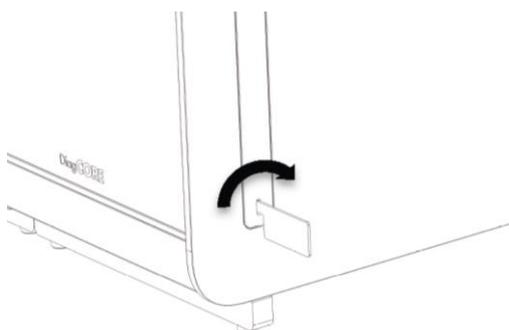
⚠ CAUTION

The DiagCORE Analyzer is a heavy instrument. To avoid personal injury or damage to the DiagCORE Analyzer, take care when lifting and use appropriate lifting methods.

The analyzer must be lifted and handled by taking it from the base with two hands, as shown in the figure below.



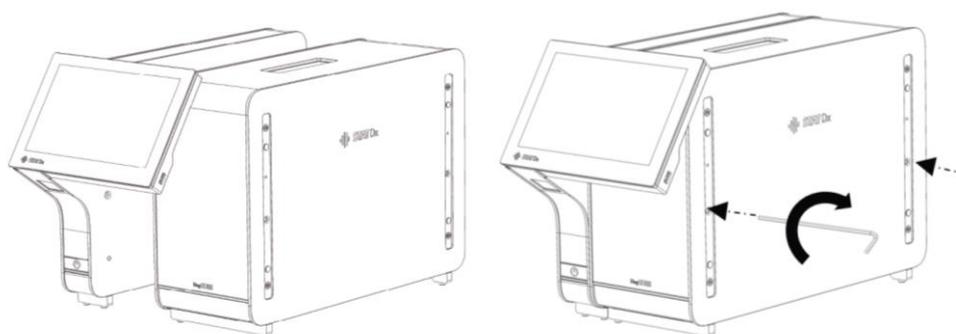
2. Remove the protective covers from the side of the Analytical Module using the protective cover removal tool delivered with the DiagCORE Analyzer.



3. Remove the Operational Module from its box and attach it to the left side of the Analytical Module. Tighten the screws using the Analytical-Operational Module assembly tool delivered with the DiagCORE Analyzer.

⚠ CAUTION Risk of mechanical damage

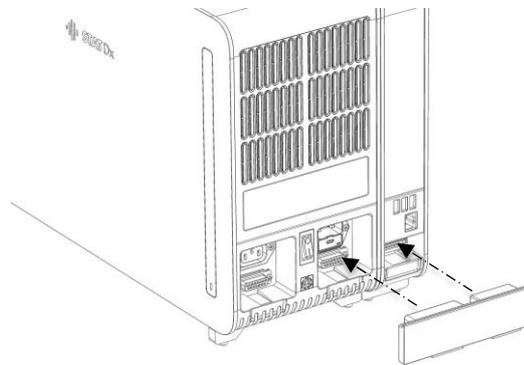
Do not leave the Operational Module without support or resting on the screen, as this may damage the touchscreen.



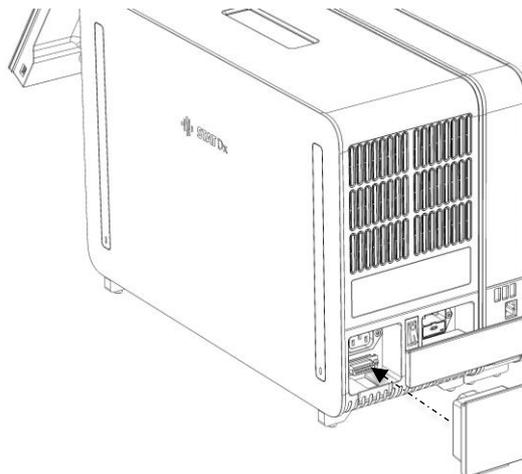
4. Reattach the protective covers on the side of the Analytical Module.



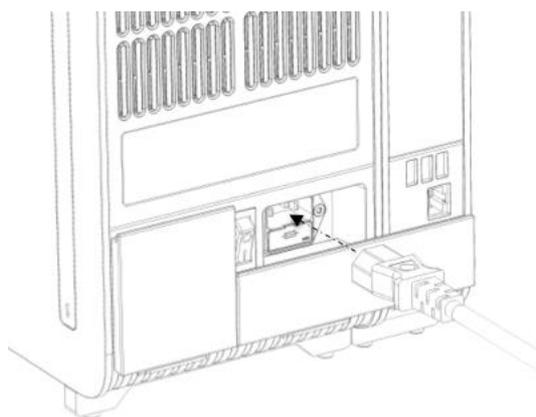
5. Connect the Analytical/Operational Module bridge at the back of the DiagCORE Analyzer to link the Operational and Analytical Modules together.



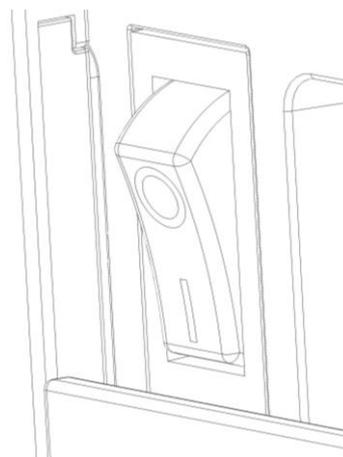
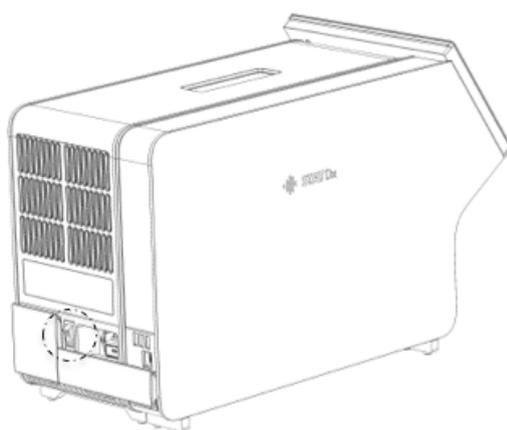
6. Connect the termination bridge at the back of the Analytical Module.



7. Connect the power cord that was delivered with the DiagCORE Analyzer to the back of the Analytical Module.



8. Connect the power cord to a power outlet.
9. Turn the power switch on the back of the Analytical Module to the "I" position. Check that the status indicators of the Analytical and Operational Modules are blue.



NOTE If a status indicator is red, there is a malfunction in the Analytical Module. Contact Technical Support using the contact information in section 8 Troubleshooting for assistance.

NOTE The instrument shall not be positioned so that it is difficult to operate the disconnecting power switch

10. The DiagCORE Analyzer is ready to be configured for its intended setup. Refer to section 6.8 Configuring the DiagCORE Analyzer system to configure the system parameters, set the system time and date and configure the network connection.

4.4 Repackaging and shipping the DiagCORE Analyzer

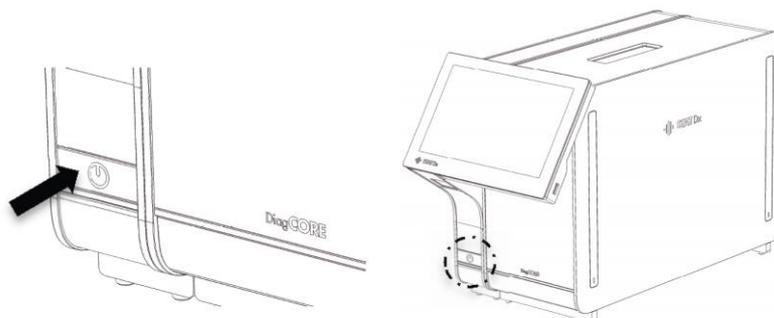
When repackaging the DiagCORE Analyzer for shipping, the original packaging materials must be used. If the original packaging materials are not available, contact Technical Support. Ensure that the instrument has been properly prepared (see section 7.2 Cleaning the DiagCORE Analyzer surface) prior to packing and that it poses no biological or chemical hazard. To repackage the instrument:

1. Ensure that the instrument is off.
2. Disconnect the power cord from the power outlet.
3. Disconnect the power cord from the back of the Analytical Module.
4. Disconnect the termination bridge at the back of the Analytical Module.
5. Disconnect the Analytical/Operational Module bridge linking the Operational and Analytical Modules at the back of the DiagCORE Analyzer.
6. Remove the protective covers on the side of the Analytical Module using the protective cover removal tool.
7. Use the Analytical-Operational Module assembly tool delivered to loosen the two screws holding the Operational Module to the Analytical Module. Package the Operational Module in its box.
8. Reposition the protective covers on the side of the Analytical Module. Package the Analytical Module with its foam pieces into its box.

5 Running a test and viewing results

5.1 Starting the DiagCORE Analyzer

Press the **ON/OFF button** on the DiagCORE Analyzer front to start the unit.



NOTE The power switch at the back of the Analytical Module must be set in the "I" position. The Operational and Analytical Module indicators turn blue in this case.

Wait until the main screen appears and the Analytical and Operational Module status indicators turn green and stop blinking.

NOTE The **Login** screen will appear if User Access Control is activated. Refer to section 6.6 User management for further details.

5.2 Preparing the cartridge

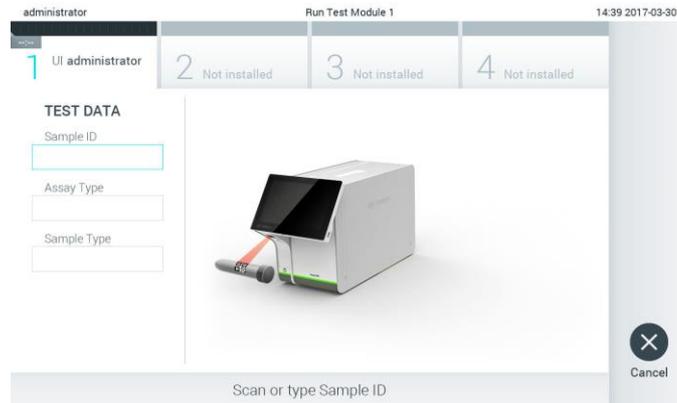
Remove the cartridge from its packaging. For details about adding the sample to the cartridge and for information specific to the assay to be run, refer to the instructions for use of the specific assay (e.g., Respiratory Panel Assay). Always ensure that both sample lids are firmly closed after adding a sample to the cartridge.

5.3 Procedure to run a test

All operators should wear appropriate personal protective equipment, such as gloves, when touching the DiagCORE Analyzer touchscreen.

1. Press the **Run Test** button  at the top right corner of the main screen.

- When prompted, scan the sample ID barcode using the barcode reader that is integrated into the Operational Module.

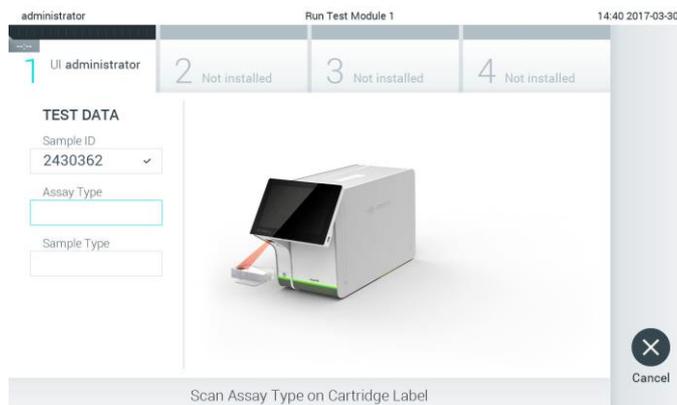


Prompt to scan the sample ID barcode.

NOTE Depending on the DiagCORE Analyzer configuration, it may also be possible to enter the sample ID using the virtual keyboard of the touchscreen. Please refer to section 6.8.2 for further details.

NOTE Depending on the chosen system configuration, entering patient ID may also be required at this point. Please refer to section 6.8.2 for further details.

- When prompted, scan the barcode of the cartridge to be used. The DiagCORE Analyzer automatically recognizes the assay to be run, based on the cartridge barcode.

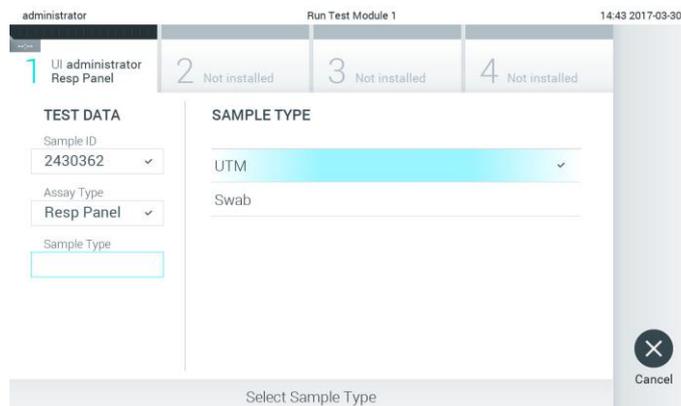


Prompt to scan the DiagCORE assay cartridge barcode.

NOTE The DiagCORE Analyzer will not accept cartridges with elapsed expiration date, previously used cartridges or cartridges for assays that are not installed on the unit. An error message will be shown in these cases. Refer to section 8.1 Errors and warning messages for further details.

Refer to section 6.7.2 Importing new assays for instructions on importing and adding assays to the DiagCORE Analyzer.

- If required, select the appropriate sample type from the list.



Prompt to select the sample type.

- The Confirm screen will appear. Review the data entered and make any necessary changes by pressing the relevant fields on the touchscreen and editing the information.



Confirm screen.

- Press **Confirm** when all the displayed data are correct. If needed, press on the appropriate field to edit its content, or press **Cancel** to cancel the test.
- Ensure that both sample lids of the cartridge are firmly closed. When the cartridge entrance port on the top of the DiagCORE Analyzer automatically opens, insert the cartridge with the barcode facing to the left and the reaction chambers facing down.

There is no need to push the cartridge into the DiagCORE Analyzer. Position it correctly into the cartridge entrance port, and the DiagCORE Analyzer will automatically move the cartridge into the Analytical Module.



Prompt to insert the DiagCORE assay cartridge.

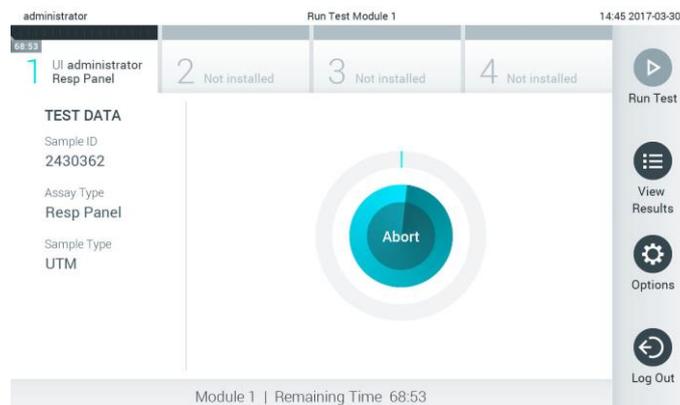
Upon detecting the cartridge, the DiagCORE Analyzer will automatically close the lid of the cartridge entrance port and start the test run. No further action from the operator is required to start the run.

NOTE The DiagCORE Analyzer will not accept a cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated and the cartridge will be automatically ejected.

NOTE Up to this point, it is possible to cancel the test run by pushing the **Cancel** button in the bottom right corner of the screen.

NOTE Depending on the system configuration, the operator may be required to re-type their user password to start the test run.

- While the test is running, the time remaining in the run is displayed on the screen.



Test execution screen and remaining run time.

- After the test run is completed, press  **Eject** to remove the cartridge and dispose of it as biohazardous waste in accordance with all national, state and local health and safety regulations and laws.



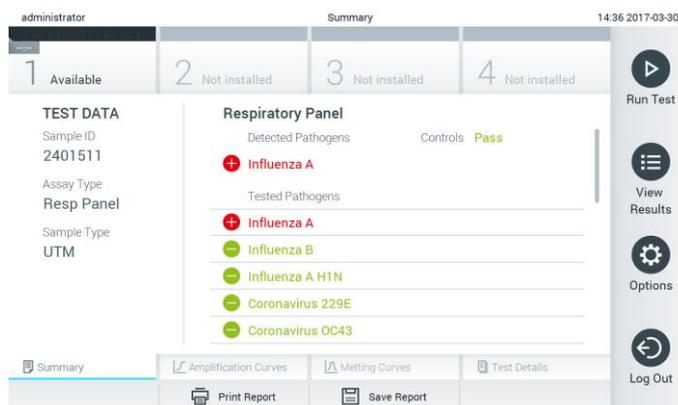
Prompt to eject the used cartridge after running a test.

The cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after a certain time, it will be automatically moved back into the DiagCORE Analyzer and the lid of the cartridge entrance port will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge.

NOTE Used cartridges must be discarded.

It is not possible to re-use cartridges for tests for which the execution was started but then subsequently aborted, or for which an error was detected.

The **Results Summary** screen will appear. Refer to section 5.4 Viewing results for further details.



Results Summary screen.

5.3.1 Instructions to abort a test

If a test run is already in progress, pressing **Abort** will stop the execution of the test.



Aborting a running test.

After aborting a test, the cartridge can no longer be processed and cannot be re-used. After pressing **Abort**, a dialog will appear prompting the operator to confirm that the test should be cancelled.



Prompt to confirm (Yes) or cancel (No) abort of a running test.

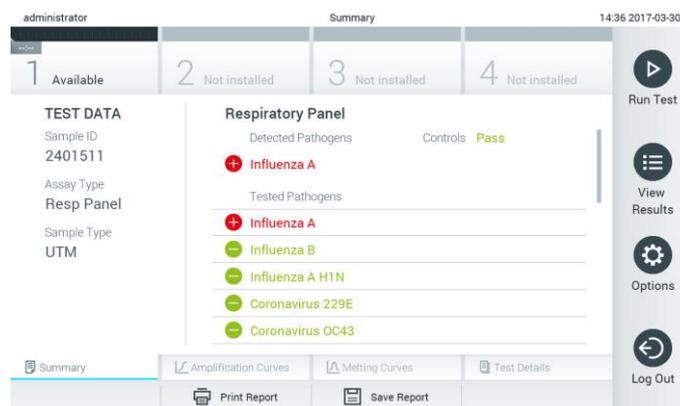
NOTE

Used cartridges must be discarded.

It is not possible to re-use cartridges for tests for which the execution was started but then subsequently aborted, or for which an error was detected.

5.4 Viewing results

The DiagCORE Analyzer automatically interprets and saves test results. After ejecting the cartridge, the **Results Summary** screen is automatically displayed.



Example screen showing Test Data on the left panel and Test Results Summary in the main panel.

NOTE Please Refer to assay-specific Instructions for Use for instructions on how to interpret assay results

The main part of the screen provides the following two lists and uses color-coding and symbols to indicate the results:

- The first list includes all pathogens detected and identified in the sample, preceded by a  sign and are colored red.
- The second list includes all pathogens tested in the sample. Pathogens detected and identified in the sample are preceded by a  sign and are colored red. Pathogens that were tested but not detected are preceded by a  sign and are colored green.

Note that the pathogens detected and identified in the sample are shown in both lists.

In case the test failed to complete successfully, a message will indicate “Failed” followed by the specific error code.

The following Test Data is shown on the left side of the screen:

- Sample ID
- Patient ID (if available)
- Assay Type
- Sample Type

Further data about the assay is available, depending on the operator's access rights, through the tabs at the bottom of the screen (e.g., amplification plots, melting curves and test details).

Assay data can be exported by pressing **Save Report** in the bottom bar of the screen.

A report can be sent to the printer by pressing **Print Report** in the bottom bar of the screen.

5.4.1 Viewing amplification curves

To view the test amplification curves, press the  **Amplification Curves** tab.



Amplification Curves screen showing the Pathogens tab.

Details about the tested pathogens and controls are shown on the left, and the amplification curves are shown in the center.

NOTE If User Access Control is enabled (refer to section 6.6 User management) the **Amplification Curves** screen is only available for selected operators.

Press the **Pathogens** tab on the left side to display the plots corresponding to the tested pathogens. Press on the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with this pathogen. Unselected pathogens will be listed in grey.

The corresponding C_T and endpoint fluorescence values are shown below each pathogen name.

Press the **Controls** tab on the left side to view the controls and select which controls are shown in the amplification plot. Press the circle next to the control name to select or deselect it.



Amplification Curves screen showing the Controls tab.

The amplification plot displays the data curve for the selected pathogens or controls. To alternate between logarithmic or linear scale for the Y-axis, press the **Lin** or **Log** button at the bottom left corner of the plot.

The range of the X-axis and Y-axis can be adjusted using the gray pickers on each axis. Press and hold a picker  and then move it to the desired location on the axis. Move a picker to the axis origin to return to the default values.

5.4.2 Viewing melting curves

To view the test melting curves, press the **Melting Curves** tab. Details about the tested pathogens and controls are shown on the left, and the melting curves are shown in the center.

NOTE

The **Melting Curves** tab is only available for assays implementing melting analysis.

If User Access Control is enabled (refer to section 6.6 User management), this screen is only available for selected operators.

Press the **Pathogens** tab on the left side to display the tested pathogens. Press the circle next to the pathogen name to select which pathogen melting curves are shown. It is possible to select single, multiple or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the melting curve associated with this pathogen. Unselected pathogens will be listed in gray.

The melting temperature is shown below each pathogen name.

Press the **Controls** tab on the left side to view the controls and select which controls are shown in the melting plot. Press the circle next to the control name to select or deselect it.

Controls that passed the analysis are shown in green and are labeled **Passed Controls**, while those that failed are shown in red and are labeled **Failed Controls**.

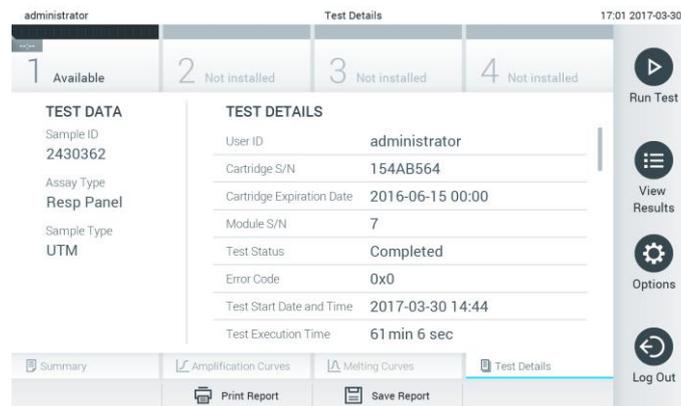
The range of the X-axis and Y-axis can be adjusted using the gray pickers on each axis. Press and hold a picker  and then move it to the desired location on the axis. Move a picker to the axis origin to return to the default values.

5.4.3 Viewing test details

Press  **Test Details** to review the results in more detail. Scroll down to see the complete report.

The following test details are shown in the center of the screen:

- User ID
- Cartridge serial number
- Cartridge expiration date
- Analytical Module serial number
- Test status (completed, failed, canceled by user)
- Error code
- Test start date and time
- Test execution time
- Assay name
- Test Result for every analyte: Positive, Negative or Failed
- List of analytes tested in the assay, with C_T and endpoint fluorescence
- List of controls, with C_T and endpoint fluorescence



Example screen showing Test Data on the left panel and Test Details in the main panel.

5.4.4 Browse results from previous tests

To view results from previous tests that are stored in the results repository, press **View Results** from the **Main Menu** bar.

Sample ID	Assay	Operator ID	Mod	Date/Time	Result
2225768	Resp Panel	labuser	1	2017-03-30 17:40	pos
2110432	Resp Panel	labuser	1	2017-03-30 17:36	pos
2230367	Resp Panel	labuser	1	2017-03-30 17:33	pos
2435366	Resp Panel	labuser	1	2017-03-30 17:31	pos
2451345	Resp Panel	labuser	1	2017-03-30 17:29	pos
2430363	Resp Panel	labuser	1	2017-03-30 17:15	pos

Example of View Results list.

The following information is available for every executed test:

- Sample ID
- Assay name
- Operator ID
- Analytical Module on which the test was executed
- Date and time when the test was finished
- Outcome of the test

NOTE

When User Access Control is enabled (refer to section 6.6 User management), the data for which the user has no access rights will be hidden with asterisks.

Select one or more test results by pressing the circle to left of the sample ID. A checkmark will appear next to selected results. Unselect test results by pressing this checkmark. The entire list of results can be selected by pressing the button in the top row.

Sample ID	Assay	Operator ID	Mod	Date/Time	Result
2225768	Resp Panel	labuser	1	2017-03-30 17:40	pos
2110432	Resp Panel	labuser	1	2017-03-30 17:36	pos
2230367	Resp Panel	labuser	1	2017-03-30 17:33	pos
2435366	Resp Panel	labuser	1	2017-03-30 17:31	pos
2451345	Resp Panel	labuser	1	2017-03-30 17:29	pos
2430363	Resp Panel	labuser	1	2017-03-30 17:15	pos

Example of selecting test results in the View Results list.

Press anywhere in the test row to view the result for a particular test.

Press a column headline (e.g., Sample ID) to sort the list in ascending or descending order according to that parameter. The list can be sorted according to only one column at a time.

The **Result** column shows the outcome of each test:

Name	Button	Description
Positive	 pos	At least one pathogen is positive.
Negative	 neg	No analytes were detected.
Failed	 fail	The test failed, either because an error occurred or the test was cancelled by the user.
Successful	 suc	The test is either positive or negative, but the user does not have the access rights to view the test results.

Press **Print Report** to print the report(s) for the selected result(s).

Press **Save Report** to save the report(s) for the selected result(s) in PDF format to an external USB storage device.

Select the report type: List of Tests or Test Reports.

Press the **Search** button to search the test results by Sample ID, Assay and Operator ID. Enter the search string using the virtual keyboard, and press **Enter** to start the search. Only the records containing the search text will be displayed in the search results.

If the results list has been filtered, the search will only apply to the filtered list.

Press and hold a column headline to apply a filter based on that parameter. For some parameters, such as Sample ID, the virtual keyboard will appear so the search string for the filter can be entered.

For other parameters, such as Assay, a dialog will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

The  symbol to the left of a column headline indicates that the column's filter is active.

A filter can be removed by pressing the **Remove Filter** button in the submenu bar.

5.4.5 Exporting results to a USB storage device

From any tab of the **Test Results** screen, select **Save Report** to export and save a copy of the test results in PDF format to a USB storage device. The USB port is located on the front of the instrument.

5.4.6 Printing results

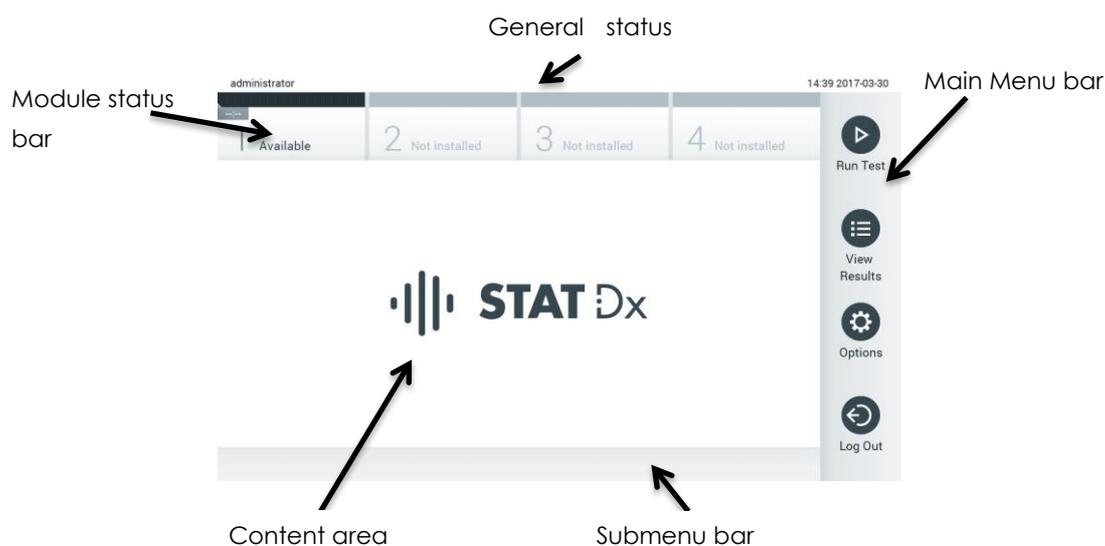
Select **Print Report** to send a copy of the test results to the system printer.

6 System reference

This chapter provides a description of all features and options available in the DiagCORE Analyzer that enable customization of the DiagCORE Analyzer settings.

6.1 Main screen

In the **Main** screen, it is possible to view the status of the Analytical Modules and navigate to different sections (Log In, Run Test, View Results, Options, Log Out) of the user interface.



Main screen of the DiagCORE Analyzer touchscreen.

The **Main** screen includes the following elements:

- General status bar
- Module status bar
- Main Menu bar
- Content area
- Tab Menu bar (optionally shown, depends on screen)
- Submenu bar and Instructions bar (optionally shown, depends on screen)

6.1.1 General status bar

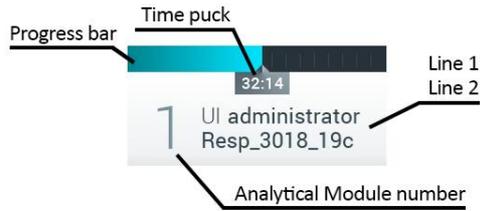
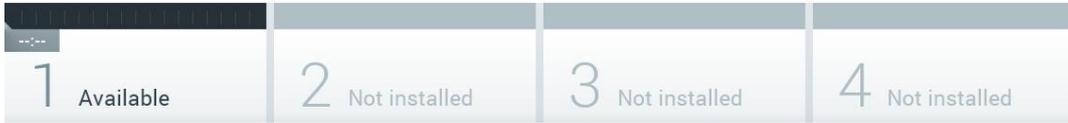
The **General** status bar provides information about the status of the system. The User ID of the logged-in user appears on the left side. The title of the screen appears in the middle, and the system date and time appear on the right.



General status bar.

6.1.2 Module status bar

The **Module** status bar displays the status of each Analytical Module (1–4) available in the system in corresponding status boxes. The boxes display “Not Installed” if no Analytical Module is available for that position.



Module status bar.

Click on the box corresponding to a particular Analytical Module to access more detailed information.

The following module states may be displayed in a status box of the **Module** status bar:

State	Description
Not installed	No Analytical Module is installed at that position.
Calibration pending	A calibration action is needed.
Maintenance pending	A maintenance action is pending.
Excluded	The Analytical Module has been excluded by the user via user settings.
Error	The Analytical Module reported a serious error. The Analytical Module is out of order.
Initializing	The Analytical Module is starting up and is performing the self-test.
Available	The Analytical Module is available for a new test. There is no test running in this Analytical Module, no cartridge is inserted and the lid of the cartridge entrance port is closed.
Test running	User administrator is currently running the Resp_3018_19c test on Analytical Module 1. There are 32 minutes and 14 seconds remaining to complete the test.



State	Description
<p>Test completed</p> 	<p>User administrator has run the Respiratory Panel test on Analytical Module 1.</p> <p>The progress bar in the box will show the test status:</p> <p>TEST COMPLETED: the test was completed successfully.</p> <p>TEST FAILED: the test was completed, but an error occurred.</p> <p>TEST CANCELLED: the user canceled the test.</p> <p>Once the cartridge has been removed and the lid of the cartridge entrance port has closed, the Analytical Module will be available again.</p>
Eject cartridge	<p>The Analytical Module contains a cartridge and the lid of the cartridge entrance port is closed, but no test is currently running. This can occur in the following situations:</p> <p>The cartridge was not removed after an ejection due to a canceled test.</p> <p>The system was powered off with a cartridge inside the Analytical Module.</p>

6.1.3 Main Menu bar

The following options are available to the user through the **Main Menu** bar:

Name	Button	Description
Run Test		Starts the run test sequence (see section 5.3 Procedure to run a test). The DiagCORE Application Software automatically selects an Analytical Module from the ones available and starts the test preparation sequence.
View Results		Opens the View Results screen (see section 5.4 Viewing results).
Options		Displays the Options submenu (see section 6.5 Options menu).
Log Out		Logs the user out (only active when User Access Control is enabled).

6.1.4 Content area

The information displayed in the main content area varies according to the state of the user interface. Results, summaries, configurations and settings are displayed in this area upon entering different modes and selecting items from the menus described below.

Depending on the content, further options may be available through the **Tab menu** bar and **Options** menu.



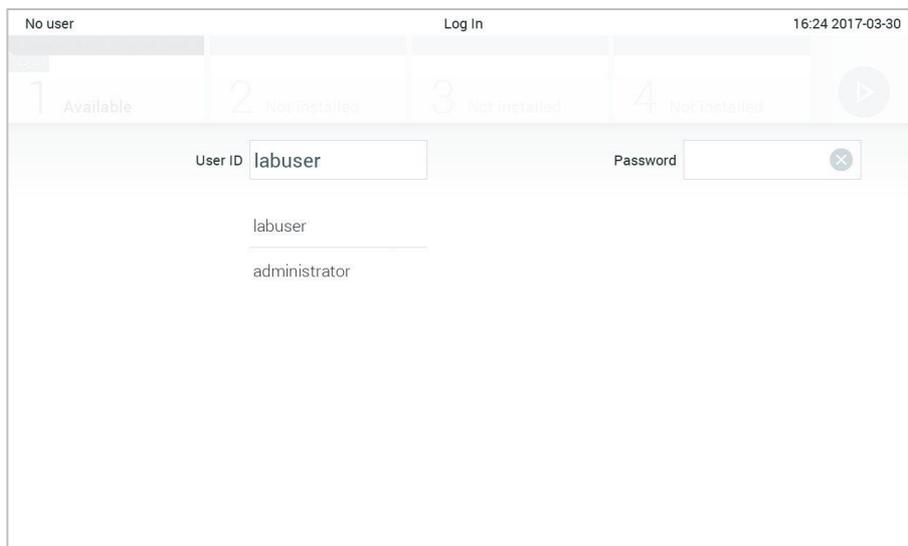
The Options submenu is accessed by pressing the Options button.

6.2 Login screen

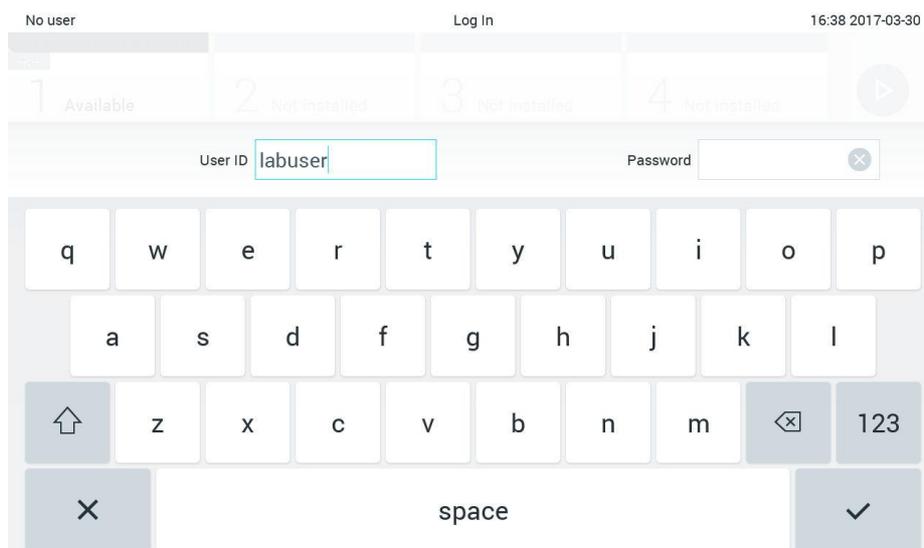
When User Access Control is enabled (refer to section 6.6 User management), users must identify themselves by logging in to access the DiagCORE Analyzer functions.

The content area of the login screen includes a text box for entering the User ID. If the option "Show previous user logins" is selected, a list of the previous five users that logged in successfully will also be displayed.

Enter the user name either by clicking on one of the names available in the list or by clicking on the **User ID** text box and entering the name using the virtual keyboard. Once the user name is entered, confirm by pressing the check mark on the virtual keyboard.



Login screen.



Virtual keyboard of touchscreen.

If the option "Require password" is selected (refer to section 6.6 User management), a password text box and the virtual keyboard for entering the password will be shown. If no password is required, the password text box will be grayed out.

If a user forgets his or her password, the system administrator can reset it.

For security reasons, if a password is entered incorrectly three times, the system will lock for one minute before the user can try to log in again.

6.3 Logging out

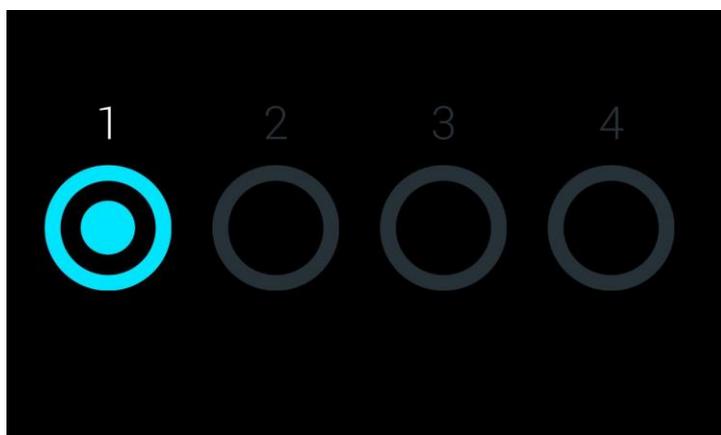
When User Access Control is enabled (refer to section 6.6 User management), users can log out at any time using the **Log Out** option in the **Main Menu**. See section 6.1.3 Main Menu bar for more information.

Users will be automatically logged out when the time of the automatic log-off expires. This time can be configured in the **General settings** of the **Options** menu (see section 6.8.2 General settings).

6.4 Screensaver

The DiagCORE screensaver is shown after there has been no user interaction for a pre-defined period of time. This time can be configured in the **Options** menu (see section 6.5 Options menu).

The screen saver shows the availability of Analytical Modules and the remaining test after test completion.



Screensaver showing one available Analytical Module.

6.5 Options menu

The **Options** menu is accessible from the **Main Menu** Bar. The menu contains the elements listed below. Options that are not available will be grayed out.

Name	Button	Description
Assay Management		Available for users with rights to manage assays.
User Management		Available for users with rights to manage users and user profiles.
System Configuration		Available for users with the rights to configure the system.
Change Password		Available if user access control is enabled.

6.6 User management

The DiagCORE Application Software is flexible in order to support different use scenarios. Concerning the management of users and rights, the following modes are available:

- “Single User” mode: User Access Control is disabled and no control of the users that log in to the DiagCORE Analyzer is performed. All DiagCORE Analyzer functions and features will be available without any restrictions to all users.
- “Multi-User” mode: User Access Control is enabled and users must log in before performing any action on the DiagCORE Analyzer. The actions they are allowed to perform are limited and defined according to their user profiles.

NOTE The user management option is available only to users with “Administrator” or “Laboratory Supervisor” profiles.

NOTE User Access Control can be enabled and disabled in the **General settings** under **System Configuration** in the **Options** menu.

The user management option permits users with “Administrator” and “Laboratory Supervisor” profiles to add new users to the system, define their rights and user profiles, and to activate or inactivate users.

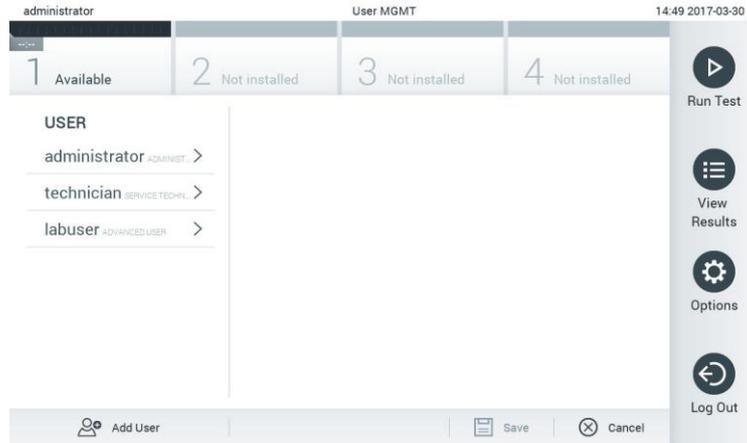
The following user profiles are available in the DiagCORE Analyzer:

User Profile	Rights	Example
Administrator	Full	Instrumentation/IT responsibility
Laboratory Supervisor	Add and delete new users Introduce and delete new assays in the assay collection Running assays and viewing results from all users	Laboratory head
Advanced User	Running assays Viewing detailed results of own user tests (amplification plots, etc.)	Microbiologist, laboratory technician
Basic User	Running assays Viewing non-detailed results of own user tests (positive/negative results)	Healthcare provider (e.g., nurse, doctor, general practitioner, etc.)

6.6.1 Accessing and managing the list of users

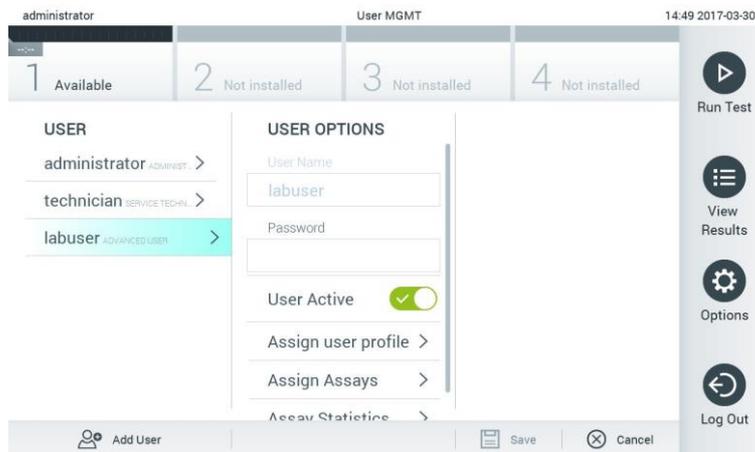
Follow the steps below to access and manage the system users:

1. Press the **Options** button and then the **User Management** button to configure users. The **User Management** screen appears in the content area of the display.



The user management menu.

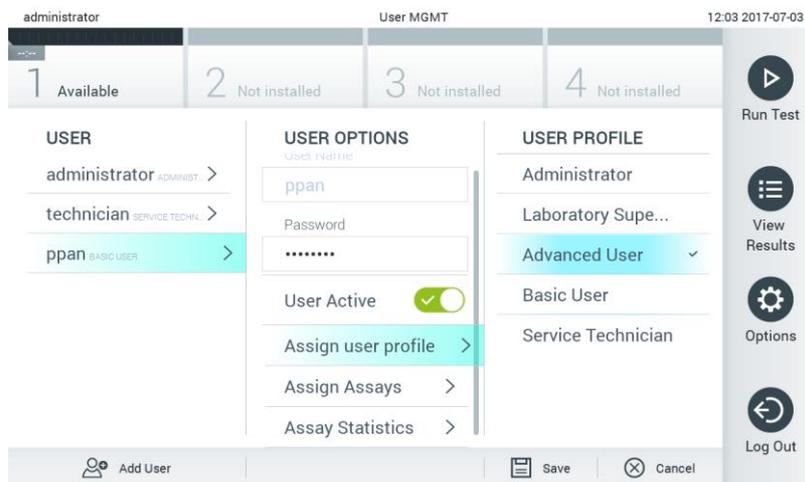
2. Select the user to manage User from the list in the left column of the content area.



Selecting and managing users.

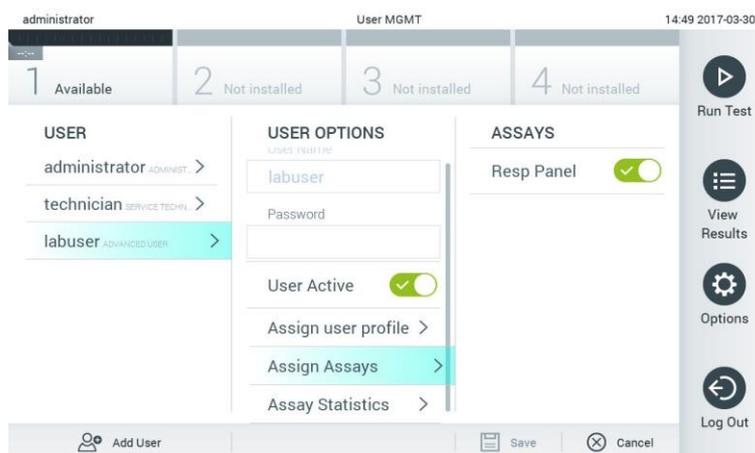
3. Select and edit the following options as needed:
 - **User Name:** allows changing the user name
 - **Password:** allows changing the password for that user
 - **User Active** (yes/no): allows changing whether the user is active or not. Inactive users are not allowed to log in or perform any action on the system

- **Assign User Profile:** allows assigning a different user profile for that user (e.g., Administrator, Laboratory Supervisor, Advanced User, Basic User). Select the appropriate user profile from the list on the right of the content area.



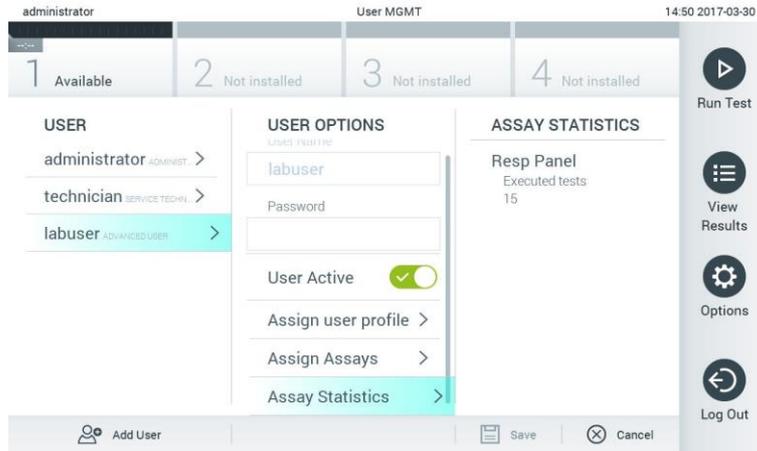
Assigning user profiles to users.

- **Assign Assays:** allows defining the assays from the assay database that the user is permitted to run. Select the assays from the list on the right of the content area.



Assigning assays to users.

- **Assay Statistics:** shows the number of times an assay was run by the selected user.



Viewing assay statistics.

4. Press **Save** and confirm to save the changes. Alternatively, press **Cancel** and confirm to discard the changes.

6.6.2 Adding users

Follow the steps below to add new users to the DiagCORE Analyzer:

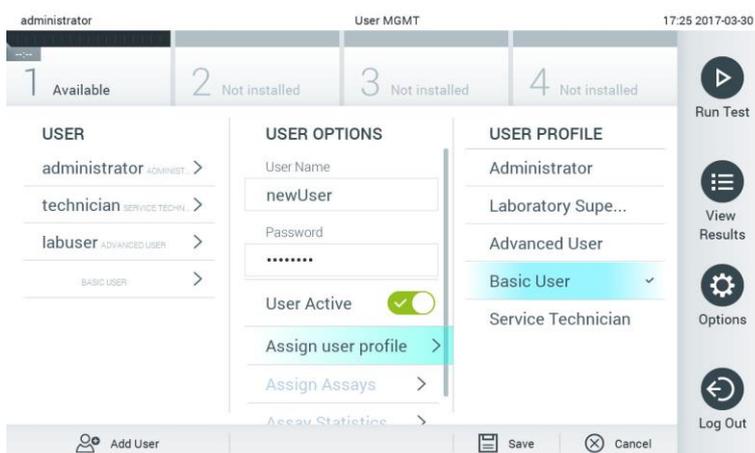
1. Press the **Options** button and then the **User Management** button to configure users. The **User Management** screen appears in the content area of the display.



Adding a new user.

2. Press **Add User** at the bottom left of the screen to add a new user to the system.
3. Use the virtual keyboard to enter the **User Name** and **Password** for the new user.

- Press **Assign User Profile** and assign the appropriate user profile the new user from the list on the right of the content area.



Assigning a user profile to a user.

- Press **Assign Assays** and select the assays that the user is allowed to run from the displayed assay list.
- Press **Save** and confirm to save and store the new information. The new user has been set up and is immediately allowed to log in to the DiagCORE Analyzer.

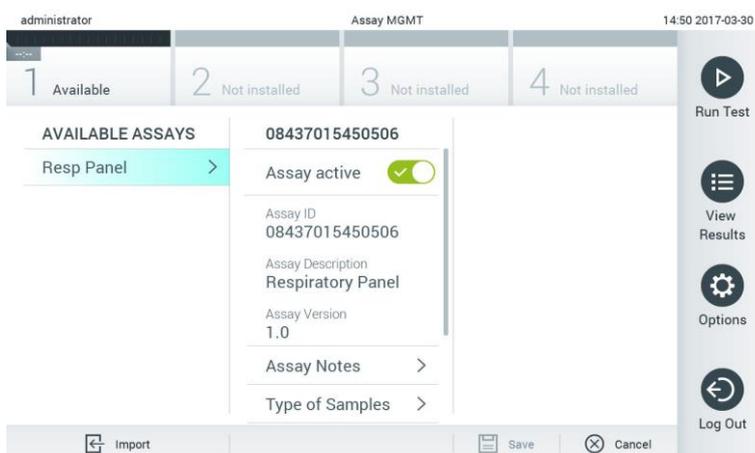
6.7 Assay management

From the **Assay Management** menu, it is possible to manage assays and access assay-related information and statistics.

NOTE The assay management option is available only to users with "Administrator" or "Laboratory Supervisor" profiles.

6.7.1 Managing available assays

- Press the **Options** button and then the **Assay Management** button to access the **Assay Management** screen. The available assays are listed in the first column of the content area.



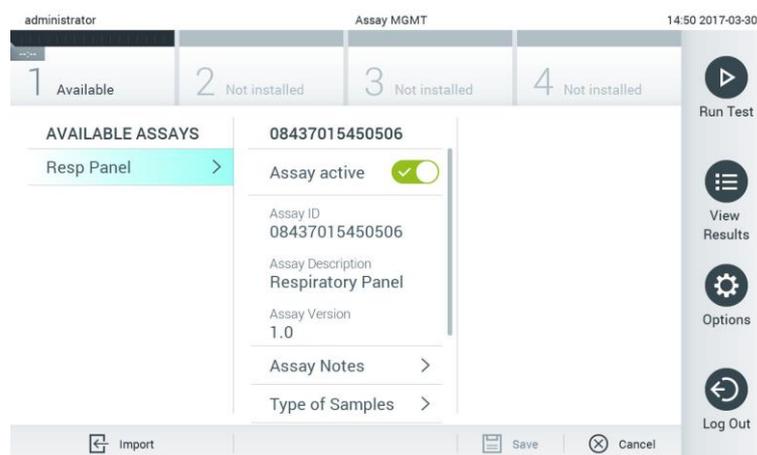
Managing available assays.

2. Press the name of the assay to manage in the left column of the content area.
3. Select one of the following options:

Option	Description
Assay Active	This button allows setting an assay to active or inactive. It is only possible to test cartridges for a particular assay if the assay is active.
Assay ID	Provides the assay identification number.
Assay Version	Provides the assay version.
Assay Notes	Provides additional information about the assay.
Type of Samples	Provides a list of the various sample types supported by the assay.
List of Analytes	Provides a list of analytes that are detected and identified by the assay.
List of Controls	Provides the lists of control analytes that are implemented in the assay.
Assay Statistics	Provides the number of tests ever run by the DiagCORE Analyzer for the selected assay, as well as the number of positive, negative, failed and aborted tests.

6.7.2 Importing new assays

1. Insert the USB storage device with assay file to import into the USB port of the DiagCORE Analyzer.
2. To import the new assay(s) to the DiagCORE Analyzer, press the **Options** button and then the **Assay Management** button. The **Assay Management** screen appears in the content area of the display.



3. Press the **Import** icon at the bottom left of the screen.
4. Select the file from the USB storage device corresponding to the assay to be imported. To be recognized by the system, the assay definition file must be contained in the root folder.
5. A dialog will appear to confirm upload of the file.

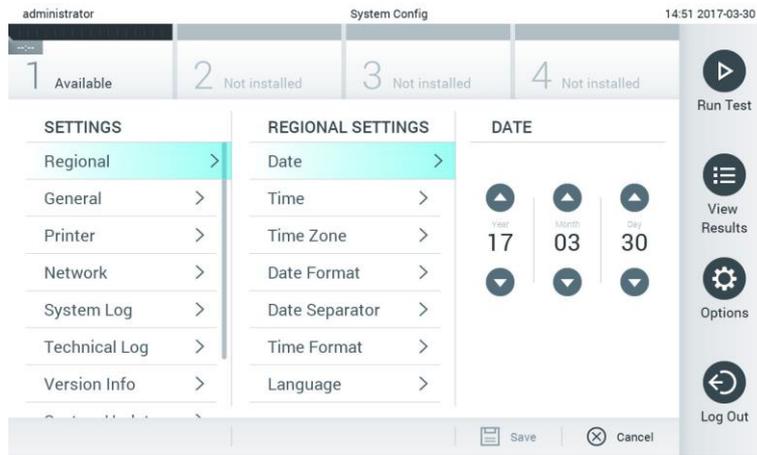
6.8 Configuring the DiagCORE Analyzer system

In the **System Configuration** menu, it is possible to manage the DiagCORE Analyzer system and define region-specific parameters.

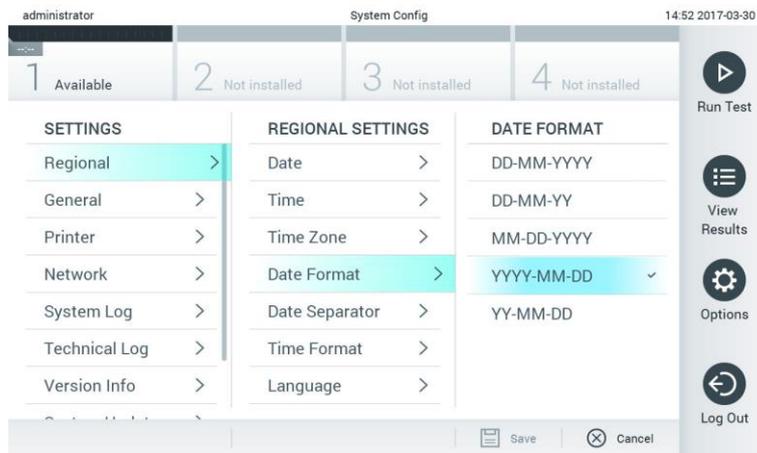
6.8.1 Regional settings

1. Press the **Options** button and then the **System Configuration** button.
2. Select **Regional** from the **Settings** list in the left column. Select and define the following settings as needed:

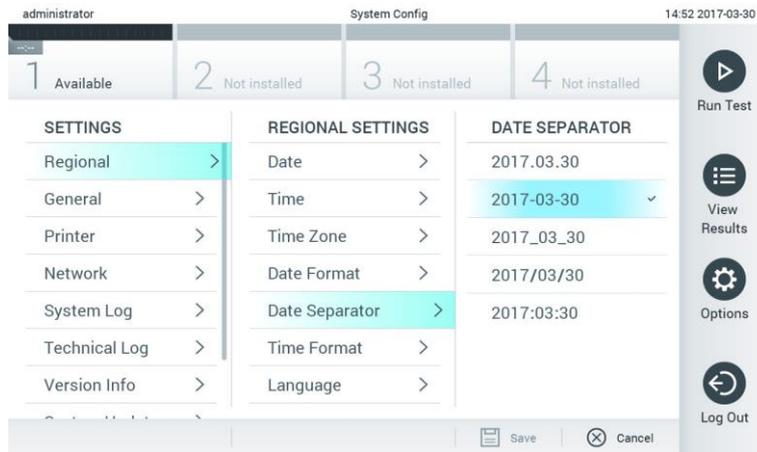
Setting	Description
Date	Defines the system date (year, month, day)
Time	Defines the system time (hours, minutes)
Date format	Defines the date format. The following options are available: DD-MM-YYYY DD-MM-YY MM-DD-YYYY YYYY-MM-DD (default) YY-MM-DD
Date separator	Defines the date separator. The following options are available: . - (default) /
Time format	Defines the time format. The following options are available: 24 hours (HH:mm:ss) (default) 12 hours (HH:mm:ss AM/PM)
Language	English (default)



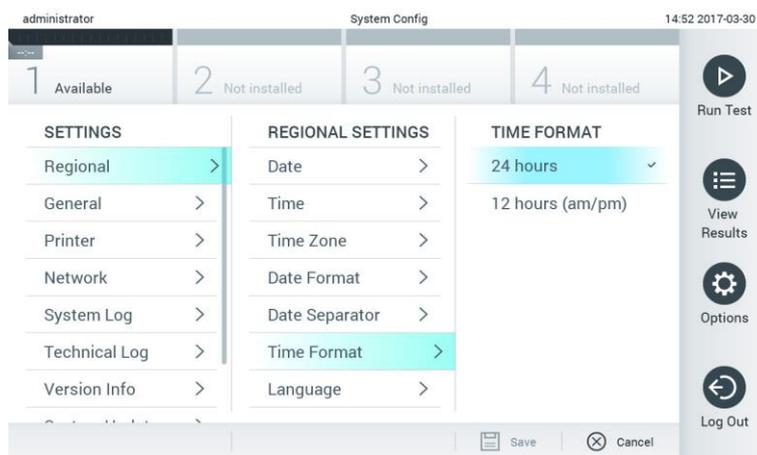
Setting the system date.



Setting the system date format.



Setting the system date separator.



Setting the system time format.

6.8.2 General settings

1. Press the **Options** button and then the **System Configuration** button.
2. Select **General** from the **Settings** list in the left column. Select and define the following options as needed:

Setting	Description
User Access Control	<p>Enables the User Access Control, which requires all users to log in to the system and limits users to only perform the actions allowed by their user profile.</p> <p>When this option is not enabled, it is not possible to distinguish between users. All features will be available as if they were run by the Administrator profile.</p> <p>This option is enabled by default.</p>
Automatic log-off time	<p>Only active if User Access Control is enabled. This setting defines the time interval after which a user is automatically logged out of the system because the DiagCORE Analyzer receives no more user input. The allowed range is from 5 minutes up to 99:59 hours. Default: 30 minutes.</p> <p>User input such as a cursor movement, cursor clicks, pressing a key on an external keyboard or a touch on the touchscreen resets the automatic log-off time.</p> <p>If a user has entered data (for example, in the Run Test screen) when the automatic log-off occurs, these data will be lost.</p>
Require password before executing assay	<p>Only active if User Access Control is enabled. With this field activated, all users will be required to enter a password before executing an assay, after pressing the confirm button.</p>

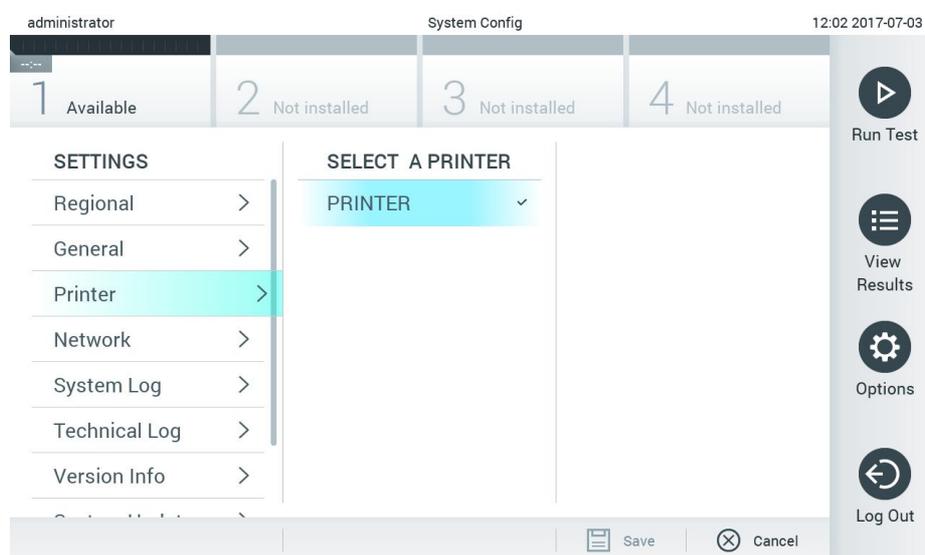
Setting	Description
Use patient ID	With Use Patient ID activated, the DiagCORE Application Software will provide the option for users to enter a Patient ID or scan a Patient ID when preparing to run a test (see section 5.3 Procedure to run a test).
Prefer patient ID barcode	Determines if users will be prompted to scan the Patient ID using the barcode reader first. Default: Disabled.
Patient ID mandatory	Only active if Use Patient ID is enabled. When activated, users will be required to enter a patient ID before executing an assay. When not activated, users can leave the patient ID data field empty. Default: Disabled.
Sample ID mandatory	When activated, users will be required to enter a Sample ID before executing an assay. When not activated, users can leave the Sample ID data field empty, and a unique Sample ID will be automatically generated by the DiagCORE Analyzer. Default: Disabled.
Prefer sample ID barcode	Determines if users are prompted to scan the Sample ID using the barcode reader first. Default: Disabled.
Exclude modules	Allows the possibility to exclude specified Analytical Modules from running tests. This may be useful in the event that a module is suspected of failure. Default: Disabled.
Number of results per page	This setting defines the number of results shown per page in the View Results list screen.
Show previously logged-in user IDs	Only active if User Access Control is enabled. When this setting is enabled, the list of previously logged-in users will be displayed on the login screen. Default: Enabled.
Require password to log in	Only active if User Access Control is enabled. When this setting is enabled, all users must enter their password to log in. When disabled, only the User ID will be required to log in. Default: Enabled.

Setting	Description
Restore factory default	Enables resetting the system back to all factory default settings.

6.8.3 Printer settings

The **Printer settings** option enables selection of the system printer. The DiagCORE Analyzer allows use of networked printers or printers connected to the Operational Module via the USB ports on the back of the instrument.

1. Press the **Options** button and then the **System Configuration** button.
2. Select **Printer** from the settings list in the left column.
3. Select a printer from the list of available printers.



Selecting a system printer.

6.8.4 Network settings

The **Network** option enables connecting the DiagCORE Analyzer to a network, accessing networked printers, and provides connectivity to the HIS/LIS (available in future software releases). Contact the network administrator for details on how to configure the following fields.

Follow these steps to define the network settings:

1. Press the **Options** button and then the **System Configuration** button.
2. Select **Network** from the settings list in the left column.
3. Select and define the options below according to instructions from the network administrator:

Option	Description
Enable IPv6	Enables the use of the IP v6 protocol. The submenu IPv6 Settings is only active if "Enable IPv6" is enabled.
Obtain IPv6 address automatically	Allows the unit to acquire the IPv6 address from the network using DHCP.
IPv6 Address	Defines the manually configured IPv6 address of the Operational Module. This option is only active if "Obtain IPv6 address automatically" is disabled.
Subnet Prefix Length	Defines the IPv6 subnet prefix length. This option is only active if "Obtain IPv6 address automatically" is disabled.
Enable IPv4	Enables the use of the IP v4 protocol. The submenu IPv4 Settings is only active if "Enable IPv4" is enabled.
Obtain IPv4 address automatically	Allows the unit to acquire the IPv4 address from the network using DHCP.
IPv4 Address	Defines the manually configured IPv4 address of the Operational Module. This option is only active if "Obtain IPv4 address automatically" is disabled.
Subnet Mask	Defines the IPv4 subnet prefix length. This option is only active if "Obtain IPv4 address automatically" is disabled.
Default Gateway	Defines the IPv6 or IPv4 default gateway, depending on which is enabled. This option is only active if either "Obtain IPv6 address automatically" or "Obtain IPv4 address automatically" is disabled.
Obtain DNS address automatically	Allows the unit to acquire the DNS configuration from the network using DHCP.
Preferred DNS Server	Defines the primary DNS server. This option is only active if "Obtain DNS address automatically" is disabled.
Alternate DNS Server	Defines the secondary DNS server. This option is only active if "Obtain DNS address automatically" is disabled.



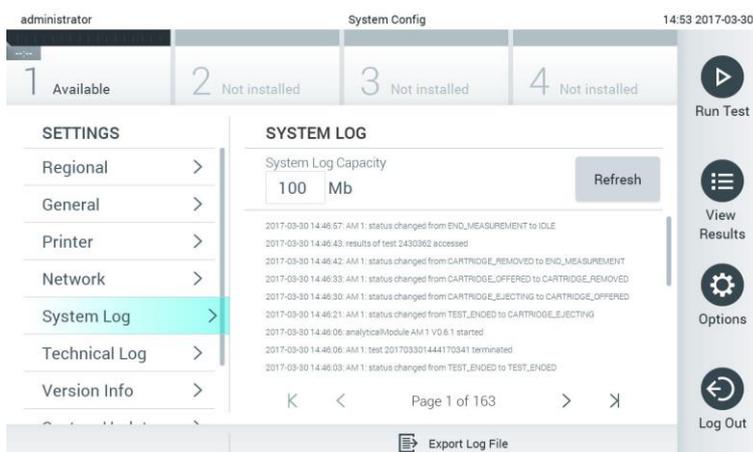
Configuring the system network settings.

6.8.5 HIS/LIS settings

The HIS/LIS functionality is not available in the current version of the software. It will be supported in future releases.

6.8.6 System log

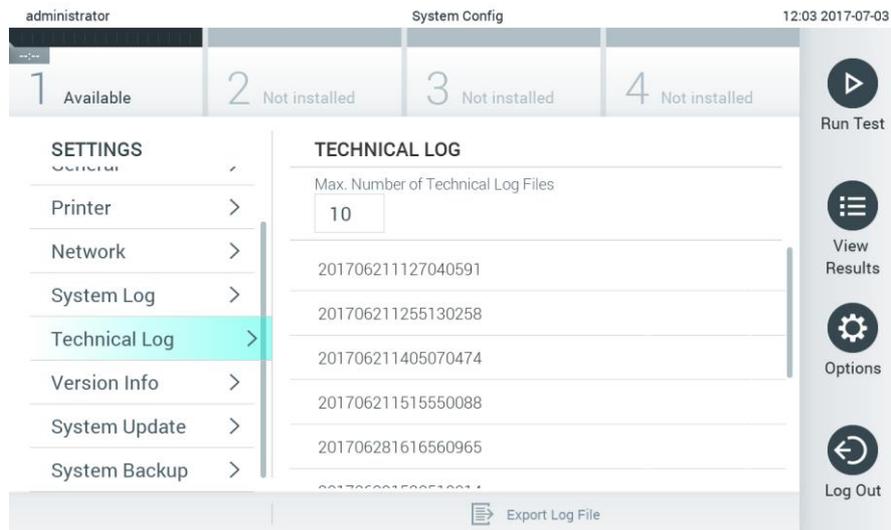
The system log records general information about the use of the Operational and Analytical Modules, such as adding or removing users, adding or removing assays, logins, logouts, starts of tests, etc. Press the **Options** button and then the **System Configuration** button followed by **System Log** to access the system log information. The System Log Capacity is shown in the center of the screen followed by the log content. Press **Export Log File** to export the content.



Accessing the system log.

6.8.7 Technical log

The technical log records detailed information about the execution of tests on the Analytical Module(s). This information is used by Technical Support for troubleshooting. Press the **Options** button and then the **System Configuration** button followed by **Technical Log** to access the technical log information. The number of files available in the technical log is configurable. Each log file is identified with date and time of creation. Press **Export Log File** to export the content. Technical logs may be requested by Technical Support.



Accessing the technical log.

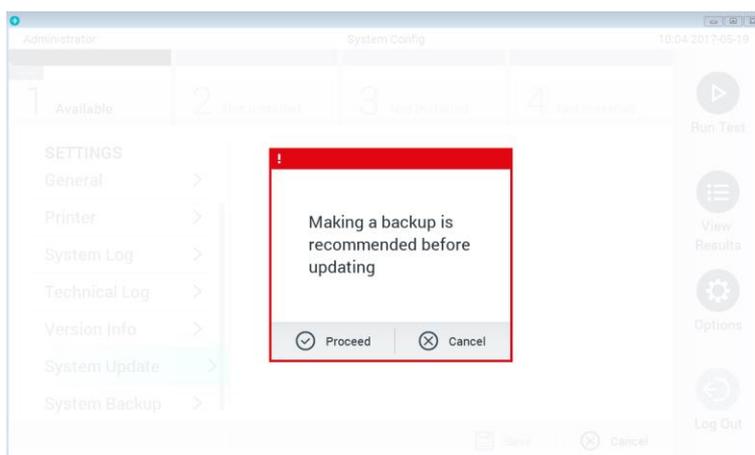
6.8.8 Version information

Press the **Options** button and then the **System Configuration** button followed by **Version Info** to view the DiagCORE Application Software version, the serial numbers and the firmware versions for the installed Analytical Modules.

6.8.9 System update

To update the DiagCORE Analyzer system, press the **Options** button and then the **System Configuration** button followed by **System Update**. Select the appropriate .dup file stored on a USB

storage device to update the system to a newer version. A message will appear recommending to perform a system backup first (refer to 6.8.10 System backup).

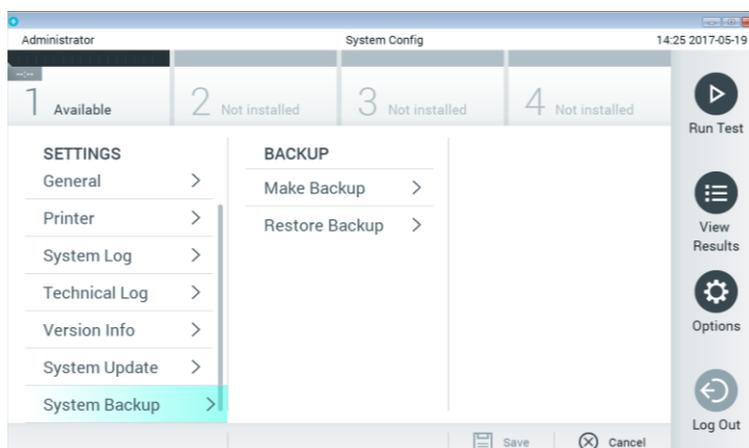


Performing a system update.

After the update, the user may be requested to shut down the DiagCORE Analyzer and start it again.

6.8.10 System backup

To back up the DiagCORE Analyzer system, press the **Options** button and then the **System Configuration** button followed by **System Backup**. Insert a USB storage device into the front USB port.



Performing a system backup.

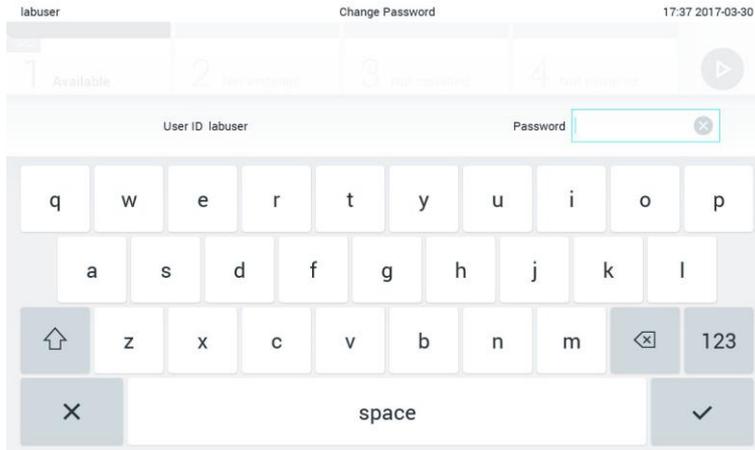
Press the **Make Backup** button. A file with the extension .dbk will be generated with a default file name.

To restore a backup, press the **Restore Backup** button and select the appropriate backup file with a .dbk extension from the connected USB storage device. A message will appear recommending to make a backup before restoring.

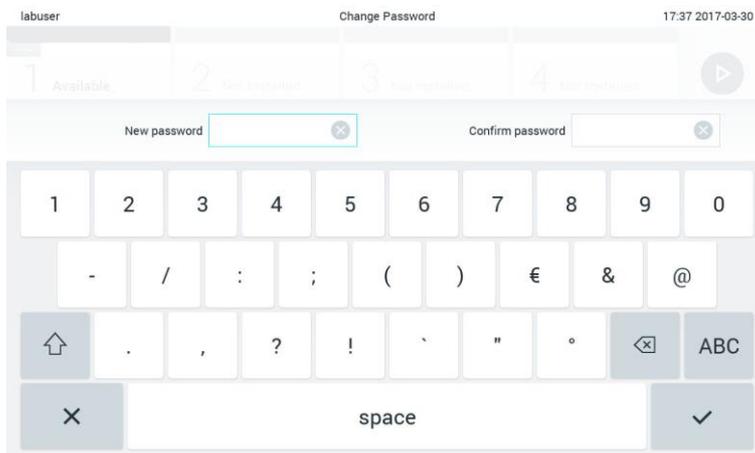
6.9 Change passwords

To change a user password, press the **Options** button and then **Change Password**. First enter the current password in the text field, and then enter the new password into the **New Password** field. Type the new password again in the **Confirm Password** field.

After three failed attempts to enter a password, the password entry field will be deactivated for one minute, and a dialog will appear with the message “Password failed, please wait 1 minute to try it again”.



First step of the password change process.



Entering and confirming the new password.

6.10 DiagCORE Analyzer status

The status of the Operational and Analytical Modules is indicated by the color of the status indicators (LEDs) at the front of the DiagCORE Analyzer.

The Operational Module can display any of the following status colors:

Status light	Description
Off	DiagCORE Analyzer is off
Blue	DiagCORE Analyzer is in standby mode
Green	DiagCORE Analyzer is running

The Analytical Module can display any of the following status colors:

Status light	Description
Off	DiagCORE Analyzer is off
Blue	DiagCORE Analyzer is in standby mode
Green (blinking)	DiagCORE Analyzer is initializing
Green	Analytical module is running

6.11 Shutting down the instrument

The DiagCORE Analyzer is designed to operate continuously. If the unit will not be used for a short time (less than a day), we recommend placing the DiagCORE Analyzer in standby mode by pressing the **ON/OFF button** on the front of the instrument. To shut down the DiagCORE Analyzer for a longer time period, turn off the main switch on the back of the instrument.

If someone attempts to put the DiagCORE Analyzer in stand-by mode while the Analytical Module is running a test, a dialog will appear indicating that shutdown is currently not possible. Allow the instrument to finish running the test(s) and try shutting it down afterwards.

7 Maintenance

This chapter describes the maintenance tasks required for the DiagCORE Analyzer.

7.1 Maintenance tasks

The table below provides a list of maintenance tasks to be performed on the DiagCORE Analyzer.

Description	Frequency
Cleaning or Decontaminating the DiagCORE Analyzer surface	To be performed in case liquids, chemicals or biological specimens (potentially infectious) are spilled on the DiagCORE Analyzer surface.
Exchange of air filter	To be performed annually.

7.2 Cleaning the DiagCORE Analyzer surface

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Wear protective glasses, a lab coat and gloves when cleaning the instrument to avoid biological and chemical hazards.

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Disconnect the DiagCORE Analyzer from the power outlet before cleaning.

⚠ CAUTION

Risk of damage to the DiagCORE Analyzer

Avoid spilling chemicals or other liquids into the DiagCORE Analyzer. Damage caused by liquid spillage will void the warranty.

⚠ CAUTION

Risk of damage to the DiagCORE Analyzer

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the DiagCORE Analyzer.

Use the following to clean the DiagCORE Analyzer surface:

- Mild detergent
- Paper towels
- Distilled water

Follow the steps below to clean the DiagCORE Analyzer surface:

1. Wear laboratory gloves, coat and protective glasses.

2. Wet a paper towel in mild detergent and wipe down the DiagCORE Analyzer surface, as well as the surrounding workbench area. Take care not to wet the touchscreen. To clean the touchscreen, use the screen suede provided with the DiagCORE Analyzer.
3. Repeat step 2 three times with fresh paper towels.
4. Wet a paper towel in distilled water and wipe down the DiagCORE Analyzer surface to rinse away detergent remains. Repeat two times.
5. Dry the DiagCORE Analyzer surface with a fresh paper towel.

7.3 Decontaminating the DiagCORE Analyzer surface

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Wear protective glasses, a lab coat and gloves when cleaning the instrument to avoid biological and chemical hazards.

Bleach is irritating to eyes and skin and may release dangerous gases (chlorine). Wear adequate personal protection equipment.

⚠ WARNING

Risk of personal injury and material damage

⚠ CAUTION

Disconnect the DiagCORE Analyzer from the power outlet before cleaning.

⚠ CAUTION

Risk of damage to the DiagCORE Analyzer

Avoid spilling chemicals or other liquids into the DiagCORE Analyzer. Damage caused by liquid spillage will void the warranty.

⚠ CAUTION

Risk of damage to the DiagCORE Analyzer

Avoid spilling liquids on or wetting the touchscreen. To clean the touchscreen, use the screen suede provided with the DiagCORE Analyzer.

Use the following to decontaminate the DiagCORE Analyzer surface:

- 10% bleach solution
- Paper towels
- Distilled water

Follow the steps below to decontaminate the DiagCORE Analyzer surface:

1. Wear laboratory gloves, coat and protective glasses.
2. Wet a paper towel in the bleach solution and wipe down the DiagCORE Analyzer surface, as well as the surrounding workbench area. Take care not to wet the touchscreen. Wait at least for three minutes to allow the bleach solution to react with the contaminants.
3. Change into a new pair of gloves.
4. Repeat steps 2-3 two additional times with fresh paper towels.

5. Wet a paper towel in distilled water and wipe down the DiagCORE Analyzer surface to rinse away any bleach solution. Repeat twice.
6. Dry the DiagCORE Analyzer surface with a fresh paper towel.

7.4 Replacing the air filter

The air filter must be exchanged every year to ensure the appropriate airflow rate inside the unit.

The air filter is located below the instrument and can be accessed by the user at the front of the instrument.

Only air filters from STAT-Dx Life, S.L. must be used as replacement.

Follow these steps to exchange the air filter:

1. Set the DiagCORE Analyzer in standby mode by pressing the front **ON/OFF button**.
2. Place a hand below the air filter drawer at the front of the DiagCORE Analyzer and use fingers to push slightly up.
3. Pull the air filter back until the filter drawer is completely removed. Dispose of it.
4. Remove the new air filter drawer from its protective bag.
5. Insert the new air filter drawer into the DiagCORE Analyzer. The unit is now ready for use.

CAUTION

Risk of damage to the DiagCORE Analyzer

Only use original parts from STAT-Dx Life, S.L. Use of non-authorized parts may result in damage to the unit and will void the warranty.

7.5 DiagCORE Analyzer repair

The DiagCORE Analyzer can only be repaired by field service technicians authorized by STAT-Dx Life, S.L. If the DiagCORE Analyzer is not working as expected, contact Technical Support using the contact information at the beginning of this manual.

WARNING

Risk of personal injury and material damage

CAUTION

Do not open the DiagCORE Analyzer housing. Do not attempt to repair or modify the DiagCORE Analyzer.

Opening the housing or modifying the DiagCORE Analyzer inappropriately may result in user injury and DiagCORE Analyzer damage and will void the warranty.

8 Troubleshooting

This section provides information on some issues that may occur with the DiagCORE Analyzer, along with possible causes and solutions. The information is specific to the instrument. For troubleshooting relevant to a DiagCORE cartridge, see the instructions for use of the respective cartridge.

If further assistance is required, contact Technical Support using the contact information below.

- Website: <http://support.qiagen.com>

When contacting Technical Support about an error with the DiagCORE Analyzer, note the steps leading up to the error and any information appearing in any dialog boxes. This will help us solve the problem.

When calling Technical Support about errors, please have the following information ready:

- Instrument serial number, type and version
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Photo of error, if possible
- Copy of support package

Problem	Possible Cause	Solution
The DiagCORE Analyzer does not start.	<p>The DiagCORE Analyzer is not connected to the power outlet.</p> <p>The power switch at the back of the DiagCORE Analyzer is not turned on.</p> <p>The DiagCORE Analyzer is in standby mode.</p>	<p>Check that the DiagCORE Analyzer is connected to the power mains.</p> <p>Turn on the power switch at the back of the DiagCORE Analyzer.</p> <p>Press the ON/OFF button to take the DiagCORE Analyzer out of standby mode.</p>
Analytical Module not detected.	Analytical/Operational Module bridge is not properly connected.	Check that the bridge between the Operational Module and the Analytical Module is properly connected.
The Analytical Module status indicator is red.	Hardware failure.	Call Technical Support.

Problem	Possible Cause	Solution
The touchscreen does not respond.	<p>The DiagCORE Analyzer is in standby mode (status indicator is blue).</p> <p>Hardware failure.</p>	<p>Press the ON/OFF button on the Operational Module.</p> <p>Call Technical Support.</p>
Barcode reader does not scan.	<p>Sample ID barcode feature is not enabled.</p> <p>Barcode reader has a hardware or software problem.</p>	<p>Contact a laboratory supervisor or instrument administrator to configure the barcode feature in the DiagCORE Analyzer.</p> <p>Call Technical Support.</p>
The cartridge is stuck inside the DiagCORE Analyzer.	Module mechanical failure.	Call Technical Support.
Lid of the cartridge entrance port does not open.	Module mechanical failure.	Call Technical Support.
The Run Test button is not active.	<p>A cartridge is still inside the DiagCORE Analyzer and must be ejected before the DiagCORE Analyzer will allow a new test execution.</p> <p>The module is not available.</p>	<p>The status box of the module in the Module status bar should show the text "Eject cartridge". Press the status box of the module and then press the Eject.</p> <p>Check that the bridge between the Operational Module and the Analytical module is properly connected.</p>
Assay does not run.	<p>The user has no rights to run the test.</p> <p>The assay is not installed on the DiagCORE Analyzer.</p>	<p>Contact a laboratory supervisor or instrument administrator.</p> <p>The assay needs to be installed. Contact a laboratory supervisor or instrument administrator.</p>

8.1 Errors and warning messages

Warning messages	Explanation	What to do
The AM in the slots has changed.	The system detects that the hardware configuration has changed. At least one of the Analytical Modules has been changed to another location.	Nothing needs to be done. The system is self-configurable after a module's location changes.
Making a backup is recommended before updating or restoring.	Data may be lost during the update process if an error occurs. A backup allows for system and data recovery.	We highly recommend making a backup of the system before a system restoration or update.
Shutdown not possible. Please stop all tests and eject cartridges.	When a test is running, the DiagCORE Analyzer cannot be shut down.	Wait until test completion, or abort the test and then shut down the system.
Calibration of <i>nnn</i> required in <i>ddd</i> days.	Calibration action needed.	Contact Technical Support.
Free disc space <i>ddd</i> reached warning or critical level.	System needs to be reviewed by Technical Support to add additional disk space.	Contact Technical Support.
The system was not shut down properly last time.	The system was not shut down following the procedure. The last test data could have been lost.	
Test result with invalid data found.	An unexpected error during last test was found.	Try to re-run the test with a new cartridge. If the problem persists or occurs frequently, contact Technical Support.
Unexpected behavior of AM <i>nnn</i> .	General system failure.	Restart the system. If the problem persists, contact Technical Support.
Update data aborted, error occurred.	Unexpected error occurred while updating the DiagCORE Analyzer.	Contact Technical Support.

Warning messages	Explanation	What to do
No backup file found!	A proper backup file .dbk was not found in the USB storage device.	Check if the file exists in the USB storage device. If the problem persists, contact Technical Support.
Assay <assay_id> not available. Code: 0x400	The assay corresponding to the cartridge has not been imported to the DiagCORE Analyzer.	Import the assay to the DiagCORE Analyzer (see section 6.7.2 Importing new assays).
Assay <assay_name> not active.	The assay is not active.	Activate the assay (see section 6.7.1 Managing available assays).
Assay <assay_name> already imported. Code: 0x0304	There is an assay with the same ID and version available in the database.	The assay is already loaded in the system. Nothing needs to be done.
Import assay failed; the assay file is invalid.	The assay file to be imported is not correct.	Download the assay file again from the STAT-Dx Life, S.L. website. Contact Technical Support if the issue persists.
Importing ADF <adf_name> failed. Code: 0x0305	The assay file to be imported is not correct.	Download the assay file again from the STAT-Dx Life, S.L. website. Contact Technical Support if the issue persists.
Login failed!	The login operation failed.	Contact the instrument administrator.
Login failed! The user is not activated.	User does not have permission to use the DiagCORE Analyzer.	Contact a laboratory supervisor or instrument administrator to activate the user (see section 6.6.1 Accessing and managing the list of users).

Warning messages	Explanation	What to do
Login failed! Wrong Password!	The entered password is incorrect.	After three failed attempts to enter the password, the user must wait one minute before trying to log in again. In case the password has been forgotten, contact the instrument administrator to set a new one.
Login failed! User identification does not exist.	User has not been added to the system.	Contact the administrator or laboratory supervisor to add the new user.
Passwords are not identical!	To set up a new password, it must be entered identically two times.	
Invalid Password! Min. length 6 characters. Max. length 15 characters. Allowed characters: 0-9, a-z A-Z, _, space.	Password does not comply with security policies.	Set a password with a minimum length of 6 characters and maximum length of 15 characters, containing only the allowed characters: 0-9, a-z A-Z, _, space.
Export failed!	An unexpected error occurred during the results export operation.	Retry the operation. If the problem persists, contact Technical Support.
USB Device not found.	USB storage device is not detected in the DiagCORE Analyzer.	Insert a USB storage device in the USB port.
Barcode reading failed.	Barcode reader malfunction.	Contact Technical Support.
Failed to scan barcode.	There is no assay loaded in the system for this barcode.	The barcode may be damaged. Use a different cartridge. Contact Technical Support if the problem persists.

Warning messages	Explanation	What to do
Test failed, Error: <error_code>.	Test failed with an error.	Retry executing the test with a new cartridge. If the problem persists, contact Technical Support and provide the error code message.
User has no right to execute assay <assay_name>. Code: 0x0402	Permission to execute the assay has not been given to the user.	Permission can be granted from the User Management screen (refer to section 6.6 User management).
Cartridge already used.	A previously used cartridge cannot be re-used.	Dispose of the used cartridge according to relevant safety and disposal regulations. Run the test using a new cartridge.
Cartridge expired.	The cartridge cannot be used because its expiration date has elapsed.	The cartridge can no longer be used. Dispose of the cartridge according to relevant safety and disposal regulations.
Different cartridge inserted.	The cartridge inserted does not match the cartridge detected by the barcode reader.	Insert the same cartridge scanned by the barcode reader.
Failed to create file.	The backup file could not be created.	The USB storage device is not working. Retry using a different USB storage device.

9 Appendices

9.1 Technical specifications

Description	Details
Power Requirements	90–264 VAC 50–60 Hz IEC 60320-1 C14 socket
Fuse	1x8A time-lag
Operating Conditions	Temperature: 15–30 °C (59–86 °F) Humidity conditions: 20–80% relative, non-condensing Altitude 0–2200 m Light up to 4000 lux
Shipping Conditions	Temperature: 0 to +38 °C (+32 to +100 °F), maximum 85% relative humidity, non-condensing
Dimensions and Weight	Operational Module: Width/Height/Depth [mm]: 234/326/517; 5 kg Analytical Module: Width/Height/Depth [mm]: 153/307/428; 16 kg
EMC Requirements	Compliant with IEC 61326 Class A The equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
Ethernet Interface	1x 10/100 –Base-T Ethernet
USB Ports	1 front and 3 rear

9.2 Disposal information

Recycling of the DiagCORE Analyzer can be provided by STAT-Dx Life upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact STAT-Dx Life for the required return form. Once the form is submitted, we will request follow-up information to schedule collection of the electronic waste or provide an individual quote.

9.3 Declaration of Conformity

Name and address of the legal manufacturer:

STAT-Dx Life, S.L.

Baldiri Reixac 4-8

08028 Barcelona, Spain

An up-to-date Declaration of Conformity can be requested from STAT-Dx Life, S.L.

9.4 Glossary

Analytical Mode (AM): The main DiagCORE Analyzer hardware module, in charge of executing tests on DiagCORE cartridges. It is controlled by the Operational Module.

Assay Definition File: An Assay Definition File is a file need in order to execute an assay on a DiagCORE analyzer. The content of the file describes what can be measured, how to measure it and how to evaluate the raw measurement results. The file should be imported in the DiagCORE Analyze before executing an assay the first time

GUI: Graphical user interface.

IFU: Instructions for use.

Operational Module (OM): The dedicated DiagCORE Analyzer hardware that provides the user interface for one to four Analytical Modules (AM).

User: A person who operates the DiagCORE Analyzer in the intended way.

9.5 Trademarks and copyright

DiagCORE® is a registered trademark of STAT-Dx Life, S.L. Windows® is a registered trademark of Microsoft Corporation.

All other trademarks are the property of their respective owners.

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9.6 Copyright, disclaimer and warranty

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TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

The DiagCORE Analyzer is equipped with an Ethernet port. The Purchaser of the DiagCORE Analyzer is solely responsible for preventing any and all computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches. Stat Diagnostica assumes no liability for computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches.

9.7 Patent statement

TO THE EXTENT PERMITTED BY LAW, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.

Purchase of the DiagCORE Analyzer, and/or associated DiagCORE cartridges, does not grant any rights under patents owned or controlled, now or later, by STAT-Dx Life except to the extent necessary to operate the DiagCORE Analyzer as specified in this DiagCORE Analyzer User Manual.

9.8 Software License Agreement

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DiagCORE®

Analyzer

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