

# User Manual

BioCheck  
***DxDATA™***

Automated Chemiluminescent  
Immunoassay Analyzing System

FOR PROFESSIONAL USE ONLY

REF DXD-0001

IVD **CE**



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## Symbols List

Symbol	Description	Symbol	Description
	In Vitro Diagnostic equipment		Catalog Number
<b>SN</b>	Serial Number		Consult Instructions for use
	Power on	0	Power off
<b>CE</b>	European Conformity		Caution
	Manufacturer		Waste of electrical and electronic equipment
	High temperature, do not touch these areas		Biological hazard

# 1 About this manual

This manual contains the necessary information for safe, proper and effective operation of the DxDATA™ Automatic Chemiluminescent Immunoassay Analyzing System (hereinafter referred to as "DxDATA™"). Please read this manual carefully before operating the DxDATA™.

## 2 About DxDATA™

This chapter includes the intended use, operating characteristics, and instrument performance of the DxDATA™.

### **2.1 Intended Use**

DxDATA™ is an automated discrete loading chemiluminescence enzyme-linked immunosorbent assay (CLIA) and magnetic particle separation analyzing system that uses indirect chemiluminescence based on a chemiluminescent substrate (APS-5) and alkaline phosphatase for qualitative or quantitative testing, including immune function, autoantibodies, tumor-associated antigens, myocardial diseases, hormones, proteins and peptides, sugars and their metabolites, liver diseases, coagulation markers and other items in human serum, plasma and whole blood samples.

## 2.2 Specifications and performance

<b>Instrument type</b>	Automated chemiluminescent immunoassay analyzing system
<b>Model</b>	DxDATA™
<b>Number of Channels</b>	8-channel parallel detection
<b>Sample material</b>	Whole blood, serum, plasma
<b>Sample volume</b>	30-150 µL
<b>Wavelength</b>	300-650nm
<b>Data storage</b>	Patient data: more than 100,000 samples (tests)
<b>QC data</b>	More than 100,000 results
<b>Size</b>	400 (W) * 610 (D) * 645 (H) mm
<b>Weight</b>	35 kg
<b>Electrical requirements</b>	110/220 VAC
<b>Rated power supply</b>	110/220V 60/50 Hz 300W
<b>Printer</b>	Built in
<b>Computer</b>	Built in
<b>Screen</b>	10 in LCD touch screen (800 x 600) pixels
<b>Operating System</b>	Microsoft Windows 10 Enterprise

## 3 Details of DxDATA™

This chapter provides an overview of the measurement principle, equipment structure, and accessories used in DxDATA™ instrument.

### **3.1 Principle of detection**

The detection principle used by DxDATA™ is Chemiluminescent Immunoassay (CLIA), and the reagents used in each test are stored in a special, individually packaged cassette sealed with aluminum foil.

The DxDATA™ detection principle is described by applying the sandwich immunoassay reaction mode. The sample is combined with an alkaline phosphatase-labeled antibody and a biotinylated antibody to form a sandwich structure. The excess streptavidin-coated magnetic particles form a complex with the biotinylated antibody, and after washing, the luminescent substrate is catalytically cleaved by an enzyme in the complex to form an unstable excited intermediate. When the particle returns to the ground state, it emits photons. The light intensity of the reaction is detected by a photomultiplier tube, and the luminescence intensity of the analyte is converted into relative light units (RLU) by the instrument operating software.



## 3.2 DxDATA™ components

This section provides description of the DxDATA™ instrument main components and their function.

### 3.2.1 Front of the Device

The necessary components for operating the DxDATA™ instrument are located on the front of the unit; see the figure below. Component names and functions are described as follows:



- **Touchscreen computer** - Displays various information about the DxDATA™ analyzer and accepts input from the user of the device.
- **Printer** - Prints results and other information.
- **Swing-up door** - Opens upwards to insert the reagent strips. The reagent strip information can be read and the experiment program can be selected automatically via the QR code auto scanning function.
- **External bar code scanner** - Linked directly to the USB port on the back of the instrument and intended to read the information contained in the QR code.

### 3.2.2 Back of the device DxDATA™




The input and output ports of the device are located on the back of the device, as shown in the figure below.



- **Main Switch** – This is the main power switch of the device. After the instrument is turned on, the computer powers up in about 1 minute.
- **Fuse: F2AL250V/F3AL250V** – Protects the internal circuitry of the instrument.
- **Voltage supply 110/220 VAC** – Provides connection to the power cable.
- **Ethernet** – Allows connection to LIS system.
- **USB** – Provide connection to the instrument`s external barcode scanner, mouse and keyboard.

### 3.2.3 Accessories

Information for the main DxDATA™ accessories is shown in the table below.

Main Accessories Description	Quantity	Remarks	Picture
Power cord	1	Standard	
Fuse: <b>F2AL250V/F3AL250V</b>	2	Alternate replacement	
Cartridge rack	2	Standard	

# 4 Storage and Operation of the Equipment

## **4.1 Environmental conditions and placement instructions**

### **4.1.1 Normal working conditions**

- 1) Altitude: no more than 2000m
- 2) Power supply voltage DxDATA™: 110/220V 60/50 Hz 300W
- 3) Ambient temperature: 10 ° C ~ 30 ° C; Relative humidity: ≤70%;
- 4) Atmospheric pressure: 85.0 kPa to 106.0 kPa;
- 5) Keep away from magnetic field interference sources, e.g., MRIs;

### **4.1.2 Placement instructions**

- 1) The instrument should be placed on a flat, stable surface.
- 2) The rear panel of the instrument requires a distance of >200 mm for the power switch access and ventilation.
- 3) Avoid placing DxDATA™ in a place where it is exposed to direct sunlight, air conditioning or other equipment.
- 4) Do not block the device vents and ensure that no paper or other objects may affect the air circulation in this area.

# 5 Software Description

This chapter describes DxDATA™ instrument software.

## 5.1 Software Overview

Software Environment:

- Device has a 10-inch touch screen built-in monitor with resolution of 800X600 pixels.
- Microsoft Windows 10 Enterprise operating system is pre-installed on the instrument.

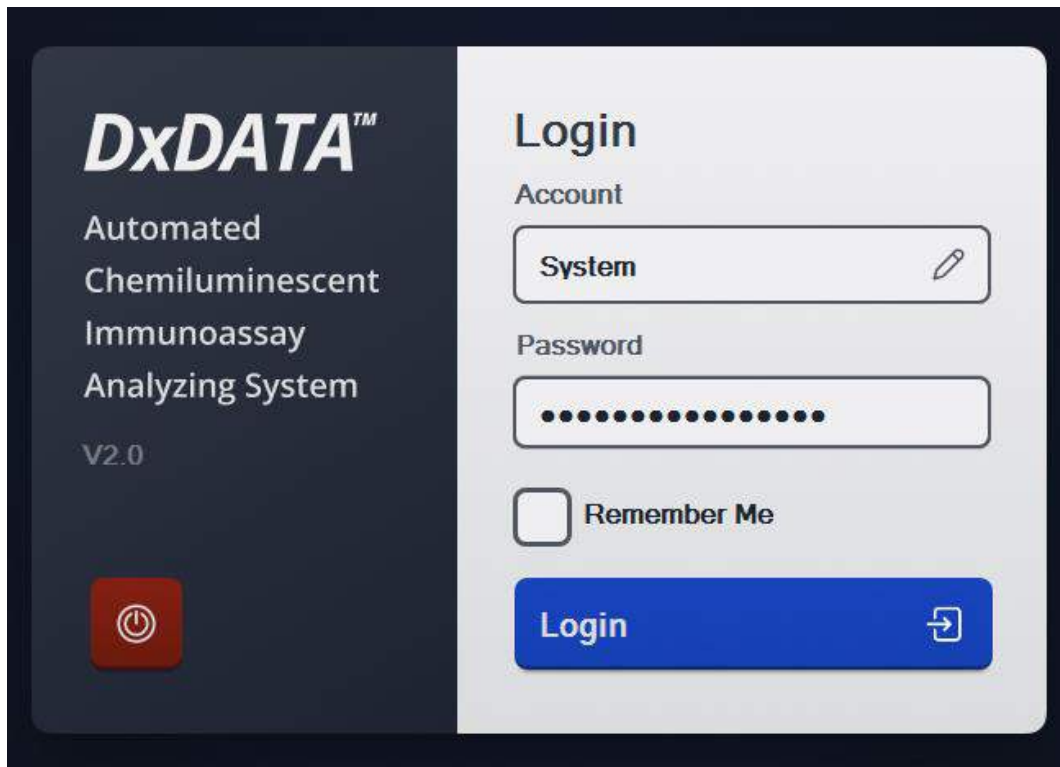
System startup

- Power on the system using the power switch on the back of the instrument.
- If the software does not automatically start, double-click the desktop shortcut **DxDAT**



## 5.2 Software Overview

In order to log in, enter the username and password. You can select an option to save the password. When the **Login** button is clicked, the system checks the username and password, then login to the system is performed if the system requirements are met.

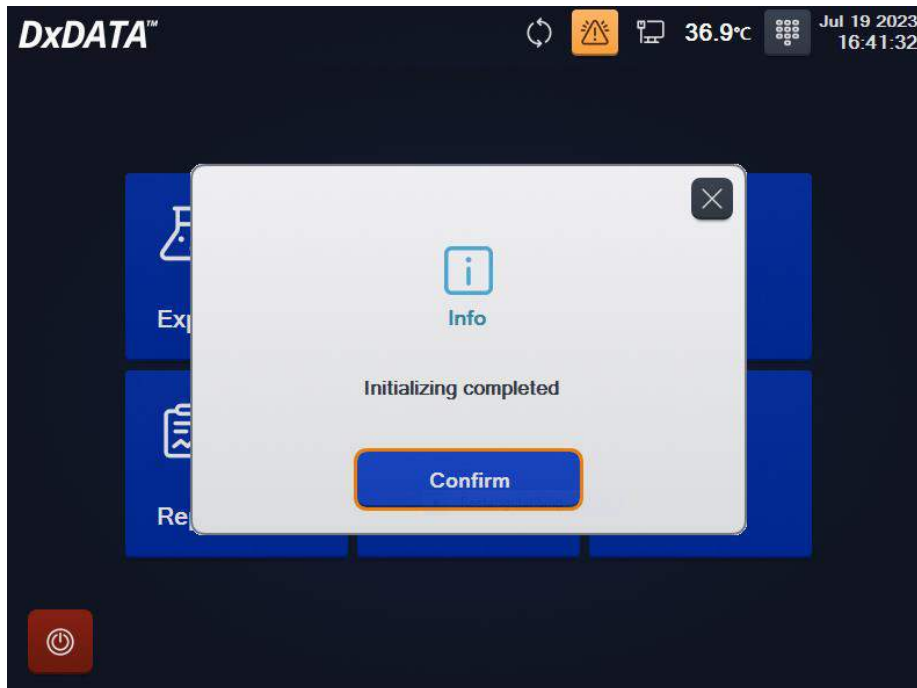


Different usernames are used according to system permissions. User permissions are divided into four levels: A, B, C and D.

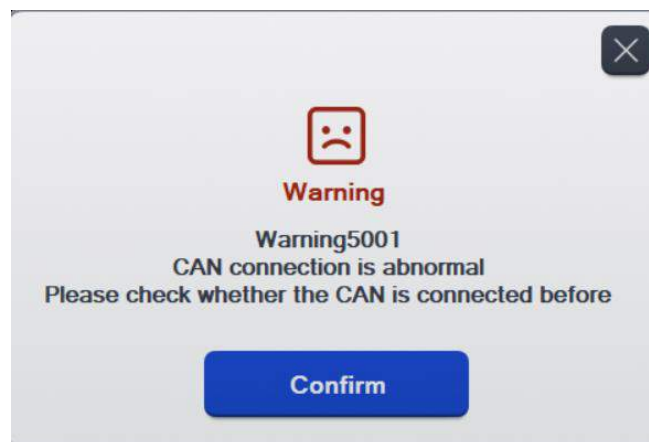
- Permission A and B: for manufacturing or distributor use only.
- Permission C: administrative permissions (user permissions, user settings, re-collection of calibration curves, etc.).
- Permission D: user permission (sample detection, calibration, quality control, result query, report printing, adding new batch of reagents)

## 5.3 Initialization check

After the login, the system will initialize. A dialogue box will display **Initializing completed** message. Click **Confirm** button to proceed to the **Main menu**.

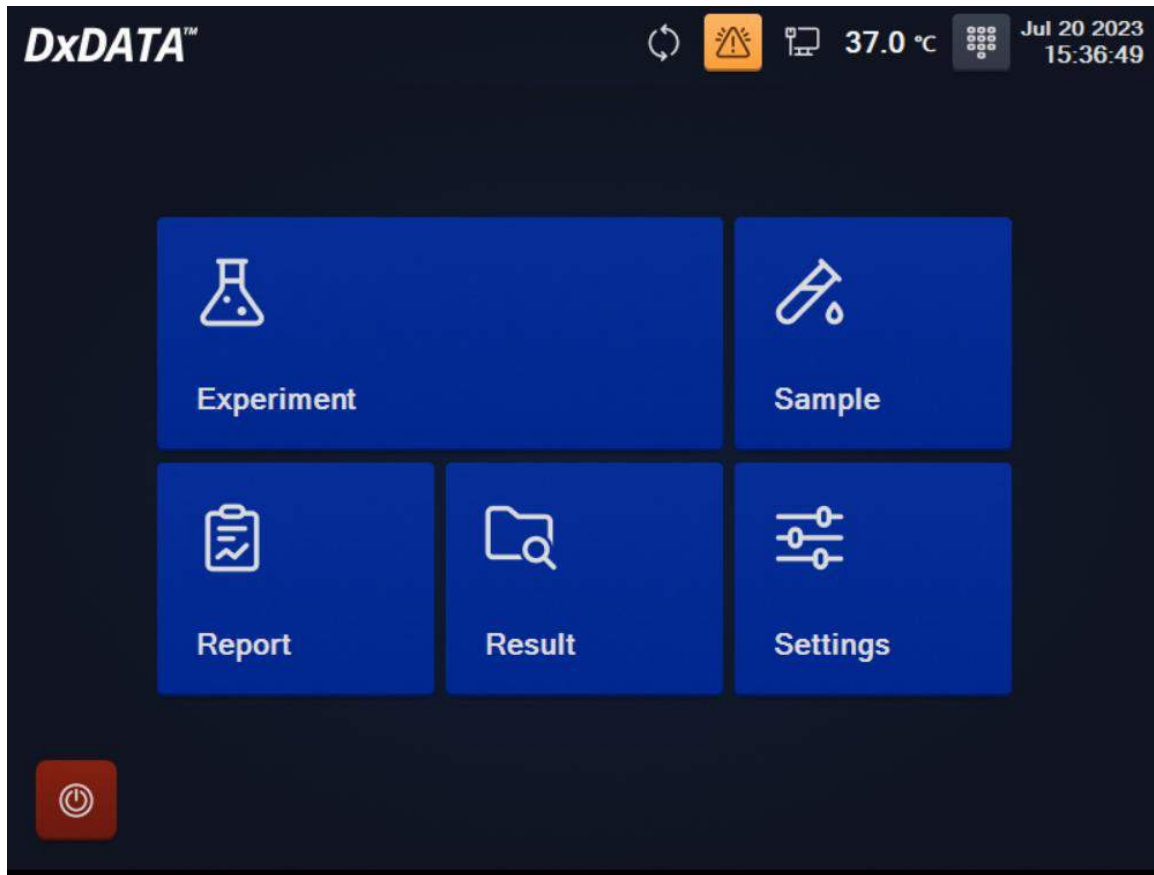


If an error is encountered, please contact **Technical Support** or your local representative.



## 5.4 Main menu window

**Main menu** window contains all the options for the end user to operate the instrument. It is the starting point of the complete list of options available to the end user.



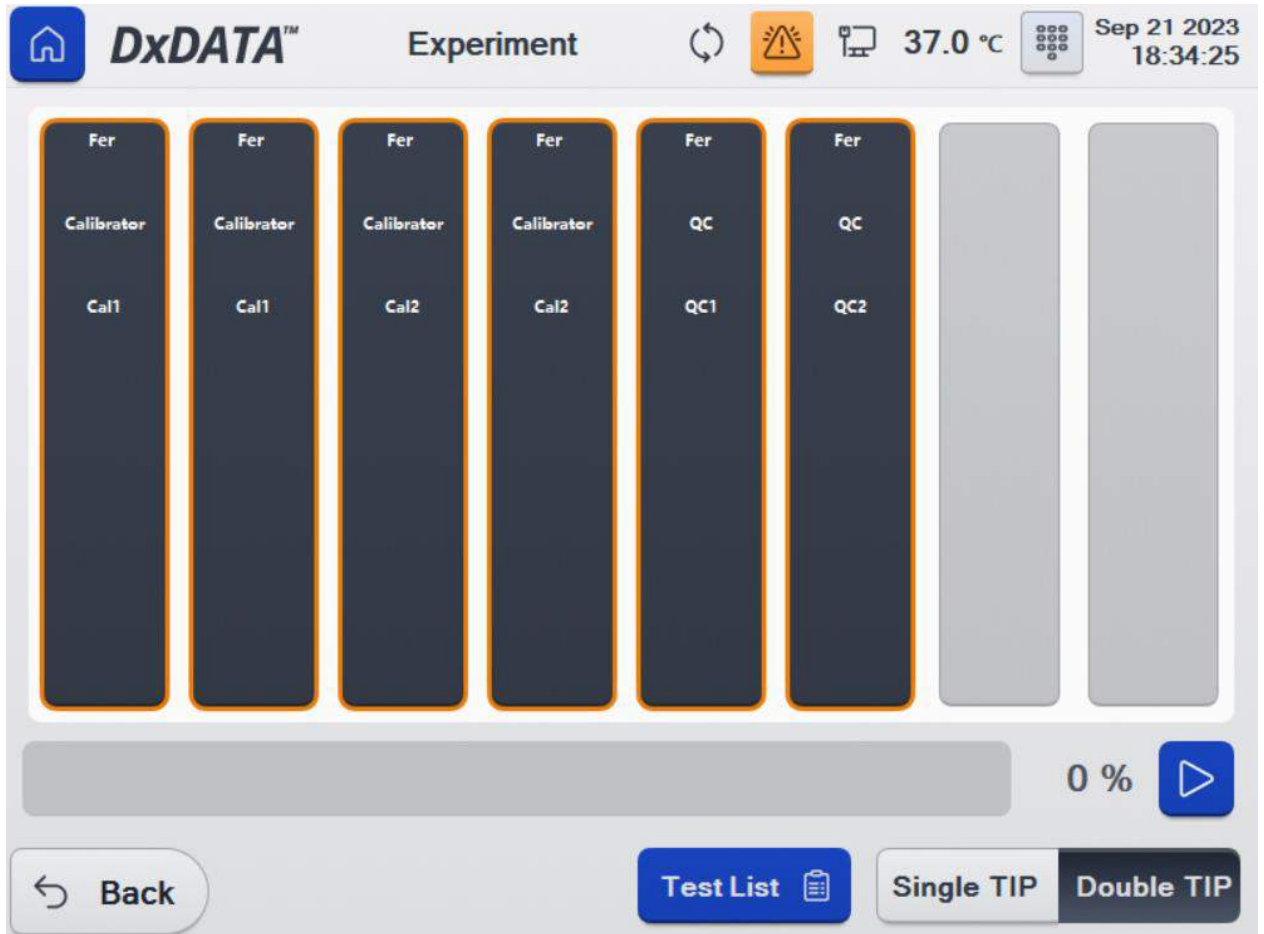
- Click **Experiment** to enter the device running window.
- Click **Sample** to go to the samples management window.
- Click **Result** to enter the results query window.
- Click **Report** to proceed to the reports window.
- Click **Settings** to open the instrument settings window.



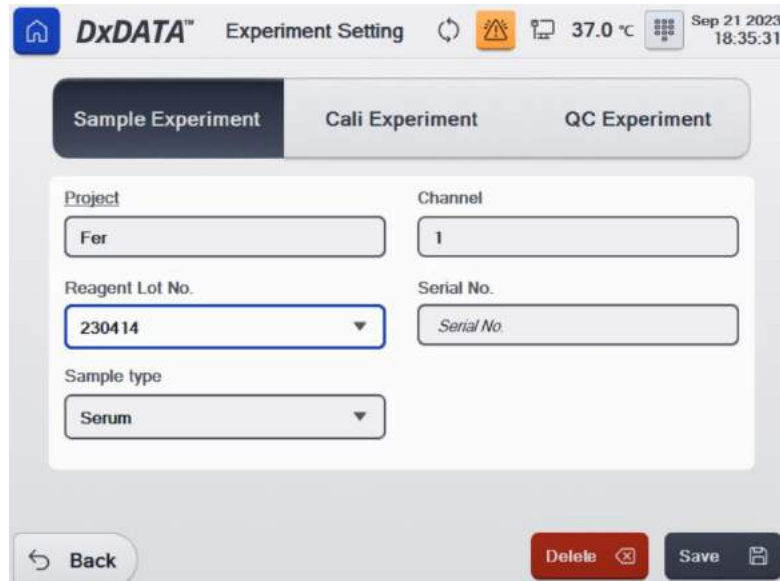
## 5.5 Experiment window

The **Experiment** window is the core part of the normal operation and shows the status of the instrument. The whole operation process is carried out in this window. All the applicable information such as project, sample and batch number can be manually added on a channel-by-channel basis in the **Experiment** window.

- 1) In the **Main menu**, click **Experiment** to enter the device running window. Double-click a project or sample position to pop up **Experiment Setting** window for editing.



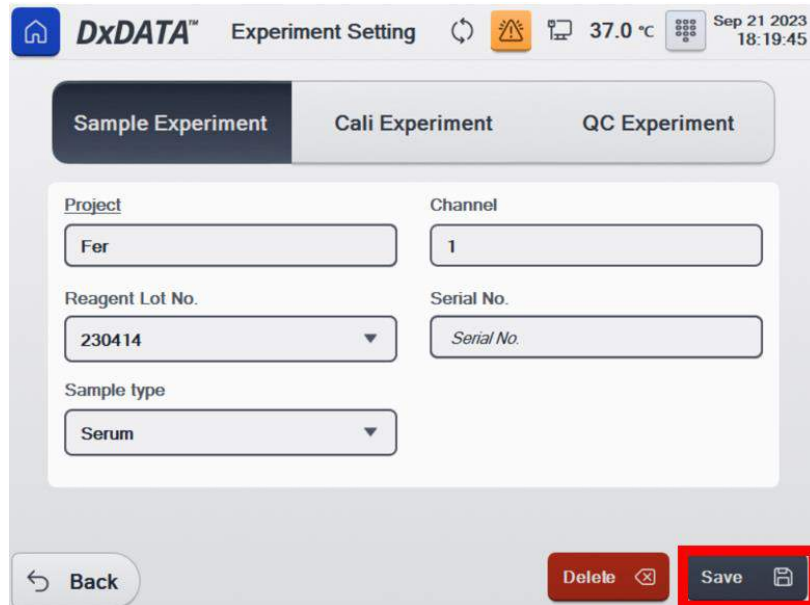
- 2) In the **Experiment Setting** window, select the type of experiment: **Sample experiment, Cali experiment** or **QC experiment**. Select the name of your **Project** and **Reagent Lot No.** In the drop-down **Sample type** menu select your sample: Serum, Plasma, Whole Blood. Confirm the correct detection **Channel** and sample **Serial No.**



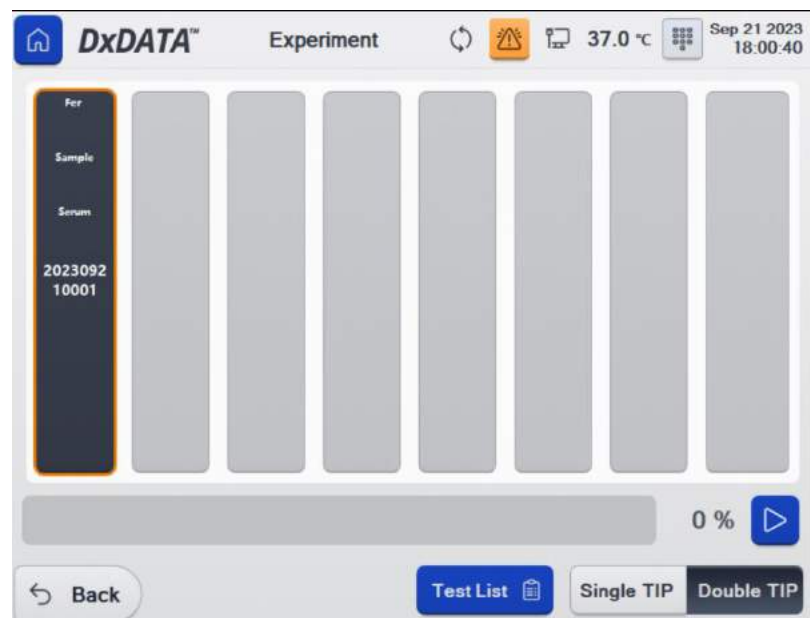
- 3) Click the **Project** field to open the reagents menu. Use scroll **Up** or **Down** buttons to find the target reagent. Select reagent name then click **Back** button. Please refer to “*Assay Group and Inspection Precautions*” information when you use different reagents in one run.



- 4) Click **Save** button in order to save setting for the selected channel.



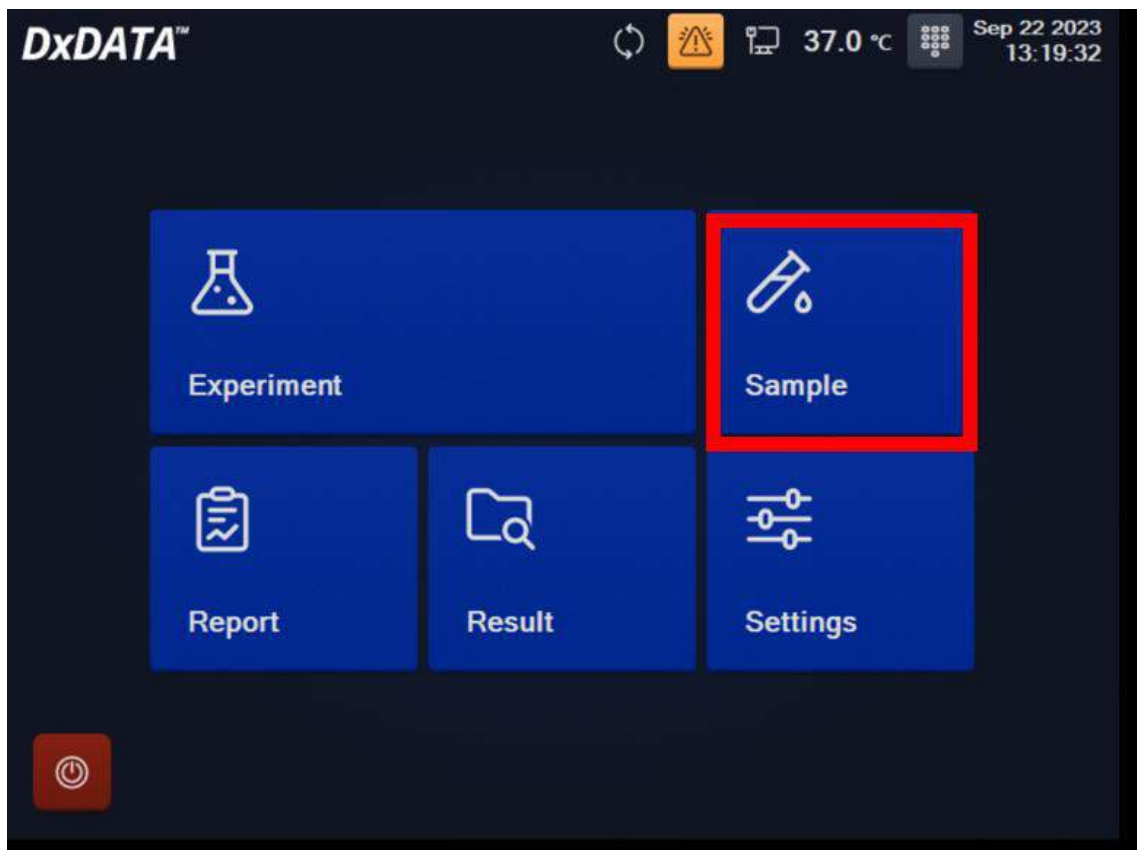
- 5) The software will return back to **Experiment** window.



## 5.6 Sample window

To prepare samples test, proceed to the **Sample** window. This will allow you to add samples and project information for the cartridges as well as display sample and project information that has been set previously, edit patient information for samples and do more.

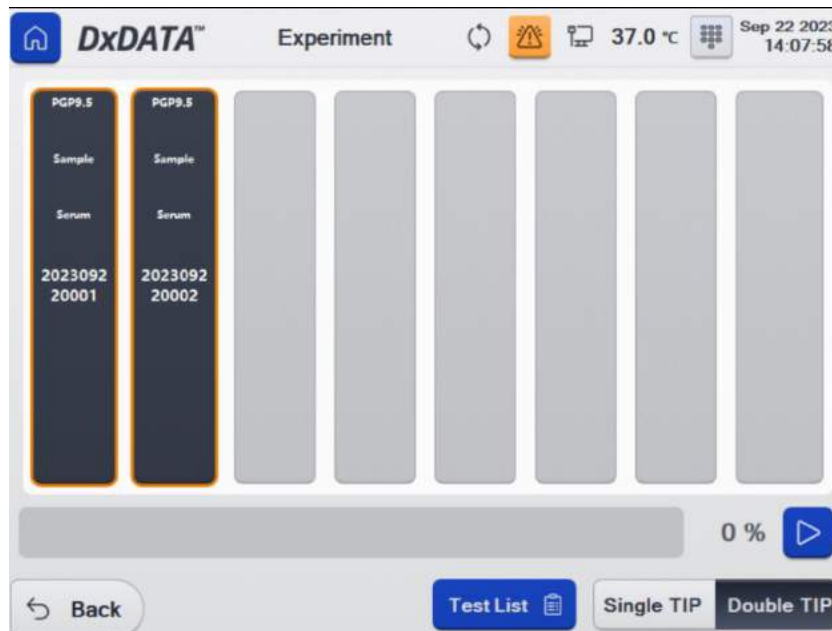
1. In the **Main menu**, click **Sample**.



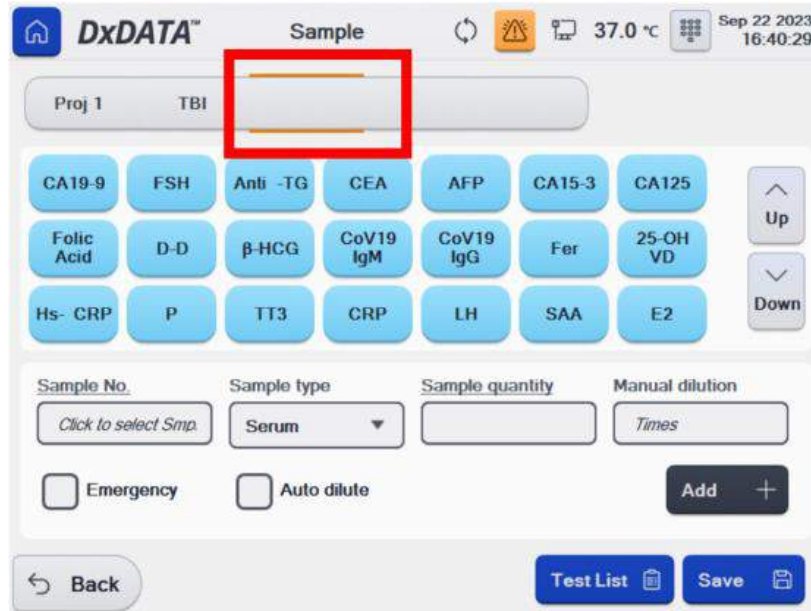
2. Select a reagent or combination of reagents: **Project**. Click **Save** and **Confirm** successful saving. Click **Back** button in order to proceed to the **Experiment** menu.



3. The samples will be assigned in the **Experiment** menu by your instrument. Click **Run** button to start your test.



- To create a new **Project**, double-click the blank area at the top of the **Sample** window. This will open the project portfolio settings window.



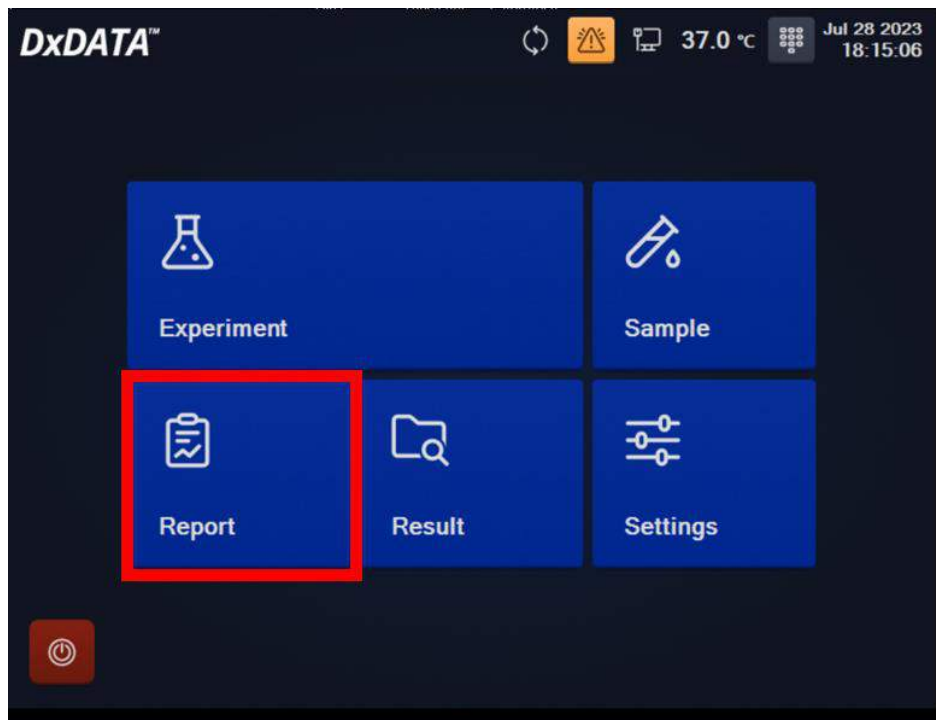
- Enter project name and click **Save**. Select or deselect the reagents, then add reagents to the project. Dark blue is selected, light blue is deselected. Use scroll **Up** or **Down** buttons for more reagents. Click **Back** to save your project and return to the



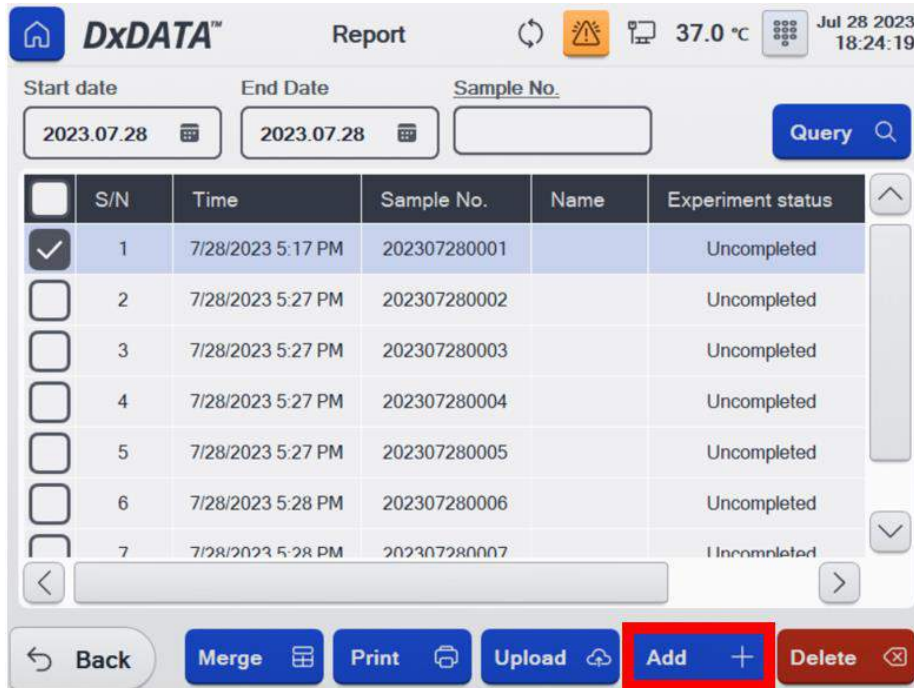
**Sample** menu.

## Report window

At the time of your samples run, you can enter patient information in the “Report” menu. In the Main menu click “Report”.



In the “Report window” use search by date and sample number, then click “Query” button. Select a sample and click “Add” button or double-click on a selected sample.



- Click “Merge” to merge the selected reports.
- Click “Print” to print the current selected search records by list.
- Click “Upload” to upload the current selected search records by list to LIS
- Click “Delete” to delete the current selected search records by list.
- Click “Add” to add a new report in the “Edit report” window.



Enter patient information for a selected sample, then click “Save” and “Confirm” button.  
Proceed to the next sample by or click “Back” to return back to “Report” menu.

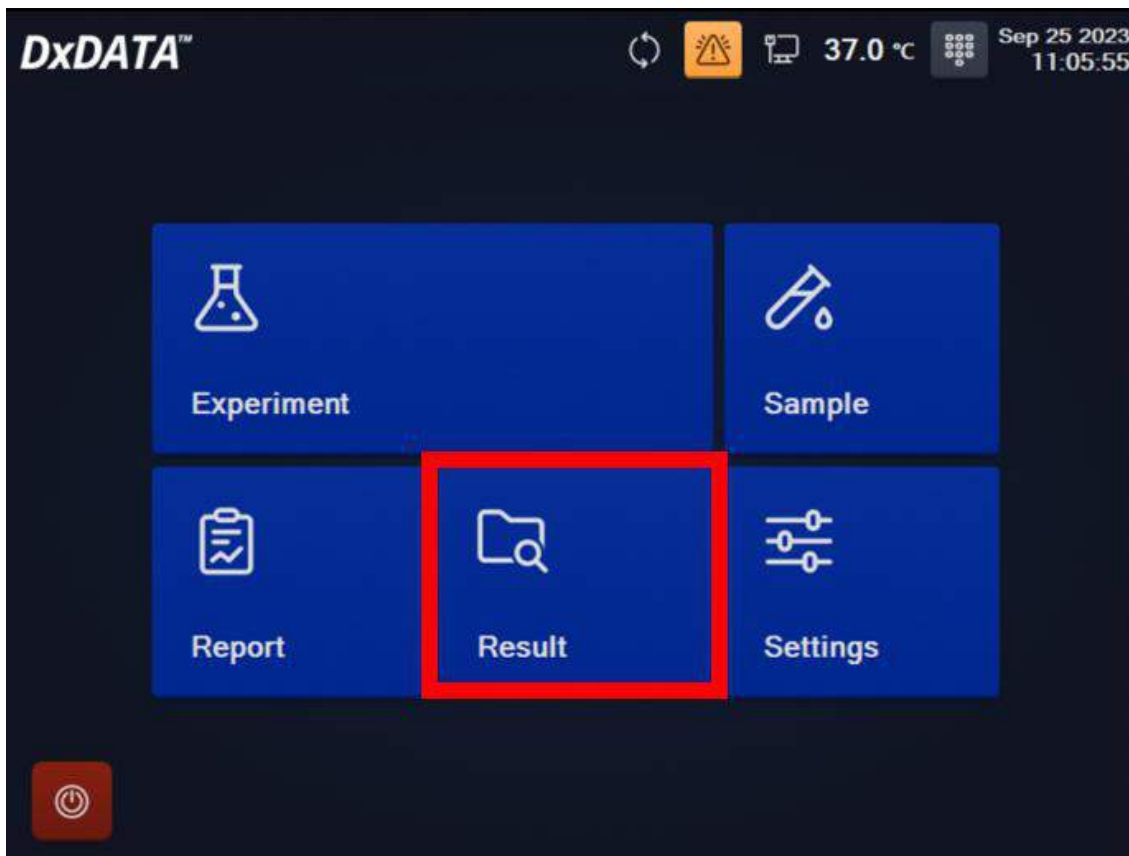
The screenshot shows the 'Edit report' interface in DxDATA. The form is organized into several sections:

- Header:** DxDATA logo, 'Edit report' title, and system status (37.0 °C, Jul 28 2023 18:35:27).
- Form Fields:** A grid of input fields and dropdown menus for patient and sample details.
- Table:** A table with columns: Project, Result, Unit, Reference interval.
- Action Buttons:** A row of buttons including 'Back', 'Save' (highlighted with a red box), 'Print', 'Export', 'Delete', 'Preview', 'Send LIS', 'Release', and navigation arrows.

- Click “Preview” for see the preview of the selected report.
- Click “Send LIS” to upload the current selected records to LIS.
- Click “Print” to print the current selected report.
- Click “Release” to release the current selected report.
- Click “Export” to export data and save as Excel document.
- Click “Delete” to delete the current report.

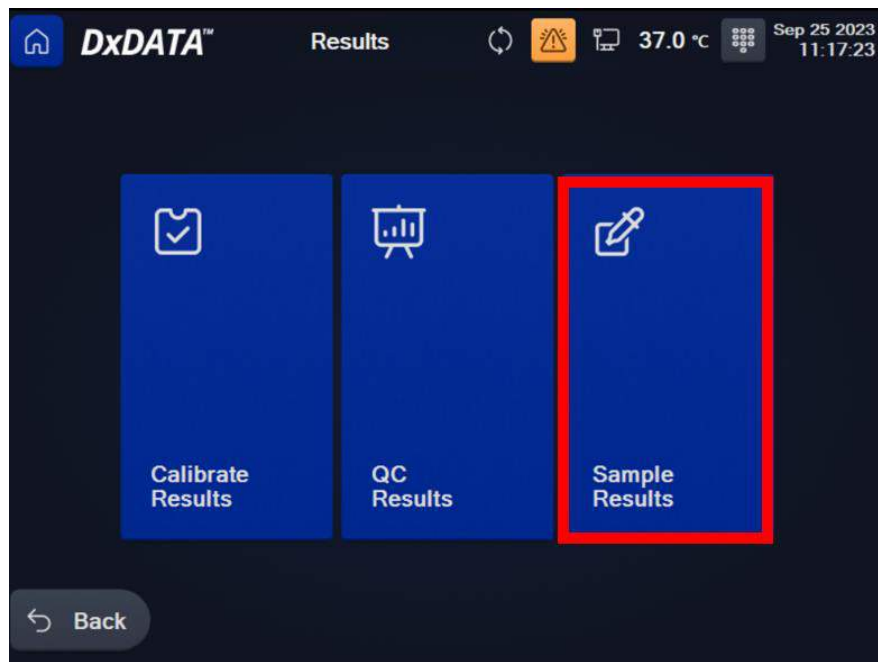
## Result window

In the "Results" window, you can search for test results, calibration results and quality control results.



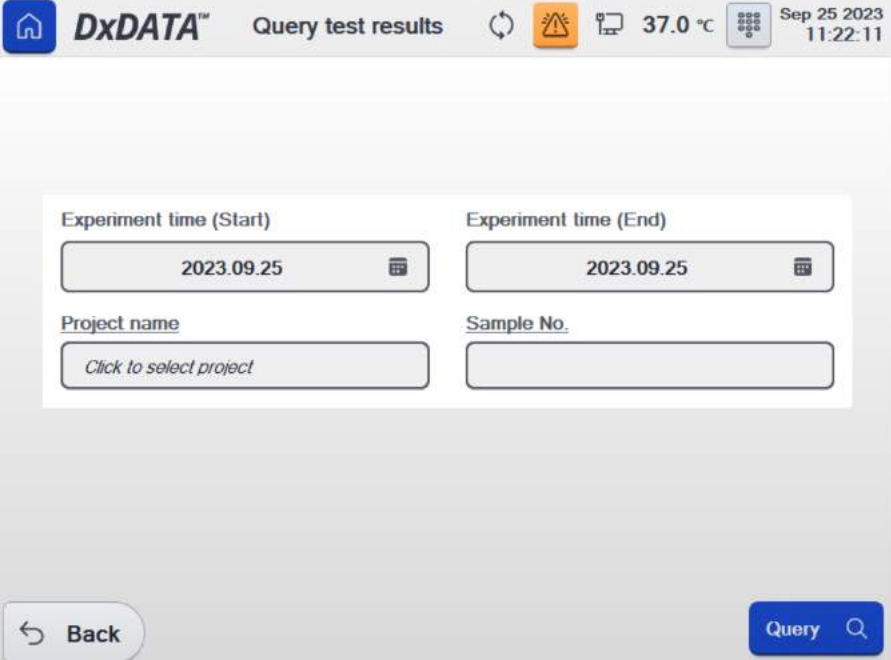
## Sample Results

Click "Sample Results", the software will display "Query test results" interface.



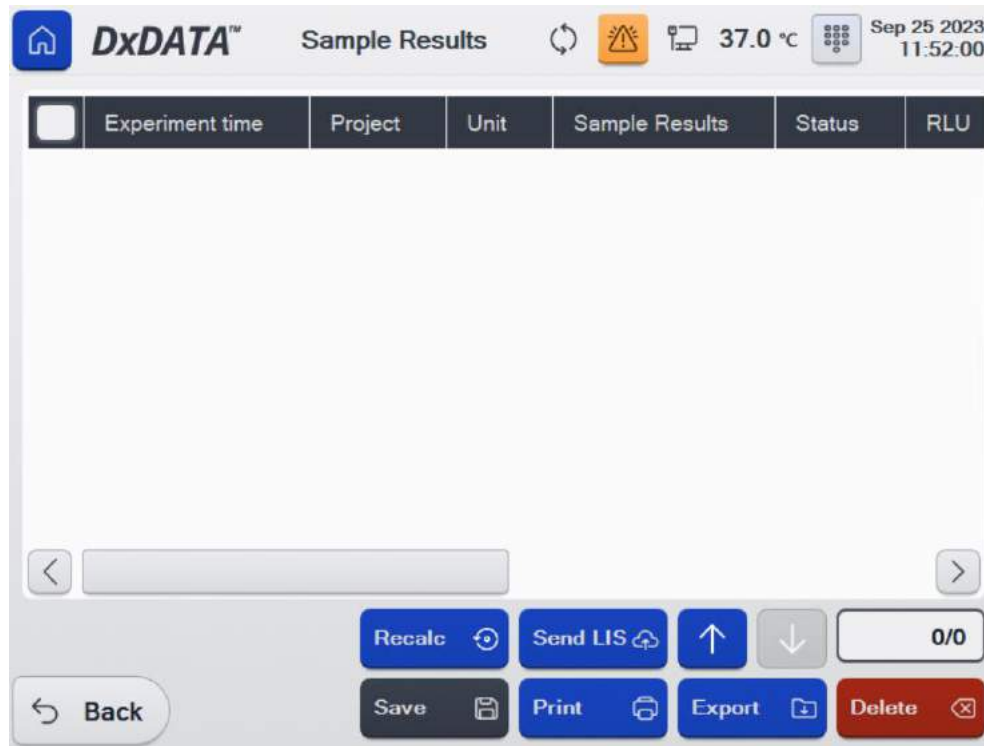
## Version 2.0

The “Experiment time” start and end is mandatory to begin results search, while all other search criteria are optional. If you do not enter information, you do not select the condition. Click “Query” button.



The screenshot shows the DxDATA interface for a query test. The header includes the DxDATA logo, the text "Query test results", a refresh icon, a warning icon, a monitor icon, a temperature reading of "37.0 °C", a grid icon, and the date and time "Sep 25 2023 11:22:11". The main content area contains four input fields arranged in a 2x2 grid. The top-left field is labeled "Experiment time (Start)" and contains the date "2023.09.25" with a calendar icon. The top-right field is labeled "Experiment time (End)" and also contains "2023.09.25" with a calendar icon. The bottom-left field is labeled "Project name" and contains the text "Click to select project". The bottom-right field is labeled "Sample No." and is currently empty. At the bottom left, there is a "Back" button with a left-pointing arrow. At the bottom right, there is a blue "Query" button with a magnifying glass icon.

Under this interface, you can select “Experiment time”, “Project” name or “Status” for your search.



- Click “Send LIS” to upload the results of the current search to the LIS system.
- Click “Print” to print the current search records by list.
- Click “Export” to export data and save as Excel document.
- Click “Recalc” to recalculate the current search records by list.
- Click “Delete” to delete the current search records by list.

## QC Results

## Version 2.0

Click "QC Results", the software will display "Query QC results" interface.

The "QC date" start and end as well as "Project name" are mandatory to begin the QC results search, while all

The screenshot shows the 'Query QC Results' interface. The top bar includes the DxDATA logo, the title 'Query QC Results', and system information like '37.0 °C' and 'Sep 25 2023 12:18:43'. The main area contains four input fields: 'QC date (Start)' with '2023.09.25', 'QC date (End)' with '2023.09.25', 'Project name' with 'Click to select project', and 'QC Lot No.' with a dropdown arrow. A 'Back' button is on the left and a 'Query' button is on the right.

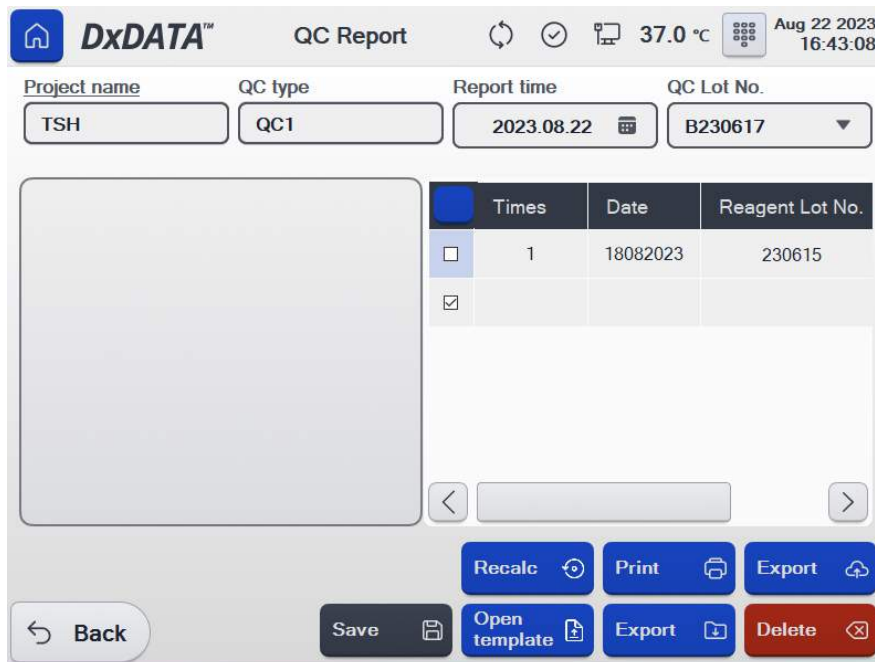
other search criteria are optional. If you do not enter information, you do not select the condition. Click "Query" button.

Under this interface, you can select "QC date", "Project name" and "QC Lot No." Select "QC1" or "QC2" as required items.

The screenshot shows the 'Query QC Report' interface. The top bar includes the DxDATA logo, the title 'Query QC Report', and system information like '37.0 °C' and 'Sep 25 2023 13:28:22'. Below the bar is a table with the following columns: Date, Project name, QC Lot No., Reagent Lot No., Result, and RL. The table is currently empty. At the bottom, there are several buttons: 'QC 1', 'QC 2', 'QC chart', 'Send LIS', 'Print', and 'Export'. The 'QC 1' and 'QC 2' buttons are highlighted with a red box.

- Click “Send LIS” to upload the results of the current search to the LIS system.
- Click “Print” to print the current search records by list.
- Click “Export” to export data and save as Excel document.

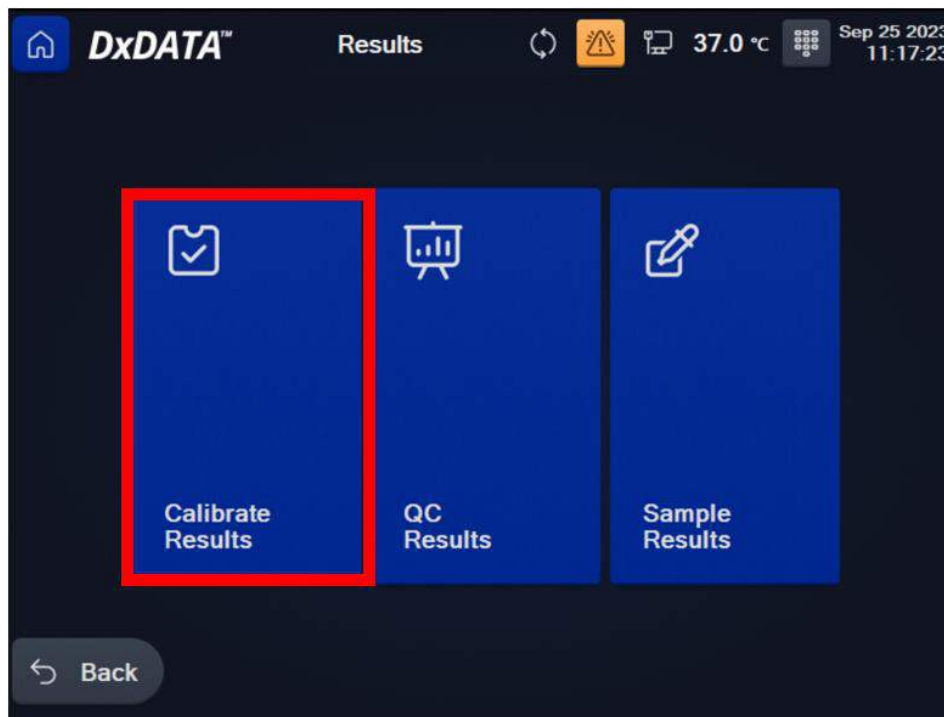
Click the “QC chart” button to retrieve all the quality control results for the selected conditions.



- Click “Recalc” to recalculate the currently displayed quality control charts.
- Click “Open template” to open template for currently displayed document.
- Click “Print” to print list format.
- Click “Export” to save as Excel document or PDF document.
- Click “Delete” to delete the selected data.
- Click “Save” to save the modified data.

## Calibration Results

Click “Calibrate Results”, the software will display "Query test results" interface.

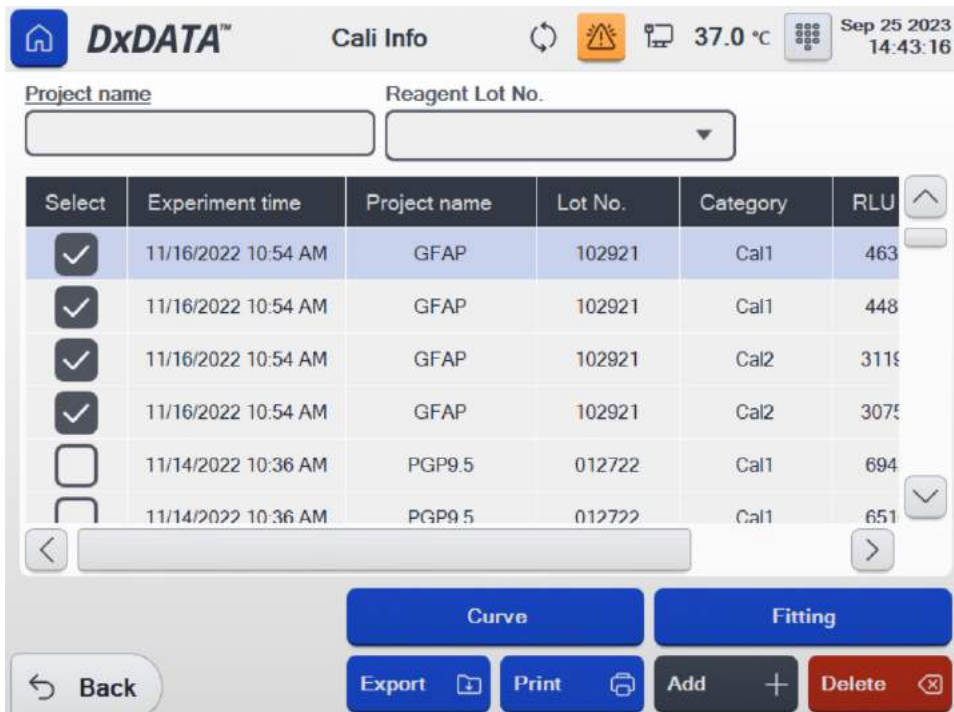




The calibration “Cali date” start and end is mandatory to begin the calibration results search, while all other search criteria are optional. If you do not enter information, you do not select the condition. Click “Query” button.

The screenshot shows the DxDATA interface for querying calibration results. The top navigation bar includes a home icon, the DxDATA logo, the page title "Query cali results", a refresh icon, a warning icon, a monitor icon, a temperature display of "37.0 °C", a calendar icon, and the date and time "Sep 25 2023 14:12:57". The main content area contains a form with two date input fields labeled "Cali date (Start)" and "Cali date (End)", both containing the date "2023.09.25" and a calendar icon. Below these is a text input field labeled "Project name". At the bottom left is a "Back" button with a left arrow, and at the bottom right is a "Query" button with a magnifying glass icon.

Under this interface, you can select “Experiment time”, “Project name” and “QC Lot No.” Select your project Calibrator 1 and Calibrator 2.

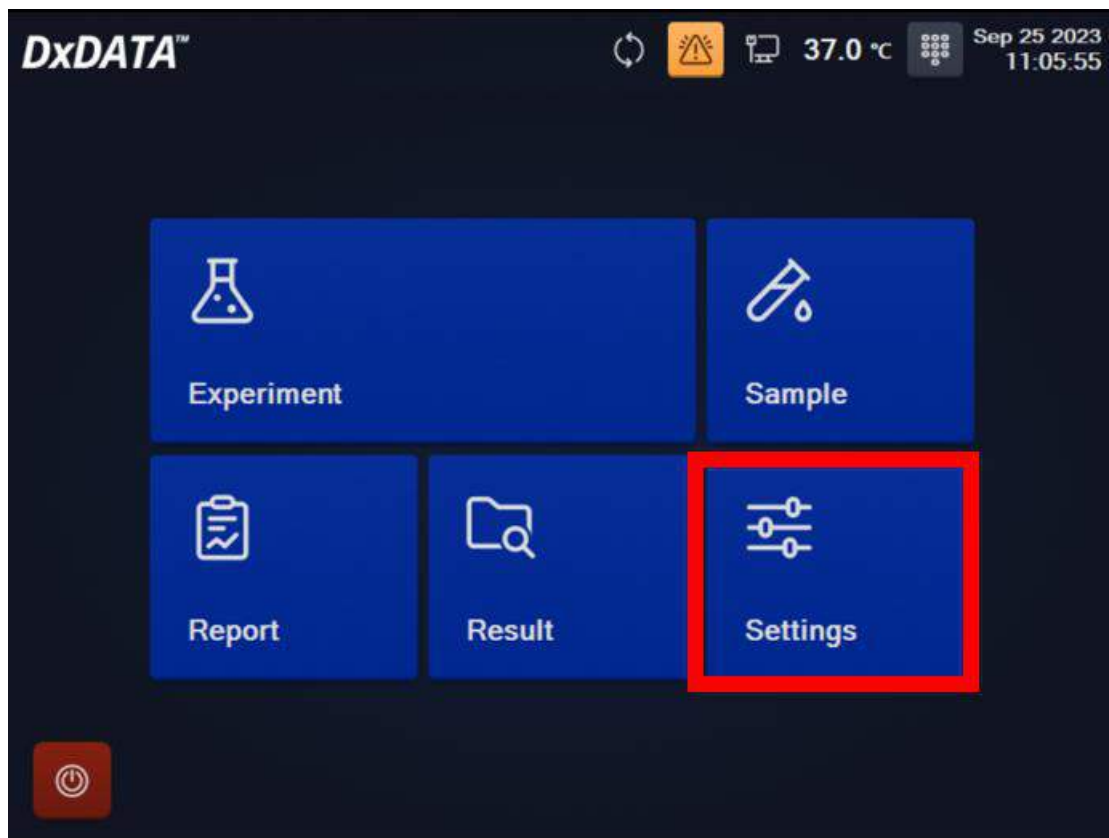


- Click “Curve” to see and save selected calibration curve.

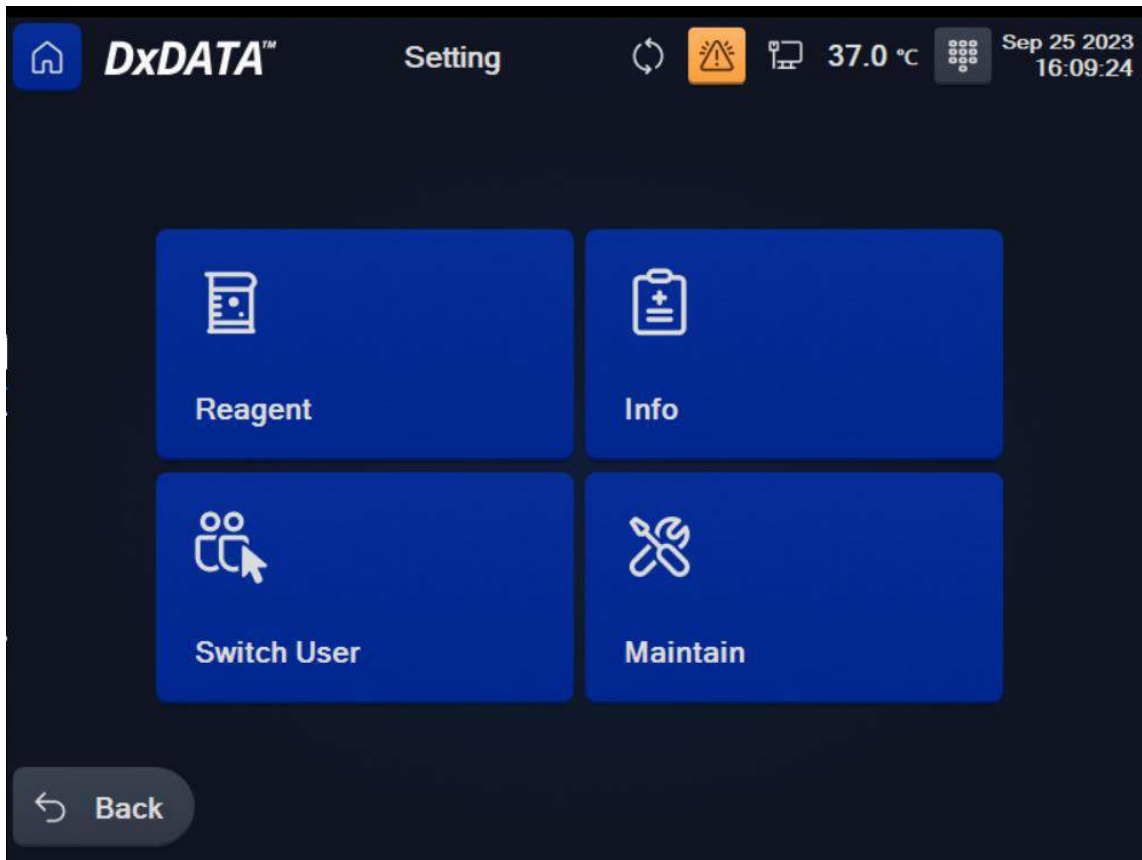
- Click “Fitting” to recalculate the calibration results.
- Click “Add” to add new calibration results.
- Click “Print” to print the current search records by list.
- Click “Export” to export data and save as Excel document.
- Click “Delete” to delete the current search records by list.

## **Settings window**

In the "Settings" window you can manage your reagents, switch users by logging in with a different user name, access instrument`s settings, functional debug, alarm records and maintenance. In the Main menu click “Settings”

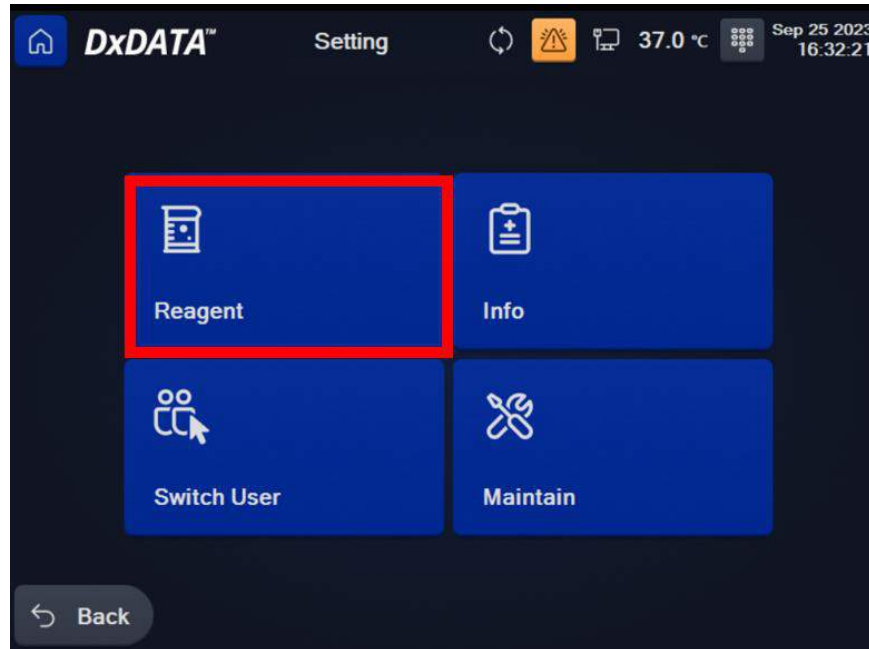


The “Settings” menu includes “Reagent”, “Info”, “Switch user” and “Maintain”. Click button to enter a corresponding window.



## Reagent

In the “Settings” menu, click “Reagent” button to go to reagent management interface where you can enable and disable projects, select project parameters and add new batch of reagents.



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To add a new reagents lot, select your reagent name on the left side of the screen. Detailed information of the currently selected reagent will be automatically displayed. Click “Add New Lot” button to add a new batch of the selected reagent.

The screenshot displays the DxDATA Reagent management interface. The top bar shows the DxDATA logo, the word "Reagent", a refresh icon, a warning icon, a temperature display of 37.0 °C, and the date/time: Sep 25 2023 17:50:28.

On the left side, there is a grid of reagent buttons:

- PGP9.5
- CA19-9
- FSH
- Anti -TG
- CEA
- AFP
- CA15-3
- CA125
- Folic Acid
- D-D
- β-HCG
- CoV19 IgM
- CoV19 IgG
- Fer
- 25-OH VD
- Hs- CRP
- P
- TT3

Below the grid are up and down arrow buttons.

The central panel contains the following information:

- Reagent Lot No.: 0032423-DD2
- Cali date: [Empty field]
- Remaining valid days of calibration: 0

Below this information is a graph showing RLU (Relative Light Units) on the y-axis versus Concentration on the x-axis. The y-axis has values: 2997, 60300, 117603, 174907, 232210, 286513. The x-axis has values: 0, 5.16, 10.33, 15.49, 20.65, 25.81. A curve is plotted with data points, and the correlation coefficient is R=0.9991.

At the bottom of the screen, there are five buttons: Back, Edit, Project, Add New Lot, and Cali history.

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With the handheld external bar code scanner, scan the QR code on the kit box. After the scan is successful, confirmation is window displayed, the current scan information is automatically added.

The screenshot displays the 'Add New Lot' screen in the DxDATA application. At the top, there is a header with the DxDATA logo, the title 'Add New Lot', a refresh icon, a warning icon, a temperature display of 37.0 °C, and the date and time 'Sep 26 2023 14:32:26'. Below the header, there are several input fields: 'Project name' with the value 'Fer', 'Project No.' with 'DxDA-1C', and 'Valid until' with '0001.01.01'. There are also fields for 'Reagent Lot No.' and 'QR Code', with an 'Add +' button next to the QR Code field. Below these fields is a table with four columns: 'ID', 'Master curve', 'Low value curve', and 'High value curve'. At the bottom of the screen, there are four buttons: 'Back', 'Save', 'Cal', and a confirmation icon.

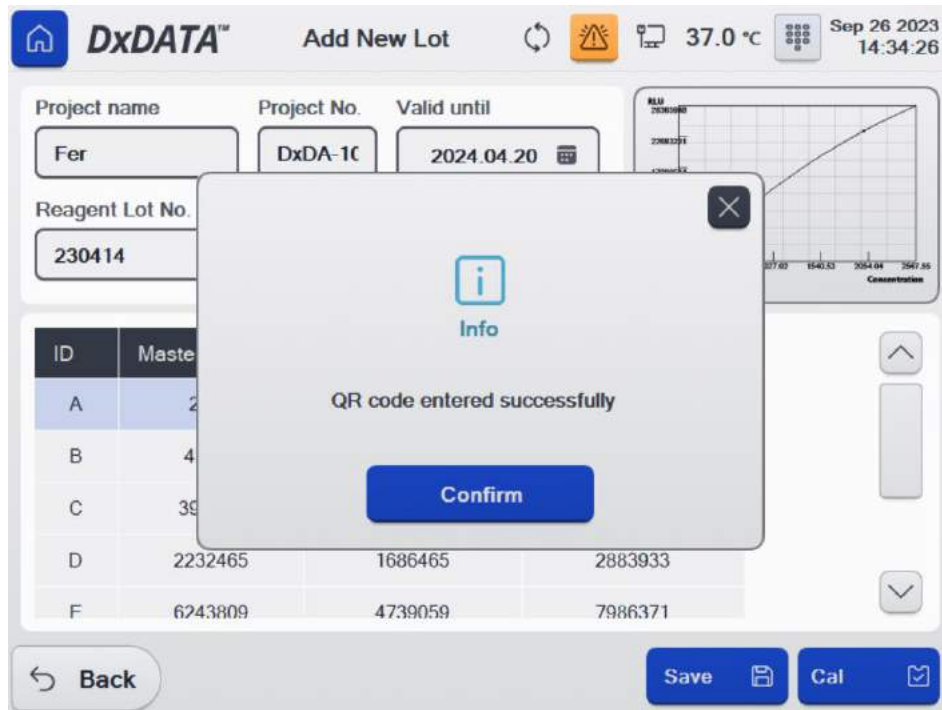
**Manual Input:** If unable to be scanned, the information can be manually added via the “Enter” key.

**NOTE:** After scanning or manually inputting the batch information, the “Reagent Lot No.” and “Valid until” values are unable to be changed.



## Version 2.0

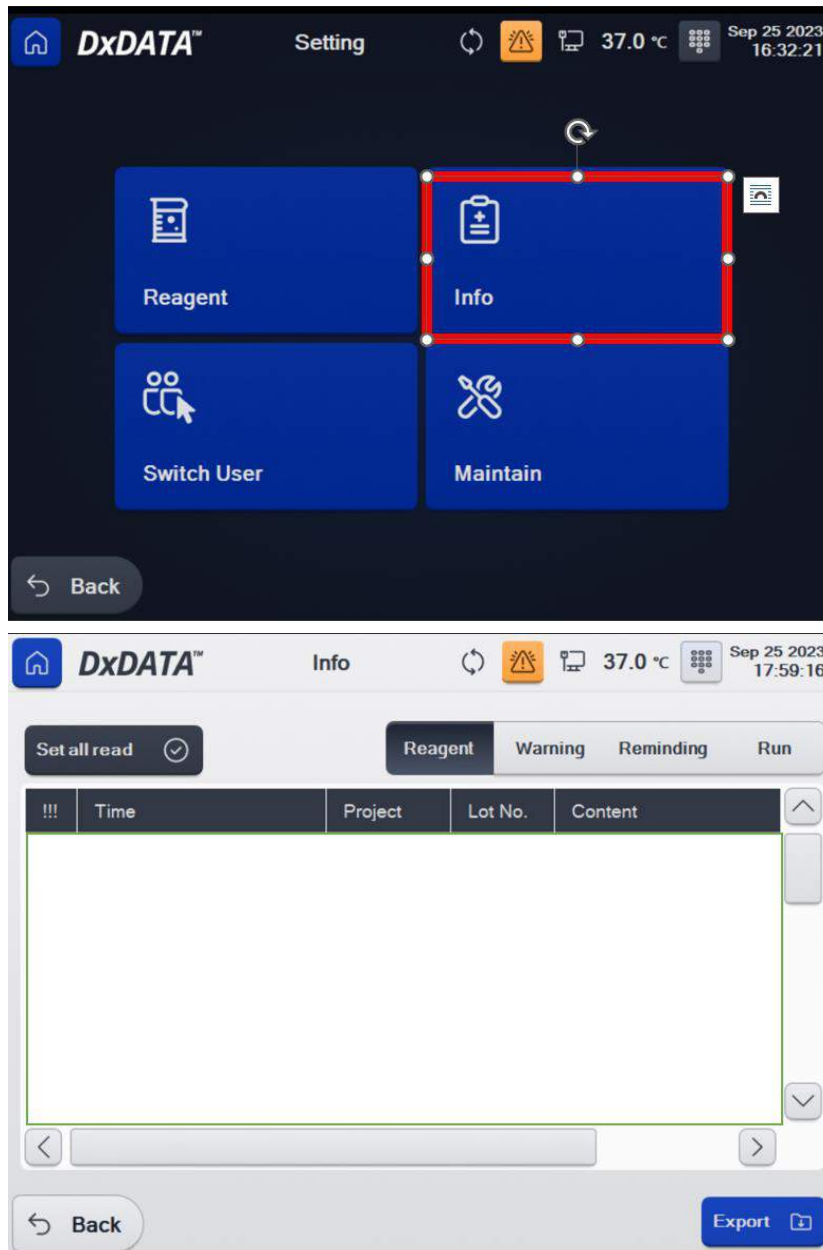
After inputting, click “Confirm”. Click “Save” button to save the current batch data and “Confirm”.



- Click the “Cal” button to proceed with reagent calibration in the “Run” menu or click “Back” button to exit the current interface and return to the “Reagent” management interface.
- You can also add multiple batches of information at once. Repeat the operation steps above.

## Info

Click “Info” button for instrument’s alarm records.

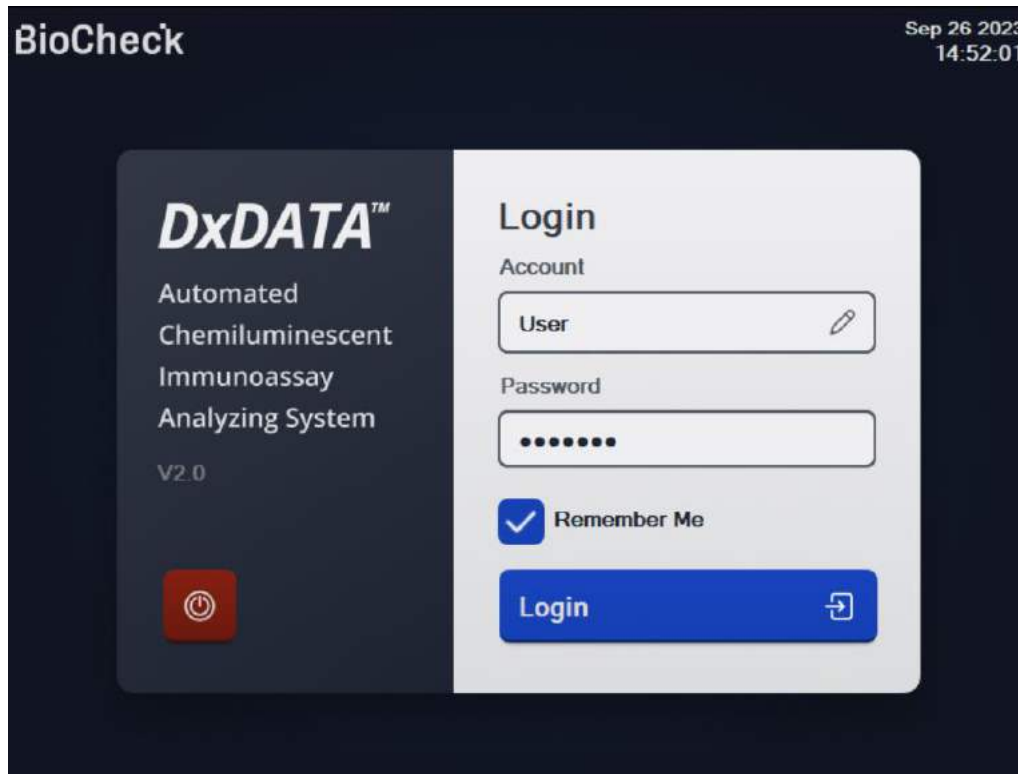


- Select “Reagent” to check the alarm information for reagents.
- Select “Warning” to see warning messages recorded by the instrument.
- Select “Reminding” to check the reminder alarm information.

- Select “Run” to check the instrument`s operation logs.

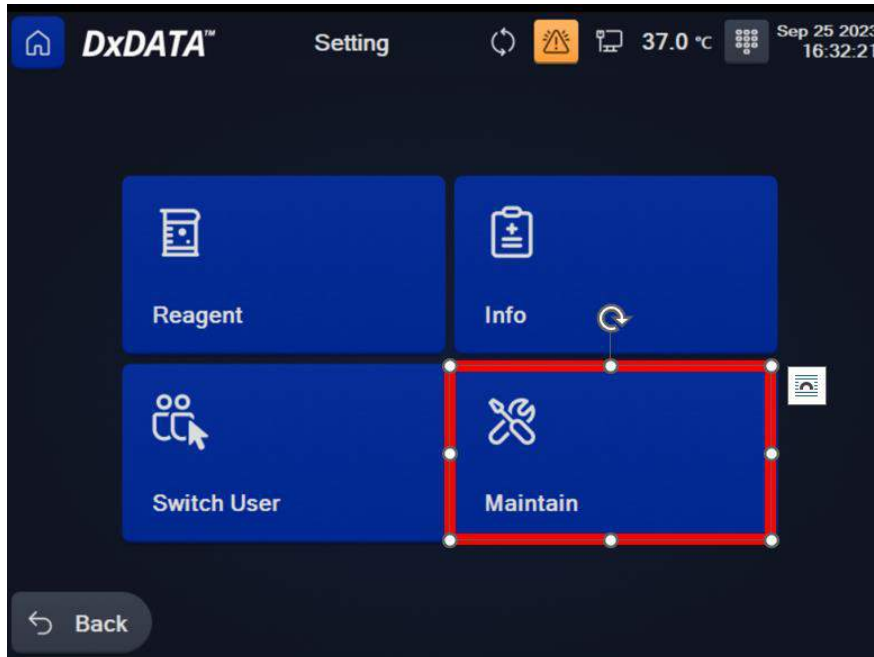
## Switch User

Click “Switch User” button to log in with a different user name. Select Account type and enter the Password in the “Login window”.

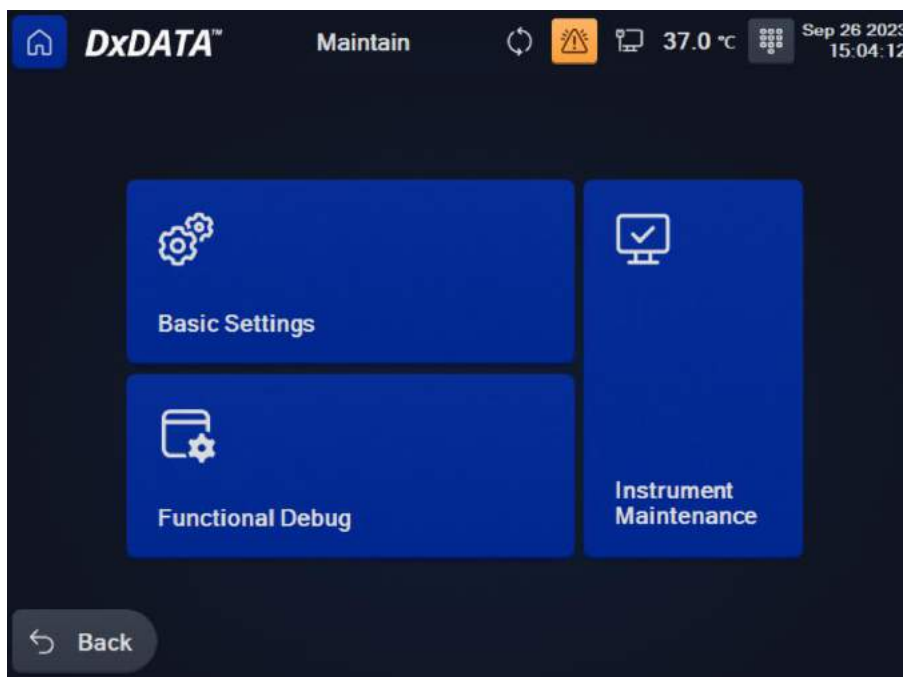


## Maintain

In the “Settings” menu, click “Maintain” button to go to “Instrument maintenance”, “Basic settings” and instrument “Functional Debug” interface.

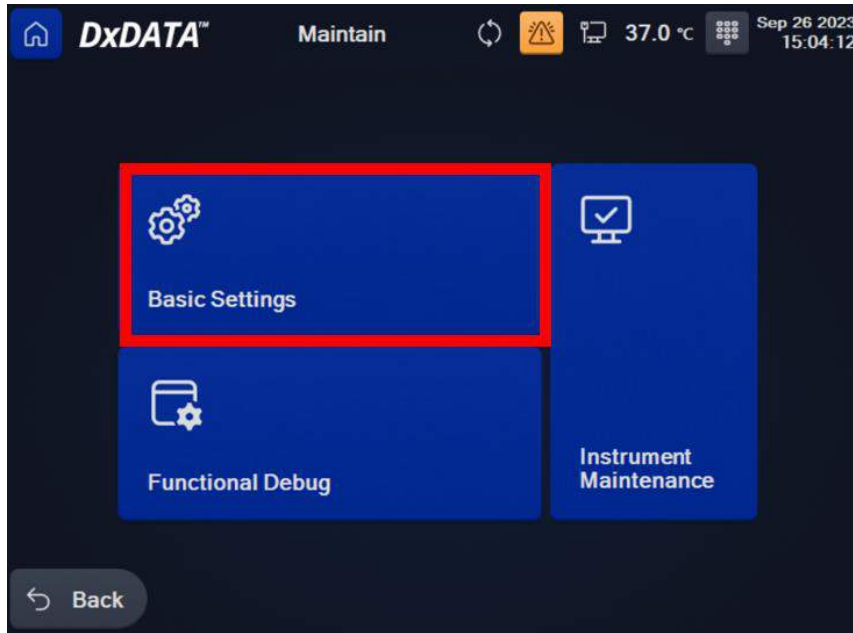


Here you can manage maintenance schedule for your instrument in “Instrument maintenance”, check your instrument functionality in the “Functional debug” and enter “Basic Settings”.

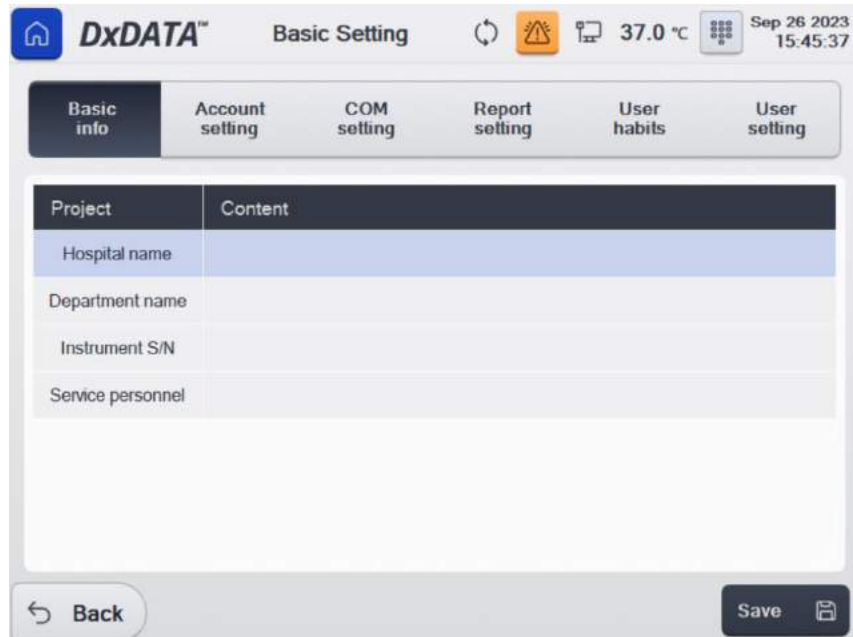


## Version 2.0

In the “Maintain” menu, click “Basic settings” to access the menu of settings.



Click on “Basic info” box to update Hospital name, Department name, Instrument S/N information and Service personnel. Click “Save” button to save the changes and “Confirm”.



## Version 2.0

Click on “Account setting” box to update Account, Password and Permission level. Click “Save” button to save the changes and “Confirm”.

The screenshot shows the DxDATA Basic Setting interface. The top navigation bar includes a home icon, the DxDATA logo, the title 'Basic Setting', a refresh icon, an alarm icon, a temperature display of 37.0 °C, and a date/time display for Sep 26 2023 at 15:57:00. Below the navigation bar are six tabs: Basic info, Account setting (selected), COM setting, Report setting, User habits, and User setting. The main content area features a table with the following headers: S/N, Account, Password, and Permission level. The table is currently empty. At the bottom of the interface, there are two buttons: 'Back' and 'Save'.

Click on “COM Setting” box to update LIS, Printer and Internal scanner settings. Click “Save” button to save the changes and “Confirm”.

The screenshot shows the DxDATA Basic Setting interface with the 'COM setting' tab selected. The top navigation bar is identical to the previous screenshot. The main content area is divided into three sections: 'LIS port', 'Printer', and 'Internal scanner'.  
- The 'LIS port' section includes an 'Enable LIS' checkbox (unchecked), an 'IP Address' field with the value '127.0.0.1', a 'Port No.' field with the value '5556', and a 'Local instrument' section with a 'Port No.' field containing '5566' and an 'Auto upload results' checkbox (unchecked).  
- The 'Printer' section includes an 'External printer' checkbox (unchecked), a 'Built-in printer' checkbox (checked), a 'Port' dropdown menu set to 'COM1', a 'Baud rate' field with '9600', and an 'Auto print' checkbox (checked).  
- The 'Internal scanner' section includes a 'Port' dropdown menu set to 'COM3', a 'Baud rate' field with '9600', and a 'Model' dropdown menu set to 'Honeywell'.  
At the bottom of the interface, there are two buttons: 'Back' and 'Save'.

## Version 2.0

Click on “Report Setting” box for report settings. Make selections to update report template for external and built-in printer. Click “Save” button to save the changes and “Confirm”.

The screenshot shows the 'Basic Setting' interface for 'DxDATA'. The 'Report setting' tab is selected. At the top, there is a navigation bar with 'Basic info', 'Account setting', 'COM setting', 'Report setting', 'User habits', and 'User setting'. Below this is a table with columns 'S/N', 'Template', and 'Valid'. The table contains one row with S/N '1' and Template 'A5 Test report template'. Below the table are several checkboxes for report fields: Hospital, Department, Inpatient No., Bed No., Clinical diagnosis, Name, Age, Gender, Sample type, Sample No., Submission Dr., Laboratory Technician, Auditor, Submission time, Report time, and Titer. At the bottom, there are buttons for 'Back', 'Open template', and 'Save'.

S/N	Template	Valid
1	A5 Test report template	<input type="checkbox"/>

Hospital     Department     Inpatient No.     Bed No.  
 Clinical diagnosis     Name     Age     Gender  
 Sample type     Sample No.     Submission Dr.     Laboratory Technician  
 Auditor     Submission time     Report time     Titer

Click on “User habits” box for user habits settings. Select or deselect options for user habits. Click “Save” button to save the changes and “Confirm”.

The screenshot shows the 'Basic Setting' interface for 'DxDATA'. The 'User habits' tab is selected. At the top, there is a navigation bar with 'Basic info', 'Account setting', 'COM setting', 'Report setting', 'User habits', and 'User setting'. Below this are several checkboxes for user habits settings: Report(Date), CV% mode, Separate calibration, Classified report, Sort by sample No., Single 2-point Calibration, Ratio report, Extreme Mode(Multi-sample), Reset sample position, Display value out of limit, Original position detection, Chest pain center, Turn off alarm, Double-click mode(select dilution factor), Auto print QC results, Auto print Cali results, and Reverse decimal (set to 2). At the bottom, there are buttons for 'Back' and 'Save'.

Report(Date)     CV% mode     Separate calibration  
 Classified report     Sort by sample No.     Single 2-point Calibration  
 Ratio report     Extreme Mode(Multi-sample)     Reset sample position  
 Display value out of limit     Original position detection     Chest pain center  
 Turn off alarm     Double-click mode(select dilution factor)  
 Auto print QC results     Auto print Cali results    Reverse decimal

## Version 2.0

Click on “User setting” box to update Patient type, Submission department, Submission doctor and Laboratory technician information. Click “Save” button to save the changes and “Confirm”.

The screenshot displays the 'User setting' screen in the DxDATA application. The top navigation bar includes a home icon, the DxDATA logo, the title 'Basic Setting', and a refresh icon. On the right side of the navigation bar, there are icons for a warning, a monitor, a temperature reading of 37.0 °C, and a grid icon, along with the date and time: Sep 26 2023, 16:19:40.

Below the navigation bar, there are five tabs: 'Basic info', 'Account setting', 'COM setting', 'Report setting', 'User habits', and 'User setting'. The 'User setting' tab is currently selected and highlighted in dark blue.

The main content area features a table with the following data:

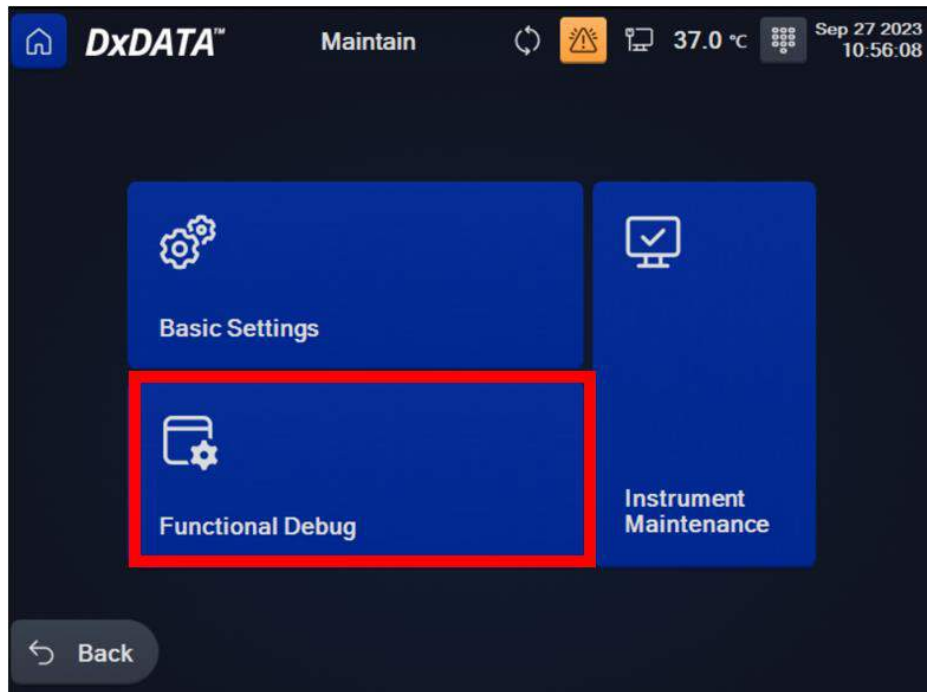
Patient type	Submission department	Submission Dr.	Laboratory Technicia
patientcate1	departname1	doctor	examiner1
		doctor	
		doctor	

Below the table, there is a search bar with left and right navigation arrows. At the bottom of the screen, there is a 'Back' button on the left and a 'Save' button on the right.

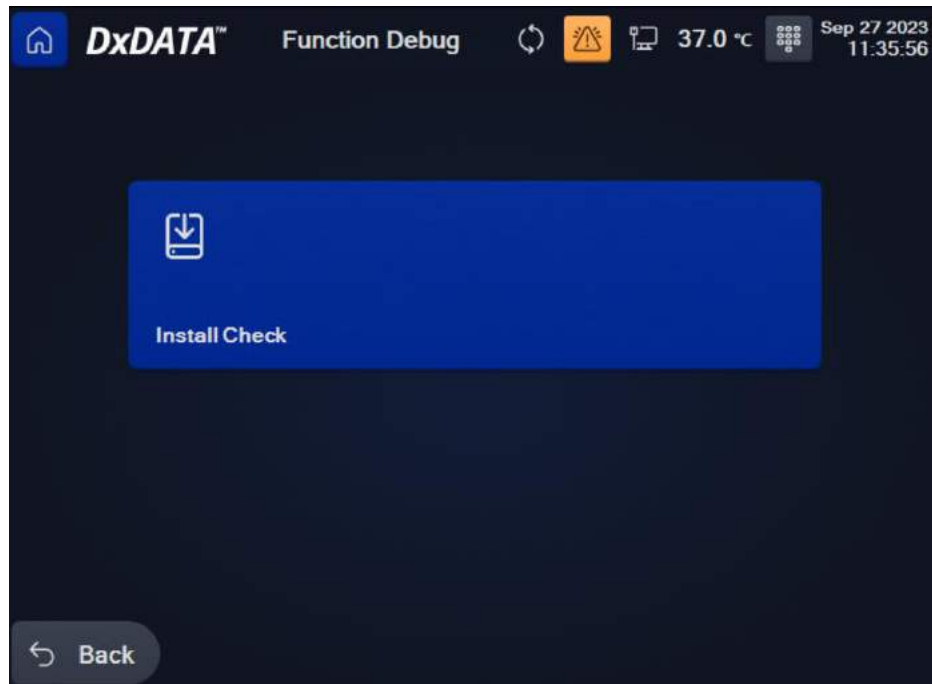


## Version 2.0

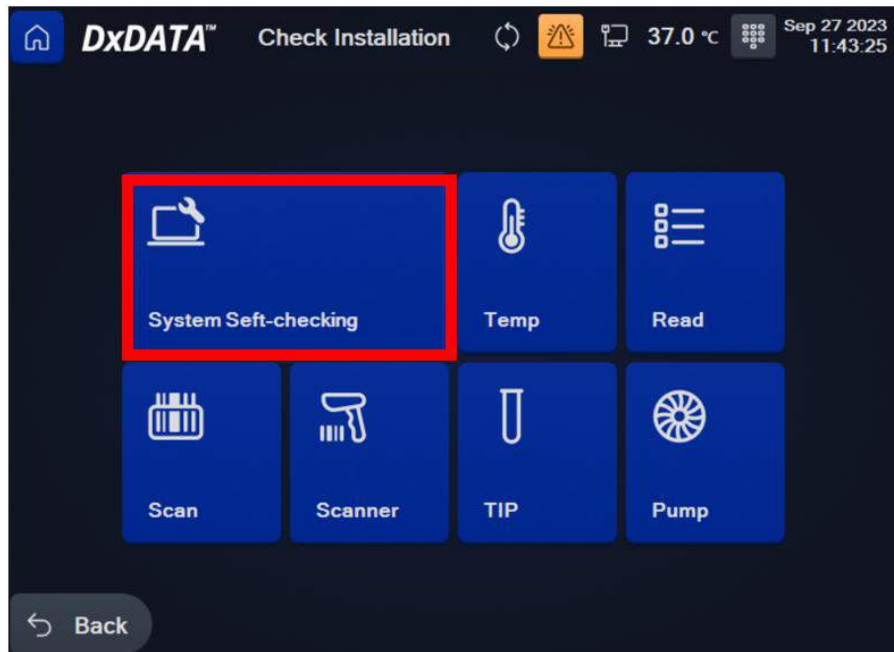
In the “Maintain” menu, click “Functional debug” to access the menu of system function tests.



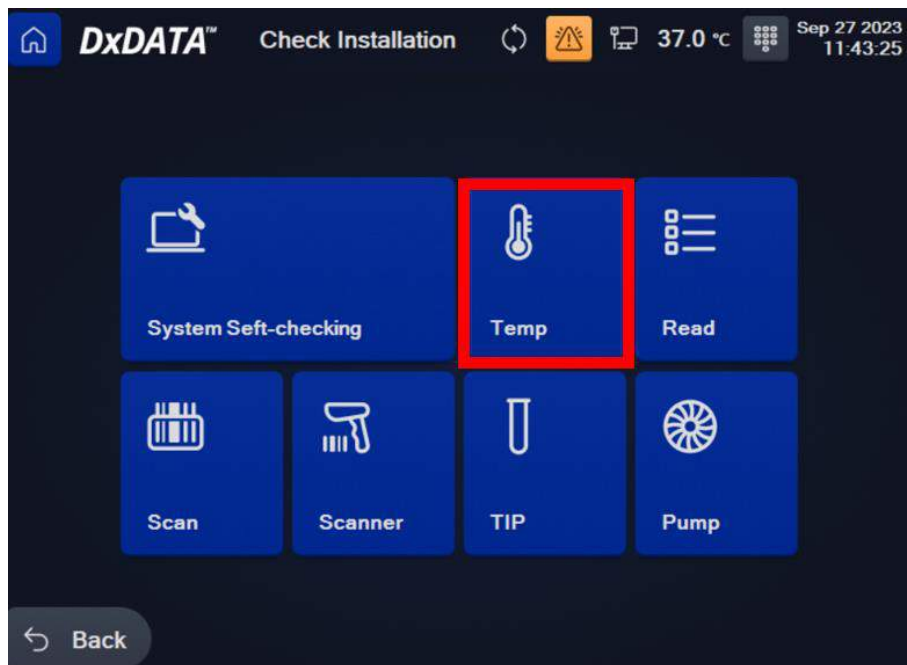
Check your instrument functionality in the “Install check “menu.



Click on “System self-checking” button. System will perform a self-test.



Click on “Temp” button for temperature test.



# Version 2.0

Set the number of reading times and click "Run". System will perform temperature test.

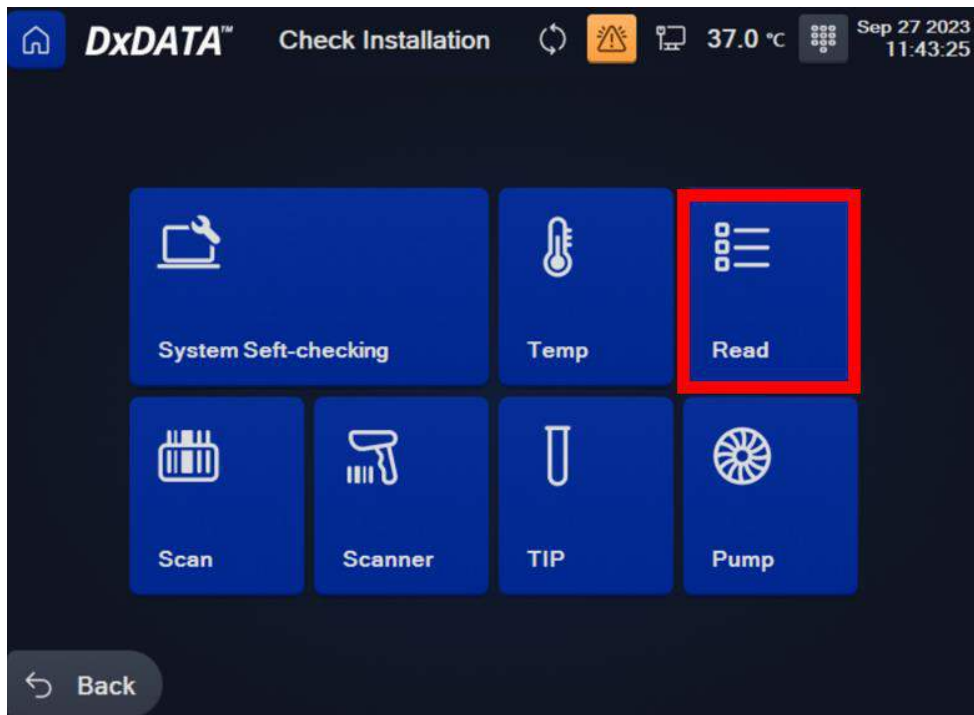
The screenshot shows the 'DxDATA' application interface for a 'Check temp' test. At the top, there is a header with the DxDATA logo, a refresh icon, a warning icon, a monitor icon, and a temperature display showing '37°C'. The date and time are 'Sep 27 2023 18:21:46'. Below the header, there are three input fields: 'Frame' (set to 1), 'Reading Times' (set to 5), and 'Time Interval' (set to 1). The main area contains a table with the following data:

S/N	Experiment time	Temperature 1	Temperature 2	Tempe
1	2023-09-27 18:21:31	37.5	37.5	<
2	2023-09-27 18:21:32	37.5	37.5	<
3	2023-09-27 18:21:33	37.5	37.5	<
4	2023-09-27 18:21:34	37.6	37.5	<
5	2023-09-27 18:21:35	37.6	37.5	<

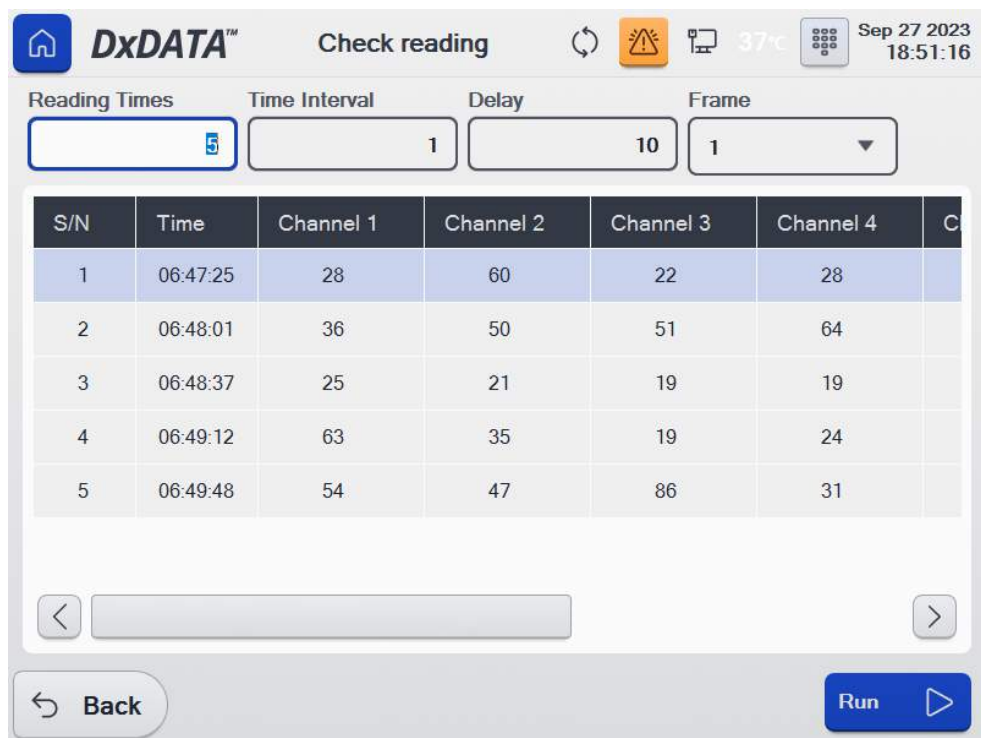
At the bottom of the interface, there are navigation buttons: a 'Back' button with a left arrow and a 'Run' button with a right arrow.

## Version 2.0

Click on “Read” button for PMT module test.

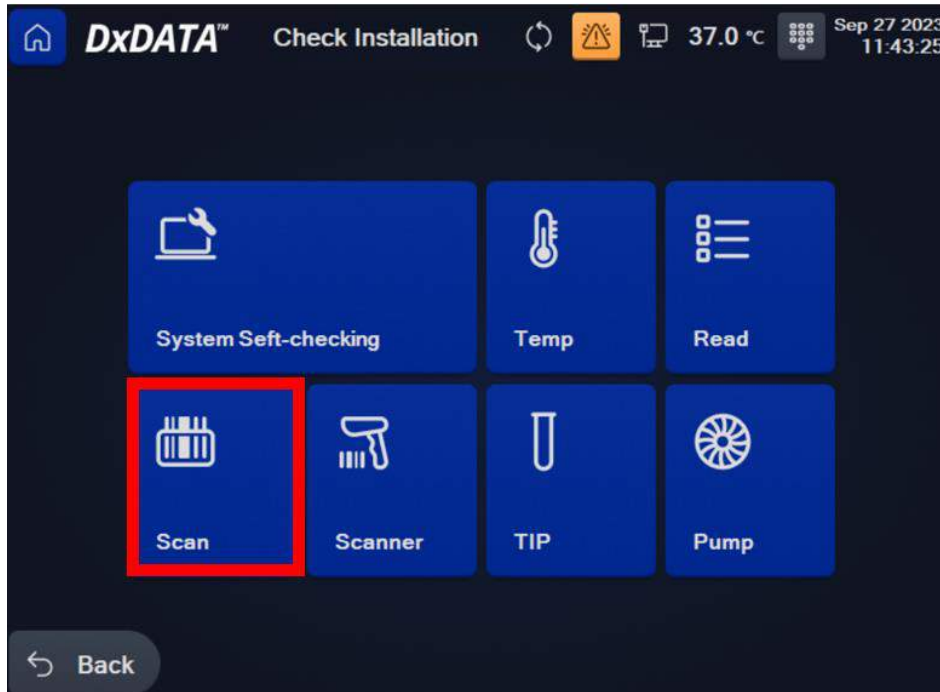


Insert 8 reagent cartridges, set the number of reading times and click “Run”. System will perform PMT module

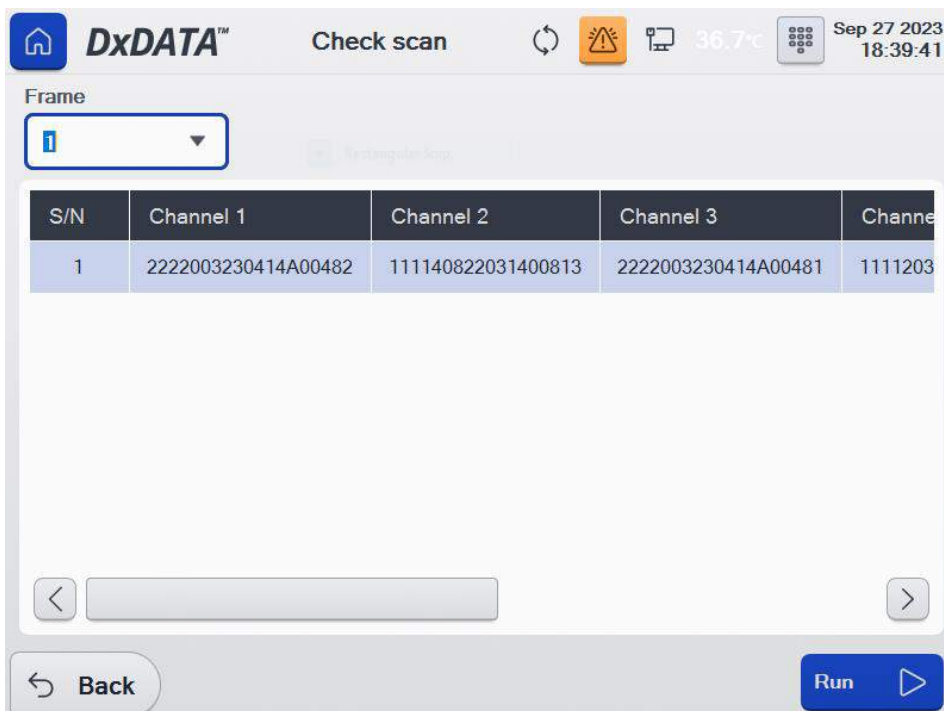


test.

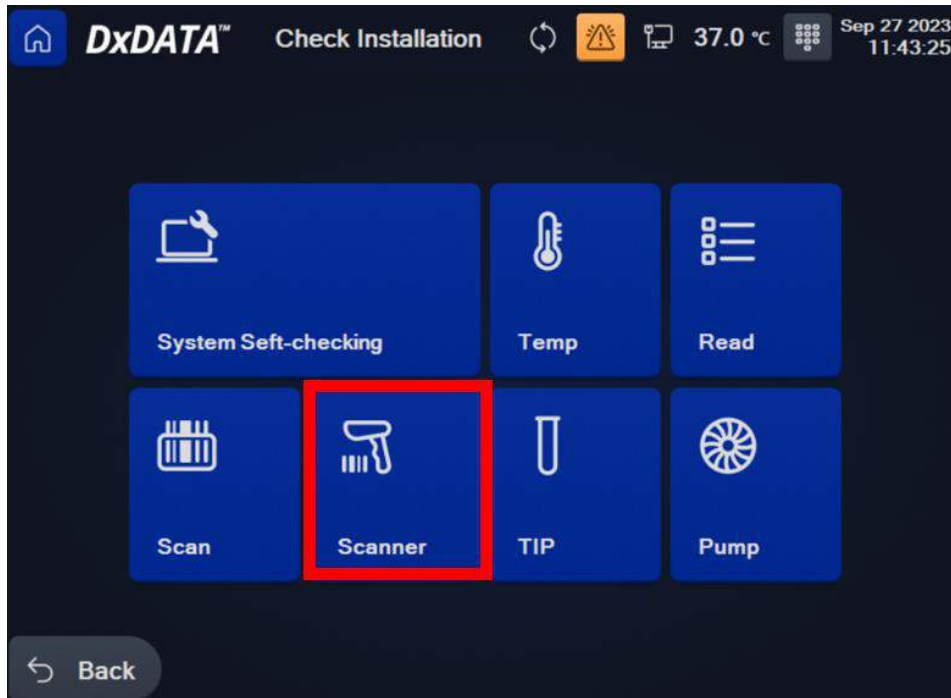
Click on “Scan” button for reagent barcode internal scanner test.



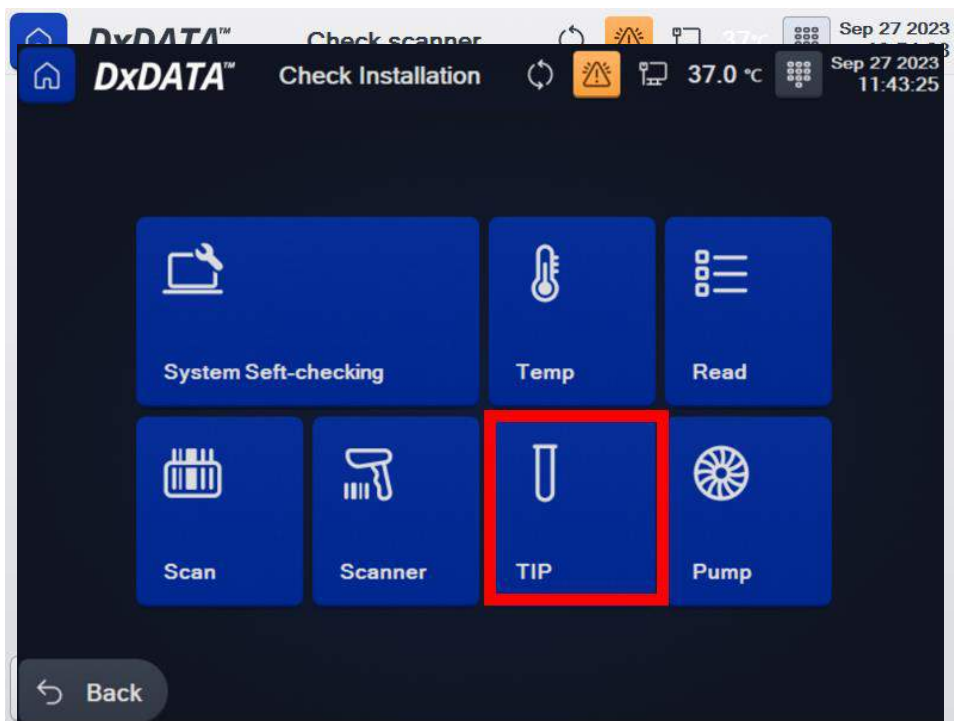
Insert 8 reagent cartridges and click “Run”. System will perform internal scanner test.



Click on “Scanner” button for the external barcode scanner test.

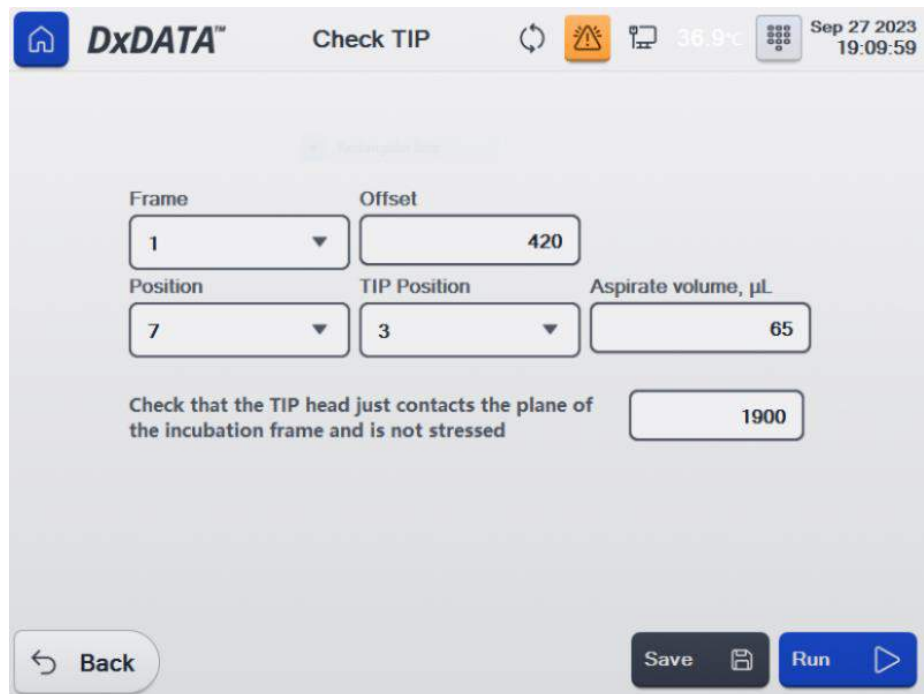


System will perform external barcode scanner test.



Click on “Tip” button for the pipette tips air tightness test.

Insert 8 reagent cartridges and click “Run”.

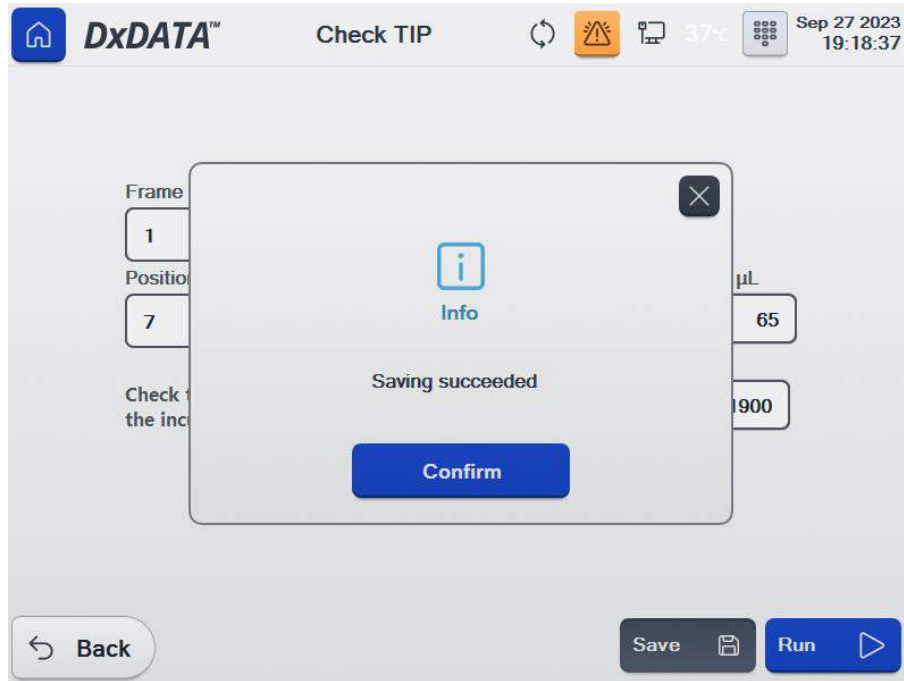


Follow procedure steps for the test.

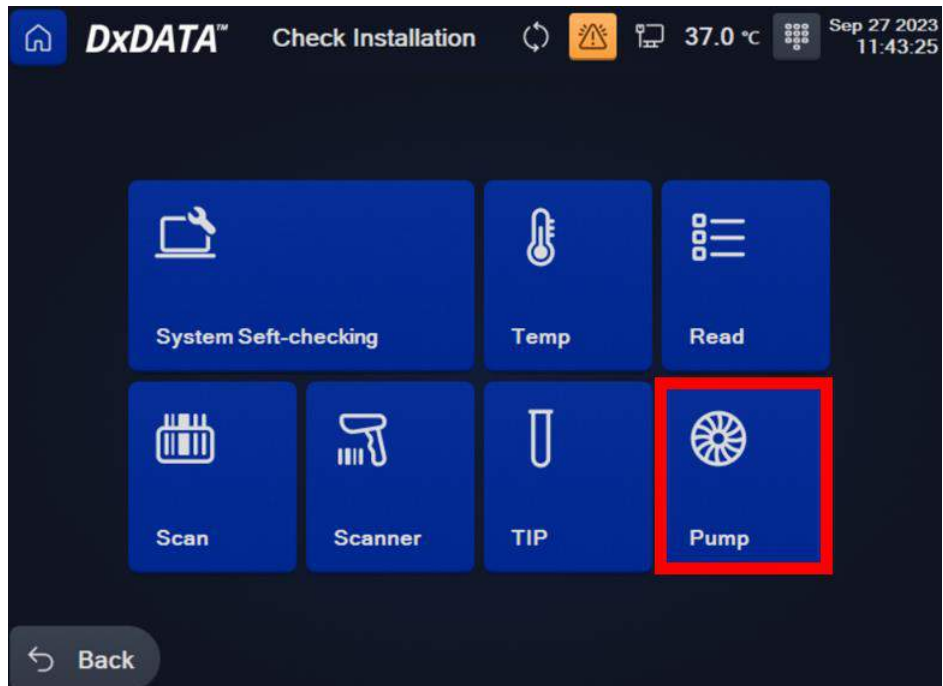


## Version 2.0

At the end of the test, click “Save” and “Confirm” button.



Click on “Pump” button for air tightness test.





Insert 8 reagent cartridges and click “Run”. System will perform air tightness test.

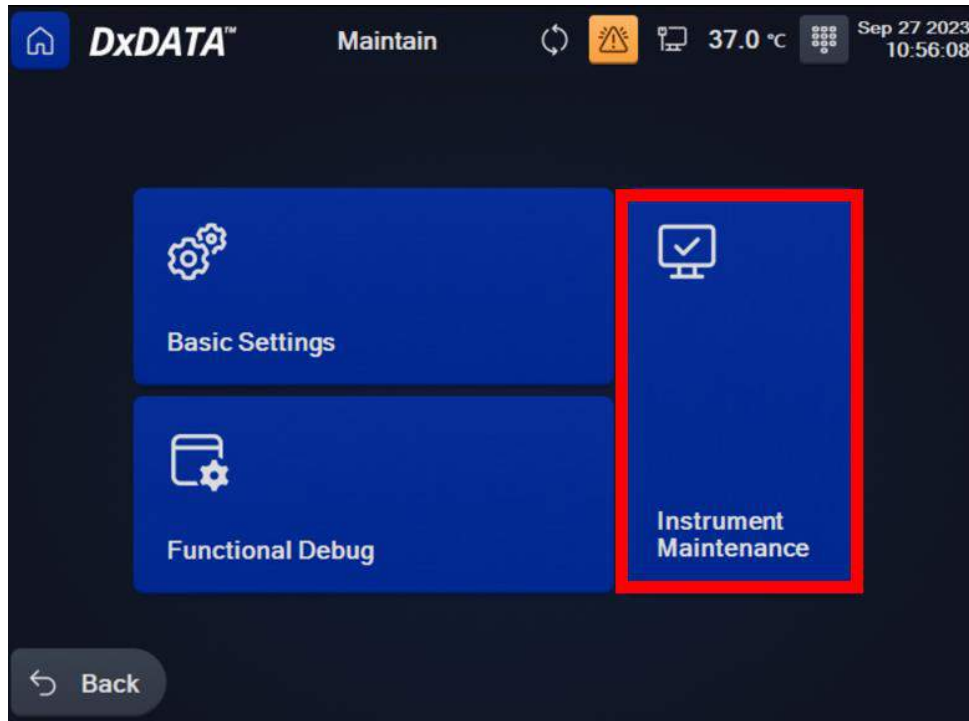
**DxDATA™** Check air tightness 37°C Sep 27 2023 19:20:22

Frame	Position	Aspirate volume, µL
1	5	1
TIP Position	Waiting time, s	
3	1	

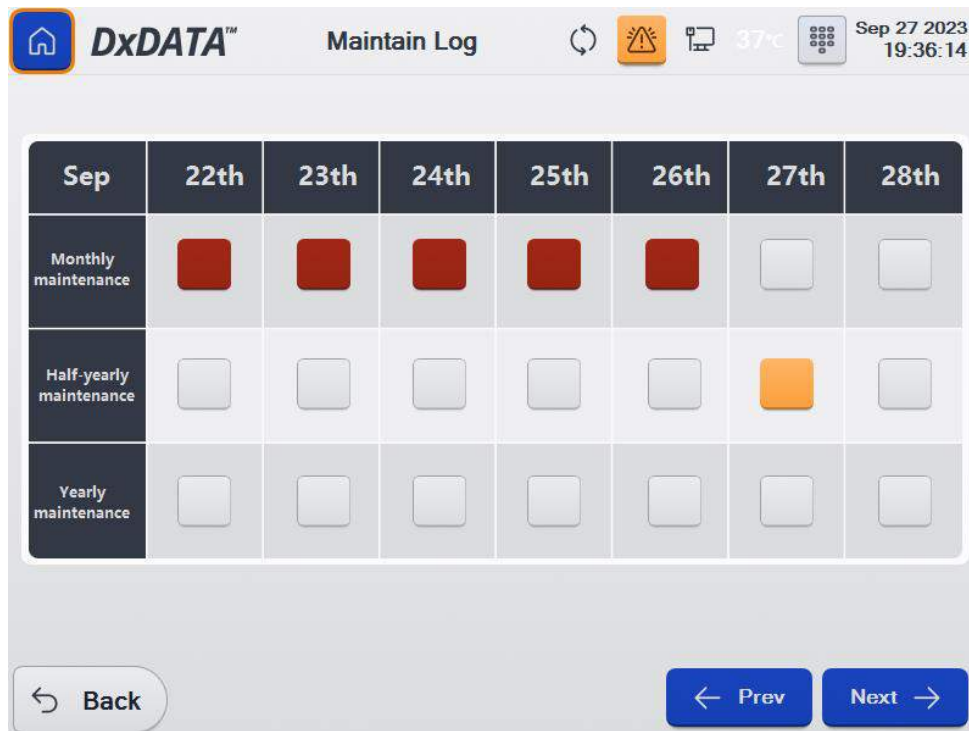
Back Run

## Version 2.0

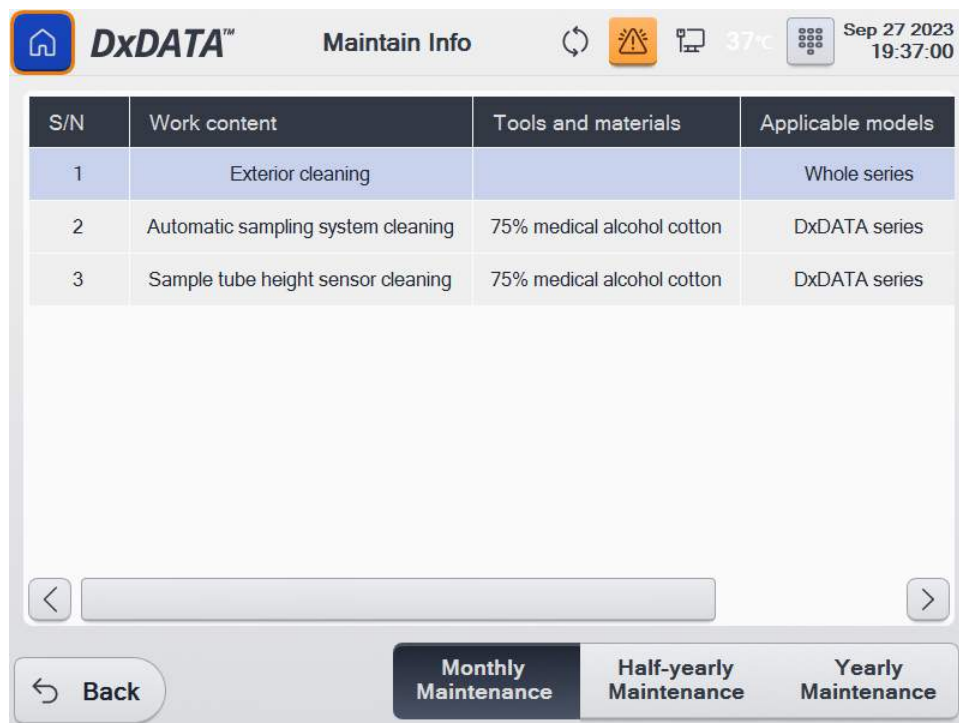
In the “Maintain” menu, click “Instrument maintenance” to access the menu of maintenance for the instrument.



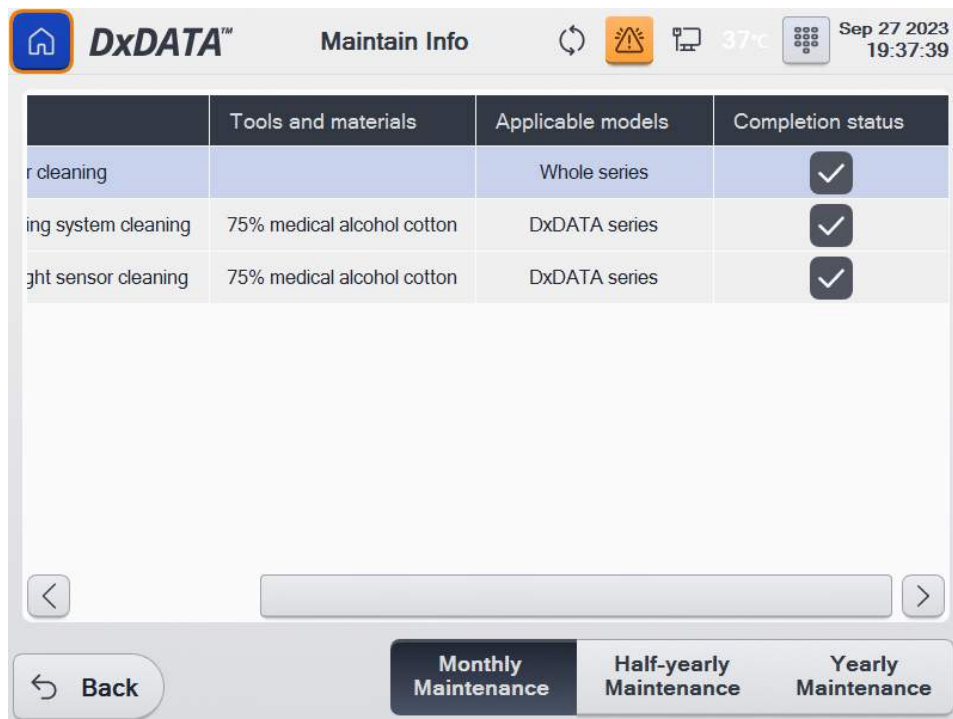
In the maintenance log, select the date and type of maintenance.



Open the maintenance info window to see the work content, tools and materials required for the maintenance.

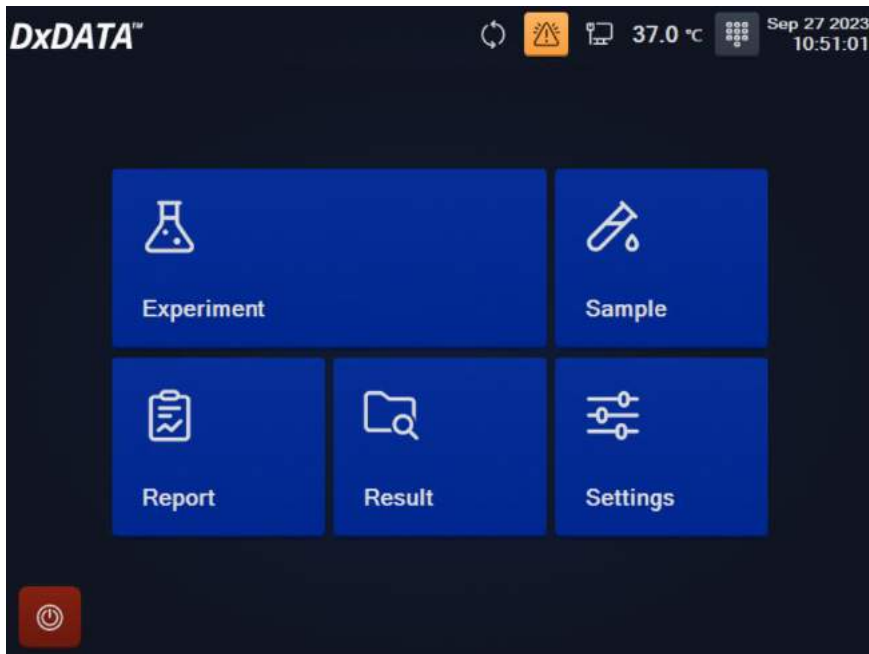


Use the check marks for the maintenance completion status.

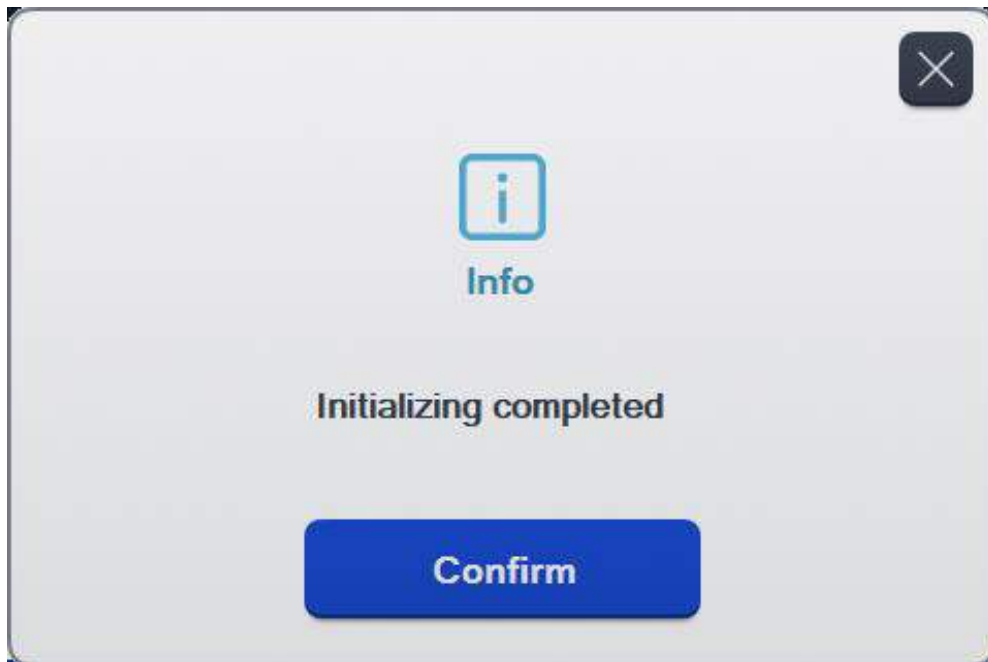


## Initialization

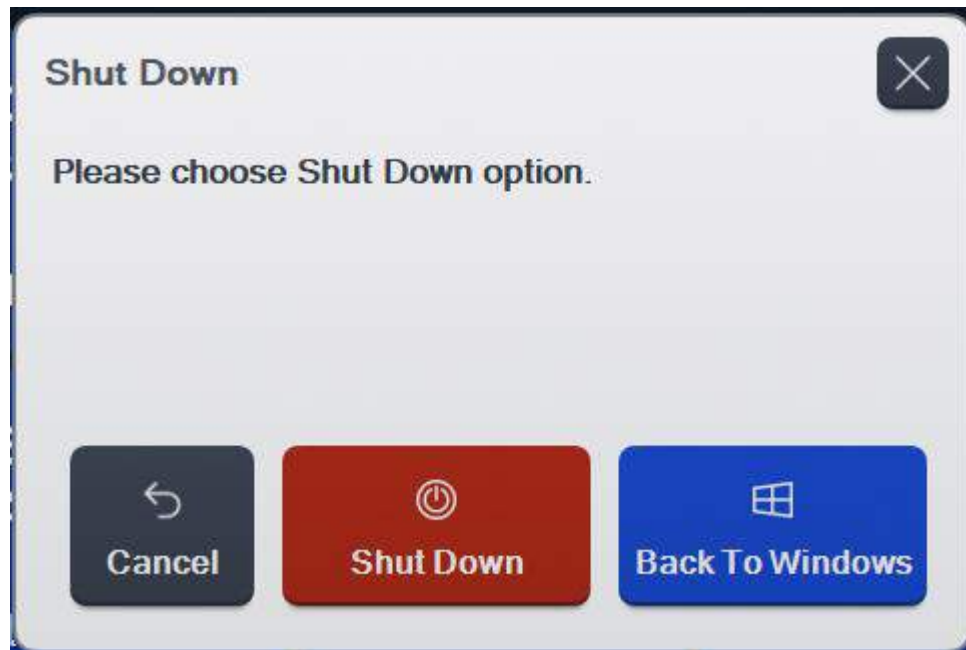
Click the “Initialization” button in the main window. System will be re-initialized.



Click “Confirm” button for successful instrument’s initialization.



## Shut down



- Click the "Shut down" button in the main window to access the instrument's shutdown options.
- Click the "Shut Down" button in order to shut down the instrument.
- Click the "Back To Windows" button to return directly to Windows, this will only close the current system.
- Click the "Cancel" button to cancel the current operation.

## **Instrument warnings and precautions**

### **Precautions**

- 1) Only trained, qualified laboratory personnel are authorized to use the instrument. Authorized personnel must wear appropriate protective gear (gloves, lab coat, safety goggles) and exercise standard precautions for handling and disposing of infectious or potentially infectious materials (e.g. patient samples or consumables).
- 2) The test cartridges provided by the manufacturer will not release toxic and harmful gases during the use of the instrument. The test sample is potentially infectious. Used test cartridges are treated according to the Medical Waste Management Regulations to avoid biohazard. If hazardous materials leak into the surface or inside the equipment, proper cleaning should be carried out (see Section 8).
- 3) During cleaning of the instrument ensure that the instrument is turned off.
- 4) Operator must follow the instructions in this manual in order to ensure safe operation.
- 5) DxDATA™ is a medical analytical instrument for testing serum. Do not use the device for other purposes.
- 6) Do not use solvents, abrasive cleaning fluids or rough cloth to clean any parts. Do not use cleaning agents or disinfectants that are not approved for cleaning or disinfections as specified in Section 8.
- 7) The door should not be opened during the operation of the instrument to avoid injury caused by touching moving parts.
- 8) The user must not open service door or remove any covers from the instrument.

## Troubleshooting

Issue	Causes of Issue	Solution
Z motion abnormality	Magnetic rod motor or magnetic sleeve magnetic sleeve motor movement abnormal	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>
TIP movement abnormality	TIP motor motion abnormality	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>
Abnormal pump motion	Sample pump motor movement is abnormal	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or authorized technical service representative.</li> </ol>
PMT movement abnormality	PMT motor motion abnormality	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>

Issue	Causes of Issue	Solution
Y-axis motion anomaly	Y-axis motor movement is abnormal	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>
X-axis motion abnormality	X-axis motor movement is abnormal	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>
Fitting exception, data processing is unsuccessful	Reagent related data processing exception	<ol style="list-style-type: none"> <li>1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists.</li> <li>2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.</li> </ol>
Open the serial port exception	Thermal printer communication is abnormal	<ol style="list-style-type: none"> <li>1. Contact the manufacturer's after-sales engineer or an authorized technical service representative</li> </ol>



## **Instrument maintenance**

When servicing the instrument, turn off the power and wear appropriate safety equipment (gloves, lab coats, goggles, etc.) to ensure the safety of the lab personnel.

### **Weekly maintenance**

- Gently clean the surface of the reagent rack with a lint free wipe soaked with disinfectant 70% alcohol.
- Ensure all channels are disinfected with 70% alcohol when cleaning the channels of the reagent rack.

### **Monthly maintenance**

- Clean the surface of the device with 70% alcohol.

### **Recommended regular maintenance**

- To ensure proper operation and reliability of DxDATA™ instrument, follow recommendations for periodic maintenance by the manufacturer's after-sales engineer or an authorized DxDATA™ technical service representative.

### **Replacing the internal printer paper**

- Power off the instrument before replacing printer paper.
- Pull the printer cover located at the lower left front of the unit.
- Open the printer cover of the device and pull open the printer cover.
- Remove the used paper roll and install new paper roll.
- Push the retaining plate back into place and use the paper cutter to cut off the excess of the paper.