

User Manual

BioCheck
DxDATA[™]

Automated Chemiluminescent
Immunoassay Analyzing System

FOR PROFESSIONAL USE ONLY

REF DXD-0001

IVD CE



The brands listed above are trademarks of BioCheck

Version 1.0



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 Symbols List

Symbol	Description	Symbol	Description
	In Vitro Diagnostic equipment		Catalog Number
SN	Serial Number		Consult Instructions for use
	Power on	O	Power off
CE	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 section 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

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

3. Details of DxDATA™

This section describes the measurement principle, equipment structure, and accessories used in DxDATA™.

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.

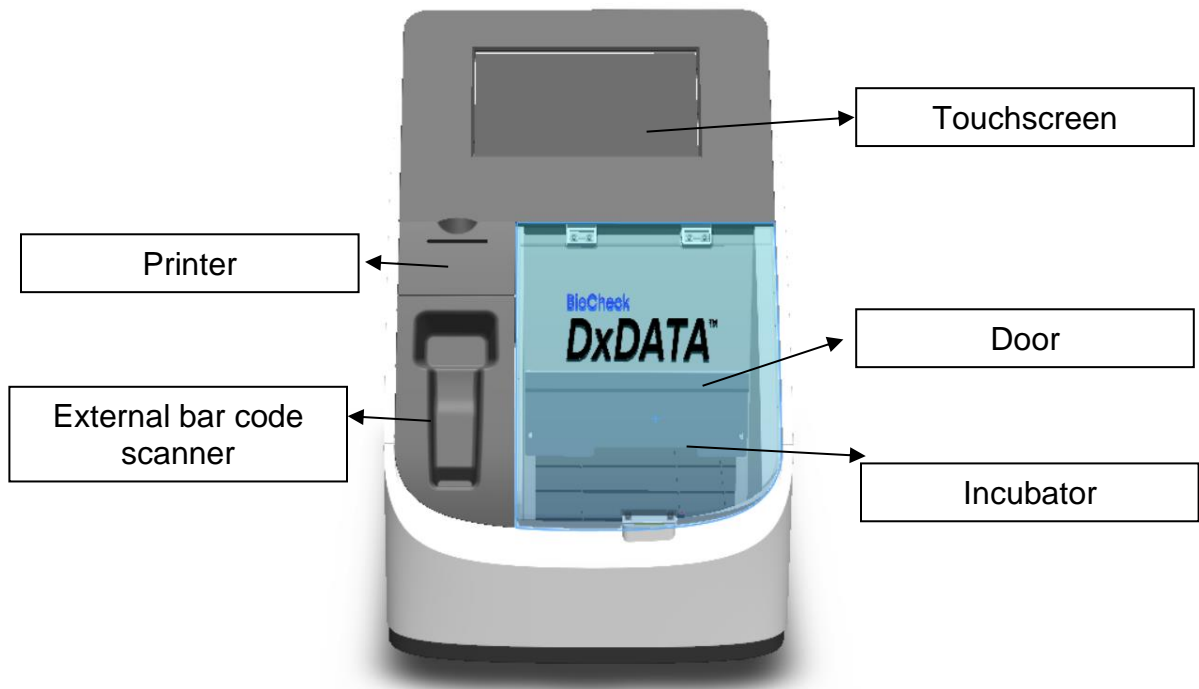
The DxDATA™ detection principle is described by applying the sandwich immunoassay reaction mode. The sample is combined with an alkaline phosphatase-labeled antibody and a biotinylated antibody to form a sandwich structure. The excess streptavidin-coated magnetic particles form a complex with the biotinylated 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 describes the components of the DxDATA™ and their functions.

3.2.1 Front of the Device

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



The necessary components for operating the DxDATA™ are located at the front and side 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 operating the device.
- **Printer** - Prints results and other information.
- **Swing-up door** - Open upwards to insert the reagent strip. The reagent strip information could be read and the experiment program could be selected automatically via the QR code auto scanning function.
- **External bar code scanner** - It is linked directly to the USB port at the backside of the instrument to read the information contained in the QR code.



The supply voltage is 110VAC






The supply voltage is 220VAC

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

- **Switch** - This is the main power switch of the device. After the instrument is turned on, the computer powers up in about 1 minute.
- **USB** - Provides connection to the instrument`s internal computer.
- **110/220 VAC** - Provides connection to the power cable.
- **Fuse: F2AL250V/F3AL250V** - Protects the internal circuitry of the instrument.

3.2.3 Accessories

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

Main Accessories Description	Quantity	Remarks	Picture
Power cord	1	Standard	
Fuse: F2AL250V/F3AL250V	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 there is no paper or other objects that may affect the air circulation in this area.
- 5) DxDATA™ is placed at an altitude of no more than 2000 meters.

5. Software Description

5.1 Software Overview

This section describes the software used with DxDATA™ instrument.

5.1.1 Software Environment

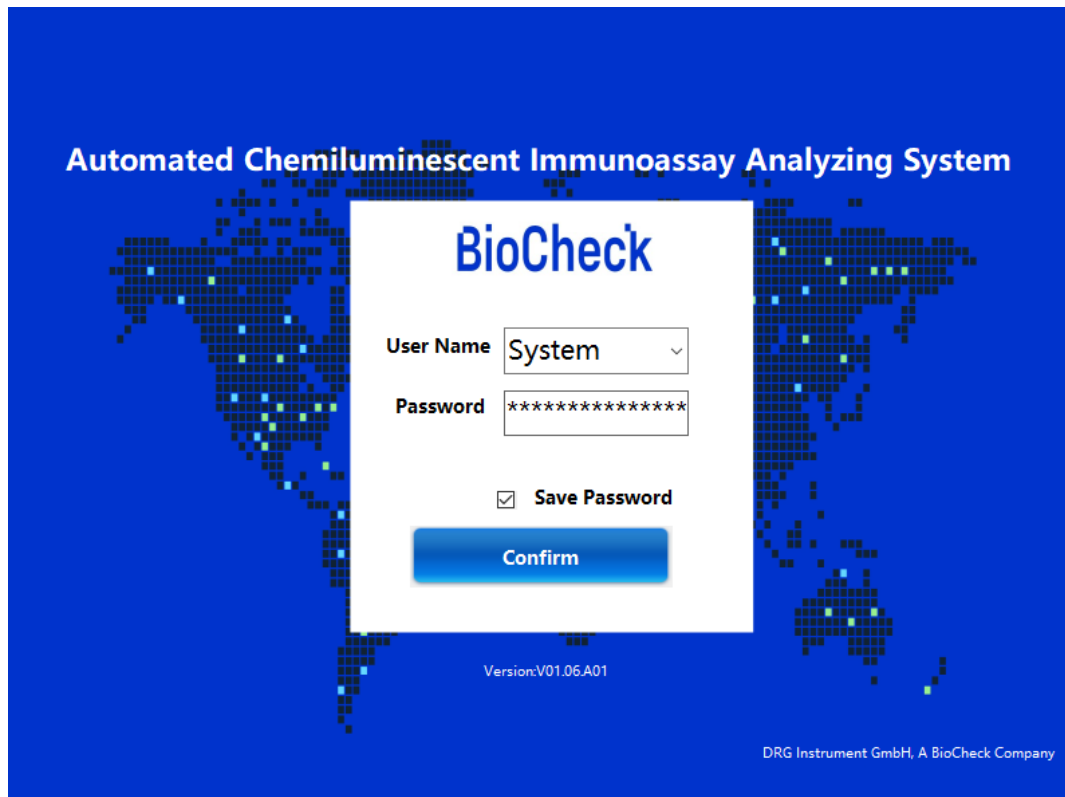
- 1) Devise uses a custom 10-inch touch screen, with a resolution of 800X600 pixels.
- 2) Pre-installed Microsoft Windows 10 Enterprise operating system.

5.2 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 “DxDATA”.





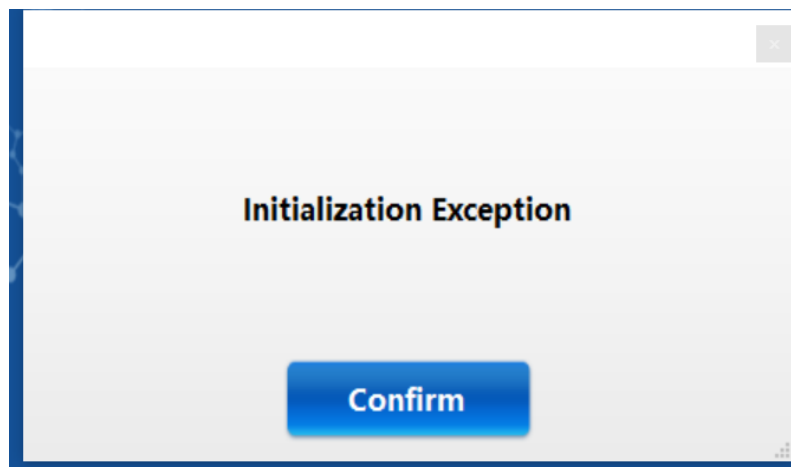
- 1) To log in, enter the username and password, you can select option to save the password. When the "Confirm" button is clicked, the system checks the username and password, and then login to the system is completed after meeting the system requirements.
- 2) Usernames are used to distinguish system 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)

5.4 Initialization check

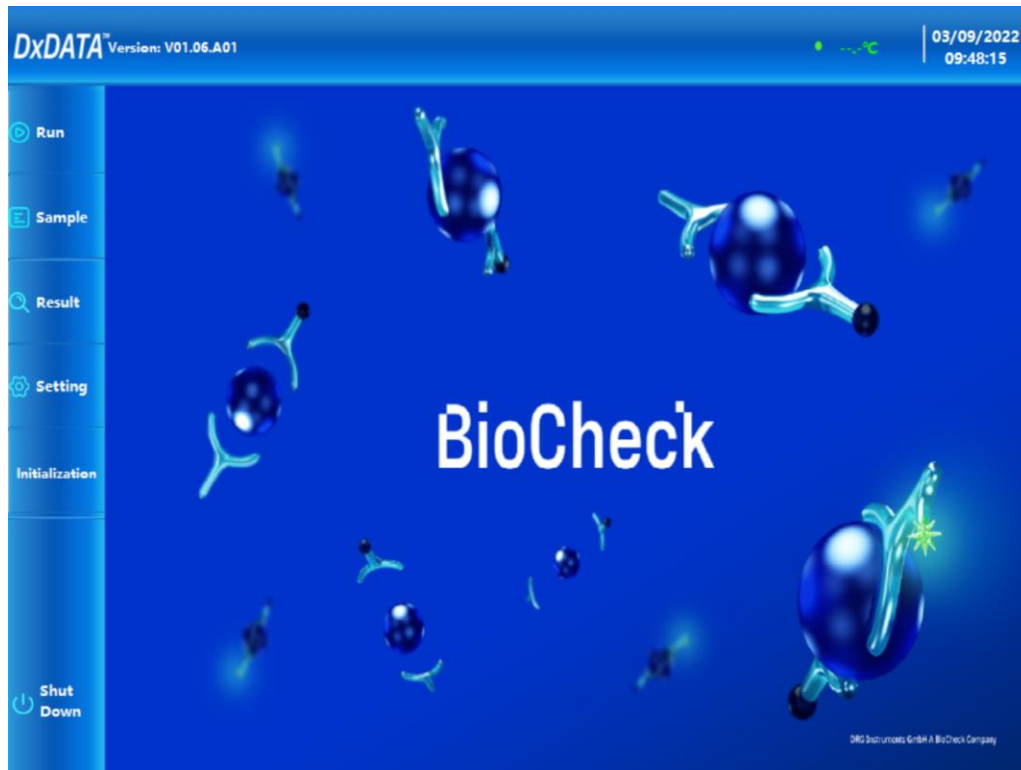
- 1) After login the system will initialize. A dialogue box will show “Initialization complete” and click on the “Confirm” button will provide access the main window.



- 2) If an error, like the ones below, is encountered contact our Technical Support or your local representative.



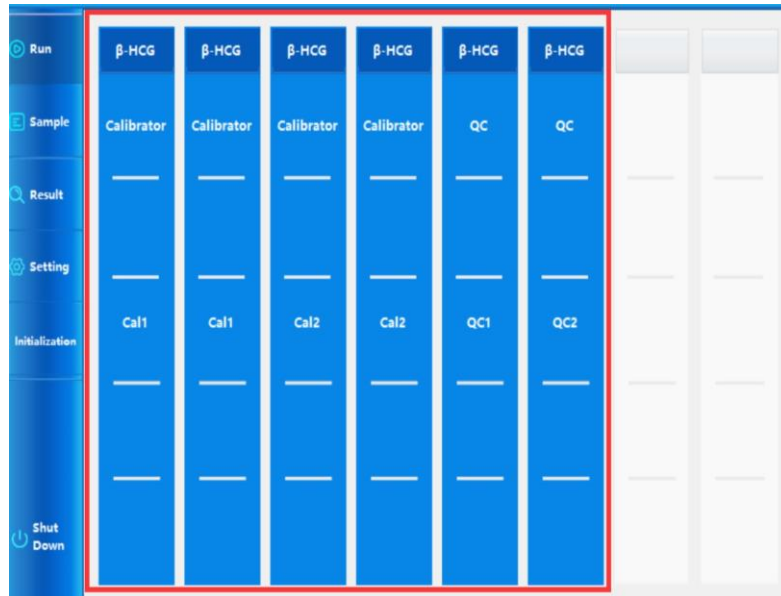
5.5 Main window



- 1) Click "Run" to enter the device running window
- 2) Click "Samples" to go to the samples management window
- 3) Click "Results" to enter the results query window
- 4) Click "Settings" to proceed to the settings window

5.6 Run window

The “Run” 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.



5.6.1 Routine detection settings

All the applicable information such as project, sample and batch number can be manually added on a channel-by-channel basis in the “Run” window.

- 1) Double-click a "Project" or "Sample" position to pop up a window for editing.

- 2) Confirm the correct detection position, select project name, batch number and sample type (Sample, Calibrator or QC).

5.7 Sample window

The “Sample” window allows you to add sample 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 more.

Select	Detection Date	Channel	Sample ID	Patient Name	Project Name

5.7.1 Scan Accession number

- 1) Select the project(s) for the cartridges and scan the accession number into the “Autoscan” toolbar.
- 2) If you do not want to add an accession number, the cartridge QR code can be scanned instead or click Sample Quantity “Add Data” button shown below.
- 3) Add data



Select the project and enter the number of samples. Click "Add Data" to automatically fill in "Detection Date", "Channel", "Sample ID" data.

NOTE: Date of testing and results follow the Year-Month-Day format.

- 1) Double-click the sample record to open information edit interface.

The screenshot displays a form for editing a sample record. The form is organized into two columns of input fields. The left column includes: Testing Date (text box with '20200602'), Sample ID (text box with '20200602002'), Name (text box), Gender (dropdown menu), Age (text box with 'year' and a dropdown arrow), Hospitalization No. (text box), Bed Number (text box), Examiner (dropdown menu), and Auditor (dropdown menu). The right column includes: Serial Number (text box with '39'), Submitting Doctor (dropdown menu), Submission Date (text box with '20/06/02 3:46:18 PM'), Contact Number (text box), Department (dropdown menu), Patient Category (dropdown menu), Clinical Diagnosis (text box), Receiving Time (dropdown menu with 'Tuesday , June'), and Notes (text box). At the bottom of the form, there are three blue buttons: 'Continue', 'Cancel', and 'Done'.

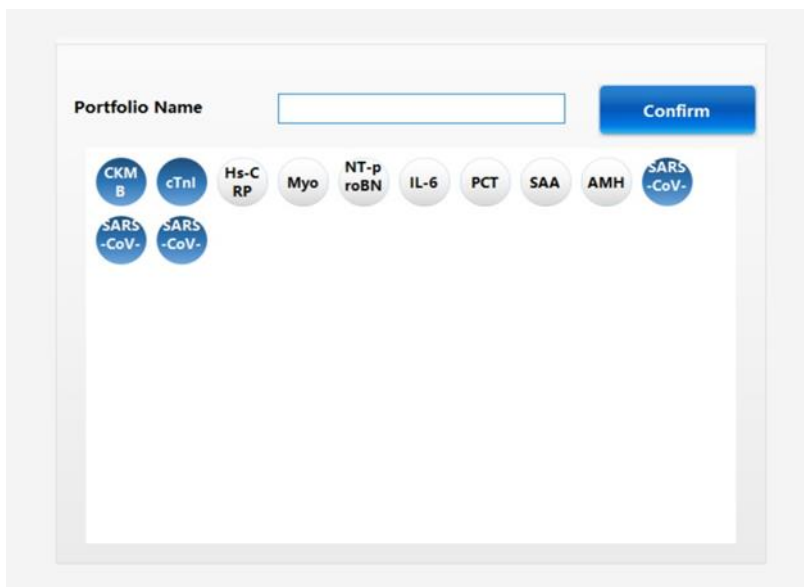
- 2) Fill in the corresponding data, click the "Continue" button in order to save the current data and load data for the next cartridge slot.
- 3) Click the "Cancel" button to cancel the current operation.
- 4) Click the "Done" button to close the current interface and return to the "Sample" window.

5.7.3 Set up project portfolio

- 1) Double-click the “Project portfolio” button at the top to open the portfolio settings window.



- 2) Enter the portfolio name and select or deselect the reagents. Blue is selected, white is deselected. Click the "Confirm" button to save the current item information.



5.7.4 Delete

- 1) In the “Sample” window select a row sample record and click "Delete" button in order to delete the sample record.



5.7.5 Historical data



- 1) In the “Sample” window click “Historical Data” to enter the history interface for sample information.

- 2) Select the testing date range and click “Search” button to display the results of the samples search.

The screenshot shows a search interface with two date selection boxes at the top, both set to "Friday, May 21, 2021". Below the date boxes are two blue buttons: "Search" on the left and "Exit" on the right. Below the buttons is a table with the following headers: "Detection Date", "Channel", "Sample ID", "Patient Name", "Age", "Gender", and "Project Name". The table body is currently empty. At the bottom of the table, there are two horizontal scroll bars, one for the table content and one for the entire interface.

Double-click the sample record to go to the information edit screen.

5.7.6 Exit



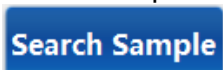
In the “Sample” window click “Exit” button to exit the current interface.

5.8 Results window

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

The screenshot displays the 'Results' window interface. At the top, there are four blue buttons: 'Search Sample', 'Search Calibration', 'Search QC', and 'Exit'. Below these are search filters: 'Detection Date' with two date pickers (both set to 'Friday, May 21, 2021'), 'Project Name' with a dropdown menu, 'Sample ID' with a text input field, and 'Patient Name' with a text input field. A row of action buttons includes 'Search', 'Upload to LIS', 'Print Result', 'Print List', 'Export-TXT', 'Export-PDF', and 'Export-EXL'. Below the buttons is a checkbox labeled 'Select All' which is checked. At the bottom is a table with the following headers: 'Select', 'Detection Date', 'Submission Time', 'Detection Time', 'Channel', and 'Concentration'. The table body is currently empty and has a grey background.

5.8.1 Search Sample



- 1) After entering the "Results" window, the software automatically displays "Search Sample" interface.

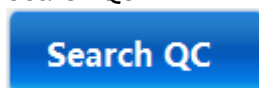
The screenshot shows a search interface with the following elements:

- Buttons: Search Sample, Search Calibration, Search QC, Exit
- Filters:
 - Detection Date: Friday, May 21, -- Friday, May 21
 - Project Name: [Dropdown]
 - Sample ID: [Text Input]
 - Patient Name: [Text Input]
- Action Buttons: Search, Upload to LIS, Print Result, Print List, Export-TXT, Export-PDF, Export-EXL
- Checkbox: Select All
- Table:

Select	Detection Date	Submission Time	Detection Time	Channel	Concentration
<input checked="" type="checkbox"/>	20200602	2020-06-02 10:33:22	2020-06-02 10:50:22	1	2020060200
<input checked="" type="checkbox"/>	20200602	2020-06-02 10:33:22	2020-06-02 10:50:22	2	2020060200
<input checked="" type="checkbox"/>	20200602	2020-06-02 12:59:39	2020-06-02 13:33:00	1	192020_01
<input checked="" type="checkbox"/>	20200602	2020-06-02 12:59:39	2020-06-02 13:33:00	2	192020_01
<input checked="" type="checkbox"/>	20200602	2020-06-02 12:00:02	2020-06-02 12:33:00	2	102020_02

- 2) Under this interface, you can select “Detection Date”, “Project Name”, “Sample ID” and “Patient Name” for your search. The “Detection Date” is mandatory to see the results, while all other search criteria is optional. If you do not enter information, you do not select the condition.
- 3) Click the “Search” button to retrieve the experimental results of all samples under the current selection condition and display them in the data area below.
- 4) Click “Upload to LIS” to upload the results of the current search to the LIS system.
- 5) Click “Print List” to print the current search records by list.
- 6) Click “Export-TXT” to export data and save as a text document.
- 7) Click “Export-EXL” to export data and save as an Excel document.

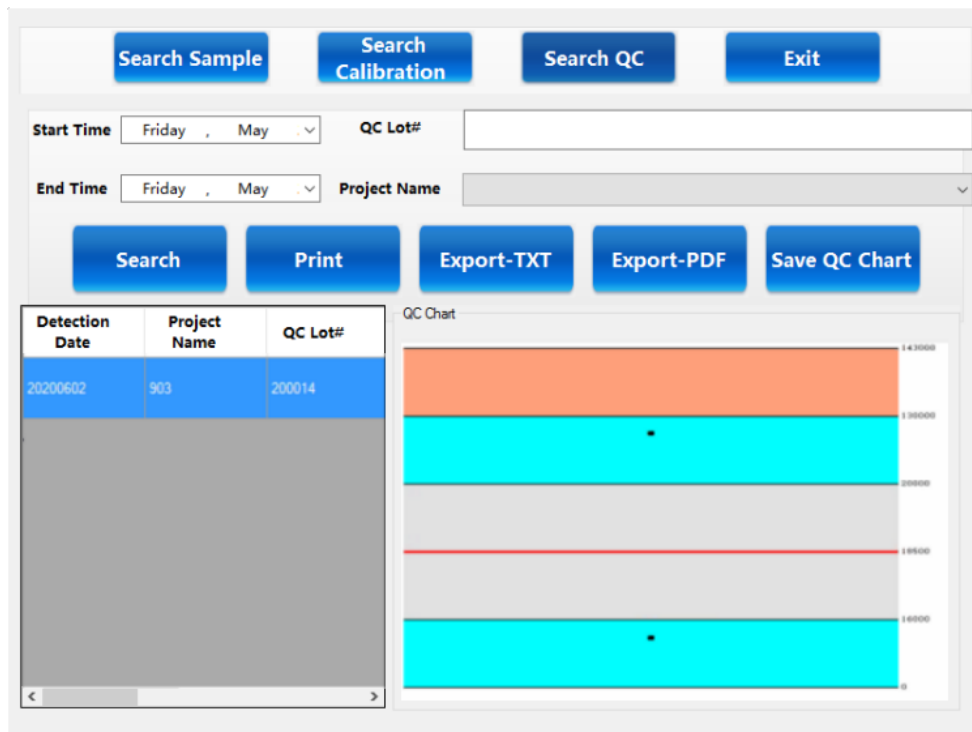
5.8.2 Search QC



- 1) Click “Search QC” button to enter the “Search QC” window.

The screenshot shows a software interface with a search section at the top. It contains four buttons: "Search Sample", "Search Calibration", "Search QC", and "Exit". Below these are input fields for "Start Time" (set to Friday, May), "QC Lot#" (empty), "End Time" (set to Friday, May), and "Project Name" (empty dropdown). A second row of buttons includes "Search", "Print", "Export-TXT", "Export-PDF", and "Save QC Chart". At the bottom left is a table with columns "Detection Date", "Project Name", and "QC Lot#". At the bottom right is a "QC Chart" area which is currently empty.

- 2) Select "Project Name", "Start Time", and "End Time" as required items, the rest are optional.
- 3) Click the "Search" button to retrieve all the quality control results for the selected conditions.



- 4) Click “Save QC chart” to save the currently displayed quality control charts.
- 5) Click “Print” to print list format.
- 6) Click “Export PDF” to save as PDF document.
- 7) Click “Export-TXT” to export data and save as a text document.

5.9 Settings window

The “Settings” window includes Reagent Management, Port setting, Hospital Information Setting, Alarm record and Switch user options.



Click the corresponding button to enter the corresponding window.

5.9.1 Reagent Management

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

The screenshot displays the 'Reagent Management' interface. On the left, a sidebar contains navigation icons for 'Run', 'Samples', 'Results', 'Settings', 'Initialization', and 'Shut Down'. The main content area features a grid of project buttons: GFAP, PGP9.5, PTH, 25-OH-V D, CKMB, cTnI, D-Dimer, Hs-CRP, AMH, E2, β -HCG, and FSH. Below this grid is a 'Project List' button. To the right, there are input fields for 'Project Name', 'Abbr.', 'Sample Type', 'Project Code', and 'Unit'. A 'Reference Interval' table is shown with columns for 'Gender' and 'Lower'. Below the table are fields for 'Reagent Lot#' and 'Expiry Date'. Further down are fields for 'Calibration Date' and 'Next Calibration Time' (with a 'day(s)' label). At the bottom, there are three buttons: 'Back', 'Add New Batch', and 'Calibration History'. The top right corner shows the date '05/23/2022' and time '17:32:41'.

1) To Add a new batch of reagents

- Select the “Project List” on the left side of the screen and detailed information of the currently selected projects will be automatically displayed.
- Click the “Add New Batch” button to select a new batch of the currently selected project.

The screenshot shows the 'Add New Batch' interface in the DxDATA software. The interface is primarily blue and white. At the top, there's a header with 'DxDATA' on the left, 'Add New Batch' in the center, and a date/time '05/23/2022 17:37:50' on the right. A vertical sidebar on the left contains several menu items: 'Run', 'Samples', 'Results', 'Settings', 'Initialization', and 'Shut Down'. The main content area is a form with the following fields: 'Project Name' (a dropdown menu showing 'D-Dimer'), 'Abbr.' (a text input field with 'D-Dimer'), 'Expiry Date' (a date picker showing 'Monday, May 23, 2022'), 'Reagent Lot#' (an empty text input field), and 'Scan' (an empty text input field). Below the 'Scan' field is a table with three columns: 'Sign', 'RLU Value1', and 'RLU Value2'. The table is currently empty. At the bottom of the form, there are four blue buttons: 'Manual Input', 'Save Data', 'Calibration', and 'Back'. The version number 'V1.0' is visible in the bottom left corner of the sidebar.

- **Scan:** 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.
- **Manual Input:** If unable to be scanned, the information can be manually added via the “Manual Input” button.

NOTE: After scanning or manually inputting the batch information, the “Reagent Lot#” and “Expiry Date” values are unable to be changed.

- After inputting, click the “Save Data” button to save the current batch data.
- You can also add multiple batches of information at once. Repeat the above operation.
- Click the “Back” button to exit the current interface and return to the reagent management interface.
- Click the “Calibration” button to proceed with reagent calibration in the “Run” menu.

5.9.2 Port Setting

Click “Port Setting” button for printer and LIS settings

- Select or deselect “Built-in printer” option for internal printer use.
- Select or deselect “Automatic Printing”
- Enter the settings data for Port ID, Baud Rate.
- Select or deselect “External printer” and enter the settings data: Printer name, Page Size.
- Define PDF printer name.
- Confirm the settings

DxDATA Port Setting 05/23/2022 18:08:52

Run
Samples
Results
Settings
Initialization
Shut Down
V1.0

Built-in Printer Automatic Printing

Port ID COM1 Baud Rate 9600

External Printer

Printer Name HP LaserJet 1020

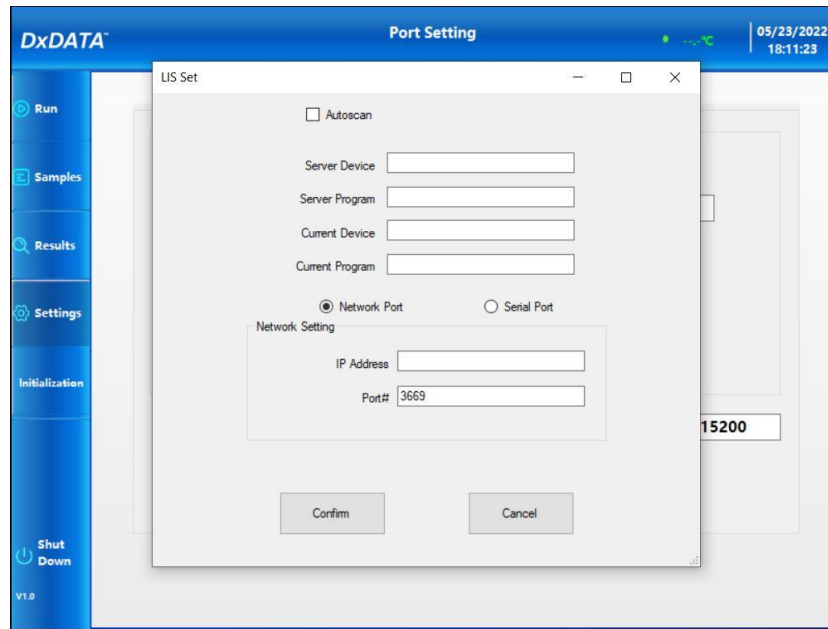
Page Size A4

PDF Printer Name Microsoft Print to PDF

Autoscan Port ID COM7 Baud Rate 115200

LIS Setting Confirm

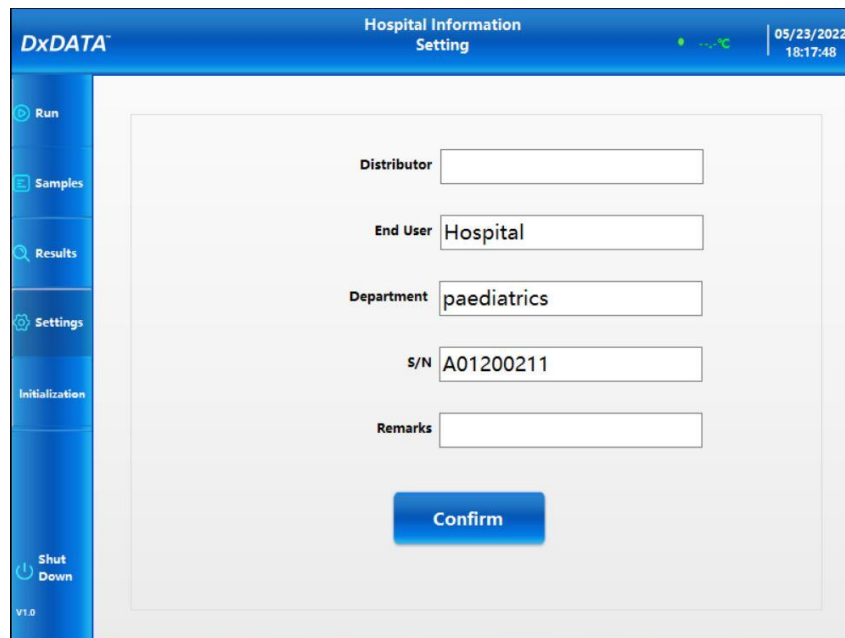
- Click the “LIS Setting” button to enter the LIS setting menu. In the LIS setting menu fill in all the information required for the LIS set up. Click “Confirm”.



5.9.3 Hospital Information Setting

Click “Hospital Information Setting” button for end-user settings

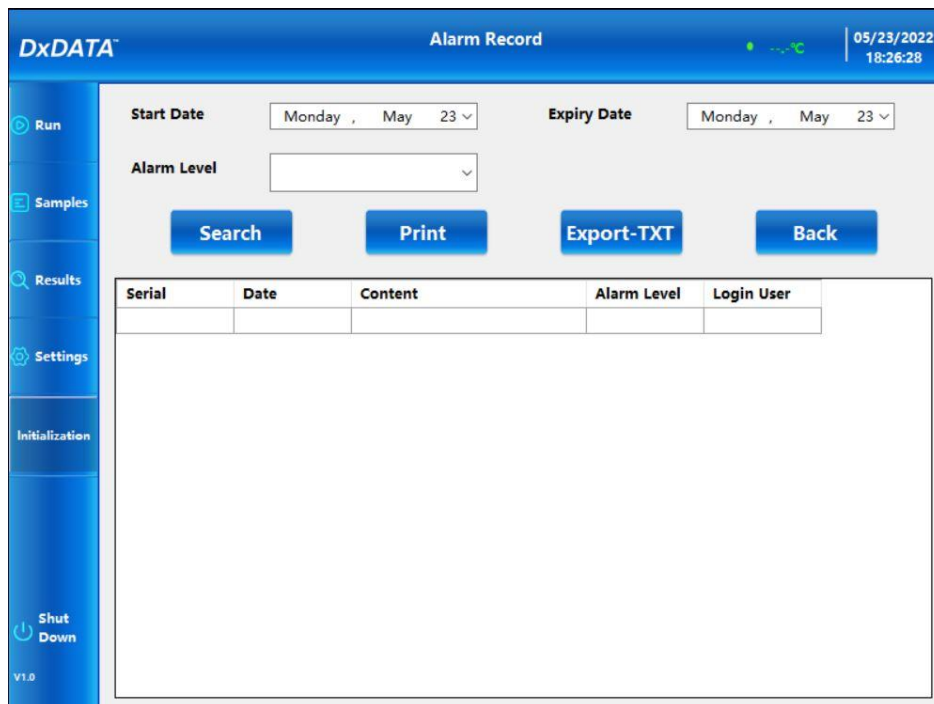
- Click on the corresponding box to update Distributor, End User, Department, Instrument S/N information and add Remarks. Confirm the changes.



5.9.4 Alarm Record

Click “Alarm Record” button for instrument alarm records history

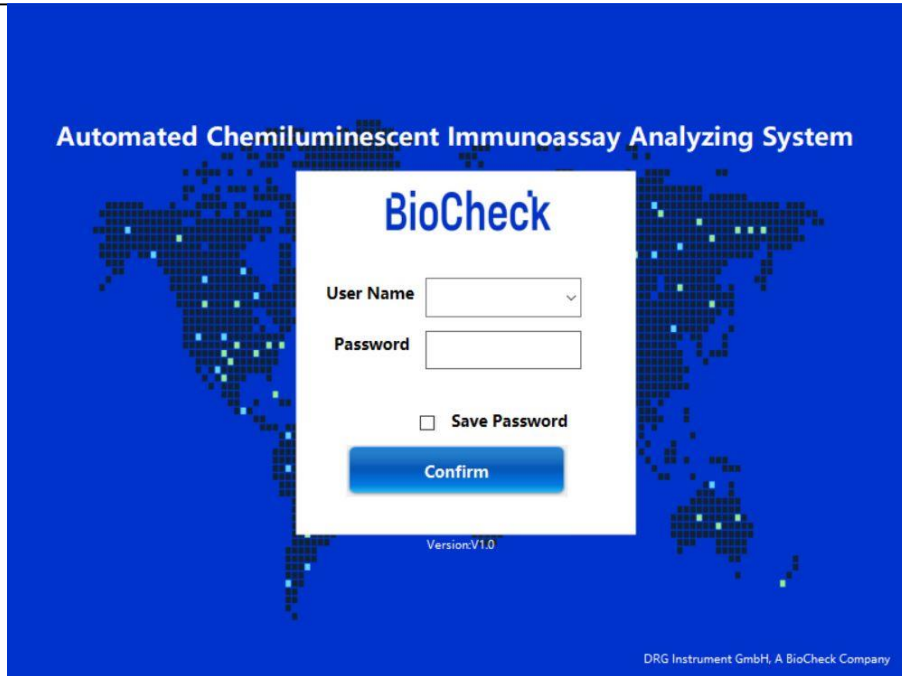
- Select the alarm record Start and Expiry dates and Alarm Level in the drop-down menus.
- Click the “Search” button in order to display all the alarm records for selected time and alarm level.
- Click “Print” button to print the results.
- Click “Export-TXT” button to save results as .txt file



5.9.5 Switch User

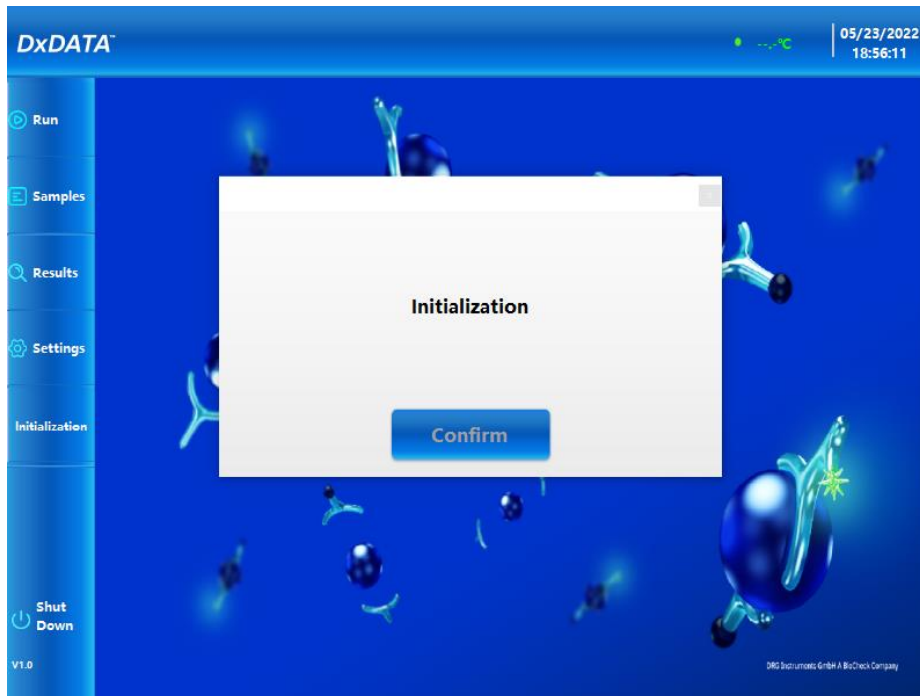
Click “Switch User” button to log in with a different user name

- Select User Name and enter the Password in the log in window.

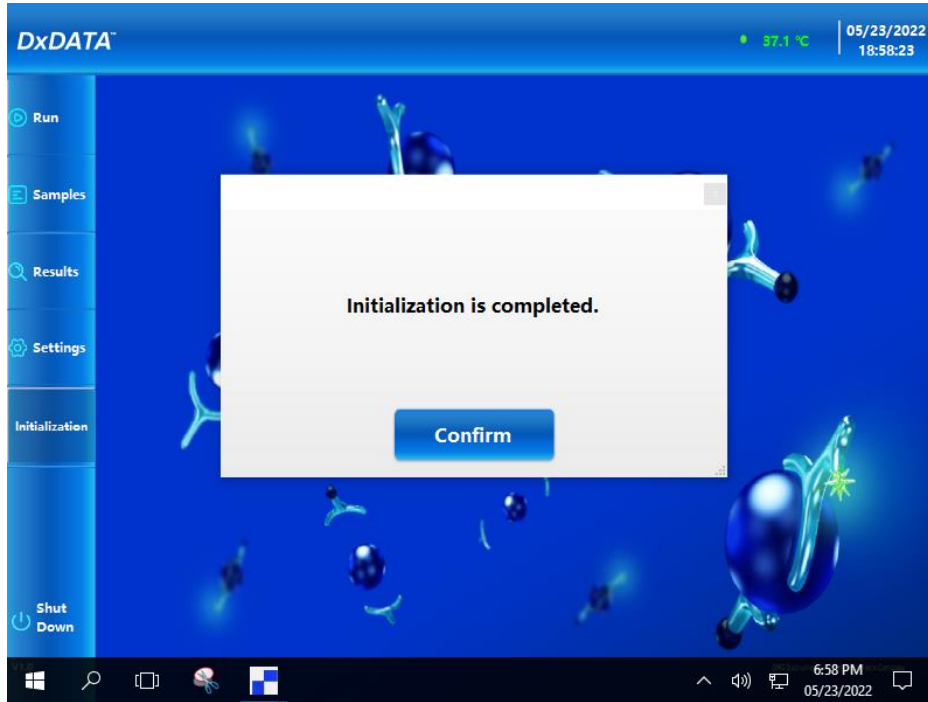


5.10 Start initialization

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

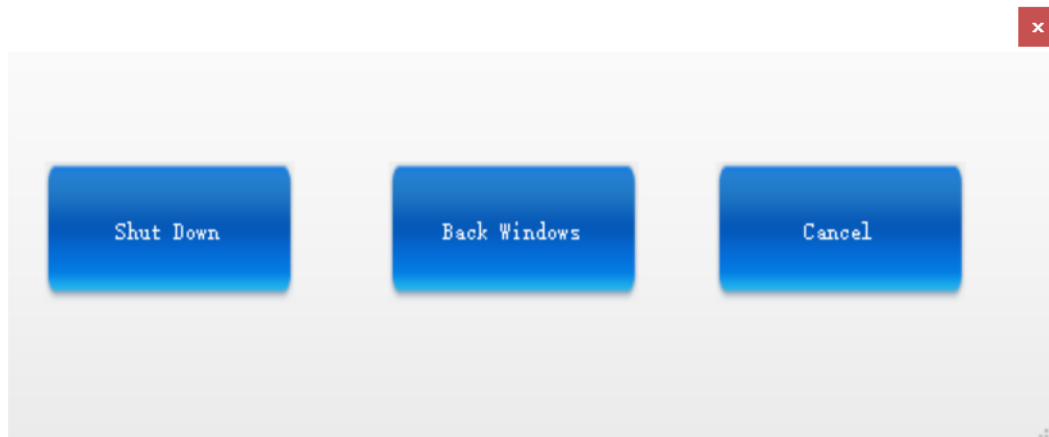


- Click “Confirm” button for successful instrument`s initialization.



5.11 Shut down

- Click the “Shut Down” button in the main window to access the instrument`s shutdown options.
- Click the "Shut Down" button to directly close the display interface.
- Click the "Back Windows" button to return directly to Windows, this will only close the current system.
- Click the "Cancel" button to cancel the current operation.



6. Instrument warnings and precautions

6.1 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.

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

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

8. 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.

a. Weekly maintenance

1) Clean the Reagent Rack

- 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.

b. Monthly maintenance

1) Clean the surface of the device with 70% alcohol.

c. 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.

d. Replacing the internal printer paper

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