



Nexus IB10 Analyzer User Manual v8.0



Revision History

Version	Date	Reference Page	Description
1.0	November 23, 2012	All	First edition
2.0	March 29, 2013	All	QC function added
3.0	May 31, 2013	All	External Wi-Fi connection support
4.0	November 28, 2014	All	Patient ID Length Edited
5.0	January 30, 2016	All	Login, user register, edit, and delete function added
5.1	May 10, 2016	All	Cautions added (Cautions for Smart Battery usage and storage)
6.0	January 31, 2019	All	Nexus Dx acquired the IB10 instrument. Rebranding to the Nexus IB10.
7.0	February 23, 2021	All	Removed discontinued features •Optional Battery •Wi-Fi USB Dongle •System Initialization
8.0	May 25, 2022	All	Removed discontinued features •Optional Battery •Wi-Fi features •USB Backup Updated error codes

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Correct Disposal of this Product (Waste Electrical & Electronic Equipment)

(Applicable in Countries with Separate Collection Systems)

This marking on the product, accessories or literature indicates that the product and its electronic accessories should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take these items for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

State of California Proposition 65 Warning (US only)

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Correct Disposal of Batteries in this Product

(Applicable in Countries with Separate Collection Systems)

This marking on the battery, manual or packaging indicates that the batteries in this product should not be disposed of with other household waste at the end of their working life. Where marked, the chemical symbols Hg, Cd or Pb indicate that the battery contains mercury, cadmium or lead above the reference levels in EC Directive 2006/66. If batteries are not properly disposed of, these substances can cause harm to human health or the environment.

To protect natural resources and to promote material reuse, please separate batteries from other types of waste and recycle them through your local, free battery return system.



Correct Disposal of Batteries in this Product

(Applicable in countries with separate battery return systems.)

The marking on the battery, manual or packaging indicates that the battery in this product should not be disposed of with other household waste. Where marked, the chemical symbols Hg, Cd or Pb indicate that the battery contains mercury, cadmium or lead above the reference levels in EC Directive 2006/66.

The battery incorporated in this product is not user replaceable. For information on its replacement, please contact your service provider. Do not attempt to remove the battery or dispose it in a fire. Do not disassemble, crush, or puncture the battery. If you intend to discard the product, the waste collection site will take the appropriate measures for the recycling and treatment of the product, including the battery.

For battery recycling go to call2recycle.org; or call 1-800-822-8837 (US Only)



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Safety Warnings and Precautions

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Safety Warnings and Precautions

Follow the safety warnings and cautions in this manual for safe and appropriate use of the analyzer and its components.

Repairs and maintenance work not discussed in this User Manual are to be performed by a designated Nexus Dx service provider. Any attempt to repair the product by the user may result in injury. Do not use the product in an area with combustible gas or high levels of contamination.

Malfunctions and damage caused by any use other than specified in the User Manual is excluded from the manufacturer's warranty.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Symbols Used in Manual and on Label

Symbol	Explanation
CE	This product conforms to the EC Directives named in the Declaration of Conformity.
	Biohazard. A sample, as well as a used disc containing a sample, is potentially hazardous. Handle with care.
Â	Caution: To safely and properly use this product, safety precautions and warnings in this manual must be followed.
ĺ	Consult Instructions for Use.
	Temperature limitation/Allowed Temperature Range Shows temperature limits for storage or transport.
Ţ	Fragile/Fragile contents; handle with care.
Ť	Keep dry/Package should avoid getting wet.
11	This way up.
6	Loading Unit/Do not load more than the marked number of units.
IVD	In vitro diagnostic medical device.
SN	Serial number
	Manufacturer
\sim	Date of manufacture
KR	Made in Korea

Symbol	Explanation
X	This product should be disposed of and recycled at the end of its useful life in accordance with the Directive 2002/96/EC (WEEE) on Waste Electrical and Electronic Equipment. Contact your local distributor for instructions.
REF	Catalog number
EC REP	European Authorized Representative
UDI	Unique Device Identification
•	USB port
	Ethernet port
$\diamond \bullet \diamond$	Power adaptor connector
	Direct current
	Power On
Ο	Power Off
Ċ	Stand-by switch
	RBRC Symbol
	Importer
	Distributor
	Near Patient

Cautions for System Installation



- Install the analyzer in a stable location. The analyzer may break or cause injury if it falls.
- Use only the specified AC power adapter and cable for the product.
- Use rated voltage. Overvoltage may cause damage to the product or risk of fire. Check if the voltage is proper (100 240 V).
- Do not place any heavy items on top of the analyzer. This may cause the analyzer to malfunction, and if the objects fall, may result in personal injury or damage to the analyzer.
- Maintain at least 15 cm empty space between the wall and the analyzer for safety. The product's internal temperature may rise which could result in injury if touched.
- Do not use damaged power cables which may cause electric shock or fire.
- Do not disassemble, repair or modify the product.
- Do not block the ventilation intake under the analyzer or put anything into the ventilation intake. This may damage internal parts and increase the chance of fire or electric shock.
- Do not touch the power plug with wet hands. Keep the installation area dry.
- Connect the power cord to a grounded wall outlet. Failing to do so may result in electric shock or injury.
- Place the power supply plug within easy access. Unplug to completely turn the power off if instrument problems occur. The power button on the instrument does not completely turn off the power supply.

Cautions for Moving System



- Dropping the analyzer while moving or carrying it may cause damage to the instrument.
- Avoid impact at all times when moving the analyzer.
- In the event that the analyzer is dropped during transportation, check if there is any visible damage to the analyzer. Turn the analyzer on and see the system check results (See page 75). Contact local distributor if an error occurs during the system check.
- When transporting the analyzer, use the original packaging material.
- Follow all cautions and conditions for using and storing the analyzer specified in this manual. Follow all cautions when moving the analyzer.

First turn off the power and disconnect the AC adapter from the analyzer. Place one hand on the handle in the rear of the instrument and support the unit by placing the other hand on the bottom surface of the instrument.

Cautions Before Use

- Check for dust or other impurities on a regular basis.
- Always install the analyzer in a well-ventilated, clean, and dry area.
- Keep the analyzer away from heat-emitting products (such as heaters), which may cause deformation of the instrument, fire, or adversely influence analysis results.



Cautions During Use



■ This analyzer is for indoor use only.

- This analyzer is for use by experienced medical personnel, such as doctors and clinical pathologists.
- Avoid external shock or vibration during analysis.
- Do not use expired discs.
- Do not open the tray during analysis.
- Powder-free gloves must be worn when operating the product.
- Do not move the analyzer during operation.
- When inserting a disc into the tray, check the orientation of the disc. It must be inserted with the label side up. Consult test Instructions for Use.
- If the product produces smoke or strange odors, discontinue use, unplug the power cord from the outlet, and contact your local distributor.
- If operation has been aborted due to abnormal circumstances such as a power outage during operation, discard the disc and start over with a new disc.
- Do not turn off the power during analysis. Press Cancel to abort a test if needed. Discard the disc and start over with a new disc.
- Be careful not to damage the QR code on the disc. If the QR code is damaged, the test will not perform accurately.
- Do not place liquids near the instrument. If the analyzer gets wet, unplug the instrument from the power outlet and contact your local distributor.
- Always use designated power cables and AC adapters. Do not unplug the instrument in the middle of an analysis.
- Operating temperature of the analyzer is 15 32°C.
- Operating altitude of the analyzer is 2000 meters or below.

Cautions in Preparing Blood Samples



- Refer to Test Instructions for Use for samples that can be used and the amount of sample required.
- If more than the recommended amount of blood sample is inserted into the disc, the analyzer may become contaminated or may not work properly. Use only the amount of clinical material stated in Test Instructions for Use.
- Start analysis immediately when the sample is injected into the disc.

Cautions for Storage and Maintenance after Use

- Do not store the analyzer in humid areas or areas influenced by temperature, humidity or wind.
- Store the analyzer on a flat surface and keep it away from vibration or impact.
- Do not store the analyzer with chemicals or gas.
- Operating environment: Temperature 15 32 °C; Humidity 85% or below
- Storage/Transportation environment: Temperature -20 40 °C; Humidity 85% or below
- After use, if there are contaminants such as sample traces or oil stains in the disc tray, remove the contaminants with a soft cloth or tissue. If needed, clean with alcohol. Do not use strong corrosive organic materials such as benzene or acetone because they may damage the analyzer. When using alcohol, do not pour the solution directly onto the device; pour a small amount on a cloth or tissue and wipe clean. If the tray becomes contaminated with blood sample, contact your local distributor.



- A specimen may be contaminated with pathogens or viruses that cause infectious illnesses such as Hepatitis B. All specimens must be considered and handled as potential biohazards.
- Discard disc properly after use. Refer to local Medical Waste Treatment Laws.

EMC (Electromagnetic Compatibility)



- Do not use any wireless devices, including cellular phones, near the system. All wireless devices, whether they comply with the EMC standard or not, may emit electromagnetic interferences and cause the system to malfunction when they are used nearby.
- If you do not use the designated cables and accessories, they may negatively affect the performance of EMC.
- Do not use or put the analyzer near/on another device.

Nexus IB10

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Introduction

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Introduction

- Automatic testing process allows fast, convenient, and accurate results
 - Results reported in 20 minutes*.
 - A convenient UI (user interface) requires minimal interaction from the user.
 - Use with whole blood or plasma.
 - The analyzer centrifugates the whole blood internally, therefore separate centrifugation is not required.
- Convenient Maintenance
 - Built-in self-test feature minimizes maintenance cost.
- Convenient Portable Analysis
 - Minimal footprint for optimal space utilization.
 - Weighing about 2.4 kg, the analyzer is easy to move.

Intended Use

The Nexus IB10 analyzer is an automated in-vitro immunology analyzer that quantitatively measures antigens or antibodies in whole blood or plasma samples on a dedicated disc, in a near patient or laboratory setting. Utilizing an immunochromatographic assay (ICA) method, the Nexus IB10 measures and analyzes results with a built-in sensor.

Analysis Principle

The Nexus IB10 immunochromatography disc combines chemistry with microfluidics and centrifugal flow to rapidly prepare cell-free plasma from whole blood that can then be moved through a channel to rehydrate, solubilize and mix with freeze dried immunoconjugates. Using a combination of active flow and capillary action, the test is ready to be quantitatively measured in 20 minutes* with an optical signal level proportional to the analyte concentration.

After addition of the patient sample, the entire test is performed within the Nexus IB10 analyzer which controls the temperature of the disc, as well as the sequence, duration of measurement, centrifugal flow, mixing, incubation time, final signal measurement, quantitation and reporting of results. The disc also includes a positive internal control to ensure that the test device has operated properly. Each lot of discs is calibrated for the specific analytes to be measured to ensure that lot-to-lot variability is minimized. Lot specific calibration along with additional information such as the lot expiration date is contained on a QR code label affixed to each disc. It is recommended that external controls also be tested at appropriate time intervals to confirm that the reagent lot is performing within acceptable limits.

*22 minutes for IB10 sphingotest® DPP3



- Please check the contents of the box after purchase.
- If any of the contents are missing or damaged, do not use the analyzer. Contact your local distributor for a replacement.

Sold Separately		
Disc	EQC Disc IVR-IB60	Barcode Scanner (optional)

Parts of the Analyzer



- 1. Biological hazard warning
- 2. Printer
- 3. LCD
- 4. Tray
- 5. Power button
- 6. Handle

Rear



- 1. Rear Panel
- 2. USB Ports
- 3. Ethernet Port
- 4. Power Inlet
- 5. Power Switch
- 6. Displays basic information of the analyzer including product name, manufacturer, manufactured date and serial number
- 7. Ventilation intake

Nexus IB10

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Installation

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Installation



- 1 Carefully remove the analyzer from the packaging, and check for any damage that may have occurred during transport. If it is damaged, contact your local distributor immediately. Check and make sure that the contents of the box match the contents described in the User Manual. Contact your local distributor if any component is missing.
- 2 Place the analyzer on a flat surface near an AC power outlet. Connect the AC adapter and the power cable.
- **3** Connect the power cable to the AC power outlet. This analyzer uses free voltage (100 240V).
- 4 Connect the AC adaptor to the power connector, located on the back of the analyzer.



Please familiarize yourself with Cautions for System Installation. (See page 13)

Replacing Printer Paper

1 Open the paper lid (pull the lid upward by the handle).



- 2 Remove the used roll.
- **3** Unwind a new paper roll so that the leading edge comes out from the bottom, facing the user.
- 4 Gently insert a new roll into the receptacle, and confirm that the paper comes out through the front of the printer while holding the leading edge.



5 Close the lid and confirm that the paper is positioned between the lid and the front of the printer.





Before running any tests, recalibrate the touch screen and configure the password and date/time (see pages 59, 57, 65).

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Testing

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Testing

Cautions Before Testing

Preparing to Test Samples

- 1 Prepare a disc, sample, and injecting tool (Pipette, Pipette Tip) to be used for the test.
- 2 Use a pipette to inject the sample into the disc inlet referring to the User Manual of Disc.


Test Procedures

- 1 Turn on the analyzer.
- 2 Enter/Scan patient ID.
- **3** Inject the sample into the disc.
- 4 Insert the disc into the analyzer and run a test.
- **5** Upon completion of the test, results are displayed on the screen.

Turning the Analyzer On

1 Turn on the power switch on the rear panel.



2 Press the power button located on top of the analyzer.



3 The analyzer will turn on and start initialization.

Start-Up

Test Preparation (Main Screen)

- Turn on the analyzer. The main screen appears after the self-test of the analyzer's hardware is complete. If the log-in function is enabled, the login screen appears before the main screen is displayed.
- For enabling the login function, refer to the Settings Security settings.

NE	XUS IB10
Operator ID	admin
Password	
	Remember ID
	Login
NEXUS IB10	E
NEXUS IB10	
NEXUSIBIO	
NEXUSIBIO	Analysis
NEXUS IB10	V Analysis

- Result Archive: Review results of completed tests. Up to 5,000 test results may be archived.
- **New Analysis**: Start a new test.
- Settings: Configure the display, format, time, volume, security, peripherals, language, network, self test, and system.





- If the internal temperature of the analyzer is too low, the analyzer will warm up to adjust the temperature.
- Warm-up may take up to 30 minutes.
- The Result Archive and Settings features are available during warm-up.



Test is limited if the analyzer is out of operational temperature range.







- A screen for entering **Patient ID** appears.
- Enter **Patient ID**. Up to 20 characters may be used for the ID.
- **Patient ID** may also be entered by scanning a barcode with the optional barcode scanner. Refer to System Information for the recommended barcode scanner.



Press Analysis to open the tray

WARNING: If the Patient ID is not entered, "**None**" will print out on the test result and be saved in the Result Archive.



When the tray opens, insert a disc loaded with a sample into the tray and press Run. Disc Validation and Starting Test



When the tray closes, the analyzer performs a disc validation, and will display the name of specific disc being tested.

	TnI Test	
Patient ID : 1234	Time Remaining 18:20 08%	
Cancel		

- After validation is complete, the test starts and the remaining time and progress are displayed.
- Vou may cancel the test by pressing Cancel during testing.
- If the test is canceled, **the disc cannot be reused**.

Checking Results

ЭНо	me	TnI Te	st	
Patient Operate Analysis	ID : 1234 or ID : 5678 Date : 2012/ Jun/09 02::	39 pm		
X	Analyte	Resu	ılt Unit	Page
X	TnI	0.48	8 ng/ml	
	Pri	nt	Disc Out	

After the test is complete, the analyzed items and their results are displayed.

The results can be printed via the built-in printer.

The following symbols are displayed when the results are not within normal range.

A	When results exceed the reference range
<, >	When results exceed the analyzer's detection range
•	When QC fails



When the results are not valid, N/A will be displayed. (When the control line is invalid, the results will be displayed as N/A without error code.)



After the test is complete, press **Home** or **Disc out** to open the tray. Remove the disc and discard appropriately.

Quality Control

Running Controls

Run external quality controls to verify that the analyzer and test discs are performing accurately. Refer to the Test Instructions for Use for guidelines and recommendations.

Home ID	Entry			
	Clear	1	2	3
Scan Patient Barcode	m 20 diaits	4	5	6
Enter Operator ID		7	8	9
	Clear	+	0	-
Analysis	Q	c		

A screen for entering the Test ID appears, press **QC** button.

Home	ID F	ntrv	
			3
Sc	Disc In A	lert (QC)	6
Er	Insert t Tray will be cl	he Disc. osed in 30 sec.	9
5	Run	Cancel	-
	Analysis	QC	

When the tray opens, insert the control disc or EQC disc into the tray and press Run.

Selecting the QC Material & Run

As the tray closes, the analyzer begins disc validation and a screen for selecting the quality control material.



- If the control material does not include intended control analysis target or if the disc has expired, control test cannot proceed.
- Select the quality control material and press OK to start control test. Progress and remaining time are displayed.



- To cancel and abort control test, press **Cancel** button.
- If the test is cancelled, the disc cannot be reused.

Checking Results

G Ho	me Tr	nI Test (QC))	
QC ID : Operato Analysis	0001_Control or ID : 5678 Date : 2012/Jun/09 02:39) pm		
X	Analyte	Result	Unit	Page
V	TnI	0.48	ng/ml	
	Prin	t Disc	Out	

After the test is complete, the analyzed items and their results are displayed.

The results can be printed via the built-in printer.



Press the Home button or the Disc Out button to open the tray. Remove the disc and discard appropriately.

Searching Results

Viewing Patient Results Archive

Gack Results Archive Sea					
	Patient	_	QC	EQC	
	Date & Time		Patient ID	Panel	Page
	2016/Jan/09 07:06	6 pm	1234	IB05	
	2016/Jan/09 07:00	5 pm	2345	IB05	1
	2016/Jan/09 07:06	6 pm	3456	IB05	1
	2016/Jan/09 07:00	5 pm	4567	IB05	
	S	end	Print		

Go to the result search screen by pressing **Search** on the Main Screen.

Previous tests are displayed with **Date & Time**, **Patient ID**, and **Panel** information.

Bac	:k	TnI Test		
Patient Operato Analysis	ID : 1234 or ID : 5678 Date : 2012/Jun/09 0	2:40 pm		
X	Analyte	Result	Unit	Page
	TnI	0.48	ng/ml	
		Print		

Select an item to view its details.

Searching Patient Results



Press Search on the Patient Results Archive screen to search results by Patient ID or Date.

Gack Search Results						
	Patient		QC	EQC		
	Date & Time	•	Patient ID	Panel	Page	
	2016/Jan/09 07:06 p	m	1234	IB05		
					1	
					1	
	Sen	d	Print			

The search results are displayed.

Viewing the Control Results

Back	Results	Archive		Search
Patient	(QC	EQC	
Date & Time	•	QC ID	Panel	Page
				1
				1
S	end	Print		

- Go to the result screen by pressing **Result Archive** on the Main Screen.
- Press QC tab to see the detailed result.
- Press EQC tab to see the detailed EQC result.

Bac	:k Tr	nI Test (QC)		
QC ID : 0 Operato Analysis	0001_Control or ID : 5678 Date : 2012/Jun/09 02:40)pm		
X	Analyte	Result	Unit	Page
	TnI	0.48	ng/ml	
		Print		

Select the desired result item to view its details.

Sending Results

Эв	ack 5	Search			
	Patient		QC	EQC	
	Date & Time	•	Patient ID	Panel	Page
	2016/Jan/09 07:06 pm		1234	IB05	
X	2016/Jan/09 07:06 pm		2345	IB05	1
	2016/Jan/09 07:06 pm		3456	IB05	1
	2016/Jan/09 07:06 pm		4567	IB05	
	S	iend	Print		

- Open and login to IB10 Data Manager (Link provided at nexus-dx.com)
- Check whether the analyzer is properly connected to the PC or EMR.
- From the Patient Results Archive screen, select the results to send to a PC (check the box on the left).
- Once results have been selected, the Send button becomes active. Press the button to begin the transfer.



Printing Results

Эв	ack	Results	Archive		Search
	Patient		QC	EQC	
	Date & Time		Patient ID	Panel	Page
1	2016/Jan/09 07:	06 pm	1234	IB05	
•	2016/Jan/09 07:06 pm		2345	IB05	1
	2016/Jan/09 07:06 pm		3456	IB05	1
	2016/Jan/09 07:	06 pm	4567	IB05	
		Send	Print		

From the **Patient Results Archive** screen, select the results to print (check the box on the left).

Once results have been selected, the **Print** button becomes active. Press **Print** to print the selected results with the built-in printer.



User Settings

User Settings Screen



- Press **Settings** on the Main Screen.
- Settings and authorization are different depending on Administrator Login and General User Login.

Administrator Settings



- **Display**: Set the LCD Brightness, Screen Saver, and LCD Off settings. Calibrate the touch screen.
- **Analysis**: Change the Quality Control settings, lock, and unit of the analyzer.
- **Time**: Change the date and time format on the analyzer.
- **Volume**: Adjust the sound volume.
- **Security**: Manage analyzer users.
- **Peripherals**: Set the method for barcode entry and printing.
- Language: Set the language to be displayed.
- **Network**: Set the IP address to be assigned to the analyzer.
- **Self Test**: Check the integrity of the analyzer.
- **System**: Show the analyzer information or update the analyzer software.

General User Settings



- **Display**: Set the LCD Brightness, Screen Saver, and LCD Off settings.
- **Units**: Allow you to change analyzer units.
- **Format**: Change the date and time format on the analyzer.
- **Volume**: Adjust the sound volume.
- **Password**: Change the General User password.
- **Peripherals**: Set the method for barcode entry and printing.
- Language: Set the language to be displayed.
- **Network**: Set the IP address to be assigned to the analyzer.
- **Self Test**: Check the integrity of the analyzer.
- **System**: Show the analyzer information.





- Calibrate the touch screen or set the LCD Brightness, Screen Saver, and LCD Off settings.
- Select **Display** from the Settings screen.
- Note: If you press Back instead of OK after changing settings, the new values will not be saved.

Touch Screen Calibration



Calibration: Requires the administrator password.



- Calibrate the touch screen by touching the targets (+) in order.
- The target (+) should turn red once it has been touched.
- If the touch screen buttons are unresponsive after calibration, contact your local distributor.

LCD Brightness



- The brightness of the display is adjustable. A total of 5 levels are available.
- Adjust the brightness by pressing or +.
- Press **OK** to save changes.

Screen Saver



- A screen saver turns on to protect the display when the screen has not changed after a specified length of time.
- Press < or > to adjust the length of time before the screen saver activates. (NEVER, 15 min, 30 min, 45 min, 1 hour)



The screen saver will start after the specified time.





- The display turns off in order to protect the display and save power when the screen has not changed after a specified length of time.
- Press < or > to adjust the time before the display automatically shuts off. (NEVER, 15 min, 30 min, 45 min, 1 hour)
- The display turns off after the specified time.

Quality Control Settings



Press Analyze on the Settings screen to change QC Material, QC Lock, and the Units settings.

For more information on QC Material settings and QC Lock settings, please refer to the Quality Control Settings. (See page 84)

Changing Unit

i

lack	Units	
Analyte		Unit
TnI	∭ng/L	🖲 ng/mL





- Press **Time** on the Settings screen.
- Set the date and time and their format for the analyzer.

Changing Date and Time



- Settings Press Time on the Time screen.
- The Year can be set between 2000 and 2037.
- The Time can be in the 12-hour format (hours:minutes:seconds).
- Press **Zero Sec** to set the seconds to zero (0).
- Press OK to save changes.

Format



- Adjust the date and time format for the Main Screen and results.
- Press **OK** to save the changes.

The following formats are available:

Date			Date Separator		
Year-Month-Day	e.g.,) 2012-10-31	/	e.g.,) 2012/10/31		
Month-Day-Year	e.g.,) 10-31-2012	-	e.g.,) 2012-10-31		
Day-Month-Year	e.g.,) 31-10-2012		e.g.,) 2012. 10. 31		

Time	Time Separator
12 Hours, 24 Hours	: e.g.,) 12:30 PM . e.g.,) 12.30 PM , e.g.,) 12,30 PM

Volume



- Adjust the volume for system sounds such as boot-up, touch screen buttons, and the test completion alert.
- A total of 5 volume levels are available. Adjust the volume by pressing or +.
- Press **OK** to save changes.





- Press **Security** on the Settings screen.
- Login Activation: Enables or disables the analyzer's login function. Set to On to prompt for ID and password after system boot-up. Set to Off to allow automatic login as the Admin after system boot-up.
- Auto Logout Time: This function can be set only if Login Activation is set to On. If no operation takes place during the time period defined, the Login screen is displayed.

Operator ID Setting

G	Back	Operato	or (Export/In	nport
	Operator		Expiration Da	ate	Page
\bigcirc	admin		~		
\bigcirc	12	2010	/Aug/08 ~ 201	8/May/23	
\bigcirc	66666	2016	/Nov/11 ~ 201	7/Nov/11	1/20
0	None	2015	/Nov/30 ~ 201	6/Oct/30	
0	dfdgfdgsd	2015	/Nov/30 ~ 201	6/Oct/30	
	Add	Ed	it	Dele	te

You can create and manage operator ID accounts.

For Admin Login, press **Operator** on the **Security** screen.

For General User Login, press **Password** on the Security screen.

A list of registered operator IDs will be displayed.



Insert a USB memory into the analyzer, then press Export/Import to either export the list of operator IDs to the USB or import from USB.



Selecting Export will overwrite the existing file on the USB memory.

Adding an Operator ID



- Add a new operator ID.
- This menu is displayed when you login as an administrator.
- On the Operator Settings screen, select the **Add** button.
- Enter the ID, password, and expiration date of the account. ID should include at least 1 or more letters and the password should include 4 to 8 letters.
- Select **OK** to create the new account.

Editing Operator Information

Back	Edit	
Operator ID	test	Clear
Expiration Date (YY-MM-DD)	2016-01-01 ~	2017-12-31
New Password		Clear
Re-enter Password		Clear
	ОК	

- Vou can edit the expiration date and password of an operator ID.
- This menu is displayed when you login as an administrator.
- On the Operator Settings screen, select an operator ID then press the Edit button.
- Press OK to save changes when changing the expiration date and password of an operator ID.
- Vou cannot edit the admin ID's expiration date.

Deleting an Operator ID

Back	Operat	or	Export/Import	
			Page	
C 2	Ale	ert	<u>A</u>	
e	Delete Selected Operator ID?			
	Yes	No	-	
DDA	E		Delete	

- You can delete an operator ID.
- This function is available when you login as an administrator.
- On the Operator Settings screen, select an operator ID, then press the **Delete** button. (*An admin ID cannot be deleted.)
- If you create a new operator ID identical to the deleted one, only analysis results from the point of entry for the new ID will be available to it.
- Only the admin can browse previous analysis results.

Peripherals



The analyzer can be set to automatically or manually print test results.

The Patient ID Entry format for the barcode scanner can also be set.

[Print Result]

- **Print Result [Manual]**: User manually prints results as needed.
- **Print Result [Automatic]**: Analyzer automatically prints results after each test.

[Barcode]

- If the barcode scanner settings function is activated, the Start Point and ID Length can be set.
 - Start Point: Set a start point for Patient IDs scanned with a barcode scanner.
 - ID Length: Set the ID length for Patient IDs scanned with a barcode scanner.
- If the barcode scanner settings function is deactivated, entry without the ENTER code is allowed.
Changing Language



- Vou may set a language to be displayed.
- Press Language on the Settings screen.
- Select either Language and press OK to save the changes.

Network

Back	Network	rk Mobile EMR/LI		
	Network	Signal	Page	
Ethernet	Manual			
WIFI-0000				
WIFI-0001		(1	
WIFI-0002		(*		
WIFI-0003		(;	•	

- Press **Network** on the Settings screen.
- Connect to the Ethernet
- Click a network name to view its settings screen.
- Click the **Mobile** or **EMR/LIS** button to configure the selected function.

IP Settings



- In the network list, click the Ethernet.
- You can choose either **Auto IP** or **Manual**.
- If you select Manual, you need to enter the IP Address, Subnet Mask and Gateway manually.
- Click the **OK** button to save the changes.

EMR/LIS Settings

Back	EMR/LI	S Interfa	ace		
	ASTM	HL7	1	2	3
Protocol	POCT1A	NONE	4	5	6
Server IP	192.168.	0.99	7	8	9
Port	9100		+	0	•
		ОК			

- Press **EMR/LIS** button to set the EMR/LIS interface.
- Select a desired protocol.
- Enter the server's IP address and the port number.
- Press **OK** to save changes, and connection to EMR/LIS becomes available.

Self-Test



- If damage to the analyzer is suspected or results are questionable, you may inspect the state of the analyzer hardware.
- Press Diagnosis to start.
- The results will be displayed upon completion of the self test.
- If the self test reports any failures, contact your local distributor.



System Setup

Back	System	Initialize
System informati Boot Version : 1.00.0 Kernel Version : 1.00.0 Root File System Ve App Version : 1.00.0 Panel Version : 1.00.0 Sub Version : 1.00.0	on 00 0.02 ersion : 1.00.03 3 01 2	1/2
Serial Number : H00 Mac Address : 99:40 Analysis Archive : 9/ Battery Status : 100	2123456 :5c:26:0b:19 5000 %	
	Update	

- Press **System** on the **Settings** screen.
- Available Options: Check the system information, update the software, or initialize the analyzer.

System Initialization

Note: System initialization deletes the entire result archive from the internal memory.



- Press Initialize on the System screen.
- When the popup window appears press **Yes**.



When the Confirm Initialization popup window appears, press Yes to initialize the analyzer.

Initializing Status



- After completing the initialization, a popup window appears.
- If you select the Delete results archive and setting, the analyzer will reboot. You will need to reconfigure the password and date/time, and recalibrate the touch screen.





- The system may be updated by using a PC, USB drive, or network.
- PC or Network: The analyzer should be connected to a local area network via Ethernet.
- **USB**: Copy the update file for the analyzer onto a USB memory device and insert it into a USB port on the rear panel.
- The analyzer may reboot after updating.

Analysis Settings

GBack Settings - Analysis					
QC Material	QCLock	Units			

Press Analyze on the Settings screen to change QC Material, QC Lock, and the Units settings.

Quality Control Lock Settings



- If locked due to QC failure or EQC failure, failing a control test prevents further analysis.
- In such a case, run another quality control test or EQC test until it succeeds to enable further analysis.
- If quality control period is setted up as ON, but no quality control is done during the period, further analysis cannot be done.
- The quality control interval can be specified within a range from 1 to 365.

Quality Control Material Settings

GB	ack QC Material				
	Material	Level	Lot.No.	Expiration	
÷.	Liquid_QC	1	ABCD1234	2999-12-31	
Ō	Liquid_QC	2	ZYXWVU9876	2999-12-31	1/1
			Add		

- You can edit existing quality control material, add a new item or delete quality control material.
- Select an item to edit quality control material information.
- Use Add button to add a new quality control material.

Deleting Quality Control Material

Back		aterial	
.	Delete Material : Liquid_QC Level : 1 Lot.No. : ABCD1234 Expiration : 2999-12	Confirm	1/1
	ОК	Cancel	
	A	aa	

Press the Delete icon in front of the item to delete the quality control material information.

Press **OK** to delete the quality control material information.

Changing Quality Control Material

N	Aaterial	Level	Lot	.No.	Expiration(Y	(-M-D)
Liquid_C	2C	1	ABCD1234		2099-12-31	
	Analyte		Mean	Min	Max	
亩	TnI		0.12	0.06	0.18	1/2
	CK-MB		7.83	4.32	11.34	1/2
亩	MYO		138.02	75.92	200.12	

Name, Level and Lot number of the material are not editable.



Edit the expiration, average, minimum and maximum settings of the analyte and then press **OK**.

Adding Quality Control Material

Back	Add	QC Ma	aterial		
Material	Level	Lot	.No.	Expiration(Y	(-M-D)
				20	
Analyte		Mean	Min	Max	
					1/1
	OK		Add		

Enter the Material's name, Level, Lot number and Expiration.

Back	Ad	ld Analy	te	
	TnI		CK-MB	
	MYO		NT-proBNP	
	D-Dimer			1/1
		ОК		

- Press Add button to add the material.
- Enter the average, minimum and maximum settings of the analyte and then press **OK**.

Turning the Analyzer Off

Pressing the Power Button



Press the Power button located on top of the analyzer.

Popup Window Confirmation

NEXUS IB10			FB
	6	?	
	Power Of	ff Confirm	
	Turn off the	system now?	
Res			5
_	OK	Cancel	
Васкир		2013/Feb.	/12 Tue 06:36 pm

- Press OK on the Power Off Confirmation popup window to shut down the analyzer.
- When the analyzer is off, you can restart the analyzer by pressing the power button.

Force Shutdown



- Press and hold the Power button for several seconds.
- Use only if the analyzer does not turn off due to malfunction.





- Turn the power switch off on the rear panel of the analyzer to forcibly cut the power.
- Avoid using the power switch to turn off the analyzer unless absolutely necessary.

5

Maintenance

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Maintenance



Cleaning

Purpose

To keep the analyzer clean and disinfected. It will minimize the transmission of blood borne pathogens when testing multiple patients.

What you need

Nexus IB10, 70% Ethyl Alcohol (30% Water), Lint-free tissues, Lint-free foam swap, Gloves



Do not use any other cleaning/disinfectants solutions. Use of other solutions could result in damage to the analyzer.

Area to be Cleaned/Disinfected

Disc structure can prevent the scattering of blood from the mistakes of users when you inject blood to suggested injection hole. But incorrect injection causes blood scattering on tray. (e.g. If you drop some blood not suggested injection area of the disc, the blood can be scattered by rotation of the disc.). If scattered blood contaminates optical sensor, system check function (performing automatically) and QC test using Nexus IB10 EQC can detect sensor malfunction in advance. Tray also can be contaminated with blood. Because tray can move outside of the analyzer, cleaning and disinfection of tray is important.

Exterior Cleaning/Disinfection

- 1 Make sure the analyzer is powered off and all cables are unplugged.
- 2 While wearing gloves, remove one tissue.
- 3 Allow any excess liquid from tissue to drip over a sink or container so the tissue is damp but not dripping.



4 Wipe the analyzer's exterior. Apply solutions for a contact time of < 1 minute.



- Do not spray anything onto the analyzer and do not immerse it in liquid.
- Do not let liquid accumulate near any opening and enter the analyzer. ■ Take not to allow liquid to enter gaps around power button inside of the printer.





Tray Door - Wipe both sides. - Open tray door Do not wipe inside of guide slots (x2).



Do not wipe guide blocks (x2).









Rear



Rear of device. Take care not to allow liquid to enter the electrical socket.

- 5 With the fresh lint-free tissue, wipe away residual moisture and fluids after cleaning the exterior surface.
- 6 Allow wiped areas to dry for at least 10 minutes before performing a test.

Tray Cleaning/Disinfection

1 Turn on the analyzer. After the system check process, you can see the main UI.



2 Press the New Analysis button. After the system check process, you can see ID entry menu.



3 Do not insert ID and press the Analysis button. And then the tray will be opened.



4 Turn off the analyzer with power switch and after 30 seconds unplug power cable. (Do not press the power button on the top.)



5 Wipe most of surfaces of tray as much as possible you can. Lint-free foam swap can be helpful for wiping narrow shape and invisible surface.



- 6 Apply solutions for a contact time of > 1 minute.
- 7 With the fresh lint-free tissue, wipe away residual moisture and fluids after cleaning the tray.



CAUTION: You have to get rid of residual lint also.

- 8 Allow wiped areas to dry for at least 10 minutes before performing a test.
- 9 Plug power cable and turn on the analyzer with power switch.



10 Turn on the analyzer. Then tray will be closed automatically. If you do not want to use analyzer, turn off the analyzer.

Contact

If any of the following should occur, please stop using analyzer and contact local distributor.

- Analyzer does not turn on
- Error messages appear
- Any other unusual errors not specified in the user guide

6

Troubleshooting

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Troubleshooting



Power does not turn on

- The analyzer has two power switches, one on the rear panel and the other on the top. If the power switch on the rear panel is off, the switch on top cannot turn on the analyzer. Check if the power switch on the rear panel is on.
- Contact your local distributor if the problem persists.

Error Codes

Error Code	Content	Measure	
205001C	The LAN connection of the analyzer is bad.	Check the LAN connection. If the problem persists, contac your local distributor.	
205003C	The connection between the analyzer and PC is bad.	Check the LAN connection between the analyzer and PC as well as the cable.	
205004C	No results found when backing up to a PC.	Check if the analyzer has any test results stored in memory.	
205006C	Insufficient memory on a PC to receive the results from the analyzer.	Check the capacity of a PC (HDD or external drive) and make space.	
206001A	A QR code on the disc is not readable.	Replace the disc with a new one and rerun the test. If the problem persists, contact your local distributor.	
206002A	The disc is not for the Nexus IB10 analyzer.	Replace the disc.	
206003A	The disc is expired.	Replace the disc with a valid expiration date.	
206004A, 206005A	Disc barcode(QR Code) error.	Contact your local distributor.	
206007A	The software needs to be updated to use a disc with additional test items.	Contact your local distributor.	
208401A	The disc was already used.	Replace the disc with a new one and rerun the test.	
30001A	Power supply defect	Check power source	
305011A	Temperature error	Check room temperature, restart IB10 Analyzer and rerun test with a new disc	

Error Code	Content	Measure
307001C – 307002C	The connection with the built-in printer is bad.	Contact your local distributor.
307003C	The printing paper is low.	Replace the paper roll.

7

Other Information

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• Other Information

System Information

Category	ltem	Specifications	
Processor		32-bit CPU	
	Display	4.3-inch wide, 480 x 272, TFT LCD	
Peripherals	Touch Screen	4.3-inch 4-wire panel	
	Printer	Built-in Thermal Printer (2-inch)	
	Ethernet	10/100 Base-T	
Interface	USB Host	USB 1.1 2 port	
	USB Client	USB 2.0 port	
Dhatanatan	Light Source	Backlight Unit (BLU) with LED	
Photometer	Detector	CMOS Image Sensor	
Storage Capacity	Maximum number of analysis results stored	r 5,000 normal analysis	
Power	AC Adapter	100 V – 240 Vac, 1.5 A, 50 – 60 Hz	
rower	IB10	19 Vdc, 4.74 A, 90 W	
Operating	Temperature	15 – 32°C (59 – 89.6°F)	
Conditions	Humidity	0 – 85%	
Storage	Temperature	-20 – 40°C (-4 – 104°F)	
Conditions	Humidity	0 – 85%	
Transportation	Temperature	-20 – 40°C (-4 – 104°F)	
Conditions	Humidity	0 – 85%	
Size		177 mm (W) x 330 mm (D) x 177 mm (H)	
Weight		Approximately 2.4 kg	

Accessories (Sold Separately) Information

Category	Item	Specifications
	Thermal Paper (recommended)	Paper width (57 mm, 2.24") Paper roll size: max. 36 mm (1.42")
		CE marked USB-HID (Human Interface Device)
	Barcode Scanner (optional)	Type: 1D Barcode Scanner
Peripherals		Rated current draw: <500mA)
		Example: [Honeywell] Hyperion 1300g
		Note: Please refer to the selected barcode scanner user manual for scanners use and safety information.

Other Information

Product Type	In vitro immunology analyzer	
Model Name	Nexus IB10	
Model code	IVR-IB59	
Name and Address of the Manufacturer	Nexus Dx, Inc. 6759 Mesa Ridge Road San Diego, CA 92121 USA	
Packaging Unit	1 Instrument	
Operating System	Linux 2.6.16.11	

Warranty

Please contact your local distributor for warranty information.

Manufacturer Information

Nexus Dx, Inc. 6759 Mesa Ridge Road San Diego, CA 92121 USA

Please contact your local distributor for service information.

Guidance and Manufacturer's Declaration – Electromagnetic

Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions

The Nexus IB10 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Nexus IB10 should assure that it is used in such an environment.

Emissions test	Compli- ance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The Nexus IB10 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The Nexus IB10 is suitable for use in all establishments other than domestic, and may	
Harmonic emissions IEC 61000-3-2	Class A	be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the	
		following warning is heeded:	
Voltage		WARNING : This equipment/system is intended for use by healthcare professionals only.	
fluctuations/ flicker emissions IEC 61000-3-3	Complies	This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Nexus IB10 or shielding the location.	

Table 2 – Guidance and manufacturer's declaration - electromagnetic immunity

The Nexus IB10 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Nexus IB10 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 20 %
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5cycle 40 % UT (60 % dip in UT) for 5 cycle, 6 cycle 70 % UT (30 % dip in UT) for 25 cycle, 30 cycle <5 % UT (< 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5cycle 40 % UT (60 % dip in UT) for 5 cycle, 6 cycle 70 % UT (30 % dip in UT) for 25 cycle, 30 cycle <5 % UT (< 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Nexus IB10 image intensifier requires continued operation during power mains interruptions, it is recommended that the Nexus IB10 image intensifier be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: Ut is the a.c. mains voltage prior to application of the test level.

Table 3 – Guidance and manufacturer's declaration - electromagnetic immunity

The Nexus IB10 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Nexus IB10 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance	
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable mobile RF communications equipment should be used no closer to any part of the Nexus IB10, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:	

NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- ^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Nexus IB10 is used exceeds the applicable RF compliance level above, the Nexus IB10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Nexus IB10.
- ^b Over the frequency range 150 kHz to 80MHz, field strengths should be less than [V1] V/m.

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the Nexus IB10

The Nexus IB10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nexus IB10 can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nexus IB10 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter [m]			
Rated maximum	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
output power of transmitter [W]	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d = \begin{bmatrix} 7 \\ E_1 \end{bmatrix} \sqrt{P}$	
	V1= 3 Vrms	E1= 3 V/m	E1= 3 V/m	
0.01	0.12	0.11	0.23	
0.1	0.37	0.36	0.73	
1	1.17	1.16	2.33	
10	3.69	3.68	7.37	
100	11.66	11.66	23.33	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m)can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- **NOTE 1)** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- **NOTE 2)** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
License Notification

You can find the full preamble and other detailed information about the Open Source License at Settings > System (page 2) in Blood Analyzer.

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Nexus IB10

