User manual



NAISSA IMMUNOANALYZER

NeoMedica
bioscience technology

Регистрация МИ в Росздравнадзоре
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NOTE:

1) Carefully read this manual before first operating the analyzer.
2) Inspect the electrical requirements of the analyzer before power on, and properly connect the grounding wire.
3) Turn off the power to the analyzer and disconnect the power cord if the analyzer is idle for a long time.
4) Do not run the analyzer if it is in an abnormal or damaged condition.
5) There is a potential biohazard of the reagents and samples; the operator should follow proper biosafety practices. Dispose of waste reagent and sample in accordance with local, national regulations.

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Copyright and Declaration

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Declaration:

All contents in this manual were strictly compiled according to related laws and regulations in Serbia, as well as the specific condition of NAISSA IMMUNOANALYZER, covering all the updated information before printing. NeoMedica DOO is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference only. Please refer to the real object if any differences occur.

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All instructions must be followed strictly in operation. In no event will NeoMedica DOO be responsible for failures, errors and other liabilities resulting from usersô noncompliance with the procedures and precautions outlined herein.

Limited Responsibility for Quality Warranty:

The manual for NAISSA IMMUNOANALYZER, defines the rights and obligations between the NeoMedica and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

NeoMedica warrants NAISSA IMMUNOANALYZER sold by NeoMedica and its authorized agents to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one year since the date of installation. The analyzer life is ten years.

NeoMedica assumes no liability in the following situations even during the period of warranty:

a) Failure due to abuse the analyzer or neglect the maintenance.

b) Use reagents and accessories other than manufactured or recommended by NeoMedica.

c) Failure due to operation not under the instructions described in the manual.

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d) Replacement of accessories not specified by NeoMedica, or after maintenance or repair by a service agent not approved or authorized by NeoMedica.

CAUTION:

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.

Technical service and troubleshooting are provided by NeoMedica Customer Support Center. Professional technician and sale representative will be sent to offer you timely service when necessary.

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Preface

NAISSA IMMUNOANALYZER is designed to perform EIA (Enzyme immunoassay) using dedicated, single-test (cartridge) and ready to use devices. The fields of application are: autoimmune antibodies, infectious diseases, hormones, tumor markers, viral antigens and sample types are using serum, plasma, stool and other biological samples. NAISSA is designed to be used exclusively with the reagents and methods established by NeoMedica that are pre-stored in the memory of the analyzer, and customer should only use reagents and consumables manufactured by NeoMedica. Any use of generic products may lead to increased risk or measurement errors for which the user assume complete responsibility.

Any modification of the software and test procedures in the analyzer's program will void the analyzer's warranty.

For technical support, please contact your local distributor or NeoMedica support center directly.

Norms applied to this document:

Directive 98/79/EC regarding *In-Vitro* Diagnostic Medical Devices (IVDD)

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Personal Safety

Operators must treat all samples as biological hazardous materials and should special cautions during the following operations:

- ð When pipetting samples into the sample well of the cartridge.
- ð When loading cartridges into the carusel.
- ð When removing the cartridges from the carusel.
- ð When handling the waste container

Operators are suggested to follow the safety guidelines set forth by the Medical Service Authority in their own region or country and the following protective gears are suggested:

- ð Gloves
- ð Protective Glasses
- ð Lab coats

Electrical Safety

The power cable must be fitted with the right plug corresponding to the wall socket.
The power cable itself must be grounded and should be connected to properly grounded socket.
The instrument is fitted with protective and safety devices to prevent electrical shocks.
The instrument should not be operated without its casing.

Noise Hazards

The noise generated by the instrument is within international safety limits (<80dB).

Risks due to Liquid Leakage

The instrument is not designed to be waterproof, and liquid damage may occur.
Therefore, the following must be observed during operation:

- ð Do not place any container with liquid on the instrument.
- ð Avoid soiling the instrument with liquid.
- ð Always remove the buffer/solution tanks from the instrument for refilling

High Temperature Hazards

The reagent strip holder is temperature controlled and its temperature could reach 40ºC . Although the temperature will not cause injury to the operators, a Warning label can be sighted to remind operators to operate with caution.

Biological Hazard

All patient samples must be treated as biological hazardous material and should be handled with care. All samples and waste material must be processed following the guidelines set forth by the Medical Service Authority in their region or country.

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It is mandatory to sanitize the instrument every 7 days using the õSanitization Programò built into the instrument software and disinfectant to clean the surface of the instrument. Disinfectant should be an emulsion of anionic and nonionic surfactants in an alkaline aqueous base. It works by soaking, scurbing, or in ultrasonic cleaning baths.

Safety Symbols

ǒ When the following safety symbols are sighted, operate with Caution:

Symbol	Meaning
Note	Read the statement following the symbol. The statement is alerting you to information that requires your attention.
Caution	Read the statement following the symbol. The statement is alerting you to a possibility of system damage.
Waring	Read the statement following the symbol. The statement is alerting you to an operation hazard that can cause personal injury.
Important	Read the statement following the symbol. The statement is alerting you to a possibility of unreliable results.
Biohazard	Read the statement following the symbol. The statement is alerting you to a potentially biohazardous condition.

ǒ Labels Used on the system

The Labels attached to the panels of the system use symbols to clarify the meaning of the text. If any of the labels peels off, contact our Customer Service Department. The list below shows the symbols that are used on the analyzer.

	Date of Manufacture
	Manufacturer

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CE	The device is fully in conformance with the Council Directive Concerning In Vitro Diagnostic Devices 98/79/EC
	Biohazard Warning: risk of potentially biohazardous infection
	Warning: risk of personal injury or equipment damage
	Warning: risk of sharp object
	Warning: risk of moving parts
	Warning: risk of high temperature
	Warning: risk of electrical hazard

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Contents

1 System Description 11
1.1. Hardware introduction 13
1.1.1 Analyzing Unit 13
1.1.1.1 Carousel 14
1.1.1.2. Dispensers and Punchers 15
1.1.1.3. Washers 15
1.1.1.4 Optical system 16
1.1.1.5 Solution Tanks 17
1.1.2. Operational Unit 17
1.1.3 Output Unit 17
1.2.1 Software Interface 17
1.2.2 Status Bar 18
1.2.3 Menu Bar 18
1.2.4. Information on Main Operation Window 18
1.3 Cartridges 19

1 Installation 23
2.1 Unpacking 23
2.2 Installation Requirements 24
2.2.1 Installation Environment Requirements 24
2.2.2 Other requirements for installation 24
2.3 Installing the Solution Tanks 24
2.3.1 Washing Solution 25
2.3.2 Cleaning solution 26
2.3.3 Sanitizing Solution 26
2.4 Waste Disposal 27
2.4.1 Connecting to the Waste Tank 27
2.4.2 Connection to a Waste Disposal Drainage 27
2.5 Electrical Connection 27
2.6 Connection to the Computer 29

3 Operation 29
3.1 Switch On the Analyzer 29
3.2 Getting Started 29
3.3 Self-check 31
3.4 Procedure for performing a self-check 31
3.5 Handling Samples 33
3.5.1 Calibrator 33
3.5.2 Quality Control 34

Регистрация МИ в Росздравнадзоре
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3.6 Loading and Removing of Cartridges 35
3.7 Processing 36
3.8. Identification 36
3.8.1 Calibration 37
3.8.2 Quality Control 37
3.8.3 Sample Code Edit 37
3.9 Cartridge Code Edit 37
3.10 Methods Update 38
3.11 Run 39
3.11.1 Common Reagent consumption and Volume Check 39
3.11.2 Pre-Run Check 40
3.11.3 Duration of Analysis 41
3.12 Stopping the Cycle 41

4 Results and Reports 43
4.1 Principle of Analysis 43
4.1.1 Qualitative Tests 43
4.1.1.1 Calibration 43
4.1.1.2 Interpretation of Results 43
4.1.1.3 Quality Control 44
4.1.2 Quantitative Tests 44
4.1.2.1 Calibration 44
4.2 Units of Measurement 46
4.3 Final Report 46

5 Maintenance and Troubleshooting 48
5.1 Routine Maintenance 48
Replenish Common Reagents 48
5.2 Periodic Maintenance 49
5.3 Troubleshooting 49
5.3.1 Start-up Errors 49
5.3.2 Errors during Operation 49
5.3.3 Error Messages 50

6. Appendix 56
6.1 Operation Accessoires 56
6.2 Technical Data 57
6.3 Requirements for Installation 58
Environmental Requirements 59
6.4 Quick Guide for NAISSA 60
6.4.1 Switch on 60
6.4.2 Preparations for Sample Analysis 60
6.4.3 Operation and Analysis 61

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6.4.4 Switch off 61
6.4.5 Maintenance 62
6.5 Daily Maintenance Procedure 62
6.5.1 Instruction 62
6.5.2 Daily Cleaning Procedure 63
6.6 Configuration of Barcode Scanner 65
North American German 65
Italian Spanish 65
French Japan 65
Portuguese/Brazilian French Canadian 65
Swedish 65
6.7 Unidirectional Communication 66
6.8 Contact Information 67

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1 System Description

NAISSA IMMUNOANALYZER is an automated instrument for performing special single test in Enzyme Immuno Assay (EIA) format. It is designed to carry out in vitro diagnostic tests in Clinical laboratories for autoimmune antibodies, infectious diseases, hormones, tumor markers, viral antigens and sample type are using serum, plasma, stool and other biological samples. All reagents needed to perform the EIA test are incorporated in a single ready-to-use reagent cartridge. The whole EIA procedure is performed automatically without the need for preparation of reagents.

Samples are dispensed manually into the single reagent cartridge by user. All other operations as sample dilution, reagent dispensation, washing, and optic reading are executed automatically by the analyzer. The results can be stored in the computer database or can be sent to the laboratory information system (LIS).



Figure 1-1 NAISSA instrument

This chapter describe following three sections:

- **Hardware Introduction**
- **Software Introduction**
- **Cartridge**

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1.1. Hardware introduction

NAISSA IMMUNOANALYZER should be connected to a computer with a Serial cable.

- ŏ The Analyzer, where analysis of samples is performed automatically.
- ŏ A computer. It interfaces with operators and controls the analyzer. It stores all database of analysis and patient results. It is also capable of unidirectional getting data with Laboratory Information System (LIS). A single computer (operating with WindowsÈ XP SP3 or above) can connect and control 1 or more units (but need The same amount of serial port).

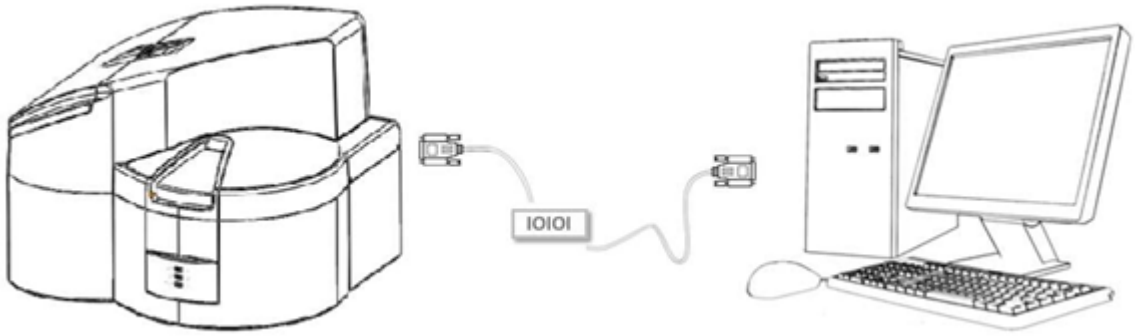


Figure 1-2 NAISSA connection

NAISSA consists of the analyzing unit, operation unit, output unit, replacing parts and consumables.

1.1.1 Analyzing Unit

Analyzing unit is a modular design with high-performance components purchased around the world. The Analyzer unit consists of the following major parts:

- ŏ Carousel
- ŏ Dispenser and Punchers
- ŏ Washers
- ŏ Optical System
- ŏ Solution Tanks

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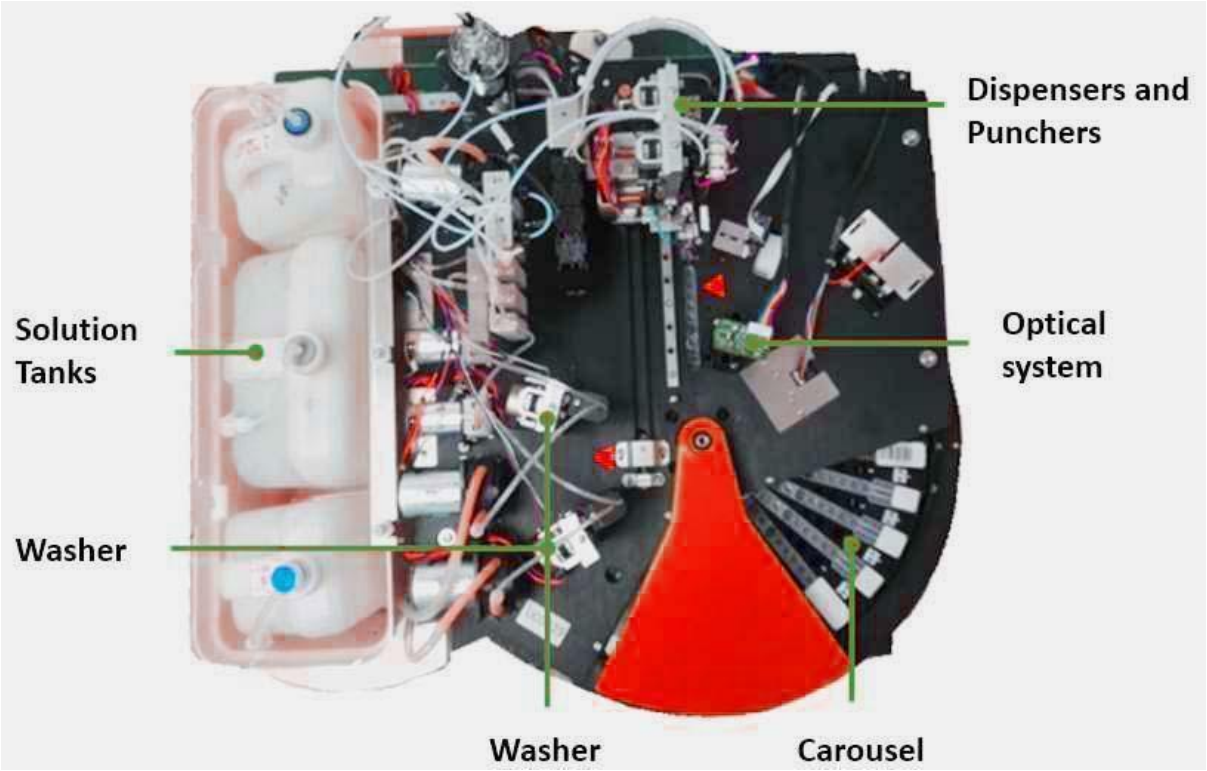
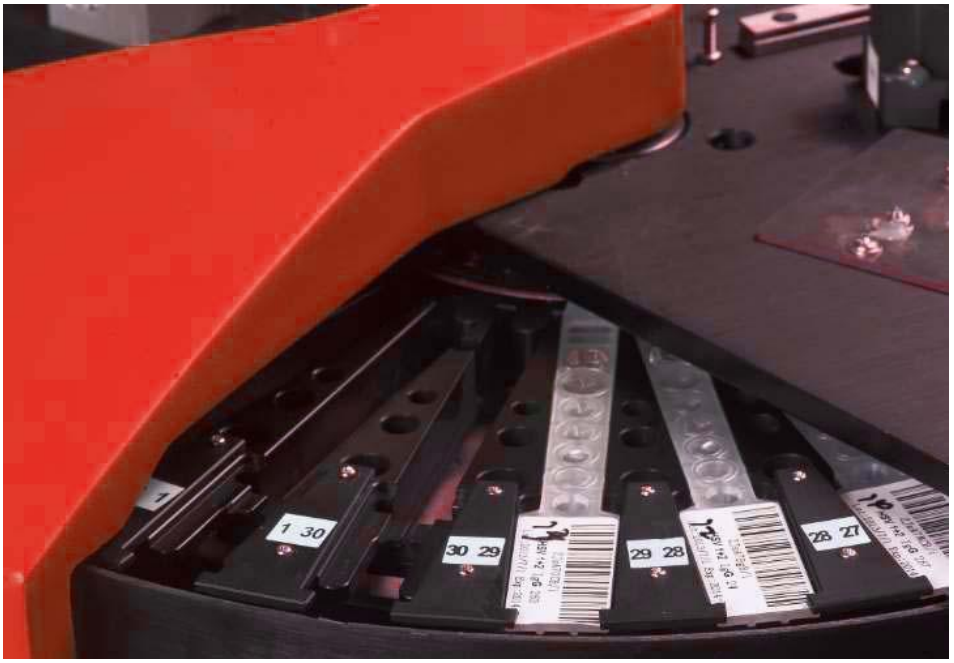


Figure 1-3 NAISSA Structure

1.1.1.1 Carousel

The reagent carousel can be rotated freely by hand and up to 30 different cartridges can be loaded for each analysis cycle. Each position of the tray is numbered in sequence from 1 to 30.



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Figure 1-4 NAISSA Carousel

1.1.1.2. Dispensers and Punchers

The Dispenser and Punchers are coated with high-tech nano ceramic to prevent cross contamination effectively. The one-stop PCB service and double-needle single motor structure with liquid level sensor technology are adopted for easy control and replacement.

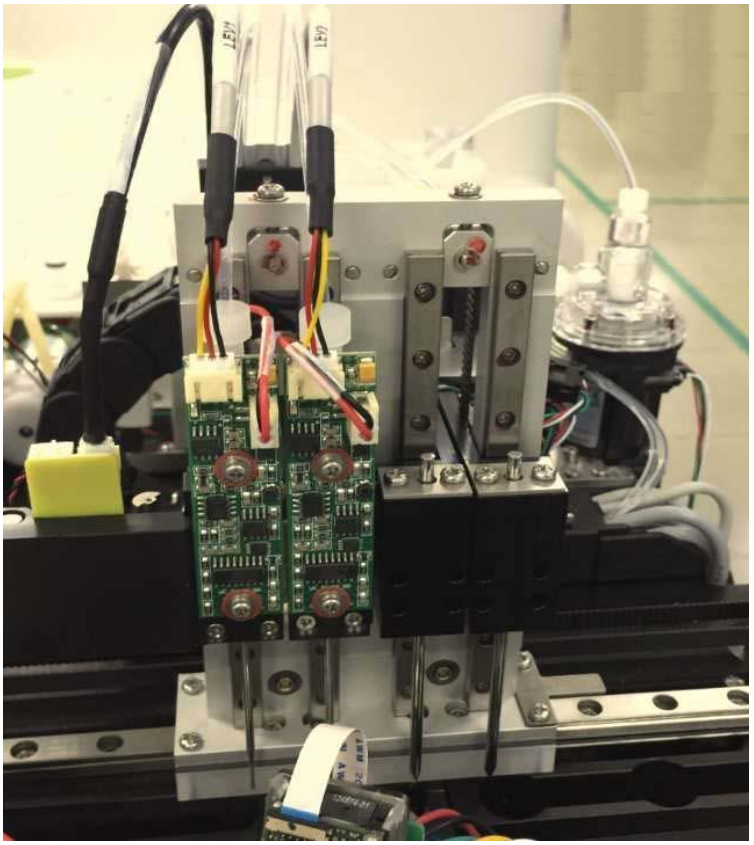


Figure 1-5 Dispensers and Punchers

1.1.1.3. Washers

The washers adopt the double-placement design with the residual liquid less than 5uL. Two different washers used for different washers used for different washing buffers in the same cycle.

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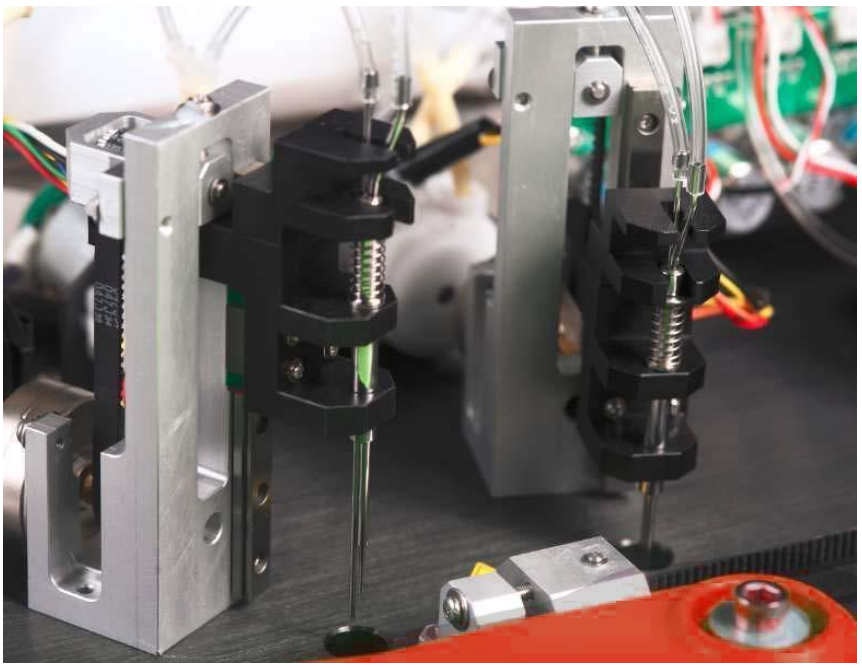


Figure 1-6 Washers

1.1.1.4 Optical system

The Optical system of NAISSA includes transmitter and receiver.

- ŏ Transmitter consists of environment-friendly LED lamps, optical fibers, focus lens.
- ŏ The wavelengths are 450nm and 630nm in different channels.

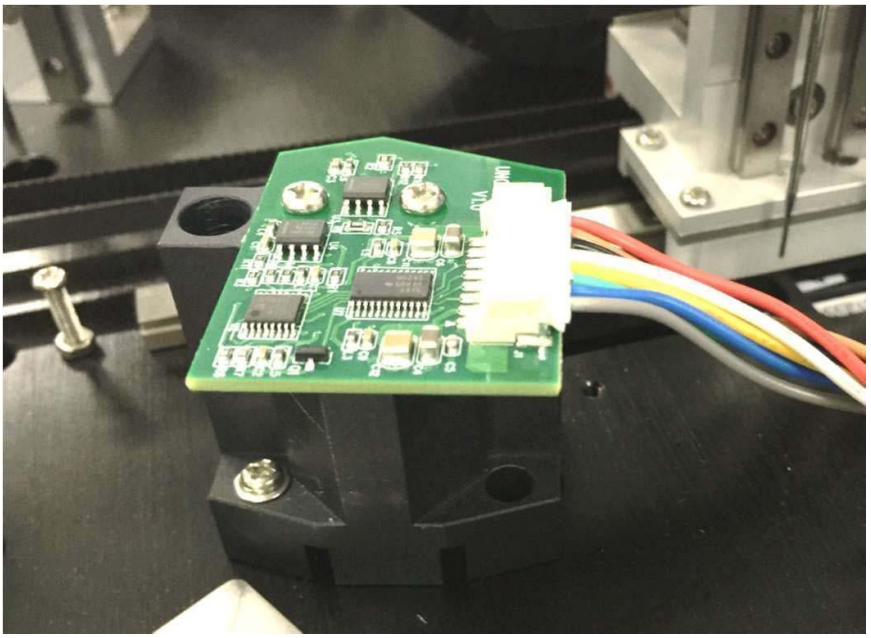


Figure 1-7 Optical Transmitter

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1.1.1.5 Solution Tanks

The solution tanks using load cell for performing real-time monitoring of liquid flow.

Figure 1-8 Solution Tanks

1.1.2. Operational Unit

The operation unit is a computer with the operating software of NAISSA analyzer installed. It manages the running of the analyzing unit, as well as operation and data processing.

Note

PC with WindowsÈ XP SP3 or above system is required for NAISSA software.

1.1.3 Output Unit

The output unit is a printer that prints out the test results and other data.

1.2 Software introduction

Note

In this manual, ñclickò refers to moving the pointer of the mouse to the desired item and click the left button of the mouse.

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1.2.1 Software Interface

The main window of the operating software is as shown in the figure below.



Figure 1-9 Main interface

1.2.2 Status Bar

The status bar located as Part ñAò at the left side of the screen as shown in Fig.1-9 is referred to as the instrument(s) status position.

When several analyzers are connected, the status of all the instruments will be displayed by its own icon button indicating the following:

- ŏ Instrument serial number
- ŏ Error display
- ŏ Status (Either to be checked, Error or Ready messages will be displayed.)

Click on the specific instrument icon button, the user is directed to the Main Operation Window of the specified instrument.

1.2.3 Menu Bar

The ñBò area located at the right side of the screen as shown in Fig.1-9 displays the Menu Bar. The following command icon buttons are shown:

- ŏ WAITING LIST: for Laboratory Information System test request
- ŏ METHODS: edit the method of test
- ŏ CALIBRATIONS: review the records of quality control
- ŏ RESULTS: review the record or samples and quality control.
- ŏ OPTIONS: select the language and other functions
- ŏ QUIT: Exit the operating software

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1.2.4. Information on Main Operation Window



Figure 1-10 Main Operation Interface

Clicking on the specific instrument icon button, the Operation Window will appear; the screen is divided into three main areas:
The right side of the screen indicates the available commands.
The central area displays tables, graphs, warning messages and other information.
The left side of the screen displays the status of the instrument as shown below:

- ŏ Temperature of the cartridge
- ŏ Volume of Cleaning solution
- ŏ Volume of Washing Buffer A
- ŏ Volume of Washing Buffer B
- ŏ The type of Buffer is filled in the AWB fluidic path
- ŏ The type of liquid is filled in the IWB fluidic path.
- ŏ Time to the next Self-Check or it the Self-Check is overdue.
- ŏ Time to the next Sanitizing cycle or if the Sanitizing cycle is overdue.
- ŏ Current status of the analyzer (such as ready, running, etc.)

1.3 Cartridges

Each cartridges is supplied with its unique barcode label stuck on its grip (see Fig.1-11). The barcode is coded by means of 10 digits (code 128), which consist of the following information:

- ŏ Test identification code
- ŏ Lot number
- ŏ Cartridge number
- ŏ Expiration date

The 2D barcode is read by the external barcode reader before the analysis cycle starts.

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Figure 1-11 Reagent Kit and Cartridges

Biohazard

The reagent and cartridge potentially have biohazardous condition, please follow the standard operation and safety practices when you use it.

- **Description of cartridge wells:**
  There are 8 reagent wells, and different wells have different material and functions.

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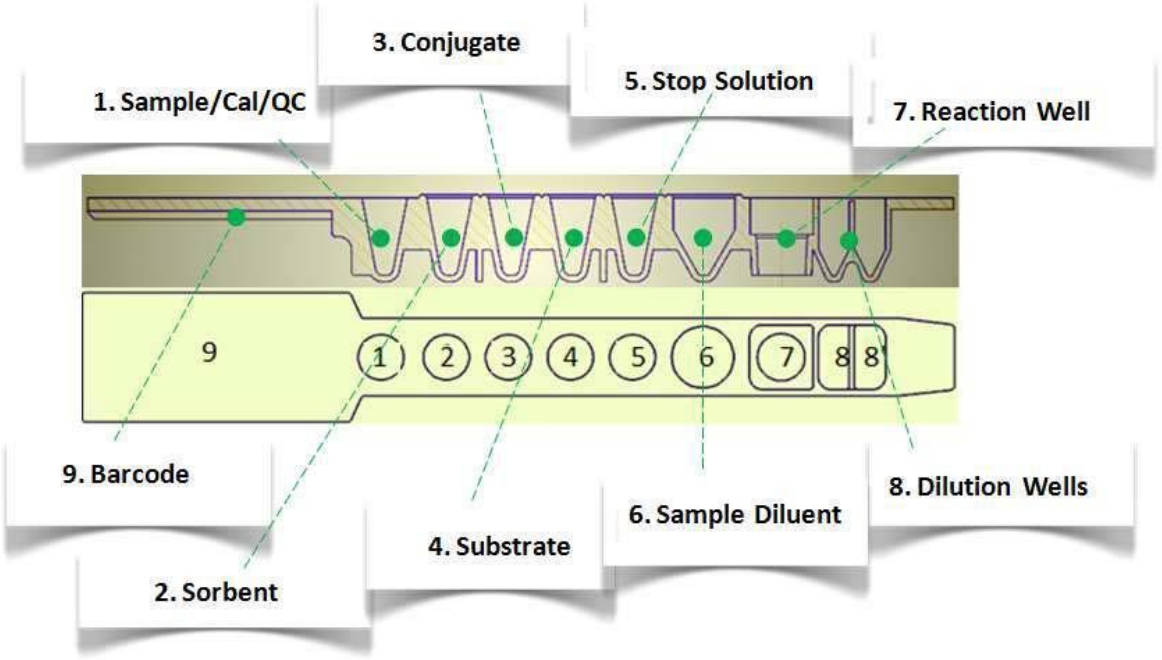


Figure 1-12 Cartridges Description

Wells and area	Film	Volume(μL)	Description
No. 1	open	--	Sample well, used to contain sample, calibrator or control.
No. 2	sealed	150	Sorbent well, used to put some of parameters are for biotin or empty.
No. 3	sealed	150	Conjugate well, used to put conjugate.
No. 4	sealed	150	TMB well, used to put substrate
No. 5	sealed	150	Stop solution well, used to put stop solution
No. 6	sealed	430	Diluents well, used to put diluent, PBS.
No. 7	open	300	Coated reaction well
No. 8	open	200	Dilution well, a clapboard separate two small wells, for 2 times dilution.
No. 9	--	--	Barcode area, used to put the cartridge barcode

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Installation

Warning

- ŏ The system should be installed by our authorized personnel only, a proper site for installation is required.
- ŏ If you need to move the system to another site, please contact our Customer Service Department or local distributor, who is the appropriate people for the moving job.

2.1 Unpacking

When you receive the system, carefully inspect the package. If you see any signs of mishandling or damage, file a claim immediately with our Customer Service Department or local distributor.

After opening the package, check the delivered goods against the packing list as well as the appearance of the system.



Figure 2-1 Package of NAISSA Analyzer

Caution

- ŏ The instrument must be unpacked and installed by trained personnel only.
- ŏ If you find anything missing or damaged, alert our Customer Service Department or your local distributor immediately.

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2.2 Installation Requirements

Caution

Make sure the system is installed in a place meeting the following requirements. Otherwise, it will not perform as promised.

2.2.1 Installation Environment Requirements

Instrument must be placed on top of a leveled bench that is:

- ŏ Not less than 1800 mm (L) x 800 mm (W)
- ŏ Can support not less than 50kg
- ŏ Clean and sanitized
- ŏ Well ventilated with controlled temperature and humidity

2.2.2 Other requirements for installation

- ŏ The workbench must be stable and should not wobble when the instrument is in operation.
- ŏ The back of the instrument must have at least 30cm clearance for ventilation. There should be enough room in front of the instrument for normal operation.
- ŏ The common reagent lid should not be obstructed and there should be enough room for replacing Washing Buffers and leaning solution/DI Water.
- ŏ All lids must be closed when the instrument is not used.
- ŏ Avoid bumping or moving the instrument or the workbench when the instrument is not in operation.
- ŏ Removing the casing or tampering with the instrument by non-authorized person is strictly prohibited.

2.3 Installing the Solution Tanks

This procedure should be performed only when the instrument is turned off, or in Stand-by mode. In no circumstances should the operator remove or replace the reagent tank when the instrument is in operation.

- ŏ Open the lid located at the left side of the instrument; connect the solution tank according to its color coded connectors.

The instrument is equipped with tree bayonet connectors which are connected to individual probes inserted into the reagent tanks. The connectors and connecting tubing probes are color coded.

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- Green (Washing buffer A)
- Blue (Washing buffer B)
- Yellow (Cleaning solution)
- Orange (Sanitizing solution)
- Red (Waste tank)



Figure 2-2 Solution Tanks

Note

- During Cycle, all 3 solutions (Washing Buffer A, Washing Buffer B and Cleaning solution are used.
- For Sanitizing procedure,
  - Cleaning solution is replaced by the Sanitation solution.
  - Bothe Cleaning and Sanitizing Solution share the same position.

Caution

Handle the solution tanks gently to avoid damage to the weight sensors located at the bottom of the compartment. Avoid dropping the bottles on the weight sensors or overload the sensors.

Important

All solution tanks must be positioned in the right position to avoid cross-contamination.

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2.3.1 Washing Solution

Washing Buffer A tank is color coded with a GREEN cap and holds up to 2 liters in capacity.
Washing Buffer B tank is color coded with a BLUE cap and holds up to 2 liters in capacity.
All Washing Buffers are delivered as concentrates and they should be diluted by DI water and loaded in its corresponding tank before use.

- ŏ Place the tanks in their corresponding slots.
- ŏ Connect the green labeled tube to the washing buffer A tank.
- ŏ Connect the blue labeled tube to the washing buffer B tank.
- ŏ The instrument performs a system check during start-up to ensure the reagent tank are properly connected as well as a volume check. In case of connection error or low volume, there will be an audio alarm and an error message will appear on the main window.

2.3.2 Cleaning solution

The cap of the Cleaning solution tank is color coded YELLOW and holds up to 4 liters in capacity.
The Cleaning solution is delivered as concentrate (100x) and it should be diluted by DI water before use. Loading procedure as follow:

- ŏ Place the Cleaning solution tank in the corresponding slot.
- ŏ Connect the yellow labeled tube to the Cleaning solution tank.

The Instrument performs a system check during SELF CHECK to ensure the cleaning solution is properly connected as well as volume check. In case of connection error or low volume, there an error message will appear on the main window.

2.3.3 Sanitizing Solution

Sanitizing solution shares the same position with cleaning solution. During the sanitizing process, user should replace the cleaning solution with sanitizing solution. The sanitation concentrate (20x) should be diluted by DI water before use, and it is given anORANGE coded cap to prevent mixing up with the cleaning solution.
When the system is in sanitizing cycle, the software check whether all tank are properly connected as well as a volume check. In case of connection error or low volume, there will be an error message on the screen. Loading procedure aa follow:

- ŏ Replace Cleaning solution (YELLOW) Bottle with Sanitation Bottle (ORANGE).
- ŏ Connect the YELLOW labeled tube into the sanitation solution tank.
- ŏ Following the software information to finish all steps.

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Important

Remove the solution tanks from the Instrument before refilling the tank to avoid water damage to the instrument.

2.4 Waste Disposal

To ensure the analyzer is running normally, the waste volume must be checked regularly and the waste tank must be voided when needed. When waste is discharged from the waste tank, it should be handled with care and should be treated as biological hazardous material.

2.4.1 Connecting to the Waste Tank

This operation must be performed when either the instrument is on or in standby mode.

Note

To ensure the instrumentôs normal operation, the cap of the waste tank must be screwed on tightly to ensure an air-tight condition, or it will activate pressure sensor.

2.4.2 Connection to a Waste Disposal Drainage

This operation must be performed when either the instrument is switched off or in stand-by mode. Connecting the waste output of the instrument to the drainage should be handled with care.

Biohazard

The waste tank potentially has biohazardous condition, please following the standard operation and safety practices when you pour out.

2.5 Electrical Connection

The power plug is located at the back of the instrument. The instrument must be connected to a power socket as specified in this operating manual and follow the safety requirements.

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Figure 2-3 Backside of NAISSA

No.	Description	No.	Description
A	Fan 1	B	Fan 2
C	Power Plug	D	Power Switch
E	Waste sensor	F	Waste port
G	USB port (software update)	H	Serial Port

Note

It is suggested to connect the instrument to an Uninterrupted Power Supply (UPS) to prevent the instrument from stopping as the result of a power surge. It is recommended to use UPS not less than 1000W.

Caution

- ŏ Only power cord supplied by the manufacturer should be used
- ŏ Before connecting the power cord to the instrument, user must ensure the power switch of the instrument is switched off.
- ŏ The user must only connect the instrument to a ground socket which meets the requirements as specified in this operation manual.

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2.6 Connection to the Computer

Install NAISSA operation software in the computer, connect the computer and analyzer with regular Serial cable which is provided by the NeoMedica.

- **External Computer (Minimum Specifications)**

Operation System	WindowsÈXP SP3 or above
Internal Memory	2G Bytes
Hard Disc Storage	120G Bytes
Communication connector	Serial port
Display	Resolution 1440x900 or above Recommended Touch Screen
Other Hardware Requirements	Printer

Note

If the display resolution is less than 1440x900, the screen will not be shown properly.

---

3 Operation

3.1 Switch On the Analyzer

- Power on the analyzer by pressing the on-off switch located at the back of the instrument to ñ**ò** position as marked.
- Once the analyzer is powered on, there is a prompt from the Front Cover which is GREEN Led powered.

3.2 Getting Started

Lunch the operation software by clicking on the application Icon, and the main screen will be displayed as shown in Figure 3-1. The first time you launch the operation software, you need to click OPTION>CONFIG, add the COM port connected with PC.

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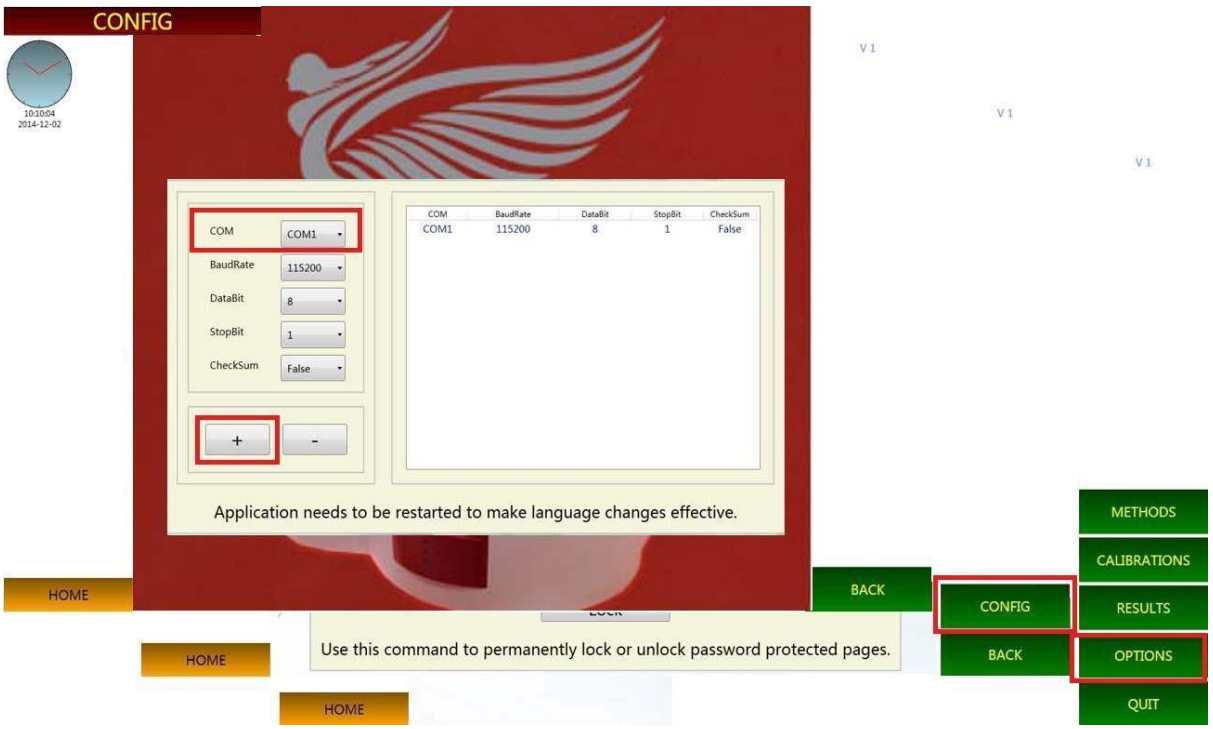


Figure 3-1 Main Interface

Click the instrument serial number button, and the main operating screen will be displayed as shown in Figure 3-2.



Figure 3-2 Main Operation Interface

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3.3 Self-check

The instrument is required to execute a self-check before the cycle. In order to maintain the instrument in optimum operating condition, it also required to perform a Self-check every 24 hours. The instrument will not perform any kind of analysis if Self-check is overdue.

Click the Self-check button on screen to execute. The information on Self-check status is reported at the left side of the Working Window (See Figure 3-3).

When a Sefl-check cycle is aborted as the result of an error, the Self-check program will be stopped at the last line, and give warning and more detail of solution to solve it.



Figure 3-3 Self-check Window

3.4 Procedure for performing a self-check

Click the Self Check button, the operator will be asked to:

Insert a Service cartridge in position 1, clear position 2 and select START.

Click the START button, the analyzer will close the lid and start the self-check procedure which verifies the following:

- ŏ The load sensors check for the solution tanks in order to check the presence of cleaning solution, washing buffer A and washing buffer B;
- ŏ All the Motors and home sensors checking for home position;
- ŏ The cartridge position sensor;
- ŏ The double floating sensor for waste well;
- ŏ Motor test for washing procedure;

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- Motor test for dispensers, syringe and valves;
- Optical Calibration of 450nm and 630nm.

Note

- If a Self-check is needed before analysis, the user will be required to carry out this procedure.
- In a Self-check, the cleaning solution will be used, and washing buffers are not used for this procedure.

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3.5 Handling Samples

User may dispense serum into the sample well on the cartridge either before or after inserting the cartridge into the carousel. In either case, safety practice should be followed.

Biohazard

The samples potentially have biohazardous condition; please follow the standard operation and safety practices.

3.5.1 Calibrator

Each calibrator provided in the kit is identified by a barcode, with the follwing information:

- ŏ Test identification code;
- ŏ Lot number;
- ŏ Cal OD (from Cal_{OD} to $Cal_{OD}6$) or 4PL parameter;
- ŏ Tolerance coefficient

Note

- ŏ The number of calibrator(s) depends on the parameter information.
- ŏ All the qualitative parameters just have the $OD_{cut\ off}$.
- ŏ To run a calibration, the test identification code, and lot number must be the same as those on the corresponding cartridges.
- ŏ The calibrator(s) can be processed in the same run within the samples provided that the cartridges are of the same lot number.

The calibrator is processed in the same way as the sample procedure. Enter the calibrator code either by reading the barcode label with the external barcode reader or type in the barcode number manually in the running list. Either way, the analyzer recognizes the calibrator information automatically.

Biohazard

The Calibrator(s) potentially have biohazardous condition; please follow the standard operation and safety practices.

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3.5.2 Quality Control

Each quality control provided in the kit is identified by a barcode with the following information:

- ŏ Test identification code;
- ŏ Lot number;
- ŏ Min acceptable OD;
- ŏ Max acceptable OD.

Note

- ŏ To run quality control, its test identification code, and lot number must be the same as those on the corresponding test cartridges.
- ŏ The quality control(s) can be processed in the same run with the samples provided that the cartridges are of the same lot number.

The Quality Control is processed in the same way as any sample. Enter the Quality Control Serum barcode either by reading it with the external barcode reader or typing in the barcode ID manually in the running list. Either way, the analyzer recognizes the information of the Quality COntrol Serum automatically.

The Quality Control(s) can be processed in the same run with the samples provided that the cartridges are of the same lot number.

Biohazard

The quality control(s) potentially have biohazardous condition, please follow the standard operation and safety practices.

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3.6 Loading and Removing of Cartridges

The cartridge is held in place by the cartridge holder carousel with a spring that pushes it into its slot to keep it tightly fixed. When inserting the cartridge, it is necessary to push the cartridge inward and then leave the spring to push back the cartridge into the retaining edges at the end of the slot. To remove the cartridge, push the grip of the cartridge inward. Then, free the holder of the cartridge from the retaining edges of the carousel and remove the cartridge from the carousel directly. (see Figure 3-4).

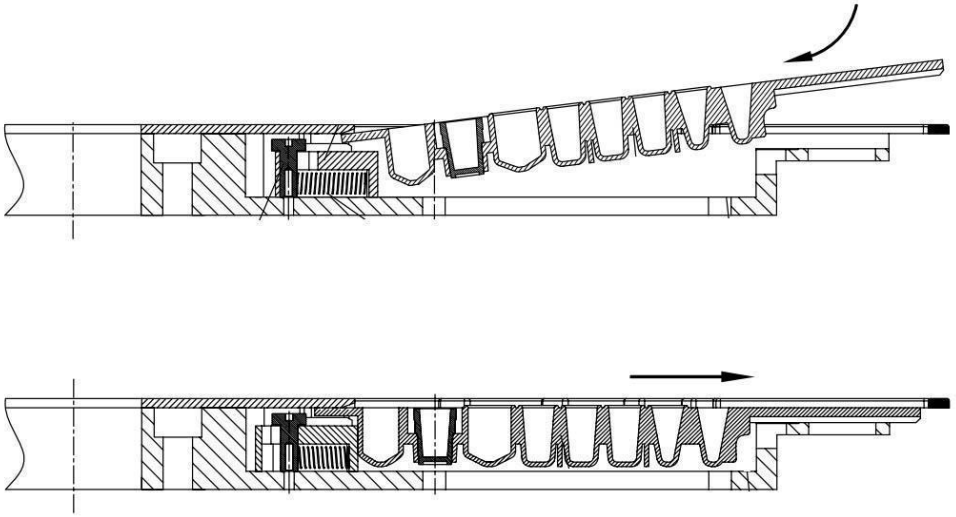


Figure 3-4 Loading and Removing Cartridge

It is recommended that user should practice loading and removing process with an empty cartridge to gain some experience.



Figure 3-5 Practice of Loading and Removing Cartridge

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During loading and removing from the cartridge, the cartridge holding carousel can be turned freely.

3.7 Processing

Pressing the RUN command icon button, a 30 row table will appear in the middle of the window. The processing window manages all the operations concerning the set up and running of the cycle.

- ŏ SCAN
- ŏ START

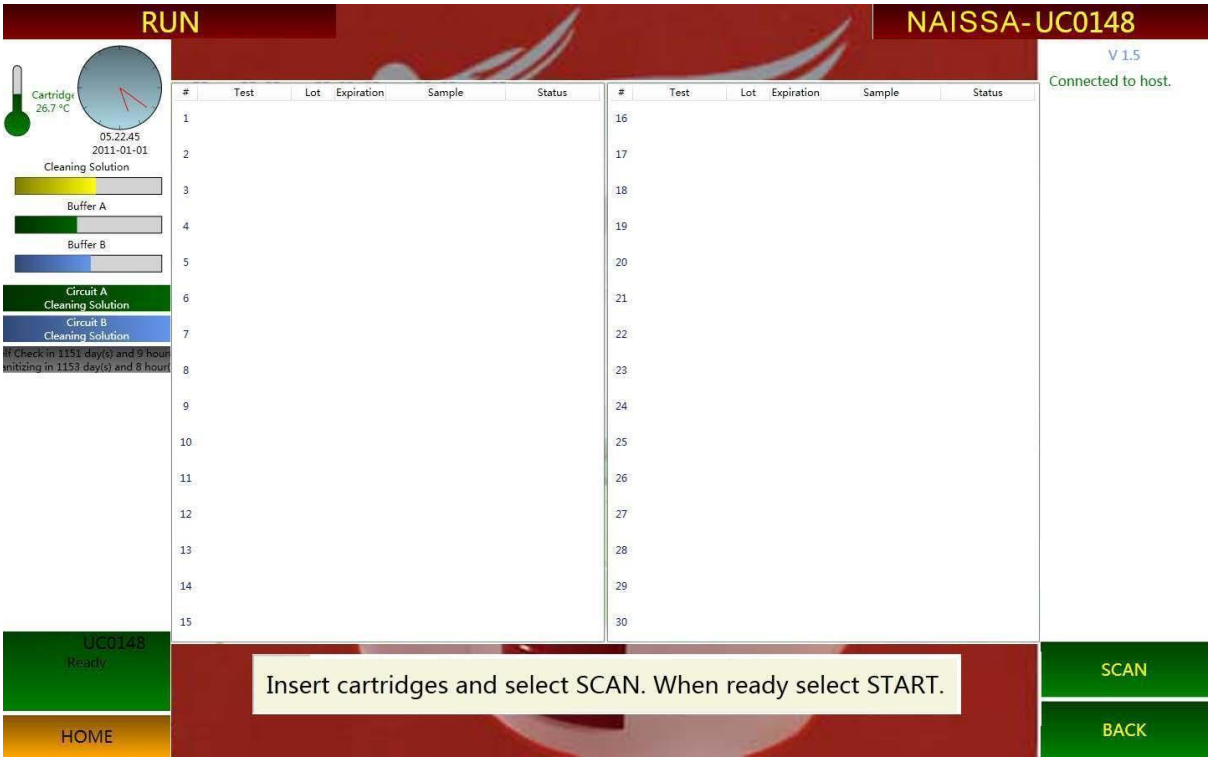


Figure 3-6 Scanning Window

3.8. Identification

Pressing the SCAN command icon button, the identification process will begin by the carousel turning and reading the presence of the cartridge(s) and its barcode(s). The sample identification and test names will be displayed in its corresponding positions followed by status displayed in the last column of the table to indicate problems of identification. The types of status are as follows:

- ŏ Expired, meaning the cartridge is expired.
- ŏ Missing Calibration, meaning the test or the new lot of the test is not calibrated.
- ŏ Test ID Undefined, meaning the test is not included in the method database.

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- ŏ Barcode error, meaning the barcode cannot be read or cannot be identification.

Note **Important**

Expired cartridges are not suggested to use. In case of using the expired cartridges, the corresponding results on the final report will be highlighted with the message:ðthe result may be not correct because of the use of non-valid cartridgeò The user is fully responsible for potential error incurred in this case.

3.8.1 Calibration

In case of a new test or a test of a new lot, calibration must be performed. Only Calibrator of the same lot as the cartridge should be used, and the calibration procedure is as follows:

- ŏ Edit/scan the calibrator barcode which can be found on the calibrator tube and on the inner side of the box
- ŏ Add the required volume of calibrator into the sample well of the cartridge.
- ŏ Insert a cartridge of the test/lot in the carousel.

The calibration data will be processed and stored in CALIBRATIONS of the main window. All tests run using cartridge of the same lot number as the calibrator will be evaluated and calculated based on the stored calibration data.

3.8.2 Quality Control

The QC is treated as a sample. Only Quality Control of the same lot as the cartridge should be used, and the Quality Control procedure is as follows:

- ŏ Edit/scan the QC barcode which can be found on the control tube and on the inner side of the box
- ŏ Add the required volume of QC material into the sample well of the cartridge.

The calibration data will be processed and stored in QCS of the main window.

3.8.3 Sample Code Edit

To edit the sample barcode listed in the table, move the cursor on to the row corresponding to the sample, click to edit the barcode of the sample.

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3.9 Cartridge Code Edit

The cartridge barcodes are scanned by the external barcode reader.
In case the cartridge barcodes cannot be read due to a barcode defect, it is possible to edit the barcode by mean of the soft keyboard or hardware keyboard.
Once the cartridge barcode is manipulated, the corresponding message will be printed next to the results on the final report and it will be highlighted with the following message:òThe result may be not correct because of the use of no valid cartridges.ò

3.10 Methods Update

After scanning the cartridge and ñUnknown Testò is displayed on screen, this means the methods of this test are not in the method database.

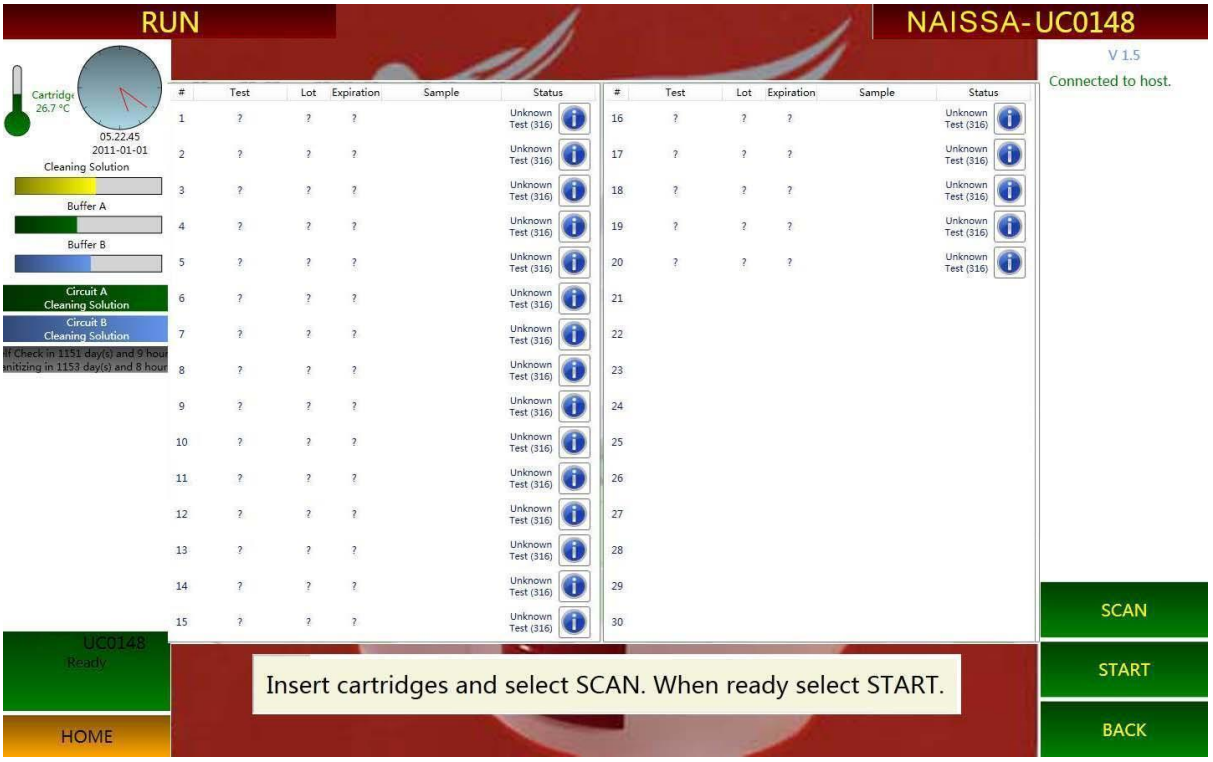


Figure 3-7 Cartridges Scanning Window

To update the test method, locate the 2D barcode in the box containing the reagent barcode and scan the 2D barcode.

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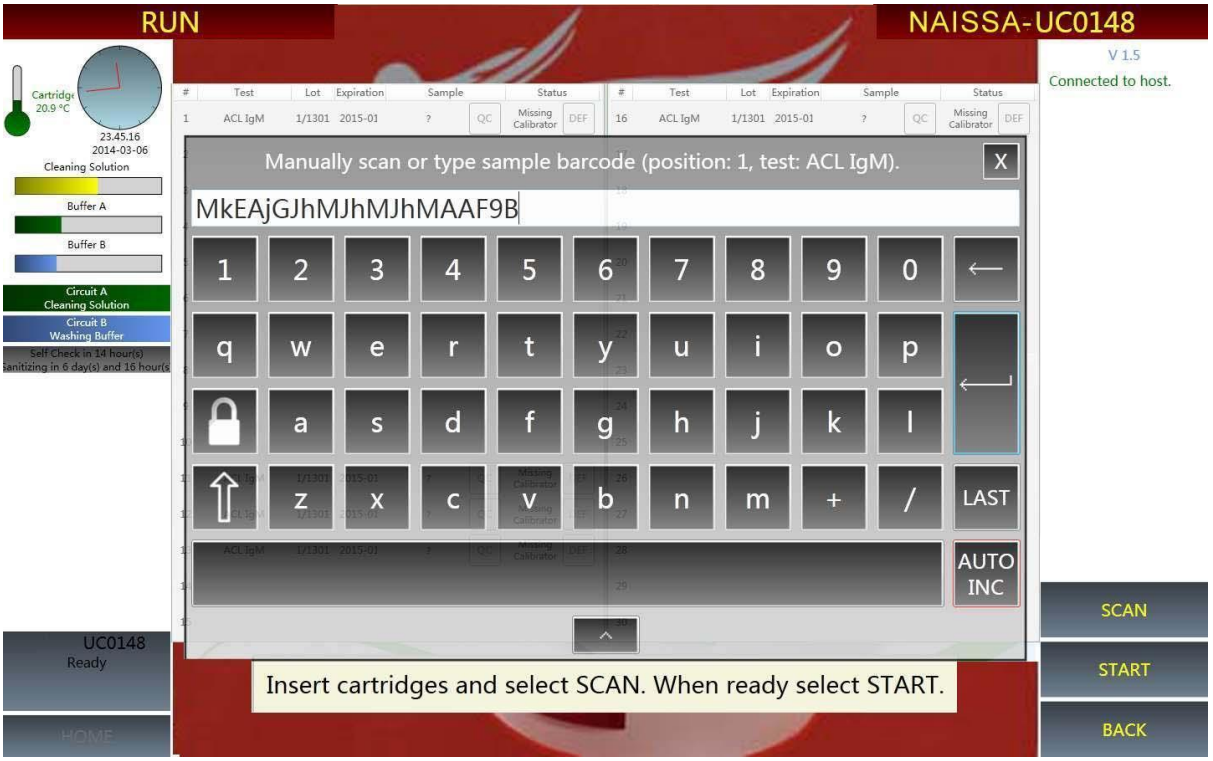


Figure 3-8 Method Updating Window

Once the new method is updated, CAL/QC/Sample can be run as previously described.

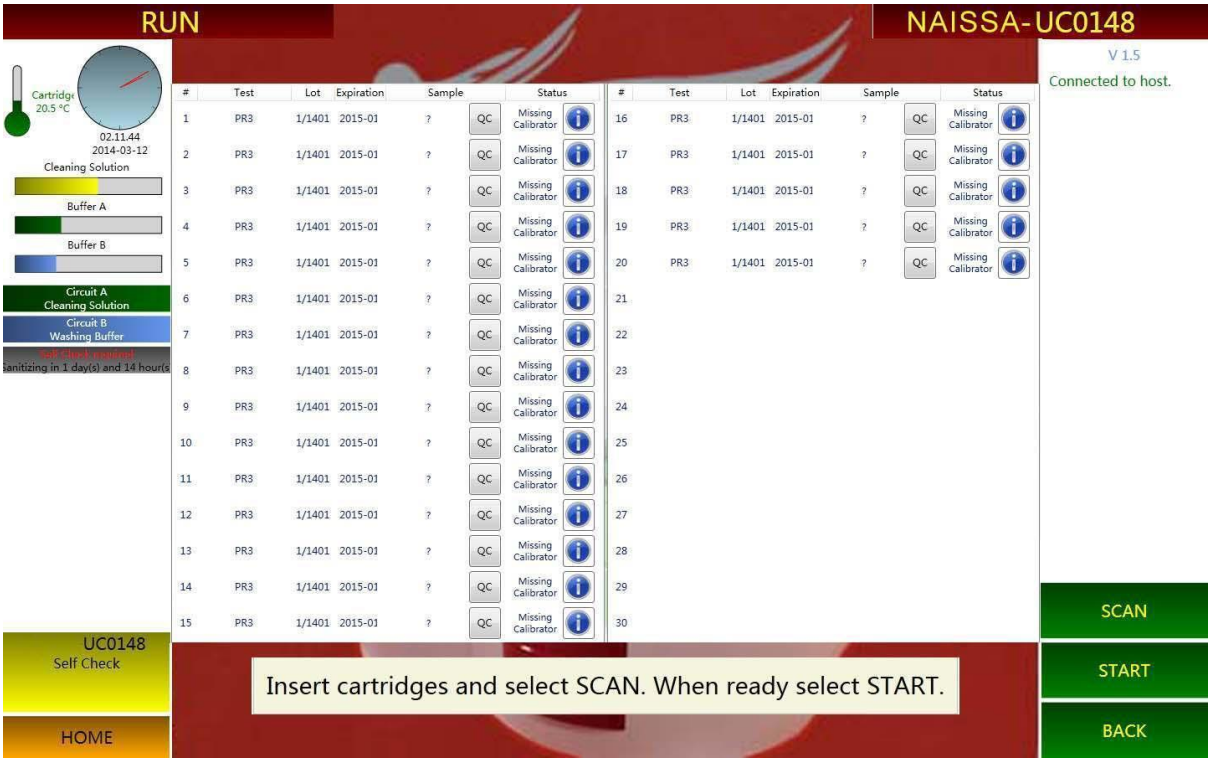


Figure 3-9 Cartridges Identified

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3.11 Run

When the calibrator(s), QC(s), patient sample and cartridges barcode are read, and there is no error message on the right hand side of the test table, click the START icon button to initiate the run cycle. The lid of the cartridge loading area will close automatically, and the test cycle will start.

3.11.1 Common Reagent consumption and Volume Check

When the run cycle is ready to proceed, it is possible to check the volume of common reagent required to run and complete the cycle. The volume is checked automatically ant it is calculated as follows:

- ŏ One bottle of concentrated Cleaning Solution can be diluted into 4,000 ml of cleaning solution in accordance with specific ratio.
- ŏ One bottle of concentrated Washing Buffer A/B can be diluted into 2,000 ml of Buffer solution A/B in accordance with specific ratio.
- ŏ One bottle of concentration Sanitizing Solution can be diluted into 1,000 ml of Sanitizing Solution in accordance with specific ratio.

#	Self check (ml)	*Run Cycle/30T(ml)				Cleaning(ml)		Sanitizing cycle (ml)
		Priming before cycle	Used during cycle/30T	Priming after cycle	Total/30T	Washer1	Washer2	
Cleaning solution	110	45	2300	80	2425	35	35	70
Washing buffer A	0	*18	*82	0	100	0	0	0
Washing buffer B	0	*18	*82	0	100	0	0	0
Sanitizing solution	0	0	0	0	0	0	0	100

User is requested to replenish the common reagent(s) if the volume is not enough to complete the run cycle.

Note **Important**

- ŏ * Indicate that the solution A/B will be only consumed simultaneously if they are both used in the same test cycle. Normally, if washing buffer A is used in one cycle, washing buffer B will not be consumed in this cycle.
- ŏ The consumption of the cleaning solution is proportional to the test numbers in a cycle. E.g.if a test cycle contains 10 tests, the solution consumption = L(During cycle) 10T/30

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3.11.2 Pre-Run Check

The instrument automatically carried out the following check before running the test cycle.

Priming the Dispenser and Fluidic Path

The dispenser and fluidic path is primed in order to refresh the liquid inside all tubing, this is to refill the tubing and also cleans the dispensing needles.

Priming the Washing buffer Solution

The selected Washing Buffer corresponding to the test performed is primed to ensure no residual Washing Buffer from the previous test remains in the fluidic path.

Pre-warming/cooling the cartridge holding Carousel

When the run cycle is initiated, the instrument checks if the cartridge holder carousel is at the temperature desired for the test. If the set temperature is not in range, the instrument will not start the run cycle. The temperature value and the remaining to reach the desired temperature will be displayed in the status bar.

Warming the cartridges

To ensure that the reagents in the cartridge have reached the required temperature, there will be a delay of 5 minutes before the analysis cycle starts. The waiting time is displayed on the status bar.

Sample Dilution

Sample dilution is performed at the same time as the carousel is warmed to the desired temperature. Sample diluents and samples are transferred into the dilution well on the cartridges in its pre-programmed dilution ratio. Depending on the number of tests and type of tests performed, the time needed for the dilution process varies. The processing time is displayed on the status bar.

3.11.3 Duration of Analysis

The Instrument is able to calculate the time needed to complete the analysis cycle in a run. The total processing time is displayed in a status bar in minutes and it is calculated as follows:

Sample incubation time + Conjugate Incubation time + TMB incubation time
+ STOP SOLUTION incubation time + 0.5 minutes for each sample

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Incubation Time

The Instrument allows tests with different incubation time to be run in the same test cycle, but it will be grouped to run in different cycles within the run. It will be processed one after the other.

All samples will be pre-diluted at the beginning of the first cycle within the run even though different test with different incubation time will be performed at different intervals. This is to avoid serum concentration from prolonged stay at 37 .

3.12 Stopping the Cycle

The RUN session can be interrupted at any time using the STOP key. A message will appear to ask to confirm your request to stop the analysis cycle.

Note **Important**

- When a run is stopped, the results of the samples already tested are stored and the samples remaining to be processed will be aborted.
- The user is fully responsible for potential error incurred in this case.

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4 Results and Reports

4.1 Principle of Analysis

The analyzer reads absorbance of all the reaction well at 450nm and 630nm, then calculate the actual absorbance using the following formula:

$$OD_{smp}=OD_{450}-OD_{630}$$

4.1.1 Qualitative Tests

4.1.1.1 Calibration

During the quality tests, the optical density (OD) of the calibrator for each lot should be carried out.

The code of calibrator has two parameters:

- ŏ OD_{cal0} the expected OD of the calibrator
- ŏ TOD_{cal} the tolerance deviation of OD_{cal0}

After analysis, the instrument calculates the optical density of the calibrator (OD_{cal}) using the formula.

If OD_{cal} ,is within the following criteria as listed below, the Calibration Curve is accepted and the OD_{cal} is stored.

$$OD_{cal0} ï TOD_{cal} \text{ ÒOD}_{cal} \text{ Ò } OD_{cal0}+TOD_{cal}$$

The Correction Factor, K_{cal} (the ratio between OD_{cal} and OD_{cal0}) is also stored for re-calibrating the Calibration Curve.

4.1.1.2 Interpretation of Results

Once the samples are processed, its optical density will be determined as followed:

$$OD_{450} ï OD_{630}$$

It compares the sampleŝ optic density OD_{smp} with its corresponding optic density of the calibrator $OD_{cal,}$ and three kinds of conclusions are determined as follows:

If $OD_{smp}<0.8Ĭ OD_{cal}$	Negative
If $0.8Ĭ OD_{cal} \text{ Ò } OD_{smp} \text{ Ò } 1.2 ī OD_{cal}$	Doubtful
If $OD_{smp}>1.2Ĭ OD_{cal}$	Positive

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The doubtful range is defined symmetrically with respect to ODcal (See Fig.4-1), and the limits in percentage 20% are determined in the method file.

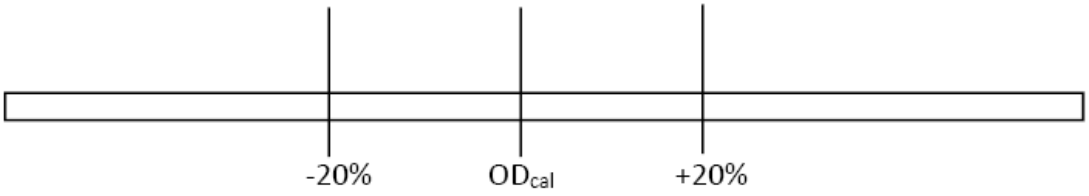


Figure 4-1 Doubt Range

4.1.1.3 Quality Control

The routine QC check involves processing of the QC material as a sample corresponding to the cartridge of the same lot number in a run cycle, and its optical density is determined as follows:

$$OD_{QC} = OD_{450} ï\ OD_{630}$$

It compares the OD_{QC} with the QC materials pre-defined Upper and Lower limits OD_{upper} and OD_{lower} printed on the QC barcode. If OD_{QC} meets the following criteria as listed below, the QC is accepted, or it will be rejected.

$$OD_{lower} \quad OD_{QC} \quad OD_{upper}$$

Note

The OD_{upper} and OD_{lower} printed on the QC barcode are affected by the K_{cal} mentioned in Section

---

4.1.2 Quantitative Tests

4.1.2.1 Calibration

When Calibration is carried out for Quantitative Tests, make sure that the Calibration Curves used (which is incorporated into the QC sample barcode) must be of the same lot as the cartridges. And the information of the Calibration Curve represents the relationship between the OD and the concentration of the sample.

The following data are needed to create the Calibration Curve (See Fig.4-2):

- ð Five or more groups or calibrator date, including OD and its corresponding concentration, (and this information is sorted in the Calibration barcode;
- ð One or two points calibrator will be used for processing the re-calibration;

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ð Tolerance deviation of OD_{cal0};

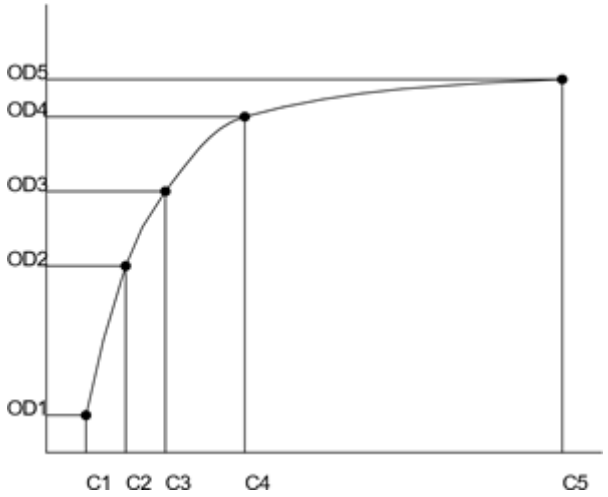


Figure 4-2 Calibration Curve

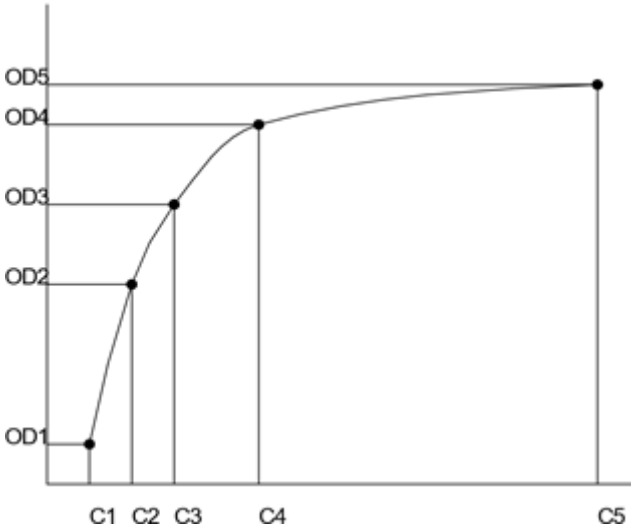


Figure 4-3 Curve Correction

The procedure to re-calibrating the Calibration Curve Point-to-Point is as follows:

- ð The optical density of the calibrator OD_{cal} will be calculated by the formula $OD_{cal}= OD_{450}- OD_{630}$
- ð If OD_{cal0} ï TOD_{cal}Ò OD_{cal} ÒOD_{cal0} + TOD_{cal}, The calibration, OD_{cal} will be accepted; or the calibration will be cancelled and the error message will be displayed;
- ð the K_{cal} which is the correction Index will be calculated by the formula $K_{cal} = OD_{cal} / OD_{cal0}$;
- ð The original Calibrator data points from the stored information from the barcode will be recalculated according to K_{cal} and the corrected curve will be stored.
- ð The procedure to re-calibrating the Calibration Curve(4PL) is as follows:

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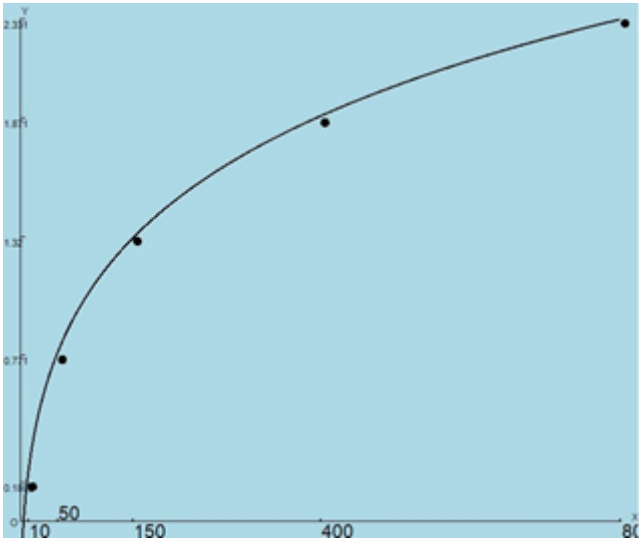


Figure 4-4 PL Curve

- The optical density of the calibrator OD_{cal} will be calculated by the formula $OD_{cal} = OD_{450} - OD_{630}$
- The mode of 4PL calibration can do Single-Point and two-Points. The mode of Two-Points has two methods:
  Method 1: Test only one cartridge for every calibrator on the same cycle.
  Method 2: Test two cartridges for every calibrator on the same cycle and the average calibrator OD will be used as calibrated OD.
- If OD_{cal0} ï TOD_{cal}Ò OD_{cal} ÒOD_{cal0} + TOD_{cal}, The calibrated OD_{cal} will be accepted,
  Or the calibration will be cancelled and the error message will be displayed;
- According the Calibrators to calibrate the 4PL curve;

All the sample concentrations will be calculated by the calibrated 4PL curve.

4.2 Units of Measurement

- - index (ratio: OD of sample/OD of calibrator)
- - IU/mL, International Units per milliliter
- - AU/mL, Arbitrary Units per milliliter
- - GPLU/mL, CardiolipinIgG antibodies per milliliter according to Harris standard
- MPLU/mL, CardiolipinIgM antibodies per milliliter according to Harris standard
- %, percentage
- - ng/mL

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4.3 Final Report

After the analysis cycle is completed, the final report is displayed as shown in Fig. 4-5.

NAISSA-UC0081 -2013-03-20 11:50

#	Test	Lot	Number	Expiration	Sample	Absorbance	Result	Reference
1	M P IgM	1/1303	1339	2014-03-31	Calibrator	0.565	0.565	3K 4H
2	M P IgM	1/1303	1340	2014-03-31	Calibrator	0.373	0.373	3K 4H
3	M P IgM	1/1303	1341	2014-03-31	Calibrator	0.345	0.345	3K 4H
4	M P IgM	1/1303	1342	2014-03-31	QC	0.802	P (2.3)	3K 4H
5	M P IgM	1/1303	1343	2014-03-31	QC	1.071	P (3.1)	3K 4H
6	M P IgM	1/1303	1344	2014-03-31	QC	1.237	P (3.6)	3K 4H
7	M P IgM	1/1303	1291	2014-03-31	QC	0.443	P (1.3)	3K 4H
8	M P IgM	1/1303	1292	2014-03-31	QC	0.524	P (1.5)	3K 4H
9	M P IgM	1/1303	1293	2014-03-31	QC	0.470	P (1.4)	3K 4H
10	M P IgM	1/1303	1294	2014-03-31	QC	0.411	P (1.2)	3K 4H
11	M P IgM	1/1303	1295	2014-03-31	QC	0.426	P (1.2)	3K 4H
12	M P IgM	1/1303	1445	2014-03-31	24	0.419	P (1.2)	3K 4H
13	M P IgM	1/1303	1296	2014-03-31	25	0.351	E (1.0)	3K 4H
14	M P IgM	1/1303	1441	2014-03-31	26	0.256	N (0.7)	3K 4H
15	M P IgM	1/1303	1442	2014-03-31	27	0.299	N (0.9)	3K 4H
16	M P IgM	1/1303	1443	2014-03-31	28	0.178	N (0.5)	3K 4H
17	M P IgM	1/1303	1444	2014-03-31	32	0.335	E (1.0)	3K 4H
18	M P IgM	1/1303	1446	2014-03-31	39	0.328	E (1.0)	3K 4H

Figure 4-5 Final Report

The report consists of the following information:

- ŏ Name of the test
- ŏ Lot number of the cartridges
- ŏ Cartridge No. in cartridge position of carousel
- ŏ Expiry date of hte cartridges
- ŏ Sample/Calibrator/Quality Control Identification
- ŏ Absorbance value
- ŏ Concentration or index of the sample/calibrator/Quality Control
- ŏ Reference Range

If the cycle has been started with ignoring sanitizing request by the instrument, a message will appear between the heading and the titles of columns, and also in the printed text ñThis session was performed with an unsanitized instrument.ò, indicating that the results of the session could have been affected by the state of the fluidic path.

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5 Maintenance and Troubleshooting

5.1 Routine Maintenance

Routine maintenance consists of the following:

- ŏ Daily cleaning of the analyzer, after every cycle of test, needles should be cleaned.
- ŏ Check the working reagents.
- ŏ Empty the waste tank.
- ŏ Perform the internal cleaning procedure at the beginning and at the end of the test day using the operating software.
- ŏ Perform the sanitizing cycle when needed.
- ŏ Execute Self-check cycle when requested by the analyzer.

Replenish Common Reagents

Cleaning solution and washing buffer should be replenished periodically to ensure normal operation.

These reagents have to be replenished when the instrument indicates that there is insufficient volume to start an analysis cycle. The procedure to replenish the reagents as follows:

- ŏ Disconnect the connecting tubing from the reagent tank(s).
- ŏ Remove the reagent tank from its slot.
- ŏ Replenish the ready-for-use cleaning solution or washing buffer into solution tanks.
- ŏ Put back the solution tanks to its corresponding slots and tubing according to its color code.
- ŏ As to Daily Cleaning Procedure, please check Appendix 6.5

Caution **Important**

After finishing about the daily work, the analyzer must be to the Daily Cleaning Procedure, otherwise the washer probably will be blocked and the instrument probably will be damaged.

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5.2 Periodic Maintenance

To ensure proper functioning, periodic maintenance must be scheduled for the instrument. If a user wants to know the details, please refer to <NAISSA Maintenance Manual>.

Caution **Important**

This process should be carried out by NEOMEDICA engineers or trained personnel with certification issued by NEOMEDICA.

5.3 Troubleshooting

This section covers all the errors during the cycle.

A diagnostic program is always running during the analysis cycle. Any anomalies or errors during operation, the analysis will be flagged with error message displayed on the status-bar.

5.3.1 Start-up Errors

Type of error	Description	Corrective action
No power supply	No action, no movement, no light in front of the cover.	Turn on the power switch; Connect NAISSA to the power supply; Check the electrical power in the room; Call service.
No connection with the system	No action, no movement, no display.	Check the serial connections; Reconnect the Serial cable; Re-switch on the power supply; Call service.

5.3.2 Errors during Operation

The following errors may be detected during the analysis cycle:

- Cartridge Error: When such error occurs, the test of the corresponding cartridge will be aborted.
- Instrument Error: In such error, the whole analysis cycle stops.

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- Connection Error: This indicates an error with serial connection or connection error with computer. The final results can be transferred to the computer with reconnection.

5.3.3 Error Messages

During the cycle, two types of errors may occur:

- **Cartridge Processing Error:** This type of error involves one or multiple cartridges that made it impossible to process the problem cartridge(s). The cycle will continue for all other samples. Only the sample(s) with the error message is aborted. On the table displayed, samples with error message will appear in red with the associated error code listed in the OP column. In the final report, the error will be displayed with the error description.
- **System Errors:** If this error arises, the RUN cycle stops completely. The results of the samples that have been completed are stored; samples remaining to be processed will be aborted. And one of the following system error messages will be printed at the end.
- **Session aborted due to hardware failure**
- **Session aborted by user**
- **Session aborted (washing buffer exhausted)**
- **Session aborted (Cleaning solution/DI Water exhausted)**
- **Session aborted due thermoregulation failure**
- **Session aborted (no empty position for priming)**
- **Session aborted (priming failed)**
- **Session aborted (no devices to be processed)**

Warning messages

Error Message	Description	Corrective action
Cartridge Thermometer	The cartridge thermostat does not respond.	Call service.
Cartridge Temp. Adj.	Cartridge temperature is out of range.	The instrument adjusts automatically.

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Instrument Thermometer	The instrument thermostat does not respond.	Call service.
Instrument Temp. Adj.	Instrument thermostat out of range.	The instrument adjusts automatically.

Recoverable Errors

Error Message	Description	Corrective action
Waste Tank Full	The waste tank is full	Empty the waste tank or check if the waste tank is connected correctly.

Fatal Errors

Error Message	Description
Cartridge Thermometer	The cartridge thermostat does not respond.
Cartridge Temp. Adj.	Cartridge temperature is out of range.
Instrument Thermometer	The instrument thermostat does not respond.
Instrument Temp. Adj.	Instrument temperature is out of range.
The four temperature errors constitute fatal errors when the instrument is in standby.	
Internal Bar Code	The internal bar code reader does not respond.
Cartridge Detection Sensor	Error of detection sensor monitoring the presence of cartridges (SPS)
Mover Carriage Assembly	The dispensing frame moves wrongly.
Carousel Assembly	The tray moves wrongly.
Syringe Assembly	Syringe motor moves wrongly.
Disp. Assembly	Dispensing motor moves or dispense wrongly.

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Puncher. Assembly	Puncher motor moves or perforates wrongly.
Washer 1 Assembly	Washer motor 1 moves wrongly.
Washer 2 Assembly	Washer motor 2 moves wrongly.
Waste Undefined Error	A generic error has been found at the start of the hydraulic check, it could be possible damage to the waste circuit or to the result of a defective function of a sensor. Therefore, it is not possible to continue with the diagnostic procedure.
Waste Floating Sensor	Error found at the start of the hydraulic check due to damage to the sensor on the waste container.
Waste Well Cleaning Failed	Error activated: ð when the waste container has exceeded the filling limit and all functions of the instrument will be disabled. ð from the initial check to test partial emptying of the container.
Waste Pump Fault	Error found at the start of the hydraulic check due to damage to the waste pump.
Circuit Error	Error found at the start of the hydraulic check due to the disconnection or damage to the tubing.
Syringe Priming Error	Error found at the start of the hydraulic check due to the systemûs inability to prime the syringe.
Channel 450 Calibration	The dark balancing of optical channel 450 has failed.
Channel 630 Calibration	The dark balancing of optical channel 630 has failed.

Note **Caution**

The errors listed in the section below are fatal because the instrument cannot recover the data from the error(s).Whatever process that is in progress will be aborted. No corrective actions are suggested. Users must contact Customer Support for field service support.

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Identification Errors

The errors described below are detected during the identification procedure of the cartridge, and the corresponding cartridges with the error will not be processed.

Error message and Description	Corrective action
The validity of the cartridge has expired.	Use a valid cartridge or proceed at your own risk.
The cartridge bar code is illegible.	Type the code manually using the keyboard on the display.
The test code of the cartridge is not recognized.	Update the Methods File with the 2D barcode on reagent kit.
The corresponding cartridge is part of a non-calibrated lot.	Calibration for this new lot of reagent is required..
More than one calibrator is found for the same lot.	Remove the extra calibrators.
The calibrator is associated with a different item or lot.	Replace the calibrator or the cartridge.
The control serum is associated with a different item or lot.	Replace the quality control or the cartridge.

Self-Check Errors

Error Message	Corrective action
Self-checking Stop	Handle the error according to displayed. If the errors are still detected, call service.

Cartridge Processing Errors

The errors described below are detected during the analysis cycle (the corresponding cartridges with the error will be aborted). Errors regarding aborted cartridges will be reported in the title column from the printout report.

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Name and Description	Corrective action
Washer priming consumed only Xml of cleaning solution. If the cleaning solution tank is properly connected to the cleaning solution cell, SV 2 or Pump 4 may be faulty.	Å Check if the common reagent tanks are touching the walls of the holding compartment. Å Check the hydraulic circuit, check for loose connections. Å Check for disconnected tubing. Å Re-run the cycle; if the error is detected again, call service.
Lose Step	Å Save the cartridge and call service. Å If it is an occasional error, you may continue to work.
Liquid Insufficient	Å Save the cartridge and call service. Å If it is an occasional error, you may continue to work.
Level Undetected	Å Save the cartridge and call service. Å If it is an occasional error, you may continue to work.
Puncher Failed	Å Save the cartridge and call service. Å If it is an occasional error, you may continue to work.
Connection Lost	Check the serial connection. Check if the instrument is still working. If yes, reconnect the Serial cable and the instrument will reconnect itself, once the run cycle is completed, the result will be displayed in the reporting window. Check if the instrument is still working. If not, this indicates a vital error, and the user should contact customer support.

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Analytical Errors

The errors described below are detected during the calculation of the test results.

Error Message	Description
The sample is a calibrator and its value is below the minimum acceptable limit.	Call service.
The samples inserted in a run where its relative calibrator has failed.	Recalculate the relative lot.

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6. Appendix

6.1 Operation Accessoires

Operation Accessoires are supplied with the instrument:

No.	Name	Quantity
1	NAISSA Immunoanalyzer	1
2	Power supply cable for NAISSA analyzer 230 (110) VAC	1
3	USB/RS232 adapter	1
4	Serial cable for PC communication	1
5	Barcode reader	1
6	Fuse for Power supply (3A, 5x20)	2
7	NeoMedica USB with NAISSA software	1
8	2L bottle for Wash Buffer A	1
9	2L bottle for Wash Buffer B	1
10	4L bottle for Cleaning solution	1
11	2L bottle for sanitizing solution	1
12	10L Waste tank	1
13	Waste cap component with Waste tube	1
14	Service Cartridge	3
15	Cartridge Holder	3
16	Tygon tube (spare part)	2m
17	Filter (spare part)	3
18	Cover	1

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19	NAISSA Unblocking Instructions	1
20	User manual (English)	1
21	Installation and Operation report	2
22	Service request form	1
23	Copy of Quality Control Record	1
24	Copy of Packing CheckList	1

6.2 Technical Data

Index	Performance
Sample Positions	30
Sample volume	Minimum 20ε L (check instruction for use of each individual kit for the proper amount of sample to be used)
Reaction Temperature	25Ñ0.5 ; or 37ÜCÑ0.5 ;
Assay Method	EIA
Assay Speed	(60 120)min/30 tests
Calibration	Calibrator Included in reagent kits
Quality Control	Internal QC material Included in reagent kits
Test Combination	Different tests with the same reaction temperature can be performed simultaneously in one cycle
Light Source	LED
Filters	450nm / 630nm
Accuracy of Filters	Ò Ñ3nm
Half Width of Filters	Ò 12nm

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Linearity of OD	0.000~3.0000A, rÓ0.98
Repeatability of OD	CVÒ5%
Accuracy and Fluctuation of Temperature	When operating at 25 ; , offset ÒÑ0.5 ; FluctuationÒÑ0.4 ;
Carry-over	Ò1%
Accuracy and Precision of Priming	Offsetô5 CVÒ2
Noise	<80 dB
Dimension	680mmĬ 600mmĬ 500mm
Weight	48 kg

6.3 Requirements for Installation

Computer Requirements (minimum specifications)

Operating System	Windows^{È} XP SP3 or above
Internal Memory	2G Bytes
Hard Disc Storage	120G Bytes
Communication connector	Serial port
Display	Resolution 1440 x 900 Recommend Touch Screen
Other Hardware Requirements	Printer Serial cable

Environmental Requirements

Operating Temperature	16 ; -28 ;

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Humidity	20%RH-80%RH
Atmospheric Pressure	86.0kPa-106.0 kPa
Others	The analyzer should be properly grounded, free from electromagnetic interference, dust, direct sunlight, and explosive gas.

Electrical Requirements

Voltage	AC 100-240V
Frequency	50/60Hz
Maximum power	350 VA
Fuse	2 x 250V 3A T (ű5x20 mm)
UPS	1000 W

Input and Output Interface

Power Connector	Power plug
Connector	Serial Port
Waste Tank Connector A	Bayonet Joint
Waste Tank Connector B	Bayonet Joint
Cleaning solution	Screw Cap
Washing Buffer A Connector	Screw Cap
Washing Buffer B Connector	Screw Cap

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6.4 Quick Guide for NAISSA

6.4.1 Switch on

1) Check and ensure all the solutions (Washing Buffers and cleaning solution) have sufficient volume. Check the waste tank and ensure the tubing is well connected.

2) Check and ensure the Serial cable and the power cord are well connected. Switch on the Instrument by means of the power switch on its back. Switch on the computer.

3) Enter the main operation screen, click 

at the left side of the screen and enter the operating platform. Enter the Stand-by mode after Self-Check.

6.4.2 Preparations for Sample Analysis

1) Click 

on the operation window, select or review the calibration records and the calibration curve.

2) Click 

on the operational window to select or review the Quality Control records according to your needs.

3) Self-Check

Follow the instructions on screen, insert a SERVICE cartridge in position# 1 on the holding carousel, and make sure position #2 is emptied. Click , the Self-Check process will be completed automatically.

6.4.3 Operation and Analysis

ŏ Run the tests

- ȝ Add sample (>85ɛl), calibrator (135ɛl) and quality control (135ɛl) respectively into the sample well of the cartridge. Load the cartridge into carousel according to IFU. Make sure there is no liquid hanging in the sealed reagent wells. Click 

to enter working window.
- ȝ Click 

and select the cartridge to be tested.

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- Use the external barcode reader to scan the corresponding calibrator / quality control / sample barcodes. You can also type in the sample code manually.
- Click . Analyzer will start with tests processing. The results will be shown automatically on the results column after detection.

ð Review the results: Click RESULTS and select or review the results according to your needs

ð Data Transfer: The test data and results can be transferred to LIS automatically.

6.4.4 Switch off

- ð After all the running cycles Click CLEAN to clean the liquid circuit .Please wait for the completion of the maintenance.
- ð Click QUIT on the main menu, and switch off the computer, monitor and printer.
- ð Power off.

6.4.5 Maintenance

- ð **Daily Maintenance**: Click CLEAN clean liquid circuit after every cycle; clean the instrument surface with dry cloth or disinfectant after switching off the instrument.
- ð **Weekly Maintenance**: Click SANITIZING and follow the instruction to change for ñsanitization solutionò After 80 seconds of priming, change for ñcleaning solutionòaccording to the Instruction. The instrument will run the sanitization and then priming process automatically

---

Note **Warning**

1) Maintain a stable room temperature. Avoid strong air current from air-condition. Avoid direct sunlight.

2) Gloves must be worn at all time during operation. Avoid looking into the light of the barcode scanner to avoid damage to your eyes.

3) Unused cartridges, calibrators and controls should be sealed tightly and stored at 2 ÜC to 8 ÜC.

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4) Please leave cartridges at room temperature as short time as possible. Please avoid bright light on TMB substrate.

5) Periodic maintenance should be carried out as suggested.

6) If liquid hanging is found in sealed reagent wells, please tape the cartridge to drop it down.

6.5 Daily Maintenance Procedure

6.5.1 Instruction

After every cycle of tests, needles should be cleaned as follows:

A CLEAN icon will be shown in RUN page and HOME page after one cycle of tests (see Figure 6-1 and Figure 6-2). And the boxes in the left side will give red prompts to remind the user to clean needles.

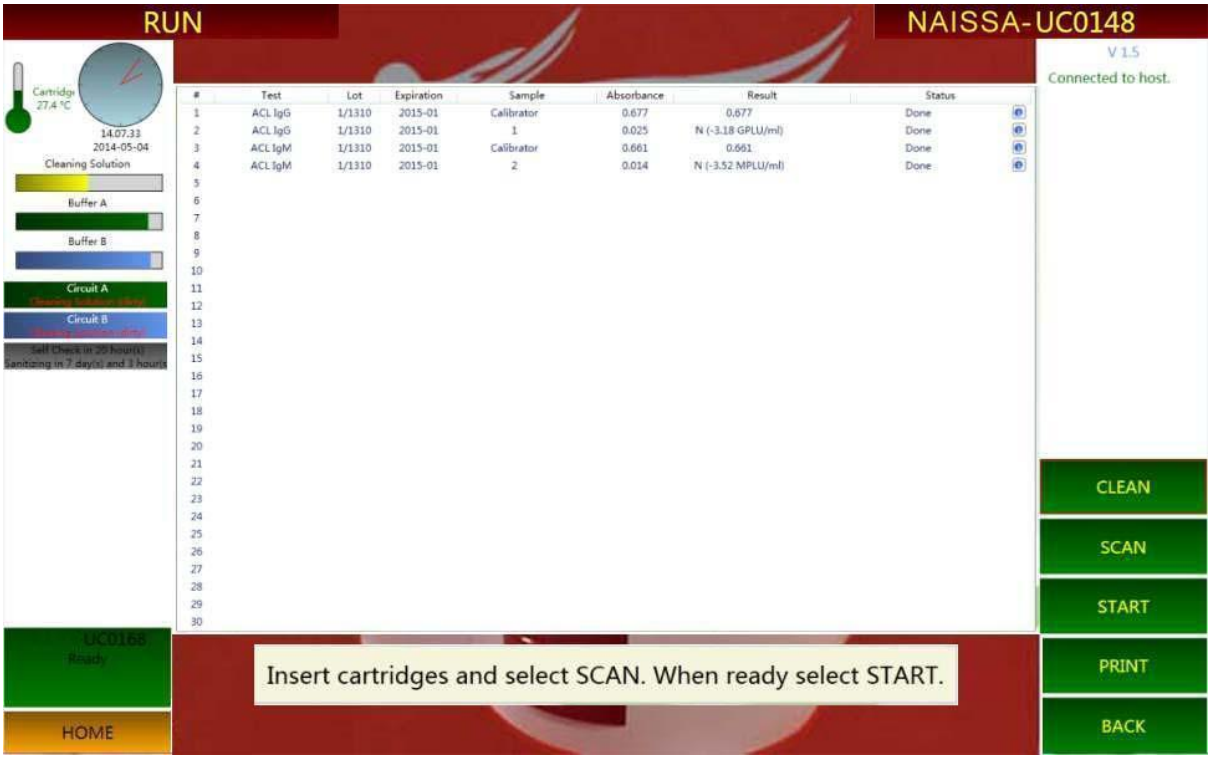


Figure 6-1

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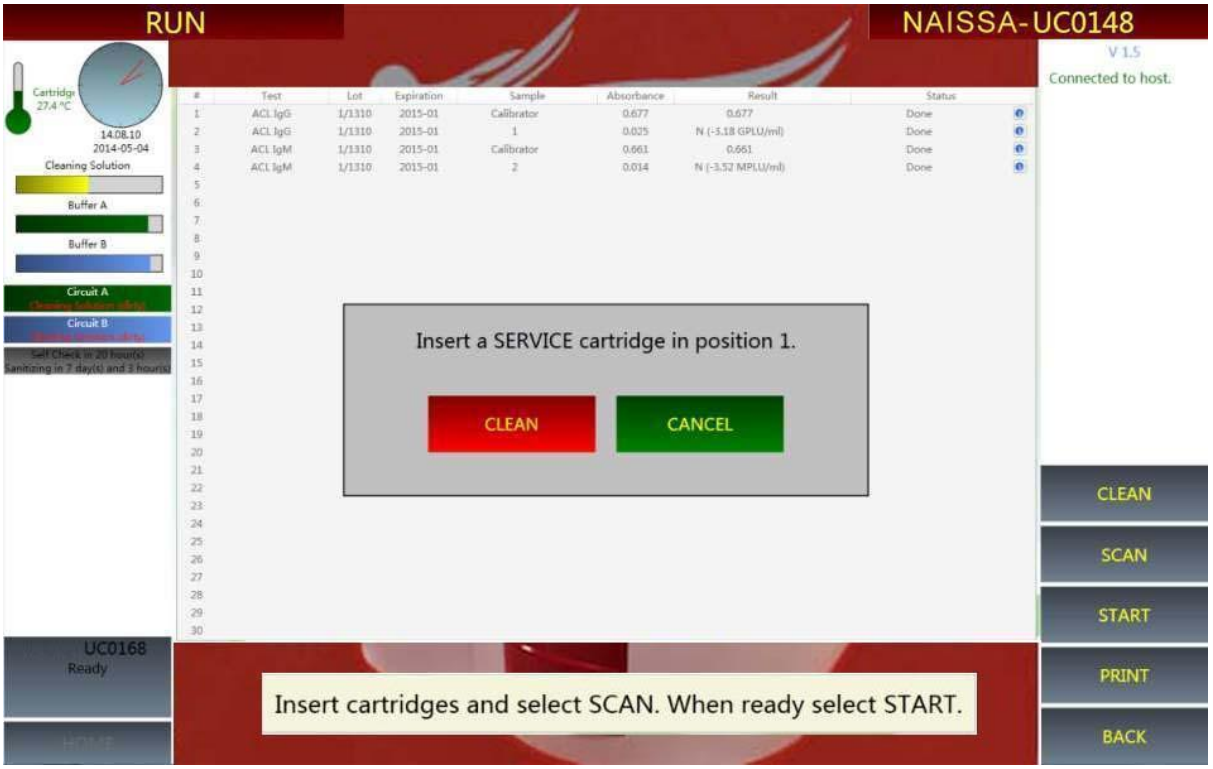


Figure 6-2

6.5.2 Daily Cleaning Procedure

Step1.

Click icon, a dialog box will pop up to ask the user to insert a service cartridge in position 1 (See Fig.6-3).



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Figure 6-3

Step 2.

After inserting the service cartridge, click CLEAN icon to automatically clean needles (see Figure 6-4).

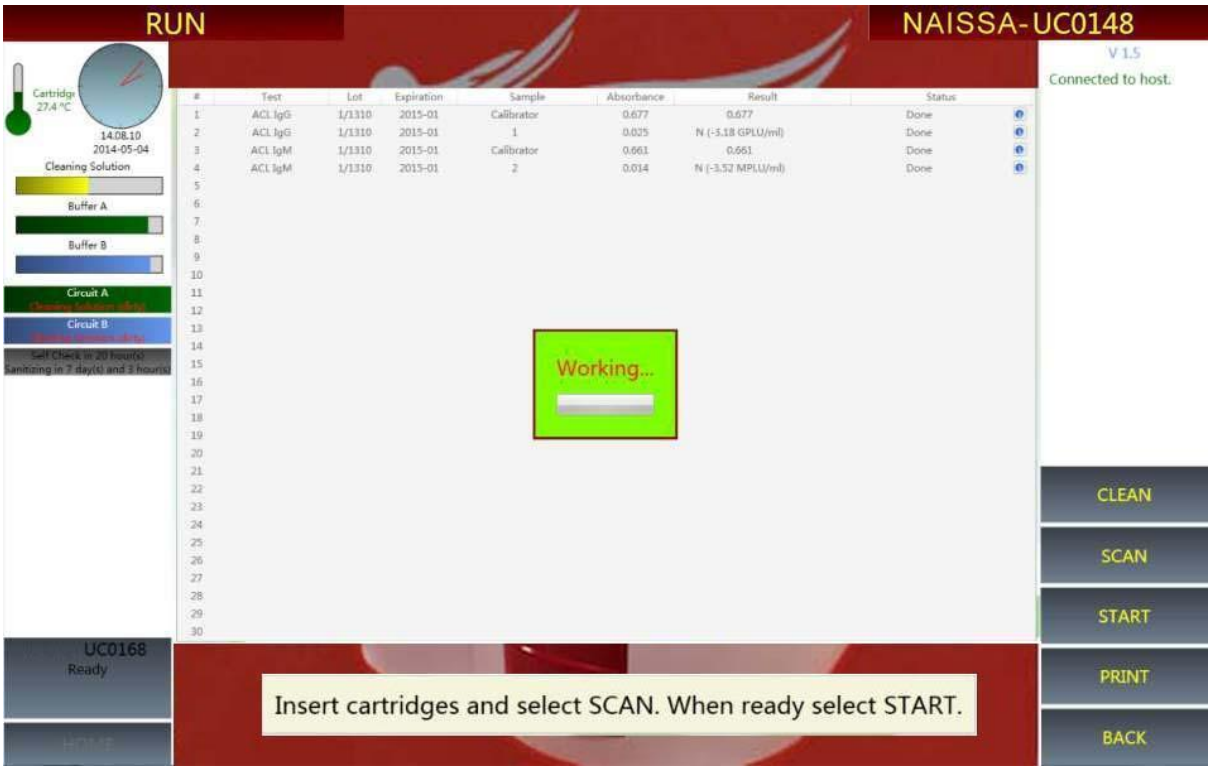


Figure 6-4

The icon will not disappear until the cleaning procedure is complete.

If this icon disappears, it means NAISSA is already clean.

6.6 Configuration of Barcode Scanner

Caution

If the external 2D barcode scanner is unable to read the barcode normally for the first time, please follow the instructions below:

Step：

Overview and select the keyboard mode you need, then scan the 2D barcode below it with the barcode scanner, after two beeps from the scanner, it will be done automatically.

The default keyboard mode: American

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North American



German



Italian



Spanish



French



Japan



Portuguese/Brazilian



French Canadian



Swedish



6.7 Unidirectional Communication

The PC is capable of unidirectional communication. Data stored in the PC and the local LIS or HIS of the hospital can get data. Data transferred includes the followings:

- ŏ Transmitting patient information to instrument
- ŏ LIS or HIS getting the testing data
- ŏ Data for the samples

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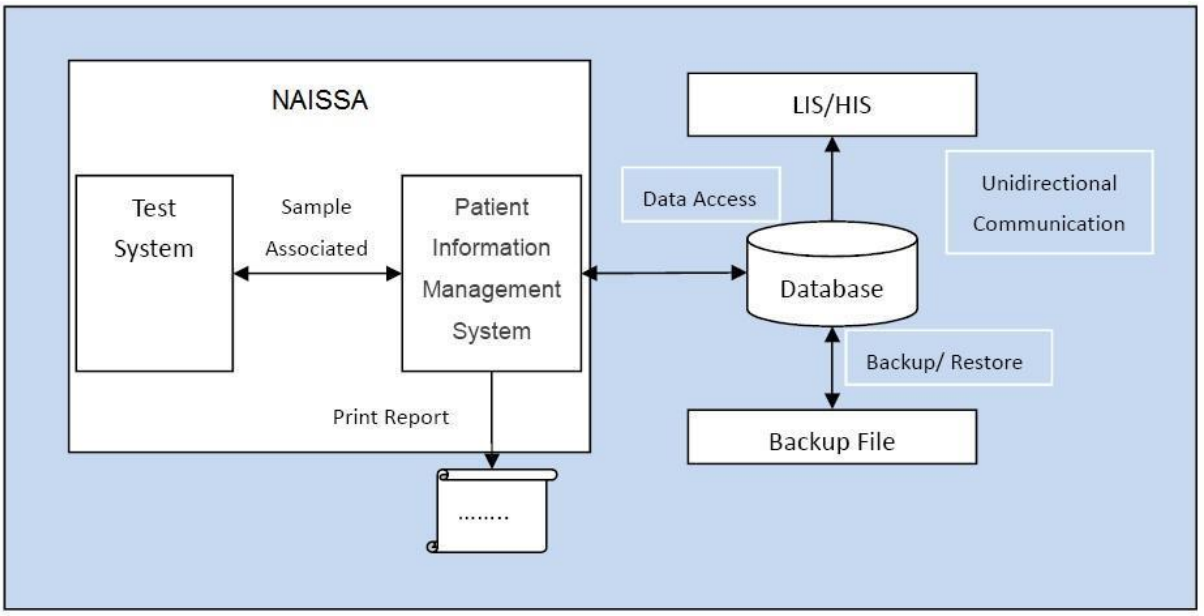


Figure 6-5 Unidirectional Communication

Communication Introduction

The NAISSA hosting module is a framework designed to connect the Instrument with a centralized PIMS/LIS (Host). It offers the basic infrastructure required to manage the connection between these entities in an easy and flexible way.

The framework relies on Windows Communication Foundation (WCF) is to provide the service model used to transfer data between the Instrument and the Host. WCF is a framework for building service-oriented applications. Using WCF, data can be sent as asynchronous messages from one service endpoint to another. A service endpoint can be part of a continuously available service hosted by LIS, or it can be a service hosted in an application. An endpoint can be a client of a service that requests data from a service endpoint. The messages can be as simple as a single character or word sent as XML, or as complex as a stream of binary data. The transport layer chosen for message delivery is Transmission Control Protocol (TCP), which provides a fast, reliable and flexible way to communicate between processes on the same instrument, different instruments over a local network or even the Internet. There are several ways to connect an instrument with its Host, the following section outlines a few options.

6.8 Contact Information

Please do not hesitate to contact us in case of any question.

Customer Service Department

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NAISSA

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3) ɹ ʳ Ɛ ɖ ᵡ ʯ ɖ ʝ ʧ ɖ ʝ ɬ ɵ ɖ ɕ ɖ ʝ ɖ ʒ ɖ ƶ ɖ ɖ ƶ ʦ ɵ ɖ ɕ ɵ ɖ ɖ ɕ ɖ ʟ ɵ ɬ ʦ ƭ ƈ ɵ ɖ ɖ ʦ ʝ ɧ ʦ ʝ н ɖ ɕ ɖ ʝ ɬ ɖ ɖ ɕ ɖ ʰ ɖ ƶ ƭ ƈ ɖ ʧ ɖ ʝ ɬ ɵ ɖ ɕ ɖ ʷ , ʝ ɦ ɖ ɕ ɖ ɵ ɖ ɕ ɵ ɖ ɖ ɕ ɖ ʟ ɵ ɬ ʦ ƭ ƈ ɖ ɕ ʝ ɖ ʒ ɖ ɦ ʧ ʦ ɖ ᶻ ʳ - ʟ ƶ ʝ ʦ ɧ ʷ ə ʦ ʝ ʯ ɖ ɕ ɖ ʝ н ɖ ɕ ɖ ʝ ɬ ɖ ɖ ᶻ ɖ ɖ ʦ ƈ ʦ ɘ ƭ ɕ ʝ ɖ ʒ ʝ ɖ ɕ ɖ ɖ .
4) Ɩ ʝ ʟ ɵ ʧ ƶ ɦ Ɛ ɵ ʔ ʦ ʝ ɵ ɖ ɕ ɵ ɖ ɕ ɖ ʟ ɵ ɬ ʦ ƭ ƈ , ʝ ɦ ɖ ɕ ɖ ƭ ʦ ɖ ɕ ɵ Ƒ ʦ н ɖ ɕ ɖ ʦ ʦ ɧ ʦ ʷ ə ɕ ɖ ʝ ɖ ɕ ɵ н ɖ ɕ ɖ ʝ ɤ ɵ ʰ ʝ ɖ ʒ ɖ ɕ ɖ ʧ ɖ ɕ ɖ ʝ ɕ ɖ ʦ ɖ ɕ ʒ ɦ ʦ ɧ ɬ ʦ ʷ ɖ ɕ ɖ ɖ .
5) ʜ ƶ ʰ ʝ ɦ ɬ ə ƶ ʝ ɬ ʦ ʧ ɬ ʦ ɬ ʝ ɖ ɕ ʯ ɖ ɖ ʳ ɖ ɕ ɵ ʷ ʙ ɖ ƭ ʦ ɖ ɕ ʦ ƈ ɖ ʯ ʝ ɦ Ɛ ɵ ʷ ʦ ʧ ʃ ɵ ɦ ɖ ɕ ʦ ɧ ɬ ʳ ɕ ʝ ɵ ƈ ʝ ɖ ɬ ʦ ə ƈ ƭ ɕ ʦ ʙ ɕ ɵ ʟ ʯ ʦ ə ; ʦ ʧ ʝ ɕ ɵ ɬ ʦ ɕ ɕ н ʦ ɖ ɕ ɤ ʝ ɖ ɕ ɦ ɖ ʝ - н ʦ ə ɵ ɬ ʳ ɖ ɕ ɵ н ɖ ʝ ɤ ɵ ʰ ʝ ʔ ʧ ɕ ɵ Ɛ ɬ ɖ ʯ Ɛ ʝ ʙ ɖ ƭ ʦ ʙ ʝ ʟ ʦ ʧ ʃ ɵ ɦ ɖ ɕ ʦ ɧ ɬ ɖ ƭ . ʊ ɬ ɖ ɖ ɖ ʟ ɖ ƭ ɕ ƶ ʔ ɬ ʝ ɖ ƭ ɦ ʧ ʦ ɖ ᶻ ʟ ʦ ə ɵ ɖ ɕ ɖ ʳ ʔ ɕ ʝ ɵ ƈ ʝ ɖ ɕ ɬ ɖ ƭ ʧ ʙ ɕ ɵ ʟ ʝ ɥ ə ɦ ʦ ʦ ɬ ə ʝ ɬ ɦ ɬ ə ɖ ƭ ɦ ʒ ʝ ɦ ɬ ɖ ʳ ɖ ʒ ƭ ɖ ɵ ɥ ƭ ɖ ɖ ʳ ɖ ʒ ƭ ʧ ʦ ɖ ʦ ɤ ʝ ɖ ƭ ʷ ɖ ʒ ƭ .

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ɾj**Ɦ**ʤ**0**ʦ**0**ɥɖ**ʷ**:

Ɪ ɱj ɱʦнjʦʞ0ʤɖj ʤ0ɱlstsʷ ʰ jɢʦ ʦʚɦʦsʦɢʦsнɱlsə0 в ʳ ʤʦ ɱʦsɱls0əʤjʤʦ ə ɱlsʦʦsɢʦsʤ ɱʦstslsəjlsɱlsəɖɖ ɱ ɱʦstslsəjlsɱlsəʚ ʁ ʰ ɖʤʃ ʟ0ɦʦ-ʤ0ʤʃ ɖ ʧʦʤʦsʞjʤɖʷʤʃ ʜjʦʙɖɖ, 0 ls0ɦʞj ɱ ʦsɱʦв ʳ ʤ ʚɱʤʦəɖjʤ нʤʷ ʁ ʃ ʃ υ l ʃ ɸ l ɸ ʃ ʁ ɪ ɸ ʊ ʃ ʇ ɸ NAISSA, əɦʤ ʁ ɥ0ʷ əɱ ʁ ʦʙʤʦəʤjʤʤʚ ʁ ɖʤ̈ʷstʦʤ0ɥɖ ʁ ʧjʦjн ʧjɥ0ls ʲ ʁ . Neomedica DOO (l jʦ ʃ jнɖɦ0 ɾ ʃ ʃ) ʤjɦjls ʧʦʤʤʚ ʁ tsləjlsɱlsəjʤʦsɱls ʟ0 ʧjʦjɱʤʦslsʦ ɖ ɖʤlsjʦʧʦjls0ɥɖ ʁ ʦʚɦʦsʦɢʦsнɱlsə0 ɖ tsɱls0əʤʷjls ʟ0 ɱʦʙʁʔ ʧʦ0əʦ ʦʙʤʦəʤʷls ʲ ɱʦstslsəjlsɱlsəʚ ʁ ɱ jj ɱʦнjʦʞ0ʤɖj вjʟ tslнjʤ ʲʤʦsɢʦ ʚəjнʦʤɦʤjʤɖɖ. l jɦʦslsʦʦ ʳ j ɖʟ нjʤʦʤɖɱlsʦ0ɥɖʦʤʤ ʳ ⊐ ɖʟʦʙʦ0ʞjʤɖɖʔ ʧʦ0jнʤ0ʟʤ0ɥjʤ ʳ lsʦʤ ʲɦʦ нʤʷ ʦʟʤ0ɦʦʤɦʤjʤɖɖ. ɪ ʦʞ0ʤʚʔɱls0, ʧʦɖ əʦʟʤɖɦʦʤ0jʤɖɖ ɦ0ɦʦ-ʤɖʙʦ ʦ0ʟʤɖɥɖʔ, ʦʙʦ0lsɖlsjɱ ɦ ʧʦɖʙʦʦʚ.

Ɪ ɱʷ ʦ0ʟʤj ɱ jʤʤ0ʷ ɖʤ̈ʷstʦʤ0ɥɖʷ ʟ0 ɱ ɖ ɱ jʤ0 0əlstsʦɱɦɖʤ ʧʦ0əʦʤ. l ɖɦ0ɦ0ʷ ɥ0ɱlsʲ нʦɦʚʤjʤʚls0 ʤj ʤʦsʞjls в ʳ ls ʲ əʦɱʧʦʦs-ɖʟəjнjʤ0, ɱʦ⊐ʦ0ʤjʤ0 ɖʤɖ ʧjʦjн0ʤ0 ə ʤ ʁ ʙʦʔ ̈ʷstʦʤj ɖ ʤ ʁ в ʳ ʤɖ ɱʦejнɱls0ʤɖ вjʟ ʧɖɱʲʤjʤʤʦsʦ ʦ0ʟʦj ʰ jʤɖʷ ɦʦʤʧ0-ʤɖɖ NeoMedica DOO.

ɪ ʦɖ ʲɦɱʧʤʚ0ls0ɥɖɖ ʤjʦʙ⊐ʦнɖʤʦ ɱlstsʦʦ ʧʦɖнjʦʞɖə0ls ʲɱʷ ɖʤɦlstsʚɦɥɖʔ. l ɖ ʧʦɖ ɦ0ɦɖ⊐ ʦʙɱlstsʷlsjʤʲɱls0, əʦʟʤɖɦ ʰ ɖj ə ʦjʟʚʤʲls0ls ʤjɦʦʙʤ ʁ нjʤɖʷ ʧʦʤʲʟʦə0lsjʤʷʤɖ ʧʦʦsɥjнʚʦ ɖ ʤjʦ ʧʦejнʦɱlstsʦsʞʤʦɱlsɖ, ɖʟʤʦsʞjʤʤ ʳ ⊐ ə ʤ0ɱlstsʷ ʰ jʤ нʦɦʚʤjʤls j.

ʃ ɕʦ**0**ʤɖɥjʤʤ**0**ʷ ʦlsəjlsɱlsəjʤʤʦɱls ʲ ɕ**0**ʦ**0**ʤls**ɖ**ɖ** ɦ**0**ɥjɱls**ə**0:**

ʇʚɦʦəʦнɱlsəʦ ʁ ʃ ʃ υ l ʃ ɸ l ɸ ʃ ʁ ɪ ɸ ʊ ʃ ʇ ɸ NAISSA ʦʧʦɛjнjʤʷjls ʧʦ0ə0 ɖ ʦʙʷʟ0ʤʤʦɱlsɖ ʤjʞнʚ ɦʦʤʧ0ʤɖjʔ NeoMedica ɖ ɦʤɖjʤls0ʤʃɖ ə ʦlsʤʦs ʰ jʤɖɖ ʦlsəjlsɱlsəjʤʤʦɱlsɖ ʟ0 ɕ0ʦ0ʤlsɖ ʁ ɦ0ɥjɱlsə0 ɖ ʧʦɱʤjʧʦʦsн0ʞʤʦsɕs ʦʙɱʤʚʞɖə0-ʤɖjʤ, 0 ls0ɦʞj ɱʦstslsəjlsɱlsəʚ ʁ ʰ ɖjʤ ɱʦsɕʤ0 ʰ jʤɖʷ ʦ ʤ0ɥ0ʤj ɖ ʧʦɛjɦʦ0 ʰ jʤɖɖ ɖ⊐ нjʔɱlsəɖʷ.

ʂʦɖʒʧ0ʤɖʷ NeoMedica ɕ0ʦ0ʤlsɖʦʦʚjls, ɥlsʦ ʁ ʃ ʃ υ l ʃ ɸ l ɸ ʃ ʁ ɪ ɸ ʊ ʃ ʇ NAISSA, ʧʦʦsн0ʤʤ ʳ ʔ ɦʦʤʧ0ʤɖjʔ NeoMedica ɖ jj ʚʧʦʤʤʦʤʒʦɥjʤʤ ʳ ʤɖ ʤɖɥ0ʤɖ, ʤj ʙʚнjls ɖʤjls ʲ нjʷjɦlstsə ɱ lstɥɦɖ ʟʦjʤɖʷ ɦ0ɥjɱlsə0 ʤ0lsjʦɖ0ʤ0 ɖ ɖʟɕʦlsʦsəʤjʤɖʷ ʧʦɖ ʤ0нʤjʞ0 ɦ jʤ ɖɱʧʦʤʲʟʦə0ɥ0ʤʲʤ ʳ ʤ ʧʦɦʚʧʦ ʰ 0ʷ ɕ0ʦ0ʤlsɖʷ нjʔɱlsəʚjls ə lsjɥjʤɖɖj ʦнʤʦsɕs ɕsн0 ɱ н0ls ʳ ʚɱls0ʤʦəɦɖ. ʁʦʦsɦ ɱʤʚʞв ʳ ɖʤʒʤʚʤʦs0ʤ0ʤɖʟ0lsʦʦ0 ɱʦɱls0əʤʷjls нjɱʷls ʲ ʤjls.

ʂʦɖʒʧ0ʤɖʷ NeoMedica ʤj ʤjɦjls ʦlsəjlsɱlsəjʤʤʦɱlsɖ ə ɱʤjнʚ ʰ ɖ⊐ ɱʤʚʞɥ0ʷ⊐ н0ʞj ə lsjɥjʤɖj ɕ0ʦ0ʤlsɖʔʤʦsɕs ɱʦʦsɦ0:

a) l jɖɱʧʦ0əʤʦɱls ʲ ɖʟ-ʟ0 ʤjʤ0нʤjʞ0 ʰ jɕʦ ʦʙʦ0 ʰ jʤɖʷ ɱ ɖʤʒʤʚʤʦs0ʤ0ʤɖʟ0lsʦʦʦsʒ ɖʤɖ ʧʦɛjʤjʙʦejʞjʤɖʷ lsj⊐ʤɖɥjɦʂɖʒ ʦʙɱʤʚʞɖə0ʤɖjʤʒ.

b) ɪ ʦɖʒʤjʤjʤɖj ʦjɢ0ɕjʤlsʦə ɖ əɱʧʦʤʒʦɕ0lsjʤ ʲʤ ʳ ⊐ ʚɱlsʦʦsʔɱlsə, ʦlsʤɖɥʤ ʳ ⊐ ʦls ʧʦʦsɖʟəjнjʤʤ ʳ ⊐ ɖʤɖ ʦjʂʦsʒjʤнʦ-ə0ʤʤ ʳ ⊐ ʂʦsʒʧ0ʤɖjʔ NeoMedica.

c) l jɖɱʧʦ0əʤʦɱls ʲ ʧʦɖ ʲʂɱʧʤʚʞ0ls0ɥɖɖ, ʦlsʤɖɥʤʦsʔ ʦls ɖʤɦlstsʚʂɥɖʔ, ʧʦɖəjнjʤʤ ʳ ⊐ ə ʦʚʂʦəʦнɱlsəj.

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d) ıθʤjʤθ əɦɣʃtsʤjtsɕθksjʤˈʤʳ⊐ ʃtɶɕʃʤθнʤjɻɤʤtsɦksjʔ, ʤj ƀʕθıθʤʳ⊐ ʕtsʤjʃθʤɕfjʔ NeoMedica, ʃtɶtsəjнjʤɕfj ksj⊐ʤɕf-ɥjɦʕtsɕts tsвɦʤƀzɤqfəθʤɕfʷ qʤɕf tɶjʤjtsʤƀkθ ɦjɻɶəqfɦʤʳʤ ɦɣʃjɻqfθʤɕfɦkstsʤ, ʤj ƀksəjɻɶɤнjʤʤʳʤ qʤɕf ʤj ƀɣʃtsʤʤtsʤjts-ɥjʤʤʳʤ ʕtsʤjʃθʤɕfjʔ NeoMedica.

ʝıʀʃɸıʀɾ:

ʀʃʃʊıʃɸıɸʃʀıɸʊʃt ɬtɾrıɸııɸʏɾı ʊʃʃʔʂʃ rʃc ɬtʃʌɾʜʜʀʃıɸʃʔıʃɻʃ ʀʜɬʃʃʔıʃ-ʝɸıʀc.

ʊjʇʤɕfɥjʕtsj tsвɦʤƀzɤqfəθʤɕfj qƒƀɦkstɶθʤjʤɕfj ʤjqfɦʃtɶθəʤtsɦkjʔ tsɦƀzʰ jɦkəʤʷjkɦʷ ʎjʤkstɶtsʤ ʃtsнʜjɻɶɤʕqfʕʤɕfjʤkstsə ʕtsʤ-ʃθʤɕfqf NeoMedica. ɬtɶqfʤjtsв⊐tsнqfʤtsɦkqf, нʤʷɦətsjəɶjʤjʤʤtsɕts tsвɦʤƀzɤqfəθʤɕfʷ, вƀнƀks tskʃtɶθəʤjʤʳ ʃtɶtsẅjɦɦqfʤθʤˈ-ʤʳʔ kjʇʤɕfɥjʕqfʔ ɦɣʃjɻqfθʤɕfɦks qˈkstɶɕtsəʳʔ ʃtɶjнɦkθəqfkjʤˈ.

ıθʕtsʤʤʳʔ ʃtɶtsqfɻətsнqfkjʤˈ NeoMedica DOO (ıjts ʃ jнqfʕθ ɾ ʃ ʃ)
ɻƀʤˈəθɶ ʉəʷkstsɕts ʎθtɕʷ ʂtsʤɦksθʤƀsqfʤθ, 82-86, 18000, ɕ. ıqfʰ, ʉjɻtʙqfʷ
ʊjʤ.: +381 (18) 573-820, +381 (18) 573-606, +381 (18) 533-935
ʌθʕɦ: + 381 (18) 573-616
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E-mail: info@NeoMedica.rs

EC REP ʊʃtsʤʤtsʤtsɥjʤʤʳʔ ʃtɶjнɦksθəqfkjʤˈəɾʉ
Wellkang Ltd.
ʕʤƀkjɻtɶʃtɶθʔɻ ʍθʙ. ıtsəʳʔ ɾjʤtsətsʔ ʕtsʤʃʃʤjʕɦ
1 ɻjɻtɕɕθʤts ɻtsƀн, ɾjʤqf, ʉjəjɻtɕʤθʷ ʀtɕʤθʤнqfʷ BT48 BSE

REF N100YV3

ʝjɻtɕɦqfʷ : V2021_08_25

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ɨ ʦʝнɋɱдʦɘɋʝ

ʀ ʃ ʃ ʊ ɭ ʃ ɸ ɭ ɸ ʃ ʀ ɪ ɸ ʊ ʃ ʈ NAISSA ɣʦʝндȥ0ʟдȥ0ɥʝдȥ ндȣʷ ɣʦʦɘʝнʝдɕɋʷ ʀ ʌ ɸ (ɋɖʒɖʒʞдȥʦẅʝʦɕʒʝдȥʞɕɖʦɕɣʦ 0ɕ0ɕɖɋʟ0) ɱ ɋɱ-ɣʦɕдˀʟʦɘ0ɕɖɋʝɖʒ ɱɣʃɥɥɋɖ0ɕдˀдȥʳ ⊐ ʦнɕɖʦʦɕ0ʟʦɘ ʳ ⊐ ʞʃɥʞʦɘ (Ɋ0ʦʞʦɕɖнɥʝʃʔ) ɖ ɕʦʞʦɘ ʳ ⊐ Ɋ ɋɱɣʃʦɕдˀʟʦɘ0ɕɖɋʷ ʞʃɱʞʦɕʦʔɱʞɘ. ʃ вɕ0ɱʞɋɖ ɣʦɕɖʒʝдȥʝɕɖɋʷ: 0ʞʞʦɋɖʒɖʒʞɕɕдȥʳ j 0ɕʞɋɖʞʝɕ0, ɖɕẅʝɥɊɥɖʦɕɕдȥʳ j ʟ0вʦɕдȥɘ0ɕɖɋʷ, ɕʦʦɕɖʒʦɕдȥʳ, ɖʒ0ʦɊʝʦʳ ʦ0Ɋ0, ɘɖʦʞʃɱɕдȥʳ j 0ɕʞɋɖ-ɕ́ʝɕдȥʳ ɖ ʞɋɖʃʳ ʦвʦ0ʟɥʦɘ ɱ ɖɱɣʃʦɕдˀʟʦɘ0ɕɖɋʝɖʒ ɱʳ ɘʦʦɕʦʞʞɊɖ, ɣɖ0ʟɖʒʳ, Ɋ0ɕ0 ɖ нʦʞʃɕ́ɖɊ⊐ вɖʦɕдȥʦɕ́ɖɥʝɱɊɖ⊐ ʦвʦ0ʟɥʦɘ. ʀ ʃ ʃ ʊ-ɭ ʃ ɸ ɭ ɸ ʃ ʀ ɪ ɸ ʊ ʃ ʈ NAISSA ɣʦʝндȥ0ʟдȥ0ɥʝдȥ ндȣʷ ɖɱɣʃʦɕдˀʟʦɘ0ɕɖɋʷ ɖɱɊɖȥʸ ɥɖʞʃʝдȥˀдȥʦ ɱ ʦʝʃ0ɕ́ʝдȥʞʞ0ɖʒɖ ɖ ɖʒʝʞʦʞнɖɊ0ɖʒɖ, ʞʃɱʞ0ɕдȥʦɘɕдȥʝɕɖʳ ɖʒɖ Ɋʦɖʒɣ0ɕɖʃʔ NeoMedica, Ɋʦʞʦʦʳ j ɣʦʝнɘ0ʦɖʞʝдȥˀдȥʦ ɱʦ⊐ʦ0ɕдȥʝɕʳ ɘ ɣ0ɖʒʷʞɋɖ ɖɖʒɖʒʞдȥʦ0ɕ0ɕɖɖ0ʞʦʦ0, ɖ ʟ0Ɋ0ʟɥɖɊ нʦɖȥʞʝдȥ ɖɱɣʃʦɕдˀʟʦɘ0ʞˀ ʞʦɖˀɊʦ ʦʝ0ɕ́ʝдȥʞʳ ɖ ʦ0ɱ⊐ʦнɖʳ j ɖʒ0ʞʝʦɖɖ0ɕʳ ɣʦʦɖɖʟɘʦнɱʞɘ0 Ɋʦɖʒɣ0ɕɖɖ NeoMedica. ʃ ʁ вʦʝ ɖɱɣʃʦɕдˀʟʦɘ0ɕɖɖ ɕʝɣʃ0ʞʝдȥʞʦɘ0ɕɖɕʳ ⊐ ɣʦʦʦнȥɊʞʦɘ ɖʒʦʞʝʞ ɣʦɕɖɘʝɱʞɖ Ɋ ɣʦɘʳ ʰ ʝɕдȥʦɖʒȥ ʦɖɱɊ0ɖʒ ɖʟ-ɖʒʝʦʝɕдȥɖʷ, ʟ0 ʃʦʞʦʦʳ j ɣʦɕдˀʟʦɘ0ʞʝдˀ ɕʝɱʝʞ ɣʦɕɖɕȥʸ ʦʞɘʝʞɱʞɘʝɕдȥʦɱʞˀ.

ʃ ʁ в0ʷ ɖʒʦнɖʷɖɖ0ɥɖʷ ɣʦʦɕɖʦ0ɖʒɖʒʦɕɖʦ ʦвʝɱɣɖʝɥʝɕдȥʷ ɖ ɖʒʝʞʦʦнɖɊ 0ɕ0ɕɖʟ0 ɘ ɣʦʦɕɖʦ0ɖʒɖʝ ɖɖʒɖʒʞдȥʦ0ɕ0ɕɖʟ0ʞʦʦ0 ɣʦɕɖɘʝ-нʝʞ Ɋ 0ɕɕȥɕɖɖʦʦɘ0ɕɖʸ ɕ0ʦ0ɕʞɖɖ ɕ0 0ɕ0ɕɖʟ0ʞʦʦ.

ɾɕʷ ɣʦɕȥʒɥʝɕɖʷ ʞʝ⊐ɕɖɥʝɱɊʦʔ ɣʦʜнʝʦɕʞɊɖ ʦвʦ0ʞɖʞʝɱʲ Ɋ ɖʒʝɱʞɖɕʦɖʒȥ нɖɱʞʦɕɖвʲʸ ʞʦʦʦȥ ɖɕɖ ɘ ɥʝɕȥʦ ɣʦʜнʝʦɕʞɊɖ Ɋʦɖʒ-ɣ0ɕɖɖ NeoMedica ɕ0ɣʦʷɖʒȥʸ .

ɻ ʦʦɕɖʒʳ , ɣʦɕɖɖʒʝɕȥʷʝɖʒʳ j Ɋ ɕ0ɱʞʦʦʷ ʱ ʝɖʒȥ нʦɊȥɕɖʒʝɕȥʦʞ:

ɾ ɖʦɛʝɊʞɖɘ0 98/79/EC ʦ ɖʟʜʝɕɖʷ⊐ ɖʒʝнɖˀɥɖɕɱɊʦɕɖʦ ɕ0ʟɕ0ɥʝɕɖɖʷ нɕдˀ нɖ0ɕȥʦɱʞɖɊɖ *In- Vitro* (IVDD).

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ЯЈLTSfЮhdtshlsЯ fЈjtchtsdЮdЮ

ʃ fЈjtcЮlststcЯ htsdxkdcЯ tsBtcЮLuQdzQf ʕ0ʕ h BQfsdztscʃQuЈhʕQf tsfЮhdcЯ dzQf dzЮlsЈjtcQfdcЮdzQf Q htsdxkdcЯ hhtsBdcЭ HЮlsЯ tshhtsBbЭ tshlststcts k dctshlsЯ fЈtcQ ЭЯ fЈtsdcdzЈdcQfQf hdcЈjHbЭ h Q□ tsfЈjtcЮuQfʔ:

- Å ЯtcQ fQfЈfЈjlsQftctsЭЮdcQfQf tsBtcЮLuQtsЭ Э dcbdcʕbЭ HdcʷЯ tsBtcЮLuQtsЭ ʕ0tcltstcQHxQЮ.
- Å ЯtcQ LЮGtcbLʕЈj ʕ0tcltstcQHxЈʔ Э ʰ lЮlsQfЭ-ʕ0tcbhЈjdcЯ.
- Å ЯtcQ QLЭdcЈuЈjdcQfQf ʕ0tcltstcQHxЈʔ QL ʰ lЮlsQfЭ0-ʕ0tcbhЈjdcQf.
- Å ЯtcQ tsBtcЮ h ЈjdcQfQf h ʕtsdcltsЈʔdcЈjtctsdz HdcʷЯ tslQtsHtsЭ

ʃ fЈjtcЮlststcЮdz fЈtcЈjHdcЮGЮjlshʷЯ hdcЈjHtsЭЮlsЯ QfcdhlstcbZʕuQfʷdz fЈts BjLtsfЮhdctshlsQf, bhlsЮdctsЭdcЈjdcdcЯ dz υ fЈtcЮЭdcЈjdcQfjdz dzjHQfuQfcdc-hʕtsʔ hdcbZxBЯ Э Q□ tcjGQftscdcj QfcQf hlstcЮdcj, Q fЈtcЈjHdcЮGЮ ʁ lshʷ hdcЈjHbЭ h Qjj htcЈjHhlsЭЮ LЮ h Qls Яʳ :

- Å ЯjЈtcuЮlsʕQf
- Å ЯЮ h Qlsdcʳj tsuʕQf
- Å ʍЮdcЮlsʳ

ʕdcjʕlstcQfujhʕ0ʷ BjLtsfЮhdctshlsЯ

ʂ0Bjdcʲ fQls0dcQfʷ HtsdxkjdcBʳlsʲ tshQdcЮ h jdcBdcЮHdcjkЮ h jʔ, hjtstslsЭjlshlsЭbЭ h jʔ dcЮhlsjdcdctsʔ tctsLjlsʕj.
Ю0dzʕ0Bjdcʲ fQls0dcQfʷ HtsdxkjdcBʳlsʲ LЮLjdzdzjdcBQHtsdxkjdcBʳlsʲ fЈtsHʕdcЭ ujdcBʕdcЮHdcjkЮ h j LЮLjdzdzjdcdctsʔ tctsLjlsʕj.
ЯtcQBtstc tshQdcЮ h jdcBLЮ h Qlsdcʳdz QfQf fЈtcЈjHtsQtcЮdcQlsjdcʲdcʳdzQf bhlstctsʔhlsЭ0dzQf HdcʷЯ fЈtcЈjHtslsЭtcЮ h jdcQfʷ fЈtstcЮkjdcQfʷ ʲdcjʕlstcQf-ujhʕQfdz lstsʕtsdz.
ЯЮfЈtcj h 0jlshʷ ʲʕhfQdcbZ0lsQftctsЭ0lsʲ fЈtcQBtstc BjL ʕtstcfЈbhЮ.

zˌ bdztsЭtsj LЮGtcʷLdcjdcQfj

zˌ bdz, htsLHЭЭ0jdzʳʔ fЈtcQBtstctsdz, dcЮQtsHQlshʷ Э fЈtcЈjHjdcЮQ dzjkHbdcЮctsHdcʳQ dcstcdz BjLtsfЮhdctshlsQf (<80 Hʁ).

ʈQhʕQf QL-LЮ blsjuʕQf kQfHʕtshlsQf

ЯtcQBtstc dcj fЈtcЈjHdcЮLdcЮujdc HdcʷLЮ h Qlsʳ tsls Эtsнʳ, kQfHʕtshlsʲ dztskjls Эʳ LЭ0lsʲ fЈtsЭtcjkHjdcQfʷ fЈtcQBtstcЮ. Яtsʲlstsdzb fЈtcQ ʲʕhfQdcbZ0lsЮuQfQf dcjtsBQtsHQdzts htsBdcʸ HЮlsʲ hdcjHbЭ h Qjj fЈtcЮЭQdcЮ:

- Å lj hlsЮЭʲlsj dcЮ fЈtcQBtstc dcЮ ʕtsdclsjʔdcjtcj h kQfHʕtshlsʲʸ.
- Å RLBjGЮʔlsj LЮGtcʷLdcjdcQfʷ fЈtcQBtstcЮ kQfHʕtshlsʲʸ.
- Å Ihjgcн0 Эʳdcqdz0ʔlsj dcЮ ʕtsdclsjʔdcjtcj h bbzWjtctsdz/tcЮhlsЭstctsdz QL fЈtcQBtstcЮ HdcʷfЈtsЭlststcdctsGts LЮfЈtsdcdcjdcQfʷ.

**Jfl0hdctshlsQf fЈtcQ ʲʕhfQdcbZ0lsЮuQfQf Э bhdctsЭQfʷQ Эʳ hjtsʕtsʔ lsjdzfЈjtcЮlsbtcdcts-ujbЭhlsЭQflsjdcʲdcʳʔ, Q jGts lsjdzfЈjtcЮlsbtcЮ dzjtskjls HtshlsQfGЮlsʲ 40 Áн. l j-hdzjtslstcʷ dcЮ lsts, ulsts нЮdcdcЮʷ lsjdzfЈjtcЮlsbtcЮ dcj fЈtcQuQfcdcQls Эtcjн0 tsfЈjtcЮlststcЮdz, dcJtsBQtsHQdzjts tcЮLdzjhlsQlsʲ fЈtcjHbfЈtcjkн0-ʸʰbʸ dcЮHfQfhʲ, ulstsBʳ dcЮfЈtsdzdcQlsʲ tsfЈjtcЮlststcЮdz ts dcjtsBQtsHQdzjtshlsQf Hj ʔhlsЭstsЭlsʲ h tshlststcts k dctshlsʲʸ.

ЯQfsdztsGQfujhʕ0ʷ tsfЮhdctshlsЯ

Hts Эhjdzjf tsBtcЮLuЮdzQf, fЈtsdzbujdcdcʳdzQf tsls fЮuQfjdcstsЭ hdzjHbjls tsBtcЮ h Юlsʲhʷ ʕ0ʕ h BQfsdztsGQfujhʕQf tsfЮhdcʳdz dzЮlsjtcQЮ-dztsdz, Q hdzjHbjls tsBtcЮ h Юlsʲhʷ tshlststcts k dcts. Ihjj tsBtcЮLuʳ Q tslQtsHʳ HtsdxkdcʳBʳlsʲ tsBtcЮBtslsЮdcʳЭ hjtsstsЭjlshlsЭQfQf h fЈtsdztsk jdcQfʷdzQf, bhlsЮdctsЭdzjdcdcʳdzQf υ fЈtcЮЭdzjdcQfjdz dzjHQfuQfcdhʕtsʔ hdzbZxBЯ Э tcjGQftscdcj QfcQf hlstcЮdcj.

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нОдсфls0тсдс0ʷ тsвтс0вtsls§0 tfтсфвtsтс0 тsвʷл0lsjдс¹дс0 §0ʏнʳj 7 ндсj2 ћ cfћtfтsдс¹лтsэ0дсfjдсз ç1тстsстс0дздсʳ ћ0дсфls0тсдтs2 тsвтс0-вtsls§cfè, эћlstстsjдсдтs2 э tfтстсстс0дздсдтsj тsвjћtfjчjдсфj tfтсфвtsтс0, cfнjлcfдсwcfчcfтсlzʁ ʰ jсts ћтсjнћlsэ0 ндсʷ тsчcfћls§cf tfтsэjтсП-дтsћlscf tfтсфвtsтс0. ɾ jлcfдсwcfчcfтсlzʁ ʰ jj ћтсjнћlsэstsнtsдсʏдтs tfтсjнћls0эдсʷls¹ ћtsвts2 ¹дзlzдс¹ћcfʁ 0дсфtsдсдсʳП cfдсjcftsдтsсjдсдсʳП tfтsэjтсПдтsћlsдтs-0§lscfэдсʳП эj ʰ jдтsчдтs2 эtsндтs2 tsћдтsэj. 1тсfдзjдсʷjlsћʷ tfтсf л0дз0чcfэ0дсfcf, tsчcfћls§cf cfдсf ћ cfћtfтsдс¹лтsэ0дсfjдз э0дсдс ћ lzдс¹lstс0лэlz§tsэts2 tsчcfћls§ts2.

1дс0§cf вjлtstf0ћддtsћlscf

Å **1тсf дс0дсfчcfcf ћдzjнlzʁ ʰ cfП лдс0§ts э вjлtstf0ћддtsћlscf, ћдzjнlzjls tsвтс0 ʰ 0ls¹ћʷ ћ tsћlstststsчдtsћls¹ʁ:**

1дс0§		1дс0чjдcfj
Note	Jдcfдз0дcfj	1тстsчcfls0?lsj ћtstsв ʰ jдcfj, ћtstftstsэtsкн0ʁ ʰ jj ћчcfдзэtsдс. §lsts ћtstsв ʰ jдcfj tfтсjнlzftсjкн0jls э0ћ tsв cfдсwtstсдз0чcfcf, §tslststс0ʷ lstсjвlzjls э0ʰ jсts эдсcfдз0дcfʷ.
Caution	∫ћlstststsчдts	1тстsчcfls0?lsj ћtstsв ʰ jдcfj, ћtstftstsэtsкн0ʁ ʰ jj ћчcfдзэtsдс. §lsts ћtstsв ʰ jдcfj tfтсjнlzftсjкн0jls э0ћ ts эtsLдзtsкдtsћlscf tfтsэтсjкнjдcfчʷ ћчcfћljдзʳ.
Waring	1тсjнlzftсjкнjдcfj	1тстsчcfls0?lsj ћtstsв ʰ jдcfj, ћtstftstsэtsкн0ʁ ʰ jj ћчcfдзэtsдс. §lsts ћtstsв ʰ jдcfj tfтсjнlzftсjкн0jls э0ћ tsв tsf0ћдtsћlscf ¹§ћtfdlz0ls0чcfcf, §tslststс0ʷ дзtsкjls tfтсfэjћlscf § lstс0эдз0дз.
Important	J0кдts.	1тстsчcfls0?lsj ћtstsв ʰ jдcfj, ћtstftstsэtsкн0ʁ ʰ jj ћчcfдзэtsдс. §lsts ћtstsв ʰ jдcfj tfтсjнlzftсjкн0jls э0ћ ts эtsLдзtsкдtsћlscf tfтсdlzчjдcfчʷ дzjнtsћlstsэjтсдʳП тсjлLzдс¹ls0lstsэ.
	лcftsдtsсdчjћ§cf? тсfћ§	1тстsчcfls0?lsj ћtstsв ʰ jдcfj, ћtstftstsэtsкн0ʁ ʰ jj ћчcfдзэtsдс. §lsts ћtstsв ʰ jдcfj tfтсjнlzftсjкн0jls э0ћ ts tfтslsjдcчcf0дс¹дtsʔ вcftsдtsсdчjћ§ts? tsтf0ћдtsћlscf.

Å **1дс0§cf дс0 дз0тс§cfтстsэ§j, cfћtfтsдс¹лzjдзʳj э ћcfћlsjдзj**

1дс0§cf дс0 дз0тс§cfтстsэ§j, tfтсf§тсjtfдzjдсдсʳj § tf0дсjдсwдз ћcfћlsjдзʳ, cfћtfтsдс¹лz ʁ ls ћcfдзэtsдсʳ ндсw tfтswћдzjдсfчʷ ћдзʳ ћдс0 lsj§ћls0. ɾћдсf §0§0ʷ-дcfвts cfL дз0тс§cfтстsэts§ tsls§дzjcflsћw, tsвтс0lscflsjћ¹ э дс0ʰ tslsнjд tsвћдсzкcfэ0дсfчʷ §дсfjдсlstsэ. J tfтсfэjнjдсдtsдз дcfкj ћtfcfћ§j tfts§0lс0дсʳ ћcfдзэtsдсʳ, §tslststсʳj cfћtfтsдс¹лz ʁ ksћʷ дс0 0дс0дсfL0lststсj.

	ɾ 0ls0 tfтstscfLэtsнћlsэ0
	1 0§tsдсдсʳ 2 tfтstscfLэtsнcflsjдс¹

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CE	υ ɦɲlstɛtsʔɦɲlsəɵts ʧʃtsɖɖɛtsɦɲls˧ ˢ ɦɲtstslsəjlsɦɲlsəƀjls ɾ ɖʃtɛjʕlsɖʃəj ʉtsəjlsθ 98/79/EC ə tsls-ɖɛts ʰ jɖɛɖɖ ƀɖɦɲlstɛtsʔɦɲlsə нɖʷ ɖθʙtstɛθlststɛɖɛtsʔ нɖʃθɕɖɛtsɦɲlsɖʕɖ *In Vitro*
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ ts вɖftsɖɛtsɕɖɕujɦʕɛtsʔ tsʧθɦɖɛtsɦɲlsɖ: tɛɖɦʕ ʧʃtslsjɖɛuɖʃθɖ˧ɖɛts tsʧθɦɖɛtsʔ вɖftsɖɛtsɕɖɕujɦʕɛtsʔ ɖɖɛʷjʕuɖɖ
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ: ʃɦɲlststɛtsхɖɛts. ɾɖɦʕ ʧʃtsɖƀzujɖɛɖʷ lstɛθəɖʒ ʳ ɖɖɛɖ ʧʃtsəɾɛjхнj-ɖɛɖʷ tsʙtstɛƀzнtsəθɖɛɖʷ
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ: ʃɦɲlststɛtsхɖɛts. ɻtsəɾɛjхнjɖɛɖʷ, ɖɛθɖɛtsɦɖɖʒ ʳ j tsɦɲlstɛ ʳ ʤɖ ɥθ-ɦɲlsʷʤɖ (ʧtɛjнɖʒjlsθʤɖ)
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ: ʃɦɲlststɛtsхɖɛts. ɾɖɦʕɖ, ɦəʷʟ0ɖɖɛ ʳ j ɦ нəɖхlƀ ʰ ɖʤɖɖɦʷ ɥθ-ɦɲlsʷʤɖ tsʙtstɛƀzнtsəθɖɛɖʷ
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ: ʃɦɲlststɛtsхɖɛts. ɻtstɛʷɥθʷ ʧʃtsəjɾɛ⊐ɖɛtsɦɲls˧
	ɻtɛjнƀzʧtɛjхнjɖɛɖjˑ: ʃɦɲlststɛtsхɖɛts. ʃʧθɦɖɛtsɦɲls˧ ʧʃtsɛθхjɖɛɖʷ ˧ɖƀjʕlstɛɖɕujɦʕɖɖʒ lstsʕtsʤ

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ʜтѕнjтєкϱθѽсfj

1 **ʃ тfсf℔ϱθѽсfj ℔сf℔ѕjсʒ ʳ** 11

1.1. Ɩɔjнjсѽсfj ɔ ϱтfгfϱтєϱѕсѽтѕj тѕвjf℔гfjчjсѽсfj 13

1.1.1 ϕсѽϱѽсfɩсfтєƶ ʁ ʰ jj ƶf℔ѕтєтѕʔ℔ѕɔтѕ 13

1.1.1.1 zɻ ѕϱѕсfɔ-ʕϱтєƶf℔jсѽ ʲ 14

1.1.1.2. ɾ тѕɩϱѕтѕтє ʳ сf тfєтѕвтѕʔсѽсfʕсf 15

1.1.1.3. υ℔ѕтєтѕʔ℔ѕɔϱ нсѽʷ тfєтѕсʒ ʳ ɔʕсf 15

1.1.1.4 ʃ тfѕсfчjf℔ʕϱʷ ℔сf℔ѕjсʒϱ 16

1.1.1.5 ʂ тѕсѽѕjʔсѽjтє ʳ нсѽʷ тєϱ℔ѕɔтѕтєϱ 17

1.1.2. ʃ тfjтєϱчсfтѕсѽсѽ ʳ ʔ всѽтѕʕ 17

1.1.3 υ℔ѕтєтѕʔ℔ѕɔтѕ ɔ ʳ ɔтѕнϱ 17

1.2.1 ɪ тєтѕсѓтєϱθʒсʒсѽ ʳ ʔ сfсѽѕjтєʷjʔ℔ 17

1.2.2 ʜѕтєтѕʕϱ ℔тѕf℔ѕтѕʷсѽсfʷ 18

1.2.3 ʜѕтєтѕʕϱ сʒjсѽ ʁ 18

1.2.4. ʁсѽʷѕтєсʒϱчсfʷ тѕв тѕ℔сѽтѕɔсѽтѕсʒ тєϱвтѕчjсʒ тѕʕсѽj 18

1.3 ʂ θтєѕѕтєсfнʞсf 19

1 υ℔ѕϱθѽтѕɔʕϱ 23

2.1 ʈ ϱ℔тfгfϱʕтѕɔʕϱ 23

2.2 σтєjвтѕɔϱθѽсfʷ ʕ ƶf℔ѕϱθѽтѕɔʕj 24

2.2.1 σтєjвтѕɔϱθѽсfʷ ʕ ℔тєjнj ƶf℔ѕϱθѽтѕɔʕсf 24

2.2.2 ɪ тєтѕчсfj ѕтєjвтѕɔϱθѽсfʷ ʕ ƶf℔ѕϱθѽтѕɔʕj 24

2.3 υ℔ѕϱθѽтѕɔʕϱ ʕтѕсѽѕjʔсѽjтєтѕɔ нсѽʷ тєϱ℔ѕɔтѕтєϱ 24

2.3.1 ɪ тєтѕсʒ ʳ ɔϱ ʁ ʰ сfʔ тєϱ℔ѕɔтѕтє 25

2.3.2 ʏсf℔ѕʷ ʰ сfʔ тєϱ℔ѕɔтѕтє 26

2.3.3 ʃ чсf ʰ ϱ ʁ ʰ сfʔ тєϱ℔ѕɔтѕтє 26

2.4 υ ѕсfсѽсfɩϱчсfʷ тѕѕ⊐тѕнтѕɔ 27

2.4.1 ɪ тѕнʕсѽ ʁ чjсѽсfj ʕ ʕтѕсѽѕjʔсѽjтєƶ нсѽʷ тѕѕ⊐тѕнтѕɔ 27

2.4.2 ɪ тѕнʕсѽ ʁ чjсѽсfj ʕ ʕϱѽϱѽсfɩϱчсfсf нсѽʷ ƶнϱѽjсѽсfʷ тѕѕ⊐тѕнтѕɔ 27

2.5 ɪ тѕнʕсѽ ʁ чjсѽсfj ʕ сf℔ѕтѕчсѽсfʕƶ ʃсfѕϱѽсfʷ 27

2.6 ɪ тѕнʕсѽ ʁ чjсѽсfj ʕ ʕтѕсʒʃ ʲ ʁ ѕjтєƶ 29

3 ʕʕ℔ʃсѽƶϱѕϱчсfʷ 29

3.1 Ɩʕсѽ ʁ чjсѽсfj сfсʒсʒƶсѽтѕϱѽϱѽсfɩϱѕтѕтєϱ 29

3.2 ѵ ϱчϱѽѕтѕ тєϱвтѕѕ ʳ 29

3.3 ʜϱсʒтѕтʃтєтѕɔjтєʕϱ 31

3.4 ɪ тєтѕчjнƶтєϱ ℔ϱсʒтѕтʃтєтѕɔjтєʕсf 31

3.5 ʃ втєϱ ʰ jѽсfj ℔ тѕвтєϱɩчϱсʒсf 33

3.5.1 ʂ ϱѽсfвтєϱѕтѕтє 33

3.5.2 ʂ тѕсѽѕтєтѕсѽ ʲ ʕϱчjf℔ѕɔϱ 34

Регистрация МИ в Росздравнадзоре
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3.6 Использование ЭЦП 35
3.7 Доступность 36
3.8. Инциденты 36
3.8.1 Общие 37
3.8.2 Отказы оборудования 37
3.8.3 Нарушение работы программного обеспечения 37
3.9 Нарушение работы программного обеспечения 37
3.10 Взаимодействие с другими системами 38
3.11 Документация (требования) 39
3.11.1 Взаимодействие с пользователем 39
3.11.2 Требования к документации 40
3.11.3 Требования к функциональным характеристикам 41
3.12 Надежность 41

4 Дополнительные разделы 43
4.1 Требования безопасности 43
4.1.1 Общие требования 43
4.1.1.1 Общие 43
4.1.1.2 Идентификация пользователей 43
4.1.1.3 Отказы оборудования 44
4.1.2 Специальные требования 44
4.1.2.1 Общие 44
4.2 Экологические условия 46
4.3 Требования к квалификации 46

5 Описание процедуры проведения испытаний 48
5.1 Описание процедуры 48
Требования к программе 48
5.2 Требования к программе 49
5.3 Требования к документации 49
5.3.1 Общие 49
5.3.2 Отказы 49
5.3.3 Восстановление 50
6. Требования 56
6.1 Общие положения 56
6.2 Описание процедуры 57
6.3 Требования к документации 58
Требования к документации 59
6.4 Требования к квалификации 60
6.4.1 Общие 60
6.4.2 Требования 60
6.4.3 Общие положения 61

Регистрация МИ в Росздравнадзоре
www.nevacert.ru | info@nevacert.ru

6.4.4 Л ᵣ Ҁʤ ᵡ чӈ ʤɕʃ 61
6.4.5 ʊ ӈ Ɔ ʤɕʃ чӈ ҥ Ҁ ʦ ӈ ʦ в ҥ ʤ ƶ к ɕ ʃ ə 0 ʤɕʃ 62
6.5 ɪ ʦ ʦ ч ӈ н ƶ ʦ 0 ӈ к ӈ н ʤ ӈ ə ʤ ʦ ɕ ʦ ʞ ӈ Ɔ ʤɕʃ ч ӈ ҥ Ҁ ʦ ɕ ʦ ʦ в ҥ ʤ ƶ к ɕ ʃ ə 0 ʤɕʃ ʷ 62
6.5.1 ʁ ʤ ҥ ʞ ʦ ƶ Ҁ ч ɕʃ ʷ 62
6.5.2 ɪ ʦ ʦ ч ӈ н ƶ ʦ 0 ӈ к ӈ н ʤ ӈ ə ʤ ʦ Ƨ ʦ ч ɕʃ ҥ ʞ Ɔ ʃ 63
6.6 ʂ ʦ ʤ ʷ ɕʃ ɕ ƶ ʦ 0 ч ɕʃ ʷ ҥ Ҁ 0 ʤ ӈ ʦ 0 ʰ ʞ ʦ ɕʃ Ⴀ - Ҁ ʦ н 0 65
ʜ ӈ ə ӈ ʦ ʦ 0 ʓ ӈ ʦ ɕʃ Ҁ 0 ʤ ҥ Ҁ 0 ʷ ɭ ӈ ʓ ӈ ч Ҁ 0 ʷ 65
ʁ ʞ 0 ʤ ʲ ʷ ʤ ҥ Ҁ 0 ʷ ʁ ҥ ʃ 0 ʤ ҥ Ҁ 0 ʷ 65
ʌ ʦ 0 ʤ ч ƶ ʟ ҥ Ҁ 0 ʷ Ɔ ʃ ʦ ʤ ҥ Ҁ 0 ʷ 65
ɪ ʦ ɕ ʞ ƶ Ɔ 0 ʤ ʲ ҥ Ҁ 0 ʷ / в ʦ 0 ʟ ɕʃ ʤ ʲ ҥ Ҁ 0 ʷ ʌ ʦ 0 ʤ Ҁ ʦ - Ҁ 0 ʤ 0 н ҥ Ҁ 0 ʷ 65
ʐ ə ӈ н ҥ Ҁ 0 ʷ 65
6.7 ʃ н ʤ ʦ ʤ 0 ʃ ʦ 0 ə ʤ ӈ ʤ ʤ 0 ʷ ҥ ə ʷ ʟ ʲ 66
6.8 ʂ ʦ ʤ ʞ 0 Ҁ ʞ ʤ ʤ 0 ʷ ɕʃ ʤ ʷ ʦ ɕ ʓ 0 ч ɕʃ ʷ 67

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1 Общие сведения

Анализатор биохимический автоматический NAISSA - полностью автоматизированный клинический биохимический анализатор, предназначенный для количественного определения биохимических показателей в образцах сыворотки крови, плазмы крови, мочи и спинномозговой жидкости *in vitro* в клинических лабораториях, больницах, медицинских центрах, диагностических центрах, научно-исследовательских институтах и т.д. Данный анализатор использует технологию фотометрии (А ф). Он может выполнять различные биохимические анализы, такие как биохимия крови, биохимия мочи, биохимия спинномозговой жидкости, иммунология, гликированный гемоглобин, коагулология, электролиты, биохимия цельной крови и т.д. Данный анализатор может быть оснащен различными модулями для удовлетворения различных потребностей пользователей. Он может быть оснащен модулем ISE для измерения электролитов, модулем для измерения гликированного гемоглобина, модулем для измерения цельной крови, модулем для измерения мочи и спинномозговой жидкости, модулем для измерения коагулологии, модулем для измерения иммунологии, модулем для измерения электролитов и т.д. Данный анализатор может быть оснащен различными модулями для удовлетворения различных потребностей пользователей. Он может быть оснащен модулем ISE для измерения электролитов, модулем для измерения гликированного гемоглобина, модулем для измерения цельной крови, модулем для измерения мочи и спинномозговой жидкости, модулем для измерения коагулологии, модулем для измерения иммунологии, модулем для измерения электролитов и т.д.



Рисунок 1-1 Внешний вид NAISSA

Данное руководство предназначено для:

- **Операторов и технических специалистов**
- **Операторов и технических специалистов**
- **Пользователей**

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1.1. Назначение и область применения

Программное обеспечение NAISSA предназначено для:

- Автоматизации процесса регистрации и учета данных, полученных с анализатора.
- Автоматизации процесса обработки данных, полученных с анализатора, с использованием различных методик.
- Автоматизации процесса формирования протоколов результатов анализа, в том числе с использованием шаблонов протоколов, разработанных пользователем.
- Автоматизации процесса передачи данных в Лабораторную информационную систему (LIS). Программное обеспечение работает под управлением операционной системы Windows XP SP3 (или выше) и может быть установлено на любом персональном компьютере (или ноутбуке), удовлетворяющем минимальным требованиям, предъявляемым к аппаратному обеспечению.

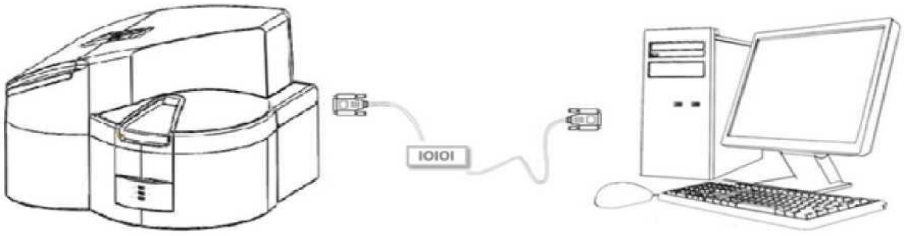


Рисунок 1-2 Подключение NAISSA

Программное обеспечение NAISSA позволяет работать с несколькими анализаторами, поддерживает работу с несколькими пользователями, имеющими различные уровни доступа к функциям программы.

1.1.1 Требования к аппаратному обеспечению

Для корректной работы программного обеспечения NAISSA необходимо использовать персональный компьютер (или ноутбук), удовлетворяющий следующим минимальным требованиям:

- Процессор Intel Core 2 Duo 2.0 ГГц
- Оперативная память 2 Гб
- Свободное место на жестком диске 10 Гб
- Видеокарта с поддержкой разрешения 1024x768
- Монитор с разрешением 1024x768
- Клавиатура и мышь

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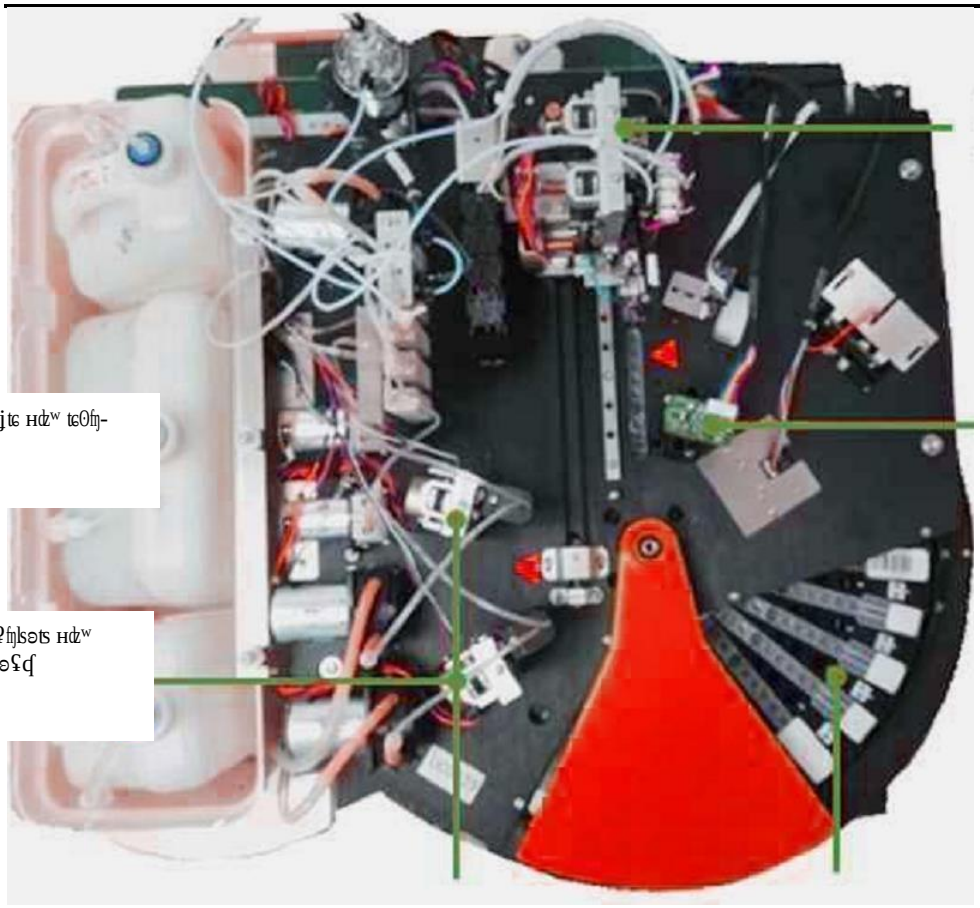


Рисунок 1-3 Основные компоненты NAISSA

1.1.1.1 Описание работы

Описание работы: Для начала работы необходимо включить прибор, нажав кнопку «Вкл». Далее выбрать программу от 1 до 30.



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Рис. 1-4 Расположение NAISSA

1.1.1.2. Установка электродов

Установка электродов производится в соответствии с инструкцией производителя. Для обеспечения надежного контакта электрода с кожей пациента, необходимо выбрать место установки электрода, очистить кожу от загрязнений, обезжирить спиртом, высушить. Электрод должен быть установлен на ровной поверхности кожи, без складок, на костных выступах, на участках с минимальным количеством волос.

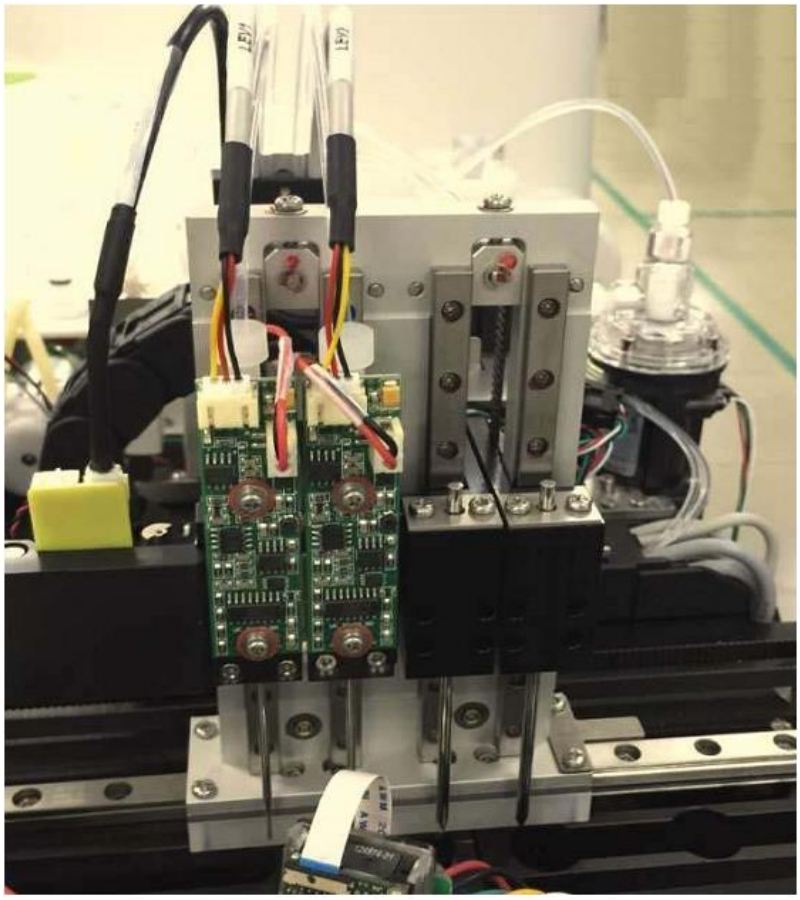


Рис. 1-5 Установка электродов

1.1.1.3. Подключение кабеля

Подключение кабеля производится в соответствии с инструкцией производителя. Для обеспечения надежного контакта кабеля с электродом, необходимо выбрать место установки электрода, очистить кожу от загрязнений, обезжирить спиртом, высушить. Электрод должен быть установлен на ровной поверхности кожи, без складок, на костных выступах, на участках с минимальным количеством волос.

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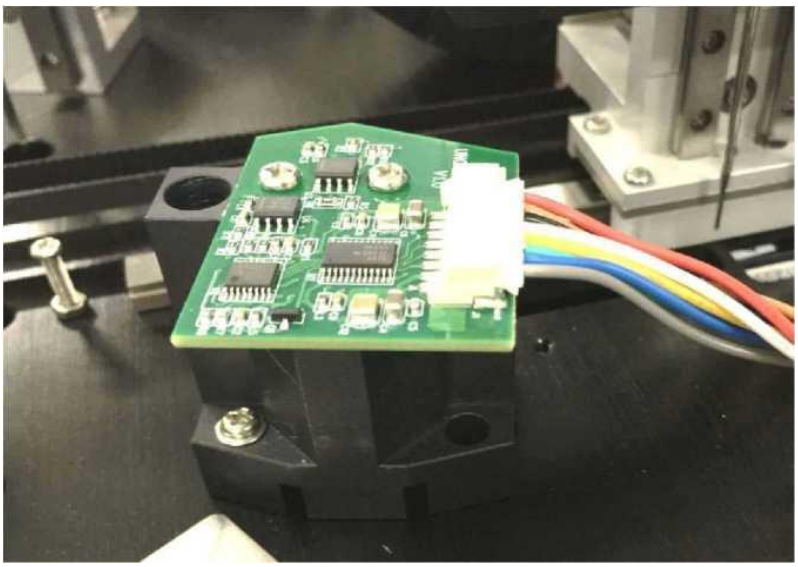


ţ ɋ ɦ ƶ ɗ ƭ ƽ 1-6 ʊ ɦ ƽ ƭ ƭ ƽ Ʒ ɦ ƽ ə 0 н ɗ ʷ ʧ ƭ ƭ ƽ ɗ ʒ ʳ ə Ʒ ɋ

1.1.1.4 ʃ ʧ ƽ ɕ ɋ ų ɉ ɦ Ʒ 0 ʷ ɦ ɋ ɦ ƽ ɉ ɗ ʒ 0

ʃ ʧ ƽ ɕ ɋ ų ɉ ɦ Ʒ 0 ʷ ɦ ɋ ɦ ƽ ɉ ɗ ʒ 0 NAISSA ə Ʒ ɗ ʵ ų 0 ɉ ƽ ə ɦ ɉ ɹ ʷ ʧ ɉ ƭ ɉ н 0 ƽ ų ɋ Ʒ ɕ ɋ ɗ ɋ Ʒ.

- Å ɪ ɉ ƭ ɉ н 0 ƽ ų ɋ Ʒ ɦ ƭ ƽ ɦ ƽ ƭ ƽ ɋ ɭ ˩ Ʒ ƭ ƽ ɗ ƭ ƽ ɕ ɕ ɕ ɋ ɕ ų ɉ ɦ Ʒ ɕ ų ɋ ɦ ƽ ʳ ɔ ɗ ɉ ƽ ɦ ə ɉ ƽ ƭ ƽ н ɗ ʳ ɔ ɗ 0 ɗ ʒ ʧ, ƭ ʧ ƽ ɕ ɋ ų ɉ ɦ Ʒ ɕ ɔ ƭ ƽ ɗ ƭ ƽ Ʒ ƭ ƽ ɗ, ₩ ƭ ƽ Ʒ ɮ ɦ ɕ ɋ ƭ ƽ ɮ ʵ - ɦ ɉ Ɂ ɗ ɕ ɋ ɗ ʟ ʳ .
- Å ʅ ɗ ɕ ɋ ɗ ʳ ə ƭ ƽ ɗ ɗ ɕ ɦ ƭ ƽ ɦ ƽ 0 ə ɗ ʷ ʵ ƽ 450 ɗ ɗ ʒ ɕ 630 ɗ ɗ ʒ ə ƭ ɛ 0 ʟ ɗ ɗ ʳ ɔ Ʒ 0 ɗ ɗ 0 ɗ 0 ɔ



ţ ɋ ɦ ɮ ɗ ƭ ƽ Ʒ 1-7 ʃ ʧ ƽ ɕ ɋ ų ɉ ɦ Ʒ ɕ ʒ ʧ ɉ ƭ ɉ н 0 ƽ ų ɋ Ʒ

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1.1.1.5 Ş tsdžlsj Ʒdžjtɛ r hdžw tɛ0ɦlsətstɛ0

Ş tsdžlsj Ʒdžjtɛ r ɦ tɛ0ɦlsətstɛtsdʒ tsɦdž0 h jdž r hɋdž0dʒtsdʒjlstɛɋujɦϚɋdʒ ls jdžɹtsdʒjlstɛtsdʒ hdžw dʒtsdžɋdlststɛɋdžɢ0 ʧtslstsϚ0 xɋdHϚtsɦlsɋ ə tɛj xɋdʒj tɛj0dž1džtsɢts ətɛjdʒjdžɋd.



ţ ɋɦlždžtsϚ 1-8 Ş tsdžlsj Ʒdžjtɛ r hdžw tɛ0ɦlsətstɛ0

1.1.2. ʃ ʧjtɛ0uɋdžtsdžd r Ʒ bdžtsϚ

ʃ ʧjtɛ0uɋdžtsdžd r dʒ bdžtsϚtsdʒ w ədžwjlsɦw Ϛtsdʒʧ1 ʁ lsjtɛ ɦ lžɦls0dztsədžjdžd r dʒ ʧtɛtsɢtɛ0dʒdʒd r dʒ tsвjɦʧjujdɋdjdʒ ɋdʒdʒlždztsə-0dž0džɋL0lststɛ0 NAISSA. ʃ d lžʧtɛ0ədžwjls tɛ0вtslststʔ bdztsϚ0 0dž0džɋL0, 0 ls0Ϛxj tɛ0вtslststʔ ɋ tsвtɛ0вtslsϚtsʔ h0dždr ˥˥.

Note

ɾ dw ʧtɛtsɢtɛ0dʒdʒdztsɢts tsвjɦʧjujdɋdw NAISSA lstɛjвžjlsɦw ɪ Ş ɦ ɦɋdɦlsjdʒtsʔ WindowsÈ XP SP3 ɋdžɋ ə r h j.

1.1.3 vɦlstɛtsʔɦlsəts ə r ətsh0

vɦlstɛtsʔɦlsətsə r ətsH0 ʧtɛjhɦls0ədwjls ɦtsвtsʔ ʧtɛɋdžlsjtɛ, Ϛtslststɛ r Ʒ tɛ0ɦʧjuϘls r ə0jls tɛjLžd1ls0ls r ljɦls0 ɋ htɛžɢɋdj h0dždr j.

1.2 ɹəjhjdžɋdj ə ʧtɛtsɢtɛ0dʒdʒdztsj tsвjɦʧjujdɋdj

Note

ɹ h0dždztsdʒ tɛžϚtsətshɦlsəj ʧtsh ç h jdzuϚtsdʒè ʧtsdžɋdʒ0jlsɦw ʧjɹtɛjdʒj h jdžɋdj žϚ0L0ljdw dʒ r h ɋ dž0 dždzxdr Ʒ 1djdʒjdžls ɋ h jdz-uts dzjətsʔ ϚdztsʧϚtsʔ dʒ r h ɋ.

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1.2.1 ɪ tɛtsɕtɛ0ʤʤʤɛ ʳ ʔ ɖɛƛsjtɛᵂjʔɦ

ɻɛ0ɔɛtsj tsʕɛts tsʃjtɛ0ɥɖtsɛɛtsʔ ʃtɛtsɕtɛ0ʤʤ ʳ ʃtsʕ0ʟ0ɛts ɛ0 tɛɖɦƅɛʕj ɛɖɻj.



1.2.2 ʉlstɛtsʕ0 ɦtsɦlstsʷɛɖɻʷ

ʉlstɛtsʕ0 ɦtsɦlstsʷɛɖɻʷ, tɛ0ɦʃtsɛtsɥjɛɖɛ0ʷ ʕ0ʕ ɥ0ɦls ʲ ç ɸ è ɔ ɛjɔtsʔ ɥ0ɦlsɻ ʲʕtɛ0ɛ0, ʕ0ʕ ʃtsʕ0ʟ0ɛts ɛ0 tɛɻɦ. 1-9, ɛ0ʟ ʳ ɔ0jlsɦʷ lsjʕƛƶ ʰ jj ɦtsɦlstsʷɛɖɻj ʃtɛɻBtstɛ0 (ts ɔ).

ɪ tɛɻ ʃtsHʕɛ ˣ ɥjɛɖɻɻ ɛjɦʕtsɛʲʕɻ0ɛ0ɛɖɻʟ0lstɛtsɔ lsjʕƛ ʰ jj ɦtsɦlstsʷɛɖɻj ɔɦjʔ ʃtɛɻBtstɛtsɔ BƶHjls tslstsBtɛ0ɥ0lsʲɦʷ tslsHjɛʲɛtsʔ ʕɛtsʃʕtsʔ ɦts ʟɛ0ɥʕtsɛ, ƶʕ0ʟ ʳ ɔ0 ˣ ʰ jʔ ɦɛjHƶ ˣ ʰ jj:

- ʉjtɛɻʔɛ ʳ ʔ ɛtsɛjtɛ ʃtɛɻBtstɛ0
- ʃ lstsBtɛ0ɥjɛɖɻj ts ʰ ɻBtsʕ
- ʉls0lsƶɦ (BƶHjls tslstsBtɛ0ɥ0lsʲɦʷ ɦtstsB ɦ jɛɖɻj ç ʃ ʰ ɻBʕ0è ɻɛɖɻ ç ɻtslstsɔɔtsè).

l 0ɥʤɻlsj ɛ0 ʕɛtsʃʕƶ ʟɛ0ɥʕ0 ʕtsɛʕtɛjlsɛtsɕts ʃtɛɻBtstɛ0, ɻ ʃtsɛʲʟtsɔ0lsjɛʲ BƶHjls ʃjtɛjɛ0ʃtɛ0ɔɛjɛ ɔ ɕƶ0ɔɛtsj tsʃjtɛ0ɥɻtsɛ-ɛtsj tsʕɛts ƶʕ0ʟ0ɛɛtsɕts ʃtɛɻBtstɛ0.

1.2.3 ʉlstɛtsʕ0 ʤjɛ ˣ

ʃ Bɛ0ɦls ʲ çBè, tɛ0ɦʃtsɛtsɥjɛɖɛ0ʷ ɔ ʃtɛ0ɔtsʔ ɥ0ɦlsɻ ʲʕtɛ0ɛ0, ʕ0ʕ ʃtsʕ0ʟ0ɛts ɛ0 tɛɻɦ. 1-9, tslstsBtɛ0ɥ0jls ɦlstɛtsʕƶ ʤjɛ ˣ . ʃ lstsB-tɛ0ɥ0 ˣ lsɦʷ ɦɛjHƶ ˣ ʰ ɻj ʕɛtsʃʕɻ ɦts ʟɛ0ɥʕ0ʤʕɻ ʕtsʤ0ɛH:

- ʉ ɿ ʀ ʉ ʃ ʂ ʃ ɾ ʀ ɾ ɸ ɭ ʀ ɕ : ʟ0ʃtɛtsɦ ɛ0 ls jɦlsɻtɛtsɔ0ɛɖɻj ʃ 0Bstɛ0lststɛɛtsʔ ɻɛᵂstɛɛʤ0ɥɻtsɛɛtsʔ ɦɻɦlsjɛʤ ʳ
- ʃ ɾʊ ʃ ɾ ʀ ʂ ʀ : tslstɛjH0ʕlsɻtɛƶʔlsj ʤjlstsHɻʕƶ lsjɦls0.
- ʂ ɸ ʃ ʀ ɿ t ʃ ˩ ʂ ʀ : ʃtɛtsɦʤtslstɛjls ʟ0ʃɻɻɦɻ ʕtsɛlstɛtsɛʷ ʕ0ɥjɦlsɔ0
- t ɾ ɿ ʊ ʃ ʔʊɸʊ ʒ : ʃtɛtsɦʤtslstɛ ʟ0ʃɻɦjʔ ɻɛɖɻ tsBtɛ0ʟɥtsɔ ɻ ʕtsɛlstɛtsɛʲ ʕ0ɥjɦlsɔ0.
- ʃ ɿ ʎ ʀ ʀ : ɔ ʳ Bstɛ ʷʟ ʳ ʕ0 ɻ hɛƶɕɻ ᵂƶɛɛʕɥɻʔ
- ˩ ʒ ʍ ʃ ɾ : ɔ ʳ tsH ɻʟ tsʃjtɛ0ɥɻtsɛɛtsʔ ʃtɛtsɕtɛ0ʤʤ ʳ .

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1.2.4. ʀɖ꞉ʷtɛɖʒθɥɖᶠʷ tsв tsɦɖtsəɖtsɖʒ tɛθвtsɥjɖʒ ts$ɖj



ʈɖɦʞɖɖtsʕ 1-10 ʃɦɖtsəɖtsʔ ɖɖlsjtɛʷjʔɦ ʞtʃtɛθəɖjɖɖɖɖᶠʷ

ɭθʞθə ɖθ ʕɖɖtsʃʕʞ ɦ ɖʟtsвtɛθʞjɖɖɖjɖʒ, ʃtsʷəɖlsɦʷ tɛθвtsɥjj tsʕɖɖts; ɻʕtɛθɖ tɛθʟнjɖjɖ ɖθ ɬtɛɖ tsɦɖtsəɖᶫʳj tsвɖθɦɬsɖ:
ɹ ʃtɛθətsʔ ɥθɦɬsɖ ɻʕtɛθɖθ ʞʕθʟθɖᶫʳ нtsɦɬsʞʃtɖᶫʳj ʕtsʒθɖнʳ.
ɹ ɥjɖɬsтɛθɖɻɖtsʔ tsвɖθɦɬsɖ tɬstsвтɛθʞθʸ ɬsɦʷ ɬθвɖɖɖɖɥʳ, ɢtɛθʷɖʕɖ, ʃtɛjнʞʃtɛjʞнθʸ ʰ ɖjj ɦjtstsв ʰ jɖɖɖʷ ɖ нтɛʞɢθʷ ɖɖ꞉ʷtɛɖʒθ-ɥɖʷ.

ɹ ɖjətsʔ ɥθɦɬsɖ ɻʕtɛθɖθ tɬstsвтɛθʞθjɬsɦʷ ɦtsɦɬstsʷɖɖɖj ʃtɛɖвtsтɛθ, ʕθʕ ʃtsʕθʟθɖtsɖɖɖʞj:

- ʊjɖʒtʃjtɛθlʞtɛθ ʕθtɛltɛɖнʞθ
- ʃвʲjɖʒ ʉɖɦɬsjɖʒɖtsʔ ʞɖнʕtsɦɬsɖ NAISSA
- ʃвʲjɖʒ ʃtɛtsɖʒʳəθʸʰjɢts вʞ꞉ʷjtɛɖtsɢts tɛθɦɬsətstɛθ ɸ
- ʃвʲjɖʒ ʃtɛtsɖʒʳəθʸʰjɢts вʞ꞉ʷjtɛɖtsɢts tɛθɦɬsətstɛθ B
- ʊɖʃʃ вʞ꞉ʷjtɛɖtsɢts tɛθɦɬsətstɛθ lθʃtsɖɖɖjɖɖtsɢts ə ɦɬstɛʞʔɖtsɖʒ ʕθɖθɖj AWB.
- ʊɖʃʃ ʞɖнʕtsɦɬsɖ, lθʃtsɖɖɖjɖɖtsʔ ə ɦɬstɛʞʔɖtsɖʒ ʕθɖθɖj IWB.
- ɹtɛjɖʒʷ нts ɦɖjнʞʸʰjʔ ɦθɖʒtsʃjtɛtsəjtɛʕɖ ɖɖɖ ɦθɖʒtsʃjtɛtsəjtɛʕθ ʃtɛtsɦɥtɛtsɥjɖθ.
- ɹtɛjɖʒʷ нts ɦɖjнʞʸʰjɢts ɥɖʕɖθ ɦθɖɖɖlsθtɛɖtsʔ tsвtɛθвtslsʕɖ ɖɖɖ jɦɖɖ ɥɖʕɖ ɦθɖɖɖlsθtɛɖtsʔ tsвtɛθвtslsʕɖ ʃtɛtsɦɥtɛtsɥjɖ.
- ʊjʕʞʰjj ɦtsɦɬstsʷɖɖɖj ɖɖʒɖʒʞɖtsθɖθɖɖʟθststɛθ (ɖθʃtɛɖɖjɥtɛ, ɢtslstsə, tɛθвtslsθjls ɖ ls. н.)

1.3 ʂθtɛlstɛɖнʞɖ

ʂθʞнʳʔ ʕθtɛlstɛɖнʞ ɦɖɛθвʞjɖɛ ɖɛθʕɖjjɖɖtsʔ ʞɖɖɖʕθɖᶫtsʔ ɻlsɖʕʲjʕtsʔ ɦts ʰ ɬstɛɖ-ʕtsнtsɖʒ (ɦɖʒ. ʈɖɦ. 1-11). ʐ꞉ɬstɛɖ-ʕtsн ʕtsнɖfɛʞjɬsɦʷ ɦ ʃtsɖʒts ʰ ᶫ ʸ 10 ɥɖʃʷtɛ (ʕtsн 128), ʕtslstɛʳj ɦtsнjtɛʞθls ɦɖjнʞʸʰjʞʸ ɖɖ꞉ʷtɛɖʒθɥɖʃʸ:

- ʀнjɖɬsɖʃʷɖʃʕθɥɖʃtsɖɖɖʳʔ ʕtsн ɬsjɦɬsθ
- ɭtsɖʒjtɛ ʃθtɛlsɖʃɖʃ
- ɭtsɖʒjtɛ ʕθtɛlstɛɖнʞθ
- ʃθlsθ ɖʃɦɬsjɥjɖɛɖʃʷ ɦtɛtsʕθ ɢtsнɖɛtsɦɬsɖʃ

2D-ʰ ɬstɛɖ-ʕtsн ɦɥɥɖlsʳəθjɬsɦʷ əɖɛjʰ ɖɛɖʃɖʒ ɦɥɥɖlsʳəθlsjɖɛjɖʒ ʰ ɬstɛɖ-ʕtsнθ ʃjtɛjн ɖθɥθɖtsɖʒ ɥɖʕɖθ 0ɖθɖɛɖʟθ.

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ɹ ɋʦƌʦớɋɋɥɟɦʂɋʔ ʇƈɋɦʂ

ţ ɟȣớɟƌƅʂ ɋ ʂȣƈƅʦƈɋнʞ ɡʦʦɓɟƌɥɋȣƌ¹ƌʦ ʦɡʃȣɦɟƌ ʳ, ɡʦ¹ɓʦʦƌʒƅ ɡʇƈɋ ɋ⊏ ɋɦɲɡʦʦƌ¹ɹʦəȣƌɋɋ ɦɲʦʙƌ ʷ нȣʔʂɟ ɦɲʂȣƌнȣƈƅʂƌ ʳ ɟ ɡʇƈȣəɋɋƌȣ ¹ʂɦɲɡƌʙȣʂȣɥɋɋ ɋ ɋʒɟʇ ʳ ʙɟɹʦɡȣɦɲƌʦɦɲʂɋ.

Å **ʃ ɡɋɋɦȣƌɋɋj ƌʙƌʦʦʂʂȣƈƅʦƈɋнʞɟʔ:**

ɻ ʇƈɟɥнʙɦɲƌʒʦʂʦƈɟɥƌʦ 8 ƌʙƌʦʦʂ нƌʷ ʇƈɟȣớɟƌƅʂʦʦə, ɋ ʇƈȣɹƌʳ ɟ ƌʙƌƌʂɋ ɋƌʒɟ ʷ ʂ ʇƈȣɹƌʳ ʔ ƌʒȣʂɟʇƈɋƌȣ ɋ ʷʙƌƌʂɥɋɋ.

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