User Manual

Delvotest® Fast Go Max

DSM

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Contents

Introduction

Thank you for purchasing Delvotest® Fast Go Max.

In order to prevent damage or loss of property, please read instructions and safety

guidelines in this user manual and be well-informed before using this reader.

Always have this user manual at hand in case of need.

(Effective version: 1.0.10 build 20180112)

1. **The Use of User Manual**

Labels and symbols shown below are used throughout the user manual.

Label	Description
☰☰☰	To indicate the direct current (DC).
CE	CE mark – To indicate that this product is appropriate for the standard of EU.
📖i	To indicate instruction manual.
REF	The catalog number of this product.
SN	The serial number of this product.
🏭	To indicate the manufacturer.
☣	Biohazard – To indicate that biological substances may damage your health.
⚠	Warning – To indicate that a user should read and consult accompanying instruction.
EC REP	Authorized representative in the European Community.
IVD	To indicate suitability of all in-vitro medical diagnostic equipment for entering Europe market.
🌡	To indicate that this product should be stored within a certain temperature range.
�	To indicate the date of manufacture.

2. <u>Please Be Well-informed before Using the Product</u>

Precautions on Installation and Storage

> ⚠️**CAUTION: Please read this user manual carefully and follow instructions for installation.**

(1) Appoint an administrator and let the administrator install and run this system.

An administrator should be medical professional, researcher or skilled operator with responsibilities. If the administrator is a non-medical professional, the person is required to keep confidentiality.

(2) Installation Method

   ① Check the rated voltage and connection of the power cord.

   ② Check the connection between the cable and the connector.

   ③ Press power button to turn on the system.

     - After the power is on, check the Power LED to see if it is working properly.

     - If the system does not turn on, check the condition of the connector.

   ④ To run the program and functions of this reader, follow test procedures guided in this user manual. (Refer to Test Method)

(3) Cautions during Installation

   ① Install this product in a place where voltage, frequency and electric power consumption are supplied appropriately.

     - Use the adapter provided.

     - The product may be damaged, in the case of an overvoltage or low voltage.

   ② Check the ground connection for grounding-type bipolar outlet.

   ③ Be careful of reader malfunction, if there is a possible inflow of electromagnetic waves.

   ④ Avoid operating this reader nearby other equipment generating short waves or

microwaves. This condition may affect the result.

⑤ Check Location of Installation.

- Install the reader in a place with humidity less than 90%.

- Install the reader in a well-ventilated place with minimal dust.

- Avoid any place where physical and chemical effect is possible.

- Avoid direct sunlight.

- Install the reader on a flat surface.

- If room temperature is too high, an error may arise.

   (Optimal operating temperature: 10~40℃)

- The use of this reader with explosive, inflammable or putrefactive substances is prohibited.

- The use of this reader in a place with radiation, a magnetic field or a vacuum is prohibited.

- The use of this reader in a place with extreme electric noise is prohibited.

- The Calibrator may be discolored under direct sunlight. It is recommended that the calibrator is stored in a dark place.

- Be careful not to extremely tilt or drop the reader during transfer.

Notice

This product optically analyzes the reaction between specific pathogenic organism and reagent in the diagnostic process of specimen, and quantifies degree of the reaction

This system is for quantitative analysis of lateral flow immunochromatographic devices. The system can be operated by a person of a non-medical field, but the result should be interpreted and analyzed by medical professionals.

You can buy supplies like the calibrator and test devices from your supplier. Supplies should be tested for adaptability with the system before it is actually used for the test. Information about applicable supplies is available by contacting DSM.

> ⚠️ **CAUTION: If you need an accurate result or have an important test to be done, wait about 30 minutes after turning the system on and do the calibration before the test (Refer to 3.2 Instrument Check).**

① Use this reader on a flat surface avoiding direct light.

② To prevent electric shock, check if the power supply is connected to the ground.

③ Use supplies only from DSM to prevent product damage.

④ Be careful not to block the air passage on the back of the reader.

⑤ Be careful not to get burnt from the heat produced by the reader due to long-term use.

⑥ Do not use this reader in a place with shock and vibration.

⑦ To prevent contamination of the reader, wait until all samples are absorbed into the RDT (Rapid Diagnostic Test) device before you insert the device in the system.

⑧ While you are operating the reader with the object of testing, prevent any vibrations that affect the system.

⑨ If there is any vibration affecting the system during the test, abort the process and restart the test from the beginning.

⑩ Do not open the tray during the test. If the device is exposed to the outside during the test, abort the process and restart the test.

⑪ When the test is completed, exit the program and turn off the system. If you turn off the system before the program normally ends, it could affect the program and unexpected errors could be generated.

⑫ Be careful not to contaminate the reader when taking the device out of the reader.

Notice on Copyrights

③ We are not responsible for the damage occurred by not using appointed standardized parts or using other software, which is not provided in the product package.

④ Specifications of this product can be changed due to company's action for improving convenience and product performance.

⑤ You may not be compensated if it is not mentioned by manufacturer.

⑥ Any problem occurred by not using equipment from the manufacturer cannot be compensated.

⑦ We are not responsible for any damage of the product caused by not following cautions and warnings in this user manual.

Product Description

1. Characteristics of Product

Delvotest® Fast Go Max, gives you quantitative assessment by capturing and analyzing images of lateral flow immunochromatography. When the Rapid Diagnostic Test (RDT) device is inserted into the tray, an internal camera captures and saves the image, and data is automatically collected to be converted to a graphical analysis. Accurate and reliable rapid diagnosis is possible since this product provides quantitative analysis through highly sensitive image analysis based on LED and the high quality image sensor. Convenient management of patient information is also possible by saving and transporting patient information through a USB port. And the system provides printing function using built-in thermal printer and network printer, you can print out test result through this function.
Intuitive user interface using touch pad controller with 10″ color LCD makes it easy to access and use.

Main Features
- ✓ Quantitative analysis of various applications for POCT
- ✓ Remote access for support
- ✓ 1D Barcode support

Convenient Features
- ✓ Data management
- ✓ Data printing
- ✓ User management
- ✓ Patient record management

2. Product Components and Installation Methods

2.1. Product Components

Components provided in the product package are as following.

Delvotest® Fast Go Max	Reference Kit	Touch Pen

AC/DC Adaptor	Power Cable	Manual

[Figure 2.1] Product Components

Product and parts composition of ***Delvotest® Fast Go Max.***

▷ AC/DC Adapter (12V, 5A output)

▷ Power Cable

▷ Touch Pen

▷ Calibrator: for QC purpose only

▷ User manual

※ If you have any questions or missing components, please contact DSM customer services

2.2. <u>Installation Methods</u>

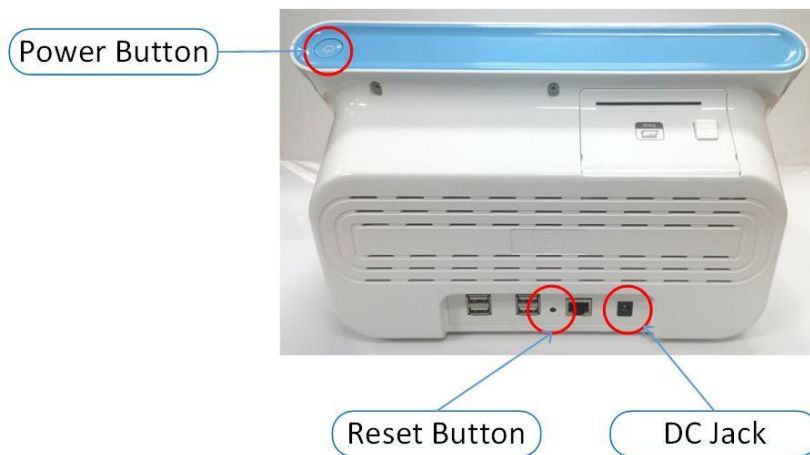⚠️ **CAUTION: Install this system on a flat surface. Be cautious with connection of AC/DC adapter.**

▶ Product Connection

(ⅰ) Connect AC/DC adapter to the Delvotest® Fast Go Max.

(ⅱ) Connect power cable to AC/DC adapter.

(ⅲ) Put the plug in the 100-240V socket.

▶ Powering On / Off

[Figure 2.2] Rear Panel

The power button is located on the top panel of the Delvotest® Fast Go Max.

After approximately one second of pressing and holding the power button, the DSM logo appears and begins the program. Although it is advisable to use the power button on the program to exit the reader, if the reader has a problem, push and hold the power button for more than 4 seconds to force the reader to power down.

▶ Front LED Bar

Front panel LED bar color indicates reader status. During operation, the color changes to a different color. Depending on the color, the status is as follows :

[Figure 2.3] Front LED Bar

LED color	Indication
No light	No power connection.
GREEN	Powered on and charging. (Adapter Operating Mode)
RED	Powered on and fully charged. (Adapter Operating Mode)
RED	Powered on. (Battery Operating Mode)
BLUE	The measurement is in progress.

▶ Battery Operating Mode

The lithium polymer battery is built-in inside of system. The purpose of the battery is for emergency back up in case of shut down of electric power system.

The maximum operation time by battery is less than 1 hour. If the electric power is shut down by accident, please finish the operation and save data.

3. Running Delvotest® Fast Go Max

3.1. Instrument Registration

[Figure 3.1] Instrument Registration Page

✓ Instrument Registration screen will be displayed when the analyzer is first booted. It will not be displayed after registered.

✓ Serial Number, Name, and Country are required, and you do not need to enter anything else.

✓ If the registration is successful, the message that the device has registered is displayed.

✓ When the registration is successful, the current time is set with the date and time entered in Date / Time (H: M) field.

3.2. Supervisor Registration


[Figure 3.2] Supervisor Registration Page

- ✓ Supervisor Registration is displayed at the first time after analyzer registered. It is not displayed after Supervisor registered.

- ✓ ID, Password and Confirm(PW) are mandatory fields.

- ✓ If Supervisor Registration succeeds, it will go to Log in screen.

3.3. Log In

[Figure 3.3] Log in Page

- ✓ Enter the ID and PW (Password) to log in and click the Log in button to log in with that ID and go to the Main screen.

- ✓ If the ID is not registered or the Password is incorrect, an error message is displayed.

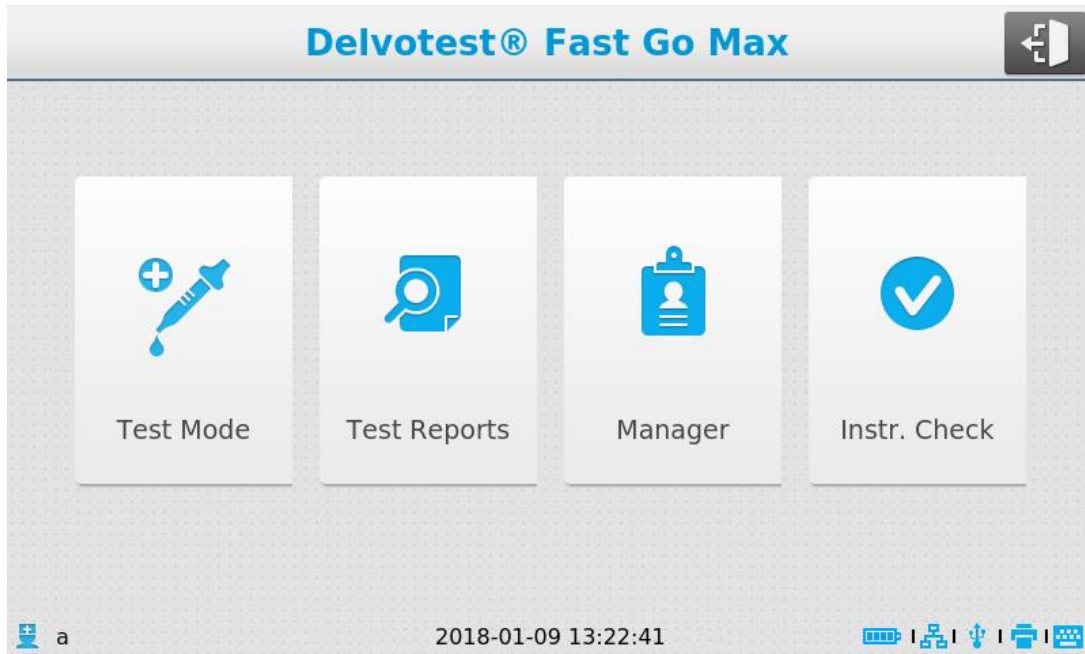- ✓ Click the bottom left ⓘ button to display the Program Information window.
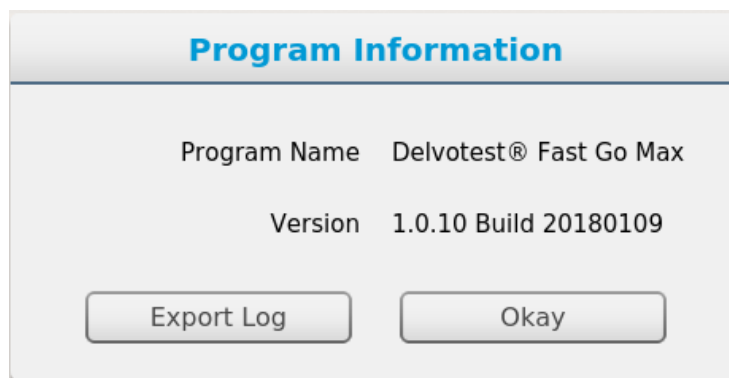
[Figure 3.4] Program Information

- ✓ When you click the power-off button ⏻, the question "Are you sure you want to exit program and turn off the unit?" pops up, and if you click OK button, the

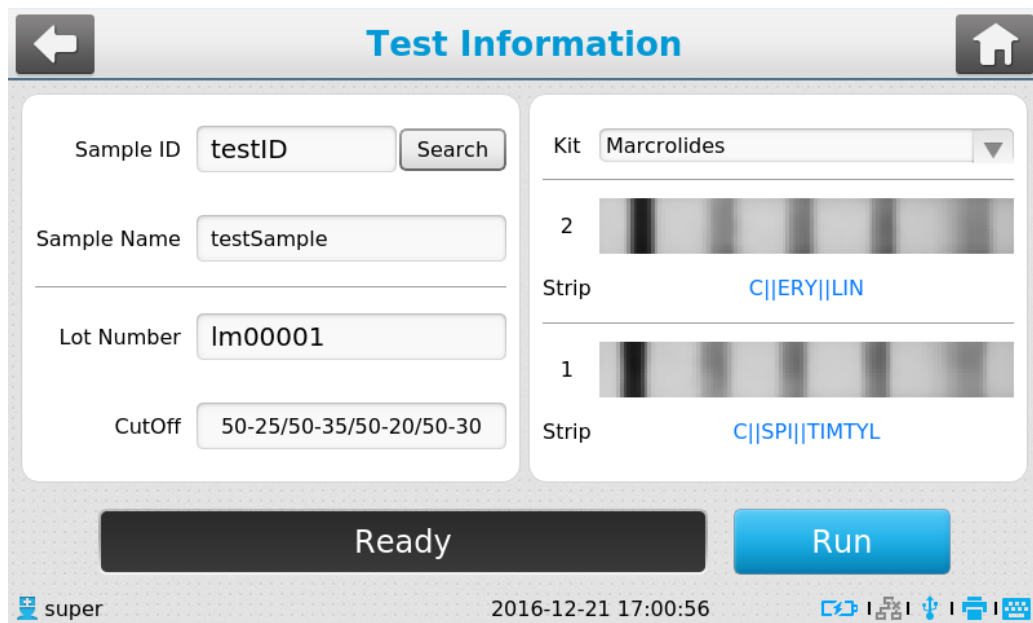program stops and the analyzer will be halted.

3.4. <u>Main Menu</u>

[Figure 3.5] Main Menu

| Menu	Description
Test Mode	Measurement mode
Test Reports	Manage test results (Review, Export, Backup)
Manager	Manage Operators, Samples, and Test Files (Add, Remove, Modify)
Instr. Check	Run the Instrument Check of the analyzer and result

3.5. Test Mode

[Figure 3.6] Test Mode Page

✓ Enter Sample ID, Sample Name, and then tap the prepared barcode to automatically enter the corresponding Kit, Lot Number, and CutOff values.

✓ By clicking the ⌊Search⌋ Button, you can search and input the sample ID already registered in the Sample list. Select the ID you want to enter as shown in the image below and click the⌊‾‾‾OK‾‾‾⌋Button, then the corresponding ID is entered in the Sample ID field in the Test Information screen.
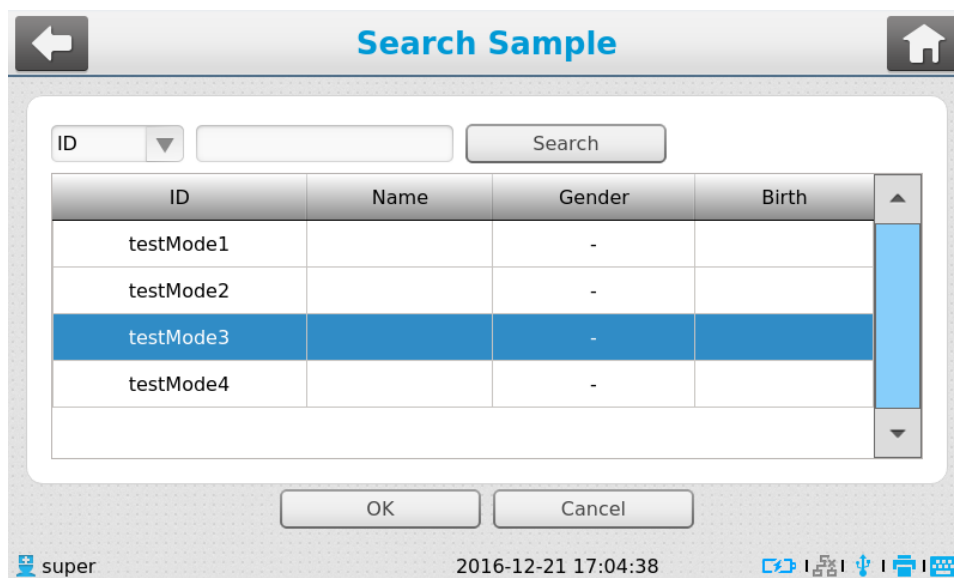

[Figure 3.7] Search Sample Page

- ✓ If the test file corresponding to the input barcode has not been imported, you cannot proceed with the test.

- ✓ Click the [Run] button to start the measurement. When the measurement is completed, the screen will move to the result screen as shown in the image below.
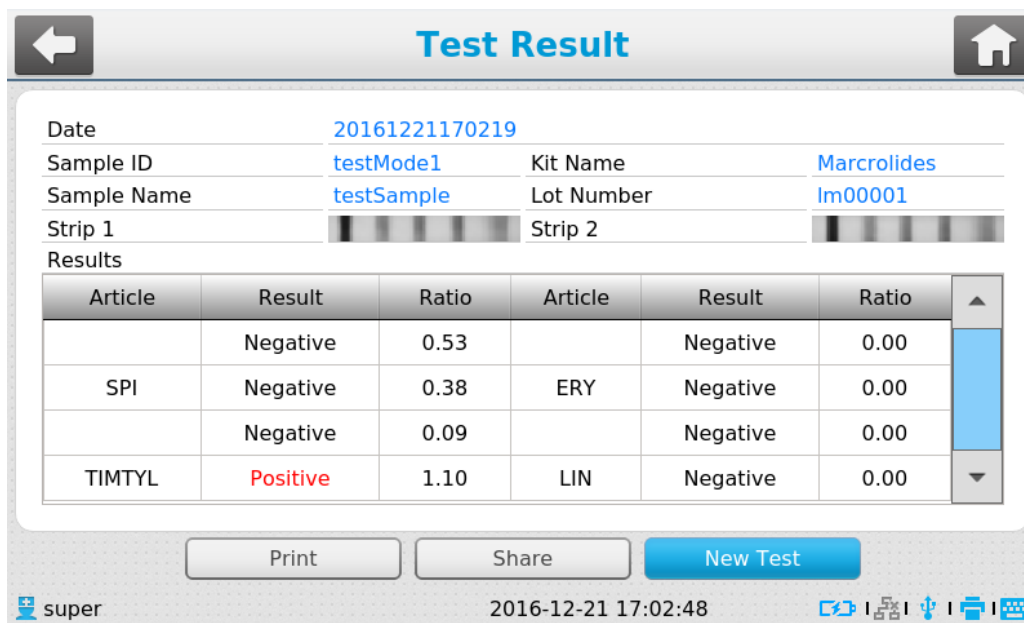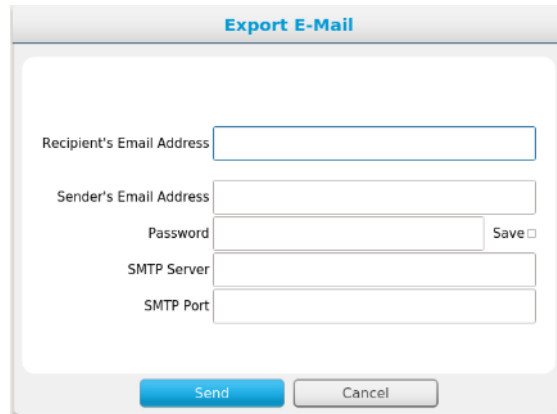

[Figure 3.8] Test Result Page

- ✓ Click the [Print] button and the result will be output to the built-in printer.

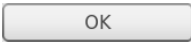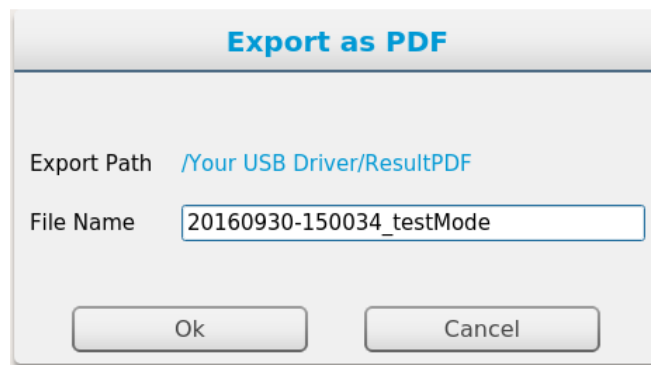- ✓ If you click the [Share] button, you can export the result as a PDF file by E-Mail or to the USB storage.
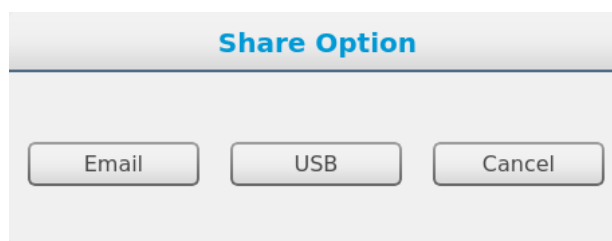
[Figure 3.9] Share Option

- ✓ By clicking the [Email] button, the Export E-Mail screen will be displayed as shown below. After entering all required fields, click the [Send] button, then you can send E-mail with an attached PDF file.
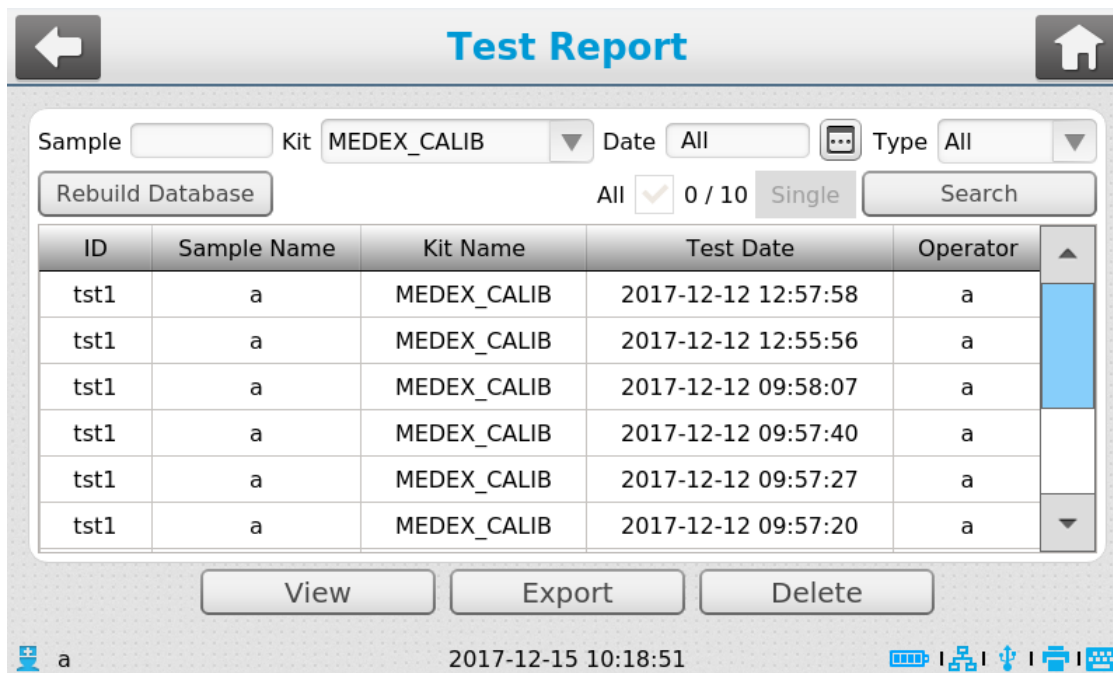
[Figure 3.10] Export E-Mail

✓ By clicking the [USB] Button, the Export as PDF screen will be displayed as shown below. Enter the File Name, and click the [OK] button, then a PDF file will be saved in the ResultPDF folder of the USB memory.

[Figure 3.11] Export as PDF

✓ Click the [New Test] button to go to the Test Information screen again to try a new test.

3.6. Test Results


[Figure 3.12] Test Report Page

✓ You can search and manage the test results in Test Report screen.

✓ When you go to the Test Report screen, all test names in the Test folder are added to the Kit combo box.

✓ In the previous versions, test results are searched based on Kit names of Test files. In 1.0.9 version or later, they are searched based on Test names. If you update the analyzer from the earlier versions, please click Rebuild Database button to regenerate test results database. (The first time you enter this screen after updating to version 1.0.9 or later, the Rebuild Database procedure will run automatically.)

✓ Enter a Sample name in the Sample [　　　] input field to search for the Sample Name. Clicking the Search button will filter the results in the list.

✓ After selecting the Kit name in the Kit MEDEX_CALIB ▼ to search for a Test name. Clicking the Search button will filter the results in the list.

✓ When you click the 🔳 button, the calendar page is displayed, where you

select the date to search. Select the date search method in the Type `All ▼` combo box. Supported types are All, Yearly, Monthly, Daily and so on. When the Type is changed, the Date field text automatically changes according to the Type. Note that even if you change the date with the calendar button, the Date field text will be displayed according to the format selected in Type. If Type is All, "All" is displayed in the date field. Clicking the `Search` button will filter the results in the list.

✓ `Single` mode is a mode where you select only one result from the list, and you can change it to `Select` mode by toggling the `Single` Button. `Select` mode is a mode where you select multiple results from the list. Toggle the `Select` button again to return to the `Single` Mode.

✓ You can select the results you want to manage and use the 'View', 'Export', 'Delete' functions the as shown below.
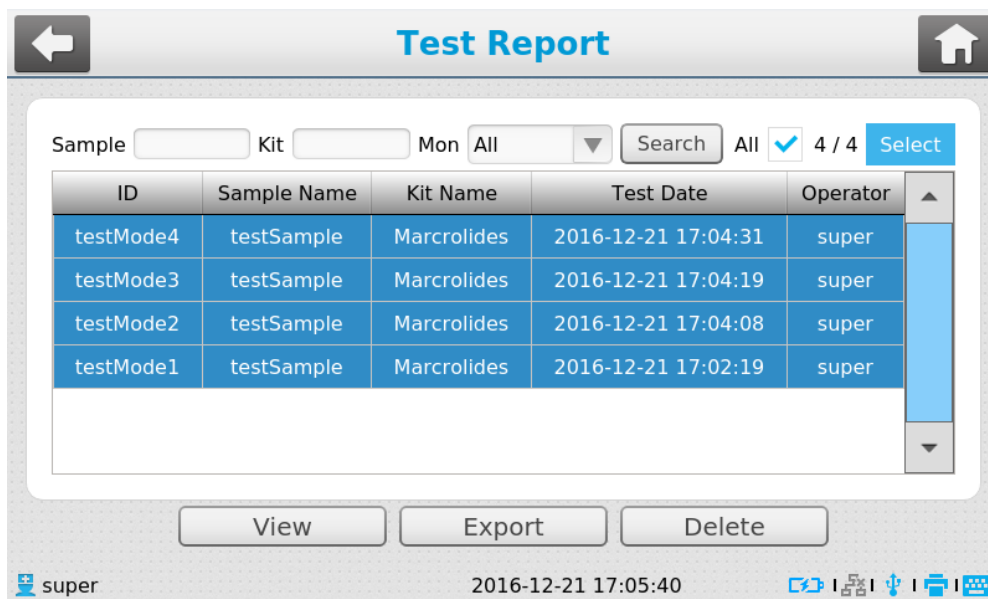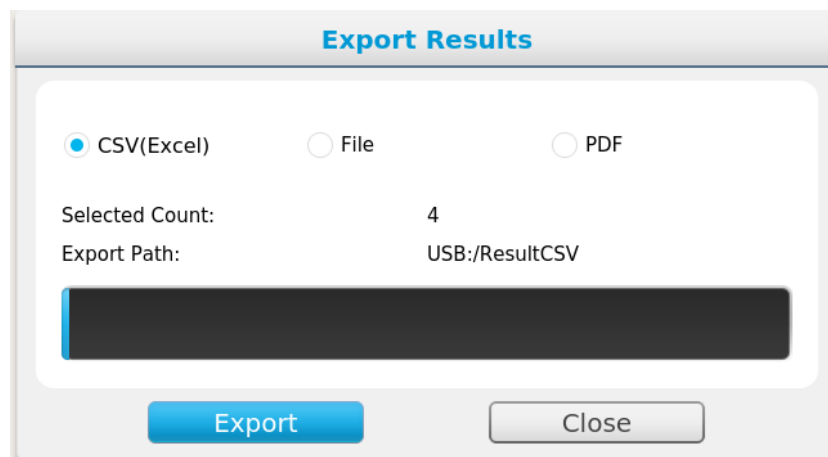

[Figure 3.13] Select Results

✓ `View` - Result Review

You can review, print, and share the results. For multiple selections, you can click the left and right buttons to navigate through the selected results.

- 20 -
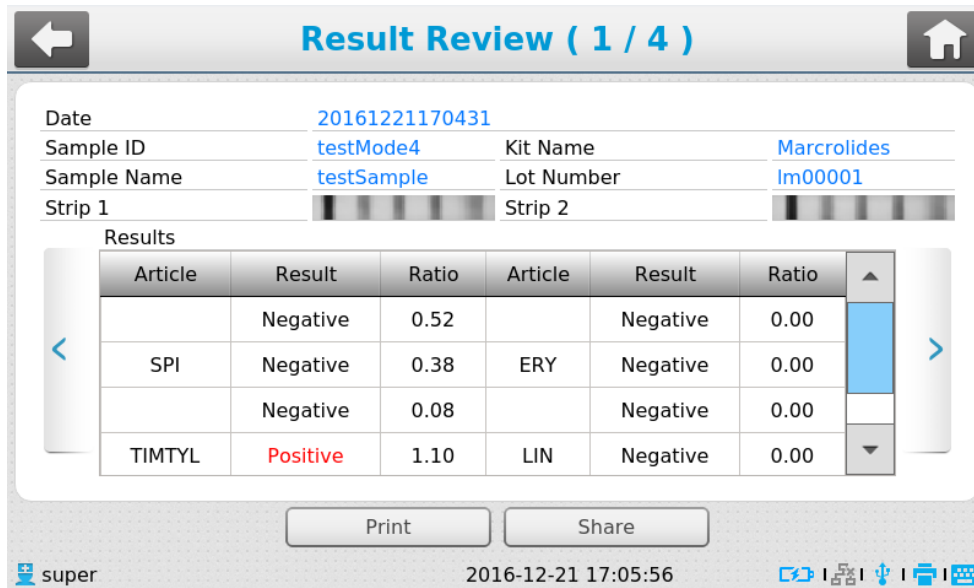
[Figure 3.14] Result Review Page

✓   Export   - Export

The selected results are exported to a CSV (Excel), File (Backup), PDF to USB.
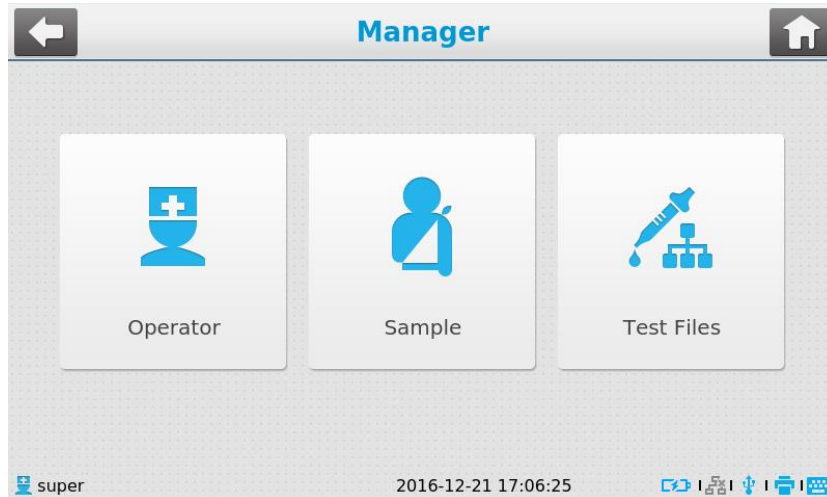

[Figure 3.15] Export Results

✓   Delete   - Delete

Deletes the selected results permanently from the analyzer.

3.7. <u>Manager</u>

You can manage Operators (Users), Samples, Test Files from Manager screen.

[Figure 3.16] Manager Select Page

A. Operator

[Figure 3.17] Operator Manager Page

✓ New

Register a new Operator. ID, Password, and Confirm (PW) are required fields. Authority can be selected between Supervisor and Operator.
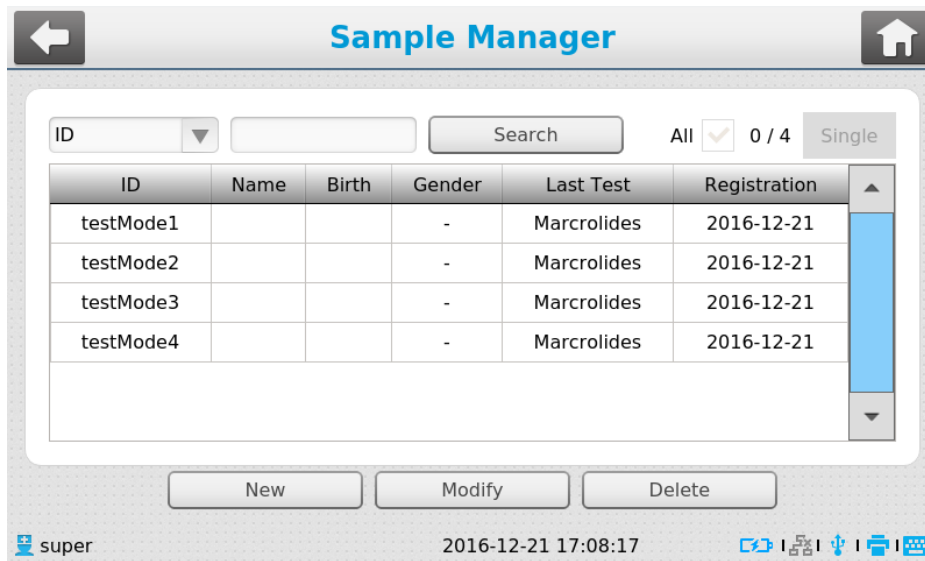
[Figure 3.18] Operator Registration Page

✓ Modify

You can modify the password and information of the selected operator from the list. ID cannot be changed.

[Figure 3.19] Operator Modification Page

✓ Delete

You can delete the selected operator from the list.
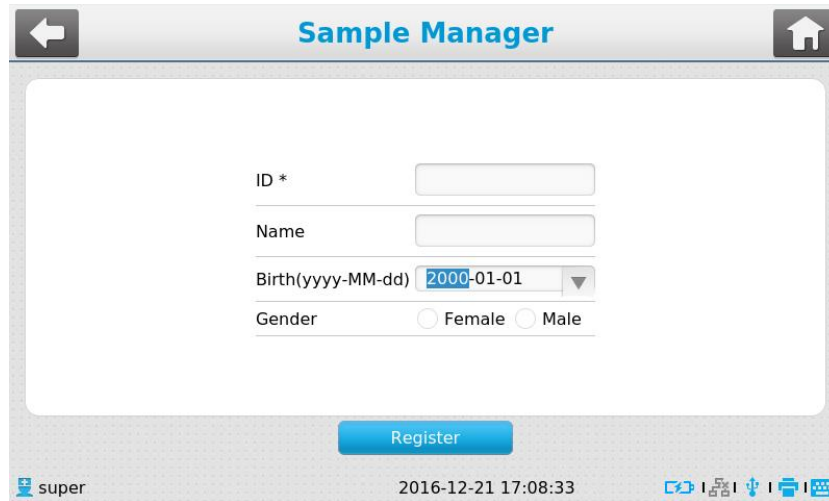
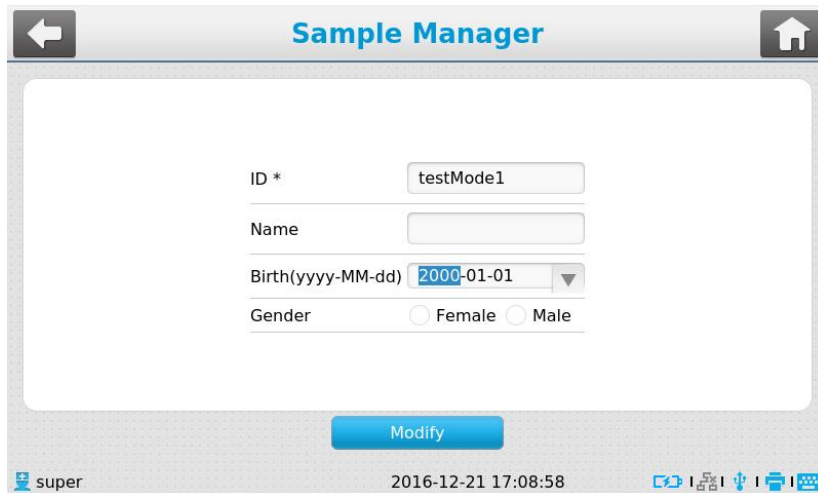B. Sample

[Figure 3.20] Sample Manager Page

✓ New

Register a Sample. ID is required and you do not need to enter anything else.
Gender can select Female and Male.

[Figure 3.21] Sample Registration Page

✓ Modify

You can modify the information of the selected sample from the list. ID cannot
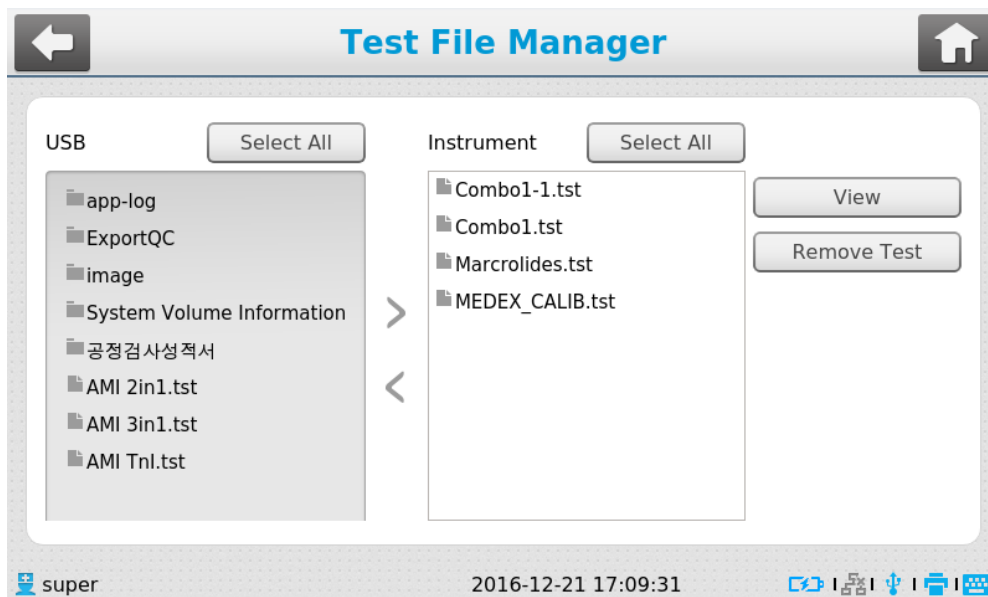be changed.

[Figure 3.22] Sample Modification Page

✓ Delete

You can delete the selected sample from the list.

C. Test Files

You can view and manage the information in the Test file.

[Figure 3.23] Test File Manager Page

✓ Test File Viewer

Select a test file in the Instrument list and click the View button to display the information of the selected test file.
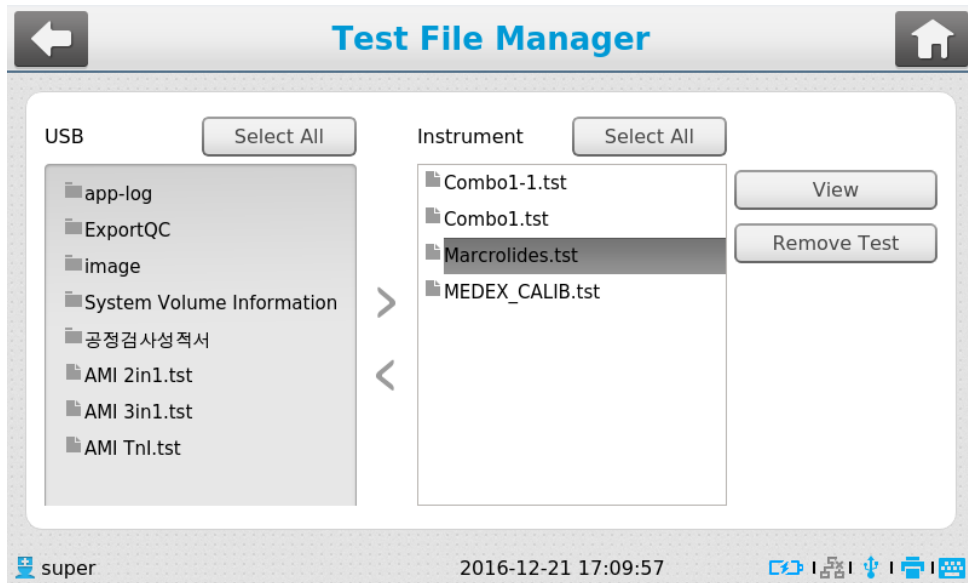
[Figure 3.24] Select Test File
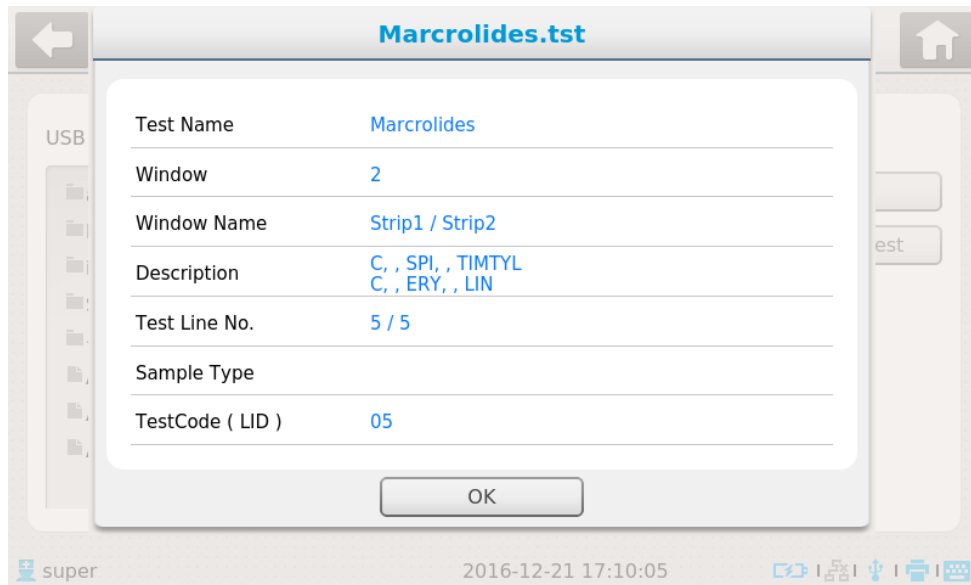
[Figure 3.25] Test File Viewer

✓ Import

Select test files in the USB list to import into the analyzer. When you click the button, the selected test files are imported from the USB storage into the analyzer.

✓ Export

Select test files in the Instrument list to export to the USB storage from the analyzer. When you click the   button, the selected test files are exported to the USB storage.

✓ Remove

If you click the Remove Test button after selecting the test files in the Instrument list, the selected Test files are deleted permanently from the analyzer.

3.8. Instrument Check

Check the status of the reader.
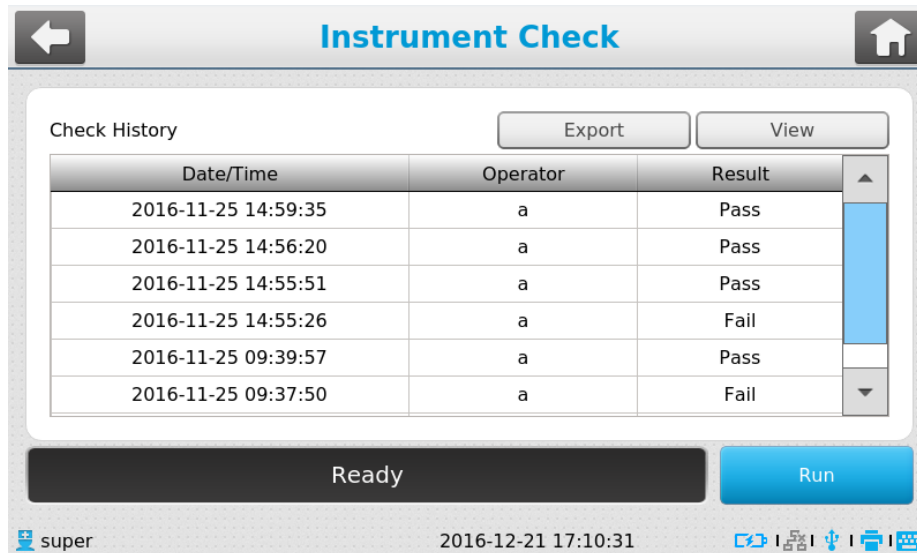
[Figure 3.26] Instrument Check Page

✓ Check

Insert the Reference cassette and click the Run button to start the Instrument Check. When the check is completed, it moves to the result page, where the Pass image is displayed when there is no problem in the analyzer, or the Fail image is displayed otherwise.
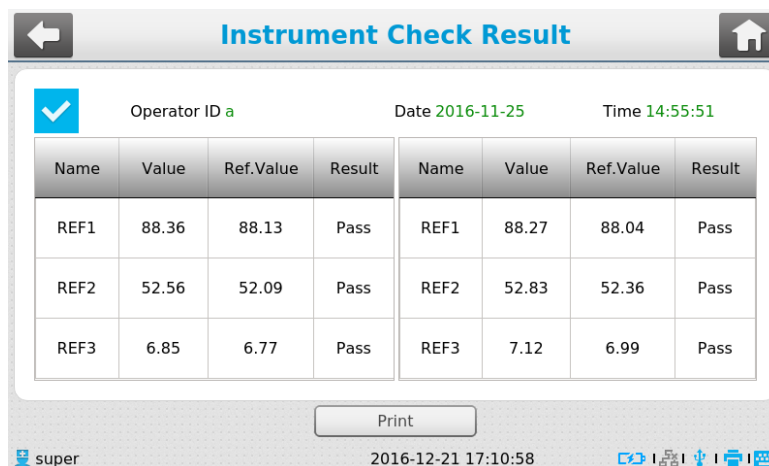
[Figure 3.27] Instrument Check Result (Pass)

[Figure 3.28] Instrument Check Result (Fail)

✓ Log & Review

In the Instrument Check screen, select the item you want to review and click the View button. The check result is displayed as shown below.

[Figure 3.29] Instrument Check Result

✓ Export

In the Instrument Check screen, you can export all the Instrument Check results to the USB storage by clicking the Export button.

3.9. Thermal Printer

Test results can be printed using the built-in thermal printer. A roll of paper is included as one of the components of the product. If you have used all the paper, you need to replace it with a new one, follow the procedures below.

The thermal printer is located on the back of the analyzer. Press the button attached to the printer case to open the top of the case.

Open the top of the case and discard the rest of the paper.

Insert a new roll of print paper into the housing.

Pull the end of the print paper out of the case by inserting it into the slot of the case from inside so that the print paper is easily released.

Press firmly the case of the thermal printer to close it.

4. Product Specification and After-sales Service

4.1. Product Specification

Parameter	Description / Value
Model name	Delvotest® Fast Go Max
Operating System	Embedded Linux
Display	10″ Color LCD (Resolution 800 x 480)
I/O Interface	4 x USB 2.0 / 1 x RJ-45 LAN Connector
Control	Touch Screen
Supported Accessories	Barcode reader, Keyboard, Mouse, USB Memory (Optional)
Patient Records	10,000 Patients
Input Voltage	12 V_{DC}
Power Consumption	12W
Dimension (W x H x D)	300 mm x 186 mm x 210 mm
Weight	1.8 kg
Operating Temperature	10°C ~ 40°C
Storage Temperature	-10°C ~ 50°C
Features	- High sensitivity & repeatability - Management of Patient records - 1D barcode support
Environmental	- For indoor use only - Main supply voltage fluctuations should not exceed ±10% - Pollution degree 2

> ⚠ **Important! Actions to take when the reader is broken:**
>
> **For your safety and right product function, the after-sales service is available only by after-sales service personnel. On any accident that is occurred due to unapproved person's illegal re-formation or fixation of reader, DSM is not responsible for that accident. If you have any problem regarding the reader, please make sure to read the following information and contact the headquarters, branches or local agency.**

4.2. Troubleshooting and Maintenance

- ✓ **Troubleshooting**
  - ■ It does not turn on.
  - ■ Inactivated Program.
  - ■ Insufficient performance test results.
  - ■ Abnormal termination during operation or detection of any function not following this manual.

※ If you find any of the above problems, contact DSM.

- ✓ **Maintenance**

  The tray of system is used for sample device and it can be contaminated from the sample. If the tray is contaminated, please remove tray from the unit and wipe out using following order, ethyl alcohol -> distilled water. The tray is removed from the unit by pulling out.

4.3. Product After-sales Service

- ✓ Check list before After-sales Service
  - ■ Product name and model.
  - ■ Purchase year (free or charged).
  - ■ Symptoms (details).

- ✓ Requirements in After-sales Service
  - ■ Place, user name, user contact.
  - ■ Product name, model, symptoms, purchased year, location of equipment.

※ If you have any questions, contact DSM.