

FREND™ System

User manual



Read me first

Thank you for purchasing the FRENTM System.

Please take a few minutes to read this user manual.

If you have any questions at any time, please contact NanoEntek, Inc. customer support.

Tel: +82-2-6220-7942

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E-mail: ivdst@nanoentek.com

This manual is considered a necessary part of the device: It must be available for the operator to use at the bench as well as for the individual responsible for instrument maintenance.

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Introduction

Warranty

NanoEntek Inc. warrants the original purchaser for one (1) year from the date of its initial purchase that this device and other devices sold by one of its authorized representatives will function as specified.

NanoEntek Inc. and its representatives shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by NanoEntek Inc., not regularly maintained, used with device not approved by NanoEntek, Inc. or used for purposes for which it was not designed.

This warranty does not apply to damages incurred during the initial shipment of the instrument and associated auxiliary materials. Any damages incurred on initial shipment are to be reported immediately to the freight carrier for the settlement of the claim. Please examine the device carefully for any damage before signing for the shipment since your signature indicates receipt of undamaged device.

NanoEntek Inc. will not be responsible for any indirect, incidental, special, consequential or punitive damages or other losses, including, but not limited to, damages to or losses of other properties or device.

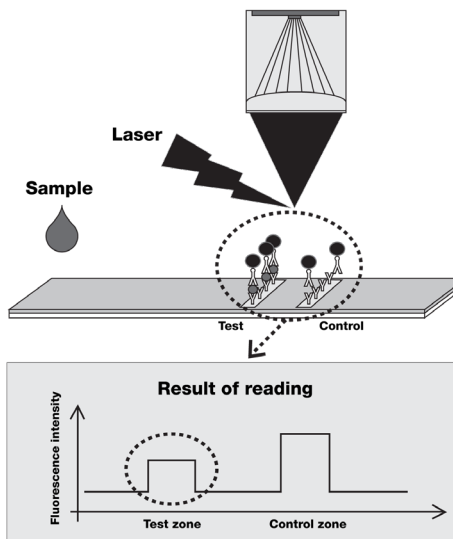
NanoEntek will not be responsible for personal injuries, whether to the purchaser or others.

Introduction

Introduction

The principle of the FREND™ System

- The FREND™ System is a portable, automated FREND™ cartridge reader.
- The FREND™ System is based on quantitative and qualitative immunoassay technology capable of quantifying single or multiple analytes by measuring laser-induced fluorescence in a single-use disposable reagent cartridge.
- The FREND™ cartridge utilizes micro-fluidics lateral flow technology where the analyte of interest in the sample forms immune complexes while moving through the fluidics pathway in the cartridge.
- The concentration of the analyte of interest in an unknown sample is calculated using the ratio of the fluorescent intensity of the test zone and the reference zone.



The principle of the fluorescence detection and calculation of the analyte concentration (drawing from the manual).

Introduction

Intended use

The FREND™ System is designed to accommodate the FREND™ cartridge, which helps in clinical management of patients by quantitatively or qualitatively measuring or diagnosing specific antigen or antibodies *in vitro* in human specimens.

Introduction

Product components

When the FRENDSM System is received, open the shipping box and carefully check the package contents. Note that the Q.C. designation is used in terms of hardware verification of performance not quality control of the actual testing process for any analytes. Note also that the mobile printer is included only if it was specifically ordered.

Main device



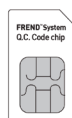
Adaptor / Power cord



Q.C. Cartridge



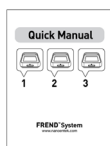
Q.C. Code chip



User manual



Quick manual



USB drive



Optional

Pipettor



Optional
















Mobile printer



Introduction
















Safety symbols & abbreviations

The following symbols are found on the FREND™ System user manual and FREND™ cartridge package inserts. Please note the meanings of the symbols and always use the device in a safe manner.

Symbol	Definition
	Caution, warning, Consul accompanying documents
	Catalogue number/Reference number
 <small>www.nanoentek.com/eifu.php</small>	Consult Instructions for Use An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.
	Serial number
	Manufacturer
	Date of Manufacturer
	General symbol for recover/recyclable
	CE marking
	UK Conformity Assessment
	In vitro diagnostic medical device
	Class I laser product
	Electrical rating
	Electric input
	Biohazard
	Meets FCC requirements per 21 CFR Part 15 This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference in which case the user will be required to correct the interference at his own expense.

Introduction

Safety symbols & abbreviations

Symbol	Definition
	Dimensions
	This product conforms to UL 61010-1, CAN/CSA C22.2 No.61010-1 "Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements." Instruments bearing the TUV symbol are certified by TUV Products Services to be in conformance with the applicable safety standard for the US and Canada
	Gross weight
	Storage temperature
	Storage Humidity
	For prescription use only CAUTION: Federal (The U.S.) law restricts this device to sale by or on order of a physician.
	This way up
	Disposal of your old appliance 1. When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2012/19/EU. 2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. 3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. 4. For more detailed information about disposal of your old appliance, please contact local distributor, waste disposal service or call the number listed in the manual.
	Keep dry Keep away from rain
	Fragile, handle with care
	US Corporation
	Authorized representative in the European Community
	Authorized representative in United Kingdom
	Authorized representative in Switzerland
	Authorized representative in Brazil

Introduction

Safety precautions

Thoroughly read all instructions before attempting to operate this device. Pay particular attention to all safety precautions. The following guidelines must be observed during every phase of operation. Breaking these rules may be dangerous, illegal or affect performance of the device and/or invalidate the device approval and/or warranty. In order to avoid instrument damage or personal harm, read this manual carefully and follow the instructions given.

- Always ensure that the power supply input voltage matches the voltage available in your location.
- This machine is air-cooled so its surface becomes warm during operation. When installing the device on the countertop always leave a space of more than 10 cm (4 inches) around the instrument in all directions. Leave adequate distance between the back of the instrument and
- the wall to allow the operation of the 'on' and 'off' power switch. This location must also be accessible to load the Q.C. Code chip and the test code chips.
Do not insert metallic objects into the FRENDS™ System as this could
- result in an electrical shock, personal injury and device damage.
insert only qualified and authorized devices supplied by NanoEntek Inc.
Do not insert any foreign materials into the air vent or the speaker.
- Always set the main switch to the 'off' position before connecting
- the power cord to the wall outlet.
When unplugging the power cord, be certain to turn the main switch
- off, then unplug the power cord.

NOTE : This device has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the device is operated in a commercial environment. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this device in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Introduction

Précautions de sécurité

Lisez attentivement toutes les instructions avant d'utiliser cet équipement. Faites particulièrement attention à toutes les précautions de sécurité. Les directives suivantes doivent être respectées au cours de chaque opération. Ne pas respecter ces règles peut être dangereux, illégal ou affecter les performances de l'équipement et / ou invalider l'approbation et / ou la garantie de l'équipement. Afin de vous éviter des dommages et d'éviter d'en causer aux instruments, lisez attentivement ce manuel et suivez les instructions données.

- Veillez toujours à ce que la tension d'entrée de l'alimentation corresponde à la tension disponible dans sur votre site de travail.
- Cette machine est refroidie par air, sa surface devient chaude pendant le fonctionnement. Lors de l'installation de l'équipement sur le comptoir, laissez toujours un espace de plus de 10 cm (4 pouces) autour de l'instrument dans toutes les directions.
- Laissez une distance suffisante entre l'arrière de l'instrument et le mur pour permettre d'actionner l'interrupteur 'ON' (Marche) et 'OFF' (Arrêt). Cet espace permet également de charger la puce électronique Q.C. (la puce électronique de test).
- N'insérez pas d'objets métalliques dans FRENDS™ System car cela pourrait provoquer un choc électrique, des blessures corporelles et des dommages matériels. Insérez uniquement des appareils qualifiés et autorisés fournis par NanoEntek Inc.
- N'insérez aucun matériau étranger dans l'évent ou dans le haut-parleur.
- Veillez à toujours régler l'interrupteur principal sur la position «OFF» avant de connecter le cordon d'alimentation à la prise murale.
- Lorsque vous débranchez la machine, assurez-vous d'abord d'éteindre l'interrupteur principal, puis débranchez le cordon d'alimentation.

REMARQUE : Cet équipement a été testé et s'est avéré conforme aux limites d'un appareil numérique de classe A, conformément à la partie 15 des règles de la FCC.

Ces limites sont conçues pour fournir une protection raisonnable contre les interférences nuisibles lorsque l'équipement est utilisé dans un environnement commercial. Cet équipement génère, utilise et peut émettre de l'énergie radiofréquence et, s'il n'est pas installé et utilisé conformément au mode d'emploi, peut causer des interférences nuisibles aux communications radio.

Le fonctionnement de cet équipement dans une zone résidentielle est susceptible de causer des interférences nuisibles, auquel cas l'utilisateur sera tenu de corriger l'interférence à ses frais.

Introduction

General safety warnings

- Before using the device, read this manual and be certain you thoroughly understand it's contents.
- Please follow the instructions in this manual to assure proper operation of the device.
- When not in use, unplug the device from the electrical outlet.
- Perform regular maintenance checks on the main body of the instrument. Inspect all components.
- After long term storage, take extra care to be sure the device operates correctly.
- Avoid handling or storing liquid on or near the device.
- Do not open the machine at any time while it is operating or when it is plugged in to the wall outlet.
- Keep the instrument away from open flames and or smoke.
- When moving the device, unplug it and move it carefully and gently.
- The instrument should be placed on a flat and stable surface.
- Refer to this manual for handling and/or maintenance.
- Keep the device (including the cable and the plug) out of reach of children.
- Disposal management.

Local regulations governing the disposal of materials containing biohazardous materials must be observed. It is in the responsibility of the user to arrange for the proper disposal of these items.

All instrument parts which may be contaminated with potentially infectious materials must be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal if this is required by the regulations under which your site operates.

The device itself and the electronic accessories must be disposed of according to the regulations for the disposal of electronic components. Be sure to understand what the rules at your site are.

Introduction

General safety warnings

- Do not attempt to disassemble/modify the device.
- Do not insert foreign objects into the device and insert only NanoEntek Inc. provided cartridges.
- Do not handle the device or the power cord with wet hands.
- Do not move, tilt, jar or shake the device when it is in operation.
- Do not store the device in direct sunlight, high/low temperatures or high humidity.
- Do not throw, drop, hit or push the device.
- Do not touch the device or the plug during an active thunder and/or lightning storm.
- Do not touch the LCD panel with sharp objects.
- Do not use the device, if it has any damaged parts (including the power cord or the plug).
- Keep Q.C. Cartridge and Q.C. Code chip in the pouch when not in use.
- Do not exposure to excessive light.



**Warning
or caution**

- There is a risk of explosion, if the instrument battery is replaced with an incorrect type.
- Class A device is intended for use in an industrial environment. In the documentation for the user, a statement shall be included drawing attention to the fact that there may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated electromagnetic disturbances from the instrument itself.



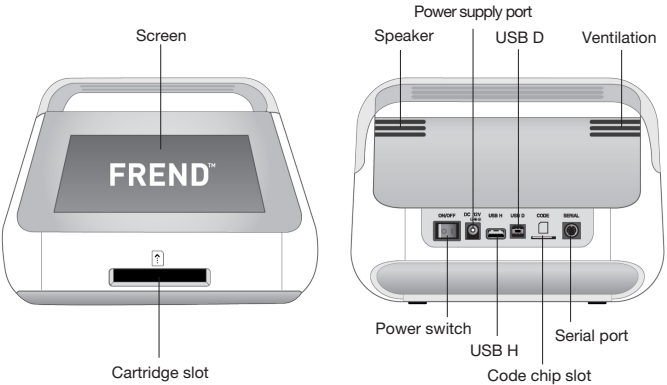
Biohazard

- The cartridge should be inserted into the device within the stipulated time.
 - The instrument should be used in a clean environment.
 - Ensure the sample is not contaminated by any foreign material or contain fibrin clots.
 - Human samples and controls should be considered potentially infectious.
-

Introduction

FREND™ System description

Name	Function
Cartridge slot	Slot for FREND™ cartridge insertion and ejection
Screen	Show the operating status and results
Ventilation	Pathway to dissipate internal heat to the outside
Speaker	Screen touch, results and error tones
Power switch	Power on/off
Power supply port	Power supply
USB H	Use to connect to a USB drive.
USB D	Use to connect to a PC. (manufacturer or supplier only)
Code chip slot	Slot for QC or cartridge Code chip insertion and ejection
Serial port	Connection for an optional mobile printer



Introduction

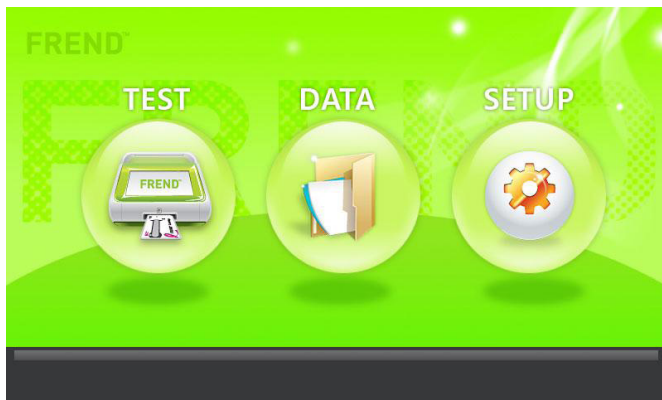
The function of the code chip and associated cartridge




Product	Definition
Q.C. Code chip	The chip containing information for the proper functioning of the Q.C. Cartridge.
Q.C. Cartridge	The cartridge used to check the mechanics and optics of the FREND™ System.
Product	Definition
Analyte code chip	The cartridge code chip is specific for a given analyte and lot of reagent. It contains information on calibration and calculation of results using readings from the FREND™ reagent cartridge.
Analyte cartridge	The cartridge contains reagents and microstructures to support a lateral flow assay, where analytes of interest form immune complexes while the specimen is moving and being separated. Ratio between test zone and reference zone is calculated.

Introduction

Software keys

Main screen

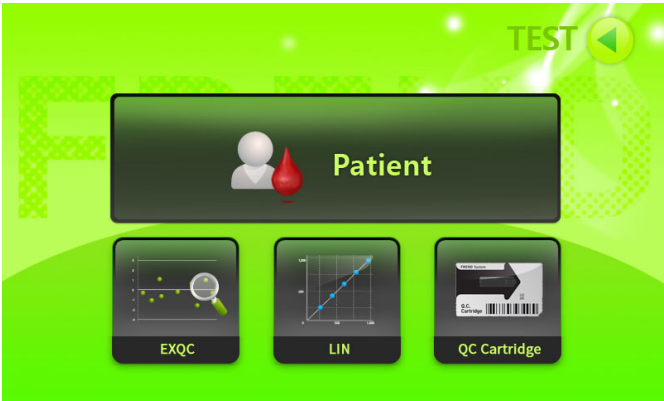




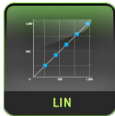

Button	Purpose
 TEST	Initiates a test sequence for an analyte using that analyte-specific cartridge.
 DATA	Check and search results. Back up the data and transfer the data to a USB drive.
 SETUP	Set up the FREND™ System parameters specific for the site and operator.

Introduction

Software keys

Test screen










Button	Purpose
	Measure the specimens of the patient on the FRENDS™ cartridge
	Measure the external or internal QC material on the FRENDS™ cartridge* <small>* Internal or external quality control materials are required</small>
	Measure the linearity material on the FRENDS™ cartridge <small>* External quality control materials are required</small>
	Run the QC cartridge for FRENDS™ instrument

Introduction

Software keys

Setup screen



Button	Purpose
	Allows user to check the information on the Q.C. or the cartridge code chip.
	Allows the user to check the serial number, software or firmware version, and the production date of the instrument.
	Allows the user to check the cartridge ID and its associated lot number.
	Allows for software updates.
	Location to adjust the time and date for the FRENDS™ system.
	Allows entry requirements and Lab ID.
	Move to the main screen. (HOME)

Introduction

Software keys

Data screen









Button	Purpose
	Enter the file name to later identify the data.
	Search files or data.
	Home button. Move to the main screen.
	View the information of the selected file or data.
	Print the detailed data, using the optional printer if it is connected to the system.
	Backup a selected set of data to the connected USB drive.

Introduction

Software keys

Data screen



Button	Purpose
	Backup all the saved data to the connected USB drive.
	Delete all the saved data. (confirmation required)
	Delete one selected piece of data.
	Select data by moving one file at a time.
	Select data by moving one page at a time.
	Display the selected data.

Setup

FREND™ System setup procedure

1. Carefully examine the box for damage. Remove all components of the FREND™ System from the box.

2. Plug the power cord into the adaptor.

3. Carefully examine the adaptor and make certain it is compatible with the power at the plug location. If it is the appropriate adaptor, plug the adaptor into the FREND™ System and the AC power cord into the wall socket.



Warning:

If you use an incorrect adaptor, the FREND™ System may explode or start to burn. If this happens, it will no longer work properly anymore.

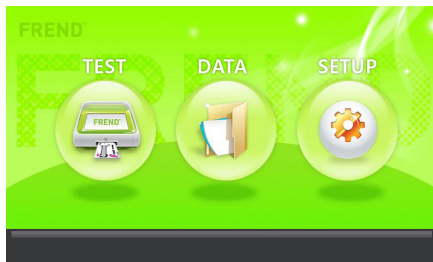
4. Turn the power switch to the ON position.



5. While the system is booting up, this image will appear.



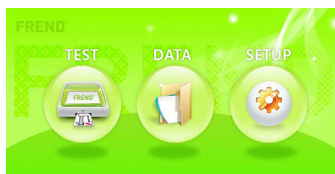
6. Check the main screen.



Setup

FREND™ System setup procedure

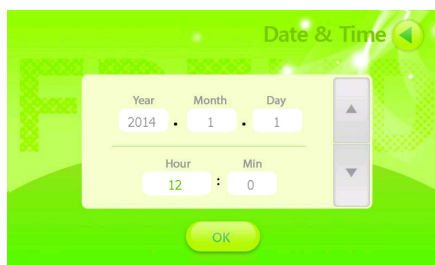
7. Press the **SETUP** button on the main screen.



8. Press the **Date & Time** button on the setup screen.



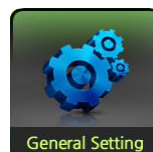
9. Set the local date and time.



10. After setting the date and time, press the **OK** button to return to the setup screen.



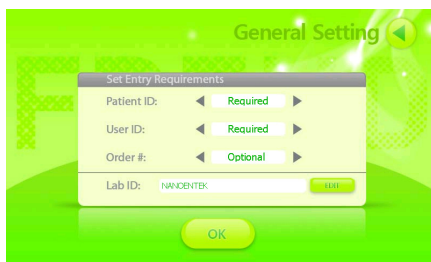
11. Press the **General Setting** button on the setup screen.



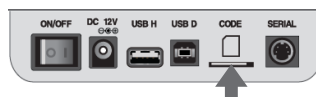
Setup

FREND™ System setup procedure

12. Set the option of Entry Requirements and edit Lab ID. Press the **OK** button to save the settings you specified.



13. Insert the Q.C. Code chip into the code chip slot in the direction of the arrow.

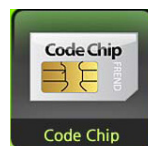


Caution:

Please check the direction in which the Q.C. Code chip should be inserted before insertion. The Q.C. Pouch contains one Q.C. Code chip which is used with the Q.C. Cartridge to do instrument validation.



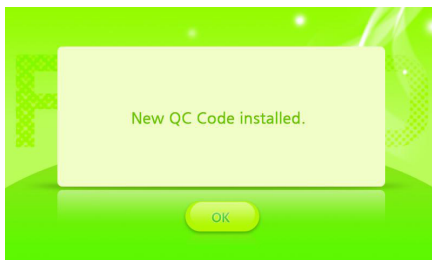
14. Press the **Code Chip** button on the setup screen.



Setup

FREND™ System setup procedure

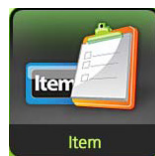
15. The information on the Q.C. Cartridge is automatically saved.



16. When the Q.C. Code chip installation is complete, press the **OK** button to go to the setup screen.



17. Press the **Item** button on the setup screen.



18. Check the Q.C. Cartridge lot number and the installation date of the Q.C. Code chip.




Setup

FREND™ System setup procedure

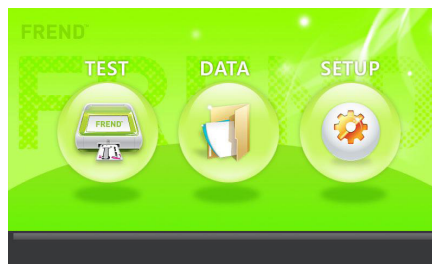
19. If the Q.C. Code chip installation is complete, press the back button to go to the setup screen.



20. After all settings are done, press the  button and move to the main screen.



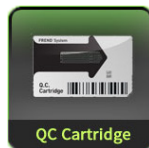
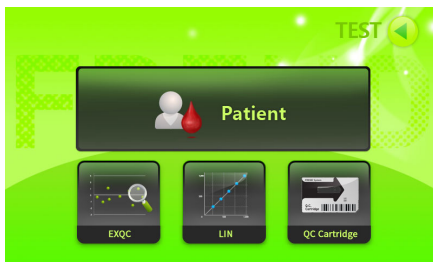
21. Press the **TEST** button on the main screen.



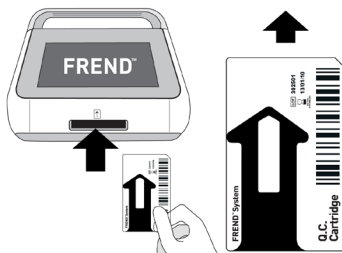
Setup

FREND™ System setup procedure

22. Press the QC cartridge button on the test screen.



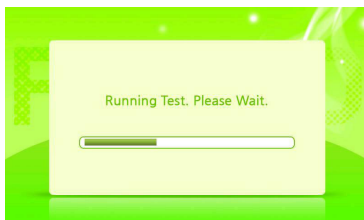
23. Insert the Q.C. Cartridge into the cartridge slot.



Caution:

Please check the direction of the Q.C. Cartridge before insertion.

24. The Q.C. check that the instrument is operating correctly will complete automatically and the Q.C. Cartridge will be expelled. Please wait patiently.



• The system automatically checks three steps while reading.

Step1. Laser power

Step2. Laser alignment

Step3. Calculate ratio

Setup


FREND™ System setup procedure

25. When the Q.C. check is done, the Q.C. Cartridge automatically emerges and the results from all the three steps are displayed. There will be three Passes, if the system is properly operating.



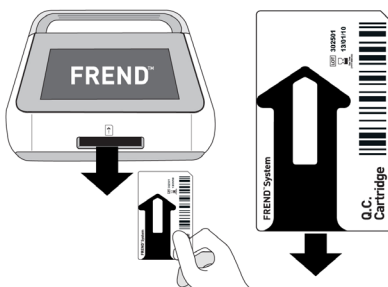
Caution:

If all tests do not pass, try steps 21-24 again. If the instrument does not pass all three steps, please contact customer support via email.

26. Press the  button and move to the main screen.



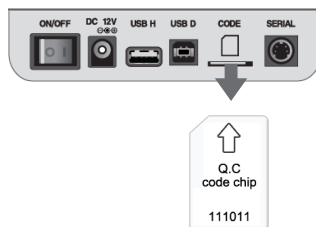
27. Remove the Q.C. Cartridge.



Setup

FREND™ System setup procedure

28. Remove the Q.C. Code chip.



Caution:

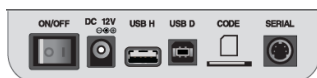
Press the Q.C. Code chip into the slot slightly in order to release it and remove the Q.C. Code chip from the slot.

The FREND™ System setup is complete!!!

Operation

FREND™ System operating procedure

1. Turn the power switch to the 'ON' position.

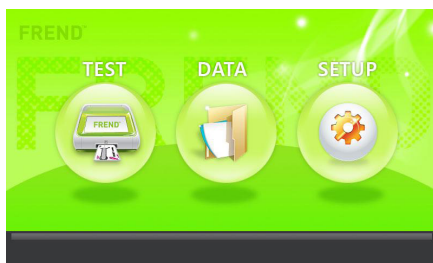


Power switch

2. The FREND™ logo will display this screen while the software boots.



3. Check the main screen.



Caution:

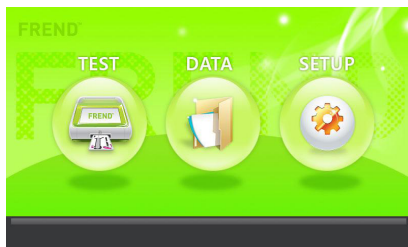
Please double check the direction of the cartridge code chip before insertion. Each cartridge box contains one analyte and lot specific cartridge code chip. The code chip works for all cartridges in the same box.



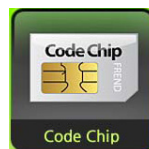
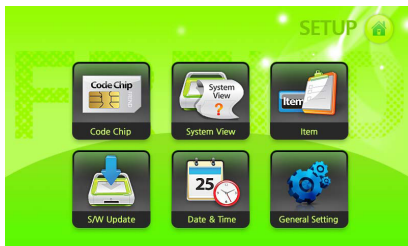
Operation

FREND™ System operating procedure

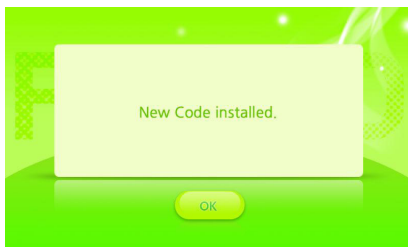
4. Press the **SETUP** button on the main screen.



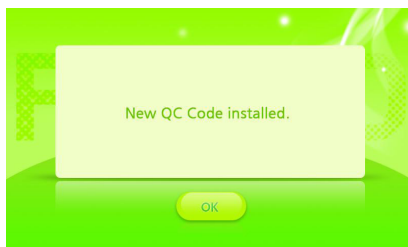
5. Press the **Code Chip** button on the setup screen.



6. The information in the cartridge is automatically saved.



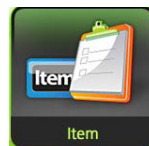
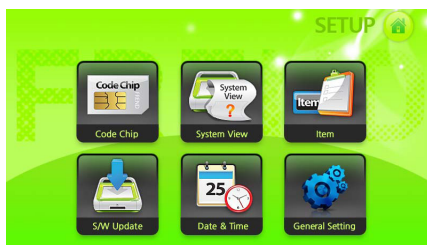
7. If the cartridge code chip installation is complete, press the **OK** button to go to the setup screen.



Operation

FREND™ System operating procedure


8. Press the **Item** button on the setup screen.



9. Check the cartridge lot number and the installation date of the cartridge code chip.



- A maximum of 3 code chips per item can be installed. Any cartridge, whose lot number matches that of any one of the three code chips' lot numbers can be used.

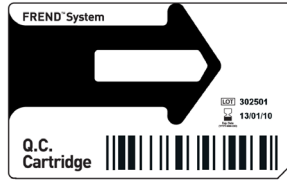
10. Press the  button and move to the main screen.



Operation

FREND™ System operating procedure

11. Prepare the cartridge and patient samples.



- For patient samples, collect 2-4 mL of blood in a 5 mL tube. Spin the tube in a centrifuge and collect the serum or plasma.

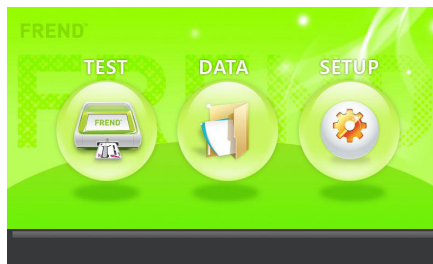
12. After writing the patient information or ID on the sticker of the cartridge, inject sample into the inlet of the cartridge using a calibrated micro-pipette and disposable tip. Refer to the package insert for specific sample volume and procedure.



Caution:

Please be careful not to overfill and not to make bubbles.

13. Press the **TEST** button on the main screen and the system moves to the 'Test mode' screen automatically.



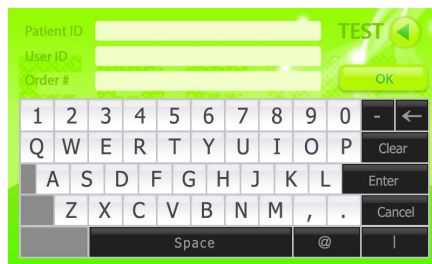
Operation

FREND™ System operating procedure

14. Press the Patient button on the main screen and the system moves to the 'patient test mode' screen automatically.

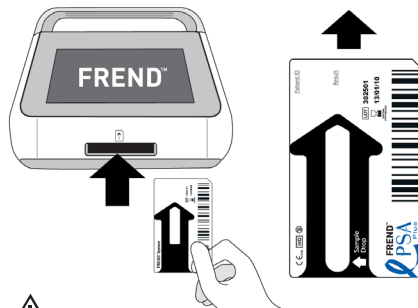


15. Type the 'Patient ID', 'User ID' and 'Order #' and press the Enter button. To start a test, press the **OK** button.



NOTE If you set the Entry Requirements as optional on General setting screen, press the **OK** button to skip this step.

16. Insert the cartridge into the cartridge slot.



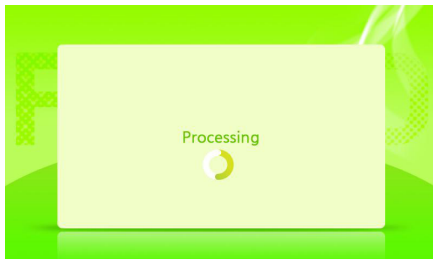
Caution:

Please check the direction of the cartridge before insertion. And also check if the insertion is complete.

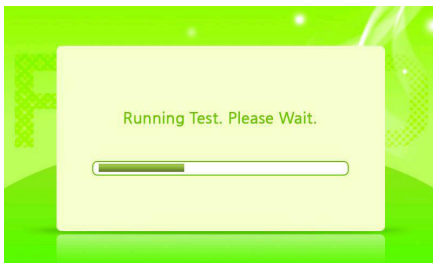
Operation

FREND™ System operating procedure

17. Wait until the test is done automatically.



18. After the reaction is complete, the FREND™ System starts to record the fluorescent readings.



Caution:

Do not turn off the FREND™ System, while there is a cartridge in the system. This is a common cause of malfunction.

19. When the test is done, the cartridge is expelled and the results are displayed automatically.



Operation

FREND™ System operating procedure

20. If the FREND™ System is connected to an optional printer, press the Print button and the results will be printed out.



- Printers is optional and if needed should be purchased separately.

21. The test is complete. If another sample is to be run, repeat again steps 12-19.

- The results are stored automatically. If the DATA button on the main screen is pressed, more information is visible.

Operation

FREND™ System data management

Press the DATA button on the main screen to check, search or delete the test data, and perform data backup.

Data selection

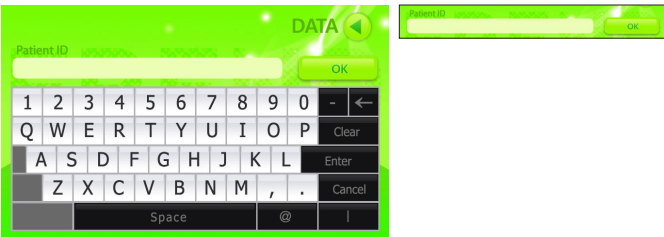


Click the direction of the arrow button on the right to select the data (moving one file moving one page). The selected data is indicated by the arrow on the left side.

Search



If you click the search box on the top left, it will be switched into the input window.



Click the Enter button after entering the Patient ID on the input window.

Operation

FREND™ System data management

Once the input is complete, it will return to the DATA screen. Click the Search button in the top center of the DATA screen to complete the search.



Result confirmation



After selecting the data, click the result button to check the results.

Print



If the printer is connected, click the Print button to print the result. If you click the List button, it will return to the DATA screen.

- Printer should be purchased separately.

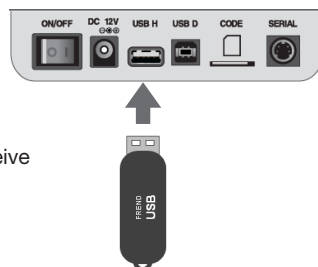
Operation

FREND™ System data management

Click DATA buttons on the main screen to check, search, delete the test data, and perform your backup.

Data backup

Connect the USB drive that will receive the data backup to a USB H port on the back of the device.



Caution:

Confirm the USB drive version(1.1), other formats will not work.



If you want to receive the backup only for a selected data, click the green **Select** button in the center after selecting the data.



If you want to receive the backup for all of the data, click the green **All** button in the upper center.

Operation

FREND™ System data management

Data deletion



If you want to delete only a selected data, click the black Select button after selecting the data and the selected data will be deleted.



If you want to delete all of the data, click the black all button and all of the data will be deleted.

Maintenance

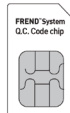
FREND™ System maintenance

The FREND™ System checks

To assure reliable and accurate test results, please check the following:

- Observe the external appearance and screen of the FREND™ System every time you use the device.
- Check the signal input part of the FREND™ System once a month regardless of the device use, using the Q.C. Cartridge and the Q.C. code chip to specifically test the optics.
- If there are any problems found in the results after the checkup, stop using the device immediately and contact the supplier's customer support.

The FREND™ System maintenance supplies



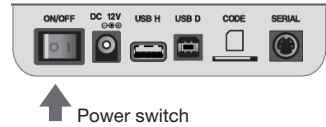
The FREND™ System checklist

1. Laser power
2. Laser alignment
3. Calculate ratio

Maintenance

FREND™ System maintenance

1. Turn the power switch to the 'ON' position.

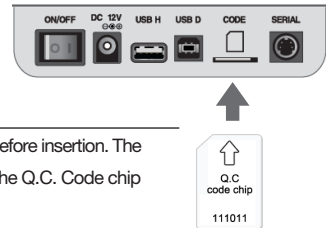


2. Insert the Q.C. Code Chip into the code chip slot in the direction of the arrow.

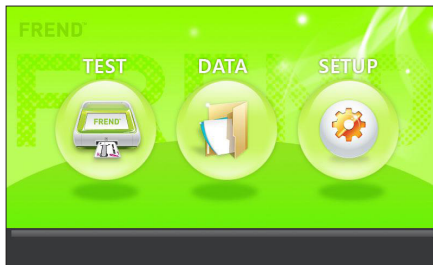


Caution:

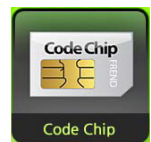
Please check the direction of the code chip before insertion. The Q.C. Pouch contains one Q.C. Code chip. The Q.C. Code chip works with Q.C. Cartridges.



3. Check the main screen and press the **SETUP** button on main screen.



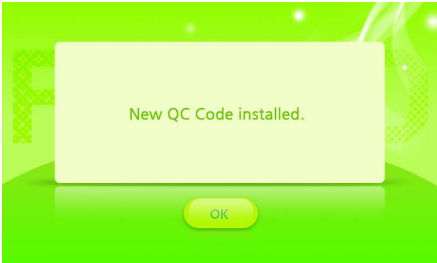
4. Press the **Code Chip** button on the setup screen.



Maintenance

FREND™ System maintenance

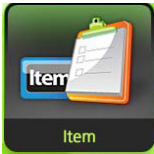
5. The Information on the Q.C. Cartridge is automatically saved.



6. When the Q.C. Code chip installation is complete, press the **OK** button to go to the setup screen.



7. Press the **Item** button on the setup screen.



8. Check the Q.C. Cartridge lot number, the installation date of the Q.C. Code Chip, and the expiration date of cartridge.




9. If the Q.C. Code chip installation is complete, press the **OK** button to go to the setup screen.



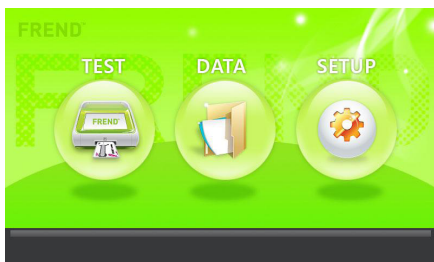
Maintenance

FREND™ System maintenance

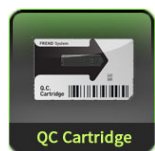
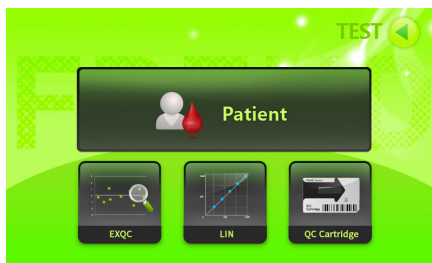
10. After all settings are edited, press the  button and move to the main screen.



11. Press the **TEST** button on the main screen.



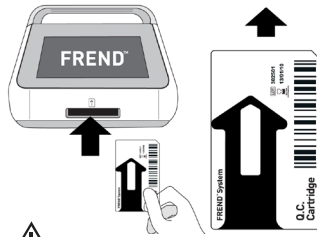
12. Press the QC cartridge button on the test screen.



Maintenance

FREND™ System maintenance

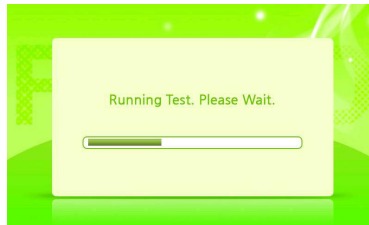
13. Insert the Q.C. Cartridge into the cartridge slot.



Caution:

Please check the direction of the Q.C. Cartridge before insertion.

14. Wait until the test is done automatically.



- The system automatically checks three steps while reading.

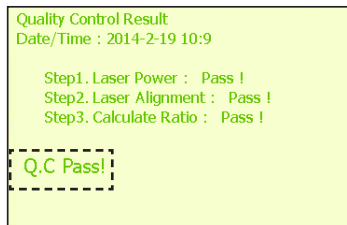
Step1. Laser power

Step2. Laser alignment

Step3. Calculate ratio

15. When the test is done, the Q.C. Cartridge is ejected and the results from each of the three steps are displayed. You will see three

Passes, if the system is properly operating.



Caution:

If you do not pass all tests, try again (11-14). But if you do not pass again, please contact the Customer support.

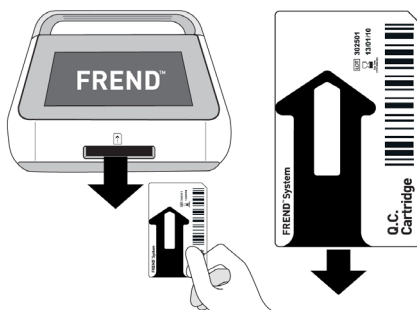
Maintenance

FREND™ System maintenance

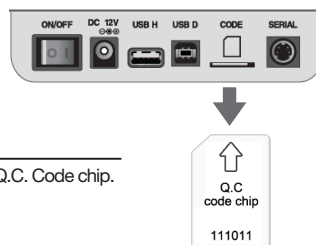
16. Press  button and move to the main screen.



17. Remove the Q.C. Cartridge.



18. Remove the Q.C. Code chip.



Caution:

Press the Q.C. Code chip first to remove the Q.C. Code chip.

The FREND™ System check is complete!!!

Maintenance

Cleaning and storage

- Do not clean the FREND™ System with strong or caustic cleansing agents, chemicals or cleansing tissues impregnated with chemicals.
- Use a soft and dry cloth to clean the FREND™ System.
- For safety reasons, disconnect the power supply from the main outlet and remove the power adapter device from the FREND™ System.
- If you want to store for a lengthy period, keep the FREND™ System covered in a dry place.
- Do not expose the device to direct sunlight.
- Recommended storage conditions are as follows:
 - Temperature: 15 ~ 30 °C
 - Humidity: 10 ~ 80 %
- Store the device on a stable surface. Avoid inclination, vibration and impact.
- Do not place the device near chemicals and/or corrosive substances.
- Keep the device, cable and other accessories well-organized.
- Keep the device clean for the next use.
- To move the device, carefully pick it up and put it down gently to avoid impact.
- Do not place heavy materials on top of the device.
- Wrap or cover the device when in storage to protect from dust.

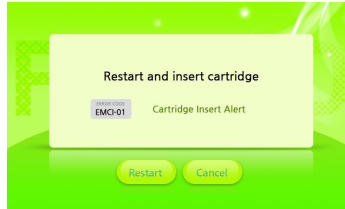
Maintenance

Trouble-shooting

If the FREND™ System malfunctions, please check the following before you contact Customer Support.

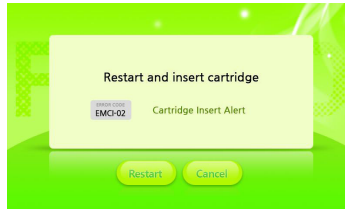
Cartridge insertion issues

EMCI-01 - The cartridge is not inserted.



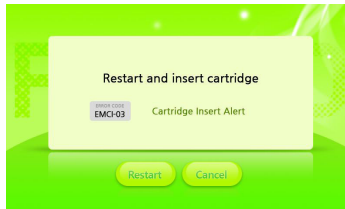
- Re-insert the cartridge within 30 seconds after pressing OK button on TEST screen.

EMCI-02 - The cartridge is not inserted completely.



- Re-insert the cartridge completely. After insertion, check to make sure the cartridge is properly and completely inserted.

EMCI-03 - The cartridge is inserted in the opposite direction.



- Re-insert the cartridge correctly. After insertion, check to make sure the cartridge is properly and correctly inserted.

Maintenance

Trouble-shooting

Cartridge insertion issues

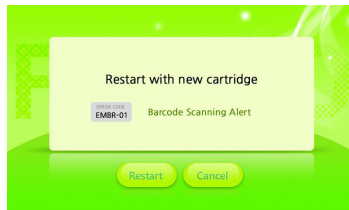
EMCI-04 - The cartridge is inserted upside-down.



- Re-insert the cartridge correctly. After insertion, check to make sure the cartridge is properly and completely inserted.

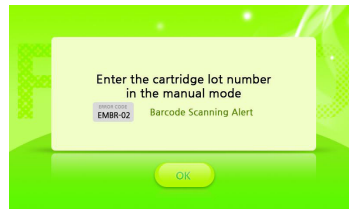
Barcode issues

EMBR-01 - The barcode printed on the cartridge may have been damaged so the reader is unable to interpret the code correctly.



- Remove the damaged cartridge from the system. Load a new cartridge with sample and reinsert the cartridge into the cartridge slot. Discard the damaged cartridge.

EMBR-02 - The barcode information related to the cartridge lot number printed on the cartridge is not readable by the system reader.



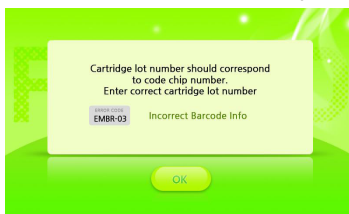
- Manually enter the lot number of the cartridge using the keypad. The lot number is printed directly above the barcode on the cartridge.

Maintenance

Trouble-shooting

Barcode issues (cont.)

EMBR-03 - The lot number entered for the cartridge does not match the lot number on the code chip.



- Carefully enter the lot number of the cartridge again. If the same message is repeated, check the lot number on the installed code chip. If code chip and cartridge lots do not match, change either code chip or cartridge so they are the same lot number and retry loading the cartridge.

Data backup issues

EMDB-01 - The USB drive version is not correct, or the USB drive is not properly connected to the FRENDS™ System. In addition, the USB drive or USB H port has somehow been damaged.



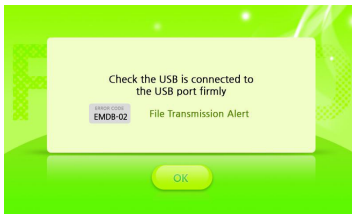
- Check to be sure the USB drive is the version 1.1 required for the FRENDS™ System and that the USB drive is connected properly to the USB H port. If after trying a second time with the same USB drive the error message is repeated, try a new USB drive version 1.1. If the problem persists, contact customer support for assistance.

Maintenance

Trouble-shooting

Data backup issues

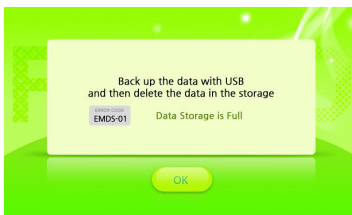
EMDB-02 - A problem has been detected when attempting to transfer data from the FREND™ System to the USB drive.



- Check to be sure the USB drive is the version 1.1 required for the FREND™ system and that the USB drive is connected properly to the USB H port. If after trying a second time with the same USB drive the error message is repeated, try a new USB drive version 1.1. If the problem persists, contact customer support for assistance.

Data save issues

EMDS-01 - The storage capacity of the FREND™ System to store the data has been exceeded.



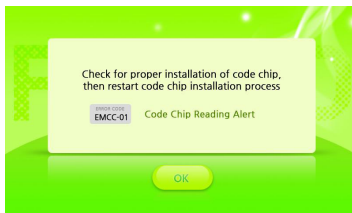
- Back up the data stored in the FREND™ System to a version 1.1 USB drive. Then, delete the data stored in the FREND™ System so space is again available on the system.

Maintenance

Trouble-shooting

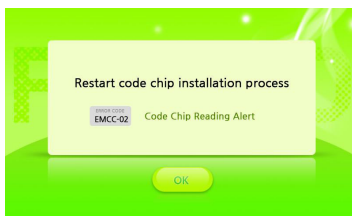
Code chip install issues

EMCC-01 - The code chip is not inserted properly, the code chip has somehow been damaged or the FREND™ System does not recognize the code chip.



- Check that the code chip is installed properly. If it appears to be properly installed, remove the code chip from the system, locate another code chip from the same lot number and restart the code chip installation process. If the problem continues, contact customer support.

EMCC-02 - The FREND™ System does not recognize the code chip.



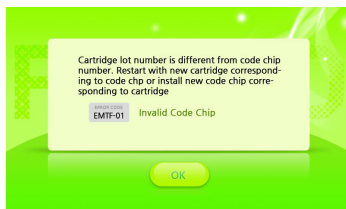
- Restart the code chip installation process. If the problem persists, locate another code chip from the same lot number and restart the code chip installation process. If the problem continues, contact customer Support.

Maintenance

Trouble-shooting

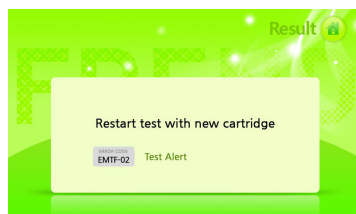
Test result issues

EMTF-01 - The lot number of the inserted cartridge is different from the lot number of the installed code chip.



- Check that the lot number printed on the cartridge is the same as the lot number on the code chip. If not, restart using a code chip and cartridge of the same lot number. If the original set were the same lot number, try a new code chip and cartridge pair in case either was damaged.

EMTF-02 - Unable to output a test result because the reference signal is weaker than the baseline.



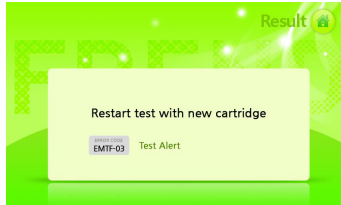
- Load the same sample into a new cartridge and load the cartridge into the system. If the problem is repeated, try a sample from a different source (different patient). If the problem continues, contact customer support.

Maintenance

Trouble-shooting

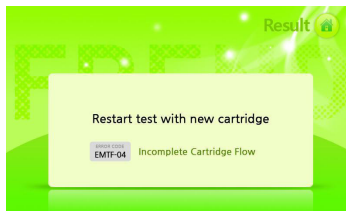
Test result issues (cont.)

EMTF-03 - Unable to output a test result because the reference signal is stronger than the baseline



- Load the same sample into a new cartridge and load the cartridge into the system. If the problem is repeated, try a sample from a different source (different patient). If the problem still continues, contact customer support.

EMTF-04 - The system cannot detect any signal.



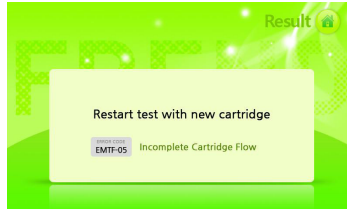
- Load the sample into a new cartridge and restart the test. If the same error message is displayed, centrifuge the sample to remove particulate matter and fibrin clots and retry with a new cartridge. If the problem persists, try a different sample. If the problem still continues, contact customer support.

Maintenance

Trouble-shooting

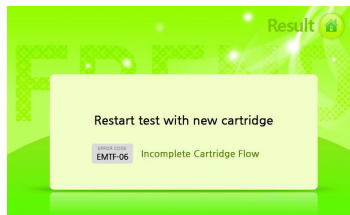
Test result issues (cont.)

EMTF-05 - The system detects more than four signals because the cartridge is damaged.



- Load the sample into a new cartridge and restart the test. If the same error message is displayed, centrifuge the sample to remove particulate matter and fibrin clots and retry with a new cartridge. If the problem persists, try a different sample. If the problem still continues, contact customer support.

EMTF-06 -The lateral flow of the sample within the cartridge is incomplete.



- Load the sample into a new cartridge and restart the test. If the same error message is displayed, centrifuge the sample to remove particulate matter and fibrin clots and retry with a new cartridge. If the problem persists, try a different sample. If the problem still continues, contact customer support.

Maintenance

Trouble-shooting

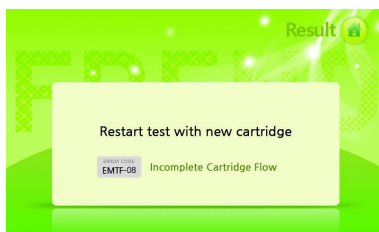
Test result issues (cont.)

EMTF-07 - Time-out error



- Load the sample into a new cartridge and restart the test. If the same error message is displayed, centrifuge the sample to remove particulate matter and fibrin clots and retry with a new cartridge. If the problem persists, try a different sample. If the problem still continues, contact customer support.

EMTF-08 - The cartridge has passed the expiration date.



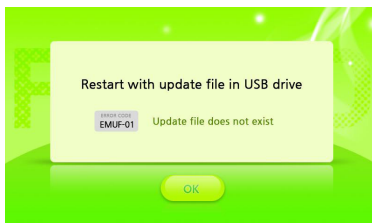
- Load the sample into a new cartridge which does not pass the expiration date and restart the test. If the cartridge does not pass the expiration date, check to make sure if date setting is correct on Date & Time screen.

Maintenance

Trouble-shooting

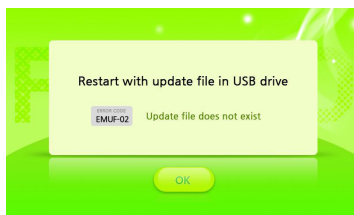
Update issues

EMUF-01 -There is no executable file (FRIEND.exe) on the USB drive.



- Save the executable file, FRIEND.exe, transfer it to the USB drive and then retry the update process.

EMUF-02 -There is no executable file (FRIENDUPDATE.exe) on the USB drive.



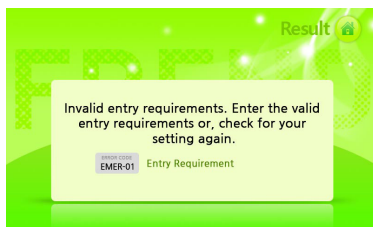
- Save the executable file, FRIENDUPDATE.exe, transfer it to the USB drive and then retry the update process.

Maintenance

Trouble-shooting

No entry requirements

EMER-01-The entry requirements are not entered.

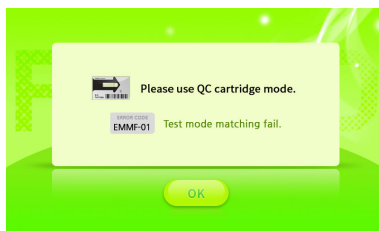


- Enter the Patient ID, User ID, and Order #. If you want not to enter the entry requirements, change the setting on the General setting screen.

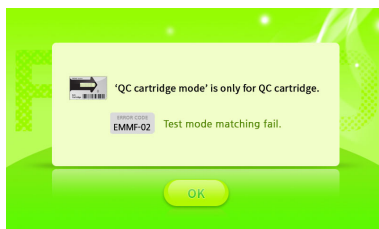
NOTE: In addition to the above, for any reason, if the instrument does not work, please turn off and turn on again.

Test mode matching failure

EMMF-01 : Read QC Cartridge in QC Cartridge Mode



EMMF-02 : QC cartridge mode is for QC cartridge only



Maintenance

General specification -normal environmental conditions

Electrical rating	Voltage	100 - 240 V~
	Current	1.7 A
Electric input	Frequency	50 / 60 Hz
	Voltage	DC 12 V
	Current	3.33 A
	240 mm x 260 mm x 175 mm (W x L x H) 9.4 inch X 10.2 inch X 6.9 inch	
Dimensions		
Weight	3 Kg (6.6 lbs)	
Degree of protection	IPX0	
Optical power	Class I	
User interface	Active screen size	7.0 inches diagonal dimension
	Pixel format	800 x 480, TFT LCD
Mobile printer (Optional)	Size	75 mm x 103 mm x 44.3 mm
	Weight	237 g
	Interface	Serial(RS232C)
	Print width	2 inch(48 mm)
	Printing speed	50 mm/sec
Environmental suggestions for optimal performance	<ul style="list-style-type: none">• Do not place unit in the direct sun.• Position the unit in a well-ventilated area.• Place the unit on a flat, dry and smooth surface with sufficient ventilation area around the unit.	
	<ul style="list-style-type: none">• Operating condition: Temperature: 15 ~ 30 °C, Humidity: 10 % ~ 80 %	
	<ul style="list-style-type: none">• Storage condition: Temperature: 15 ~ 30 °C, Humidity: 10 % ~ 80 %	

Maintenance

Customer support information

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This product is sold all over the world. Customer support services vary for each geographical region. When the FREND™ System is shipped, information will be included that lists the appropriate telephone numbers, fax numbers and email addresses from which support for your geographical region can be most readily obtained.

The information in this manual has been carefully reviewed and has been found to be as accurate.

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Documentation : **NESMU-F10-002EN**

Revision History : V.0.0 Date : Jan. 2012

V.0.1 Date : Dec. 2012

V.0.2 Date : Feb. 2013

V.0.5 Date : Jul. 2013

V.0.6 Date : Dec. 2013

V.0.7 Date : Mar. 2014

V.0.8 Date : Nov. 2015

V.0.9 Date : Sep. 2017

V.1.0 Date : Jan. 2018

V.1.5 Date : Sep. 2020

V.1.6 Date : Dec. 2021

V.1.7 Date : JUN. 2023

FREND™ System

NESMU-F10-002EN (V.1.7)



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