FREND™ System

FREND™ 2.0

User manual

NanoEntek

FREND™ System,

FREND™ 2.0 User Manual

Thank you for purchasing the FREND™ 2.0.

Please take a few minutes to read this user manual.

If you have any question, please contact NanoEntek, Inc.

Customer support.

Tel: +82-2-6220-7940

Fax: +82-2-6220-7999

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.

NanoEntek, Inc.

851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea

Tel: +82-2-6220-7940

Fax: +82-2-6220-7999

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Introduction

Warranty

NanoEntek Inc. warranties 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.

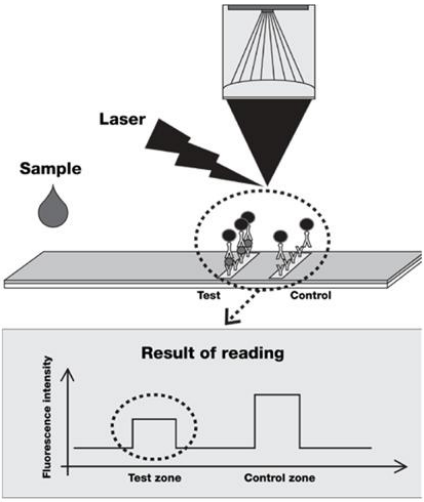
This warranty does not apply to damages incurred during the initial shipment of the instrument and associated auxiliary materials. Any damages incurred on initial shipment are to be reported immediately to the freight carrier for the settlement of the claim. Please examine the device carefully for any 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

The principle of the FREND™ System, FREND™ 2.0

The FREND™ System, FREND™ 2.0 is a portable, automated FREND™ cartridge reader.
The FREND™ System, FREND™ 2.0 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™ System, FREND™ 2.0 is a Class 1 laser product in accordance with IEC 60825-1:2014.
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, FREND™ 2.0 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

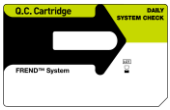
When the FREND™ System, FREND™ 2.0 is received, open the shipping box and carefully check the package contents. Note that the Q.C. designation is used in terms of hardware verification of performance not quality control of the actual testing process for any analytes.

Main Device

Adaptor/Power Cord

Pipette

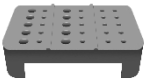
QC Cartridge



QC Code chip

USB Drive

Tube rack

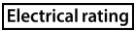


User Manual

Quick Manual

Safety symbols & abbreviations

Following symbols are found on the FREND™ System, FREND™ 2.0 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, Consult accompanying documents
	Catalogue number/Reference number
 www.nanoentek.com	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
	Electrical 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
Rx Only	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	US Corporation
European Corporation	European Corporation
EC REP	Authorized representative in the European Community
UK Representative	Authorized representative in United Kingdom
CH REP	Authorized representative in Switzerland
BRH	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 button.
- 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 FREND™ 2.0 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 ventilation.
- 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 off the device, 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, illegal 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 FREND™ System car cela pourrait provoquer un choc électrique, des blessures corporelles et des dommages matériels. Insérez uniquement des appareils qualifies 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 utilize 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 its 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 the 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.
- Place the device in a location accessible only to authorized personnel to prevent use by unauthorized individuals.

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).
- Do not look into the cartridge slot so that your eyes are not exposed to the laser.

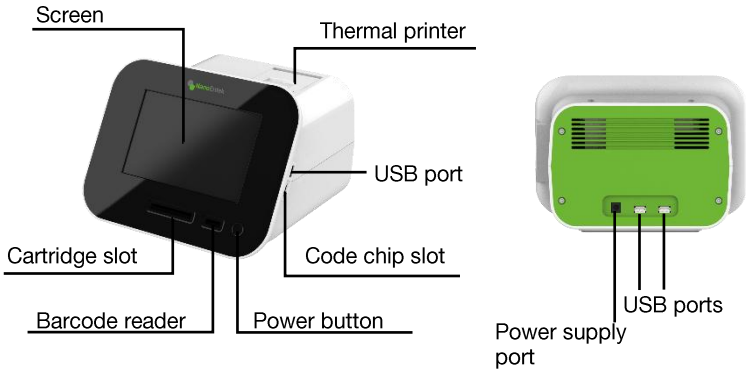
Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

 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™ 2.0 Description

Name	Function
Screen	Show the operating status and results
Cartridge slot	Slot for FREND™ cartridge insertion and ejection
Power button	Power on/off
USB port	Use to connect to a USB drive.
Code chip slot	Slot for QC or cartridge Code chip insertion and ejection
Barcode reader	Read the QR code or barcode information
Power supply port	Power supply
Thermal printer	Print the result



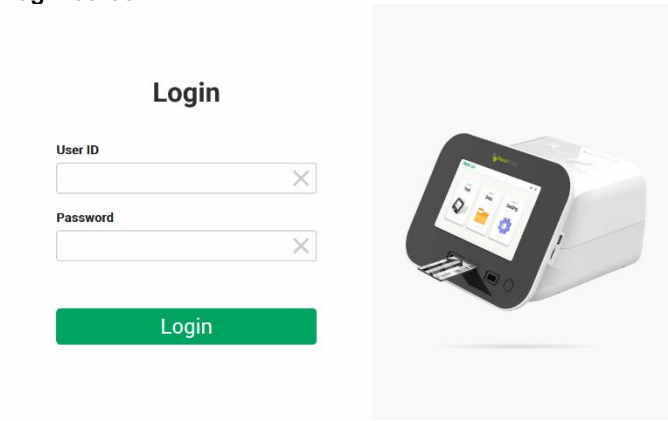
Functions of Code chip and associated cartridge

Product	Definition
QC Code chip	The chip containing information for the proper functioning of the QC Cartridge
QC Cartridge	The cartridge used to check the mechanics and optics of the FREND™ 2.0.

Product	Definition
Code chip	This cartridge code chip is specific for a given analyte and lot of reagents. It contains information on calibration and calculation of results using readings from the FREND™ reagent cartridge
FREND™ cartridge	The cartridge contains reagents and microstructures to support a lateral flow assay, where analytes of interest from immune complexes while the specimen is moving and being separated. Ratio between test zone and reference zone is calculated.

Software keys

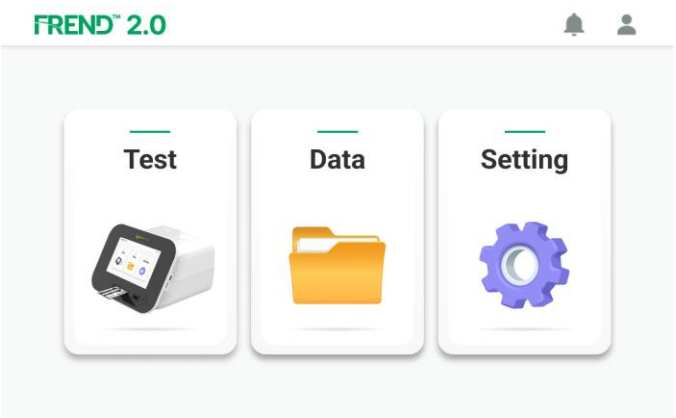
Login screen



Button	Purpose
User ID	Pre-registered user ID required for login
Password	Pre-registered user password required for login
×	Delete the entered information
Login	Login to the main page after entering all the user information

Software keys

Main screen

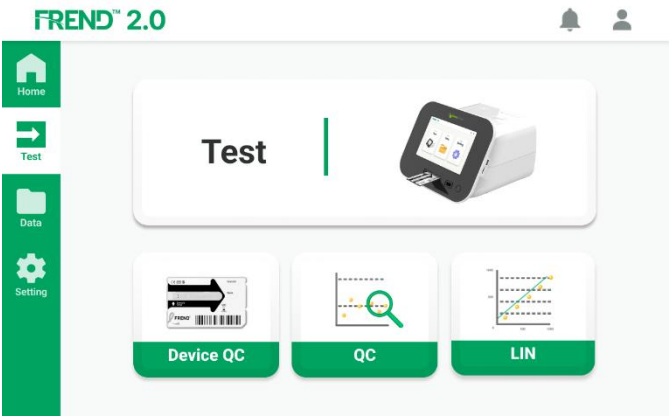


Button	Purpose
	Initiate a test sequence for specimens or maintenance using that analyte-specific cartridge or QC cartridge
	Check and search results. Back up the data and transfer the data to a USB drive or LIS/HIS.
	Set up the parameters specific to the site and operator
	Notification - Data storage status - FREND™ cartridge expiry date
	User - Logout from the system

Introduction

Software keys

Test screen

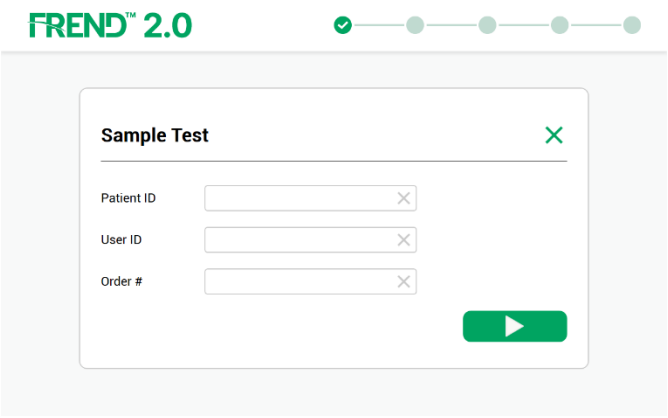


Button	Purpose
	Run the specimens of the patient on the FREND™ cartridge
	Access the device functions with QC cartridge
	Verify the FREND™ cartridge with the external or internal QC materials (Optional) *Internal or external quality control materials are required
	Verify the FREND™ cartridge with the linearity or verification kit (Optional) *External verification materials are required

*Navigation Bar	
	Navigate to Home screen
	Move to Test screen for testing specimens or maintenance
	Access the Data screen to manage the recorded data
	Access the Setting screen to check device information

Software keys

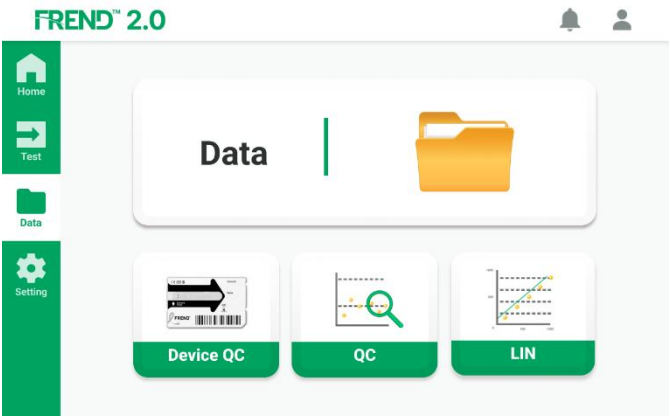
Test screen 》 Information input



Button	Purpose
Patient ID	Enter the patient identifying information
User ID	Select a pre-registered or enter a new user name
Order #	Type the patient identifying number or additional information (Optional)
	Start the test after entering information
	Cancel the test and move to the previous screen

Software keys

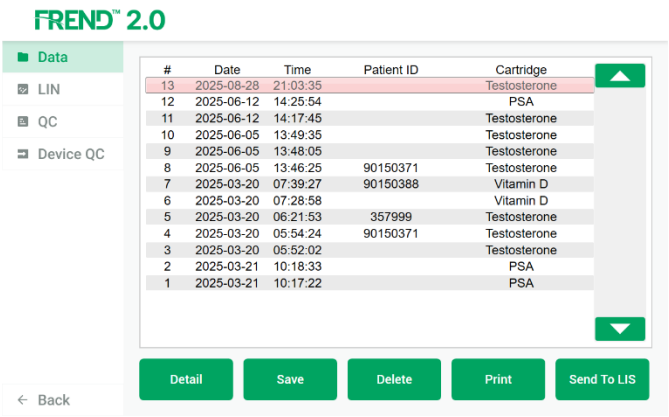
Data screen



Button	Purpose
	Review recorded patient results
	Check device performance confirmed with the QC cartridge.
	Access the product performance validated with quality control materials.
	Verify the linearity/calibration verification results on the product

Software keys

Data screen

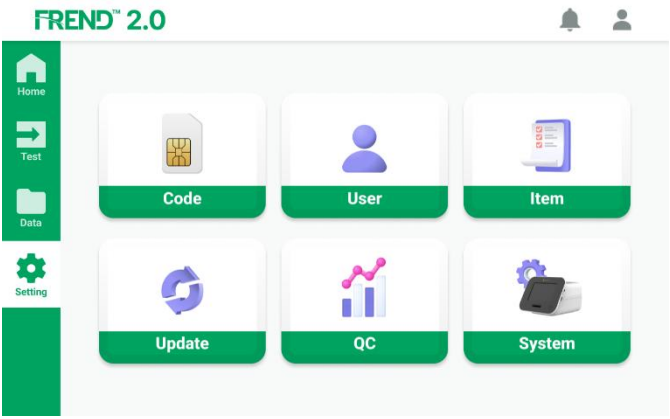


Button	Purpose
Detail	Review the recorded details
Save	Save the data to the flash drive connected to USB port
Delete	Delete the selected data
Print	Print the chosen data
Send to LIS	Transfer the selected data to the information system in the laboratory or hospital.

*Navigation Bar	
Data	Review recorded patient results
LIN	Verify the linearity/calibration verification results on the product
QC	Access the product performance validated with quality control materials.
Device QC	Check device performance confirmed with the QC cartridge

Software keys

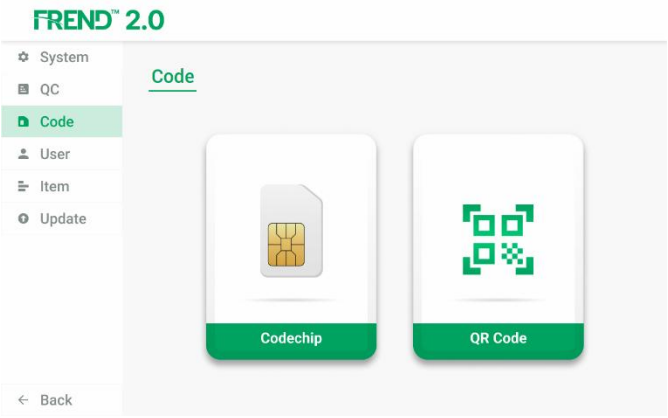
Setting screen



Button	Purpose
	Register the cartridge information using code chip or QR code
	User information registration and management
	View the registered cartridge list and manage the details
	Update the software
	Register and manage the QC and Linearity kit information
	Manage and set the device information · Information: Region/Language, S/N, S/W and F/W version · Date & Time · Test Option: Quick mode, Requirement, Lab ID · Device: Sound, LIS setting, DB Reset, System Log

Software keys

Setting screen 》 Codechip

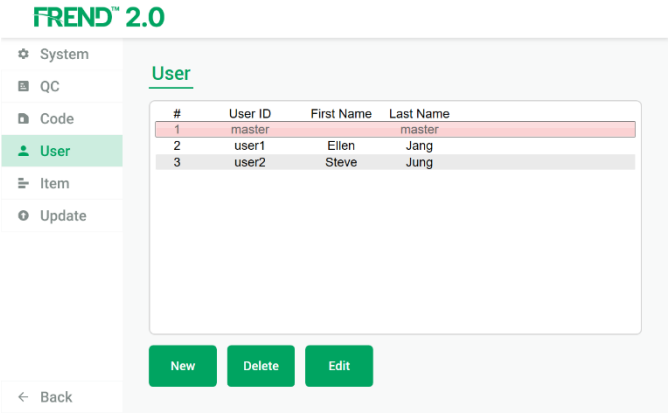


Button	Purpose
	Install using the codechip
	Scan the QR Code to save cartridge information
← Back	Move to the previous screen

*Navigation Bar	
System	Manage and set the device information
QC	Register and manage the QC and Linearity kit information
Code	Register the cartridge information through code chip or QR code
User	Manage the user information
Item	View the registered cartridge information and input the normal range
Update	Update Software

Software keys

Setting screen 》 User



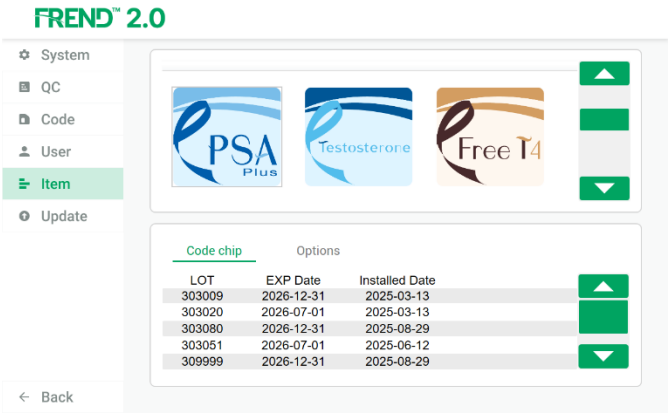
Button	Purpose
New	Register the user information
Delete	Remove the user information
Edit	Edit the user information
← Back	Move to the previous screen

Caution:

It is recommended to change the user password every six months.
Ensure that the configured password is securely managed to prevent leakage.

Software keys

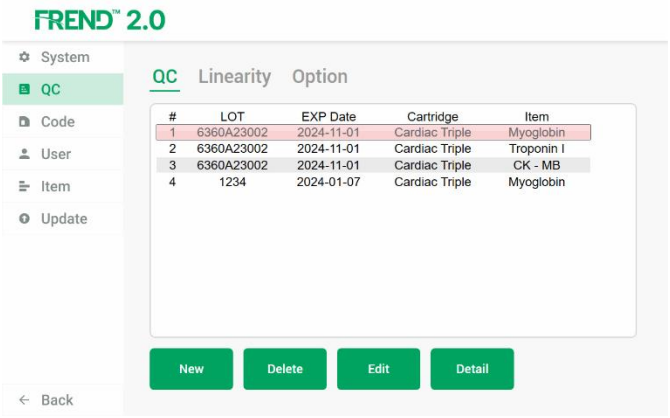
Setting screen 》 Item



Button	Purpose
← Back	Move to the previous screen

Software keys

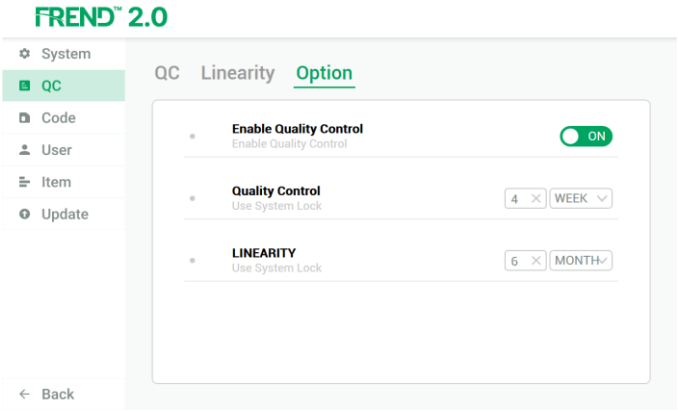
Setting screen 》 QC



Button	Purpose
QC	Manage the QC material information
Linearity	Manage the linearity kit information
Option	Enables or disables QC testing on the test screen
New	Register the Cartridge and QC material information.
Delete	Remove the QC material information.
Edit	Edit the QC material information.
Detail	Review the QC material details.
← Back	Move to the previous screen

Software keys

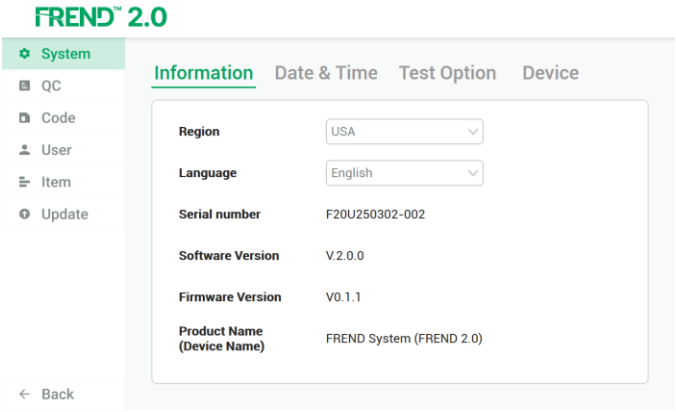
Setting screen 》 QC 》 Option



Button	Purpose
Enable Quality Control	Activate / Deactivate the quality control buttodn on the test page
Quality Control Use System Lock	Set the frequency for performing quality control. (Day / Week / Month)
Linearity Use System Lock	Set the frequency for performing Linearity control. (Day / Week / Month)

Software keys

Setting screen 》System



Button	Purpose
Information	Region selection Language selection System information - Serial number - Software version - Hardware version
Date & Time	Set the system time
Test Option	Set up the following test mode and type the default test information - Quick mode activation / deactivation - Requirement: Patient ID, User ID, Oder# - Lab ID
Device	Set the sound volume of the device Set the LIS option Database reset View log in history

Setup

FREND™ 2.0 Setup procedure

1. Carefully examine the box for any damage. Remove all the components of the FREND™ 2.0 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™ 2.0 and the AC power cord into the wall socket.

Warning:

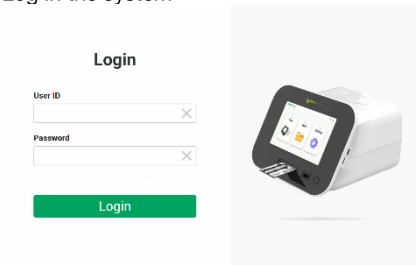
If you use an incorrect adaptor, the FREND™ 2.0 may explode or start to burn. If this happens, it will no longer work properly anymore.

4. Press the power button for 3 seconds.

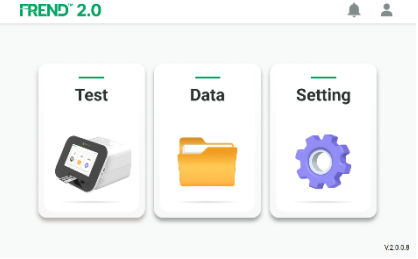
5. While the device is booting up, this image will appear.

FREND™ 2.0 Setup procedure

6. Log in the system

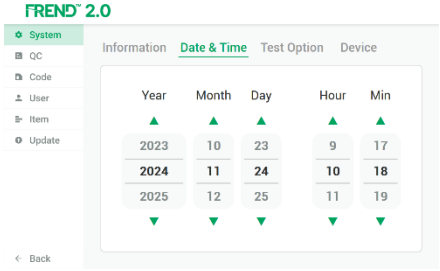


7. Tap the **Setting** button on the main screen.



8. Set the **Region** and **Language** on the Information tab
- Supporting site
  : USA, Korea, Germany, Italy, China, Japan
- Support Language
  : English, Korean, German, Italian, Chinese, Japanese

9. Tap the **Date & Time** button on the setting screen.
- Set the local date and time



10. After setting the date and time, tap the **Back** button to return to the previous screen.

11. Tap the **Code chip** button.

FREND™ 2.0 Setup procedure

12. Select the way to install the code chip.

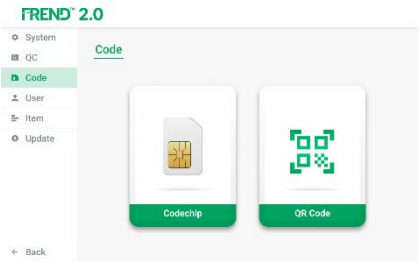
- Code chip

: Insert the QC Code chip into the code chip slot in the direction of the arrow

: Remove the code chip after the installation

- QR code

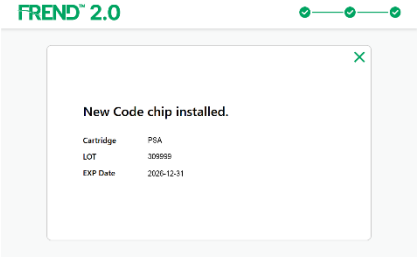
: Scan the QR code on the barcode reader



Warning:

Please check the inserting direction for the QC Code chip. The QC Pouch contains one QC Code chip, which is used with the QC Cartridge to do instrument validation

13. The information is on the screen when the QC Code chip installation is complete. Tap the **Back (X)** button to go to the setting screen.



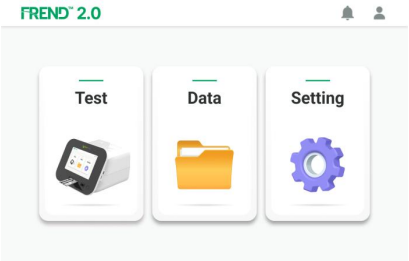
14. Tap the **ITEM** button on the setting screen.

15. Check the QC Cartridge lot number and the installed date.

FREND™ 2.0 Setup procedure

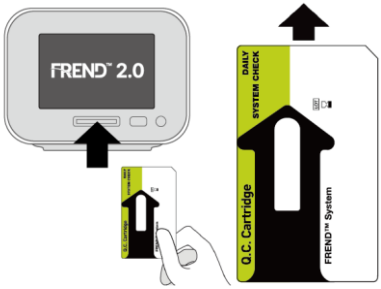
17. If the QC Code chip installation is complete, tap the **Back** button to go to the main screen.

18. Tap the **TEST** button on the main screen.



19. Tap the **Device QC** button on the TEST screen.

20. Insert the QC cartridge into the cartridge slot.

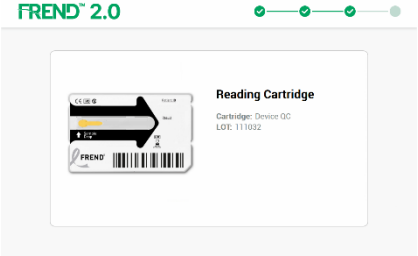


Warning:

Please check the direction of the QC Cartridge before insertion.

FREND™ 2.0 Setup procedure

21. The QC check which the instrument is operating correctly will complete automatically and the QC Cartridge will be expelled.



The system automatically checks three steps while reading.
Step1. Laser Power
Step2. Laser Alignment
Step3. Calculate Ratio

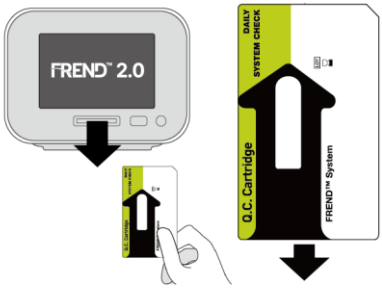
22. When the QC check is done, the QC Cartridge automatically emerges and the results from all the three steps are displayed. There will be three Passes, if the system is properly operating.

Warning:

If all results is not pass, try steps 19–20 again. If the device does not pass all three steps, please contact customer support via email.

23. Tap the **X** button and move to the main screen.

24. Remove the QC Cartridge.



The FREND™ 2.0 setup is complete.

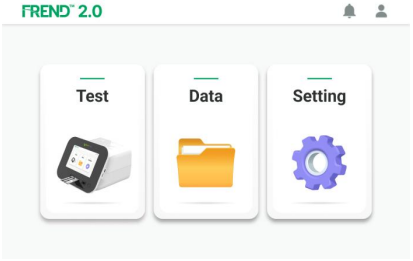
Operation

FREND™ 2.0 Operating procedure

1. Press the power button for 3 seconds.

2. While the device is booting up, this image will appear.

3. Tap the **SETTING** screen on the main screen.



Caution:

When installing with a code chip, 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.

FREND™ 2.0 Operating procedure

4. Tap the **Codechip** button.

5. Select the way to install the code chip.

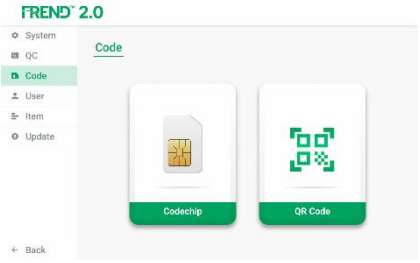
- Code chip

: Insert the QC Code chip into the code chip slot in the direction of the arrow

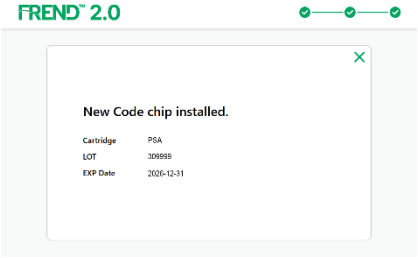
: Remove the code chip after the installation

- QR code

: Scan the QR code on the barcode reader

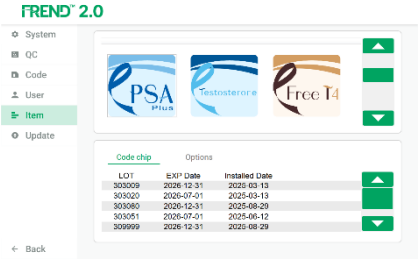


6. When the code chip installation is complete, tap the **Back (X)** button to go to the setting screen.



7. Tap the **ITEM** button on the setting screen.

8. Check the cartridge lot number and the installed date.



FREND™ 2.0 Operating procedure

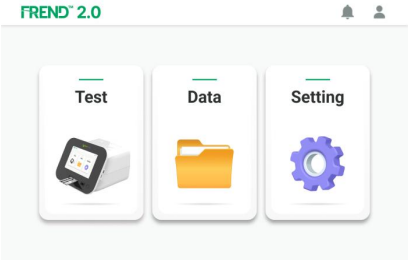
9. If the code chip installation is complete, tap the **Back (X)** button to go to the main screen.

10. Prepare the cartridge and patient samples.

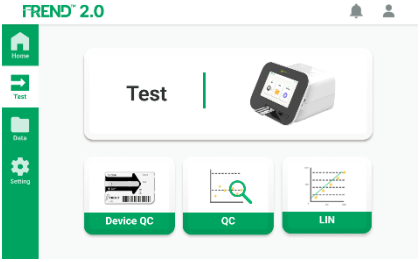
• For patient specimens, collect 2–4 mL of blood in a 5 mL tube. An approved blood sample type must be used for each item. Serum and plasma can be separated according to the blood collection tube manufacturer's recommended conditions.

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

12. Tap the **TEST** button on the main screen.



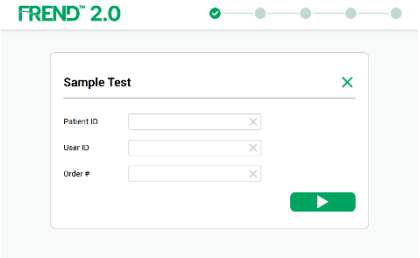
13. Tap the **TEST** button.



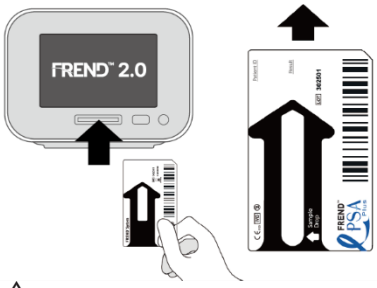
FREND™ 2.0 Operating procedure

- **Test** button is for the patient's specimen testing.
- **Device QC** button is to check the performance of the equipment such as laser power, alignment, and ratio calculation using the QC cartridge
- **QC** button is to check the performance of the cartridge with internal or external quality control material.
- **LIN** button is to check the performance of the cartridge with the linearity kit. *the USA only

14. Type the 'Patient ID', and 'Order #' and select the 'User ID'. Tap the Enter button. To start a test, tap the **NEXT**(▶) button.



15. Insert the cartridge into the cartridge slot.



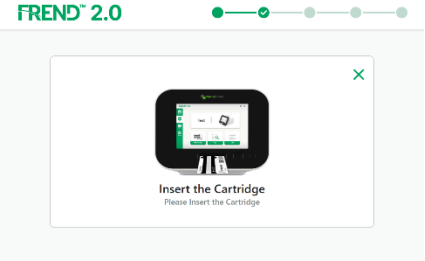
Caution:

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

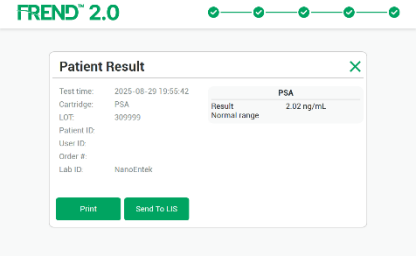
FREND™ 2.0 Operating procedure

17. Wait until the test is done automatically. After the reaction is complete, the FREND™ 2.0 starts to record the fluorescent readings.

* If you cancel the test, please tap the **X** button on the screen.



18. When the test is done, the cartridge is expelled and the result is displayed on the screen.



* Print the result by tapping the **PRINT** button.

* Tap the **Send to LIS** button to transfer the data to the management system in the clinic

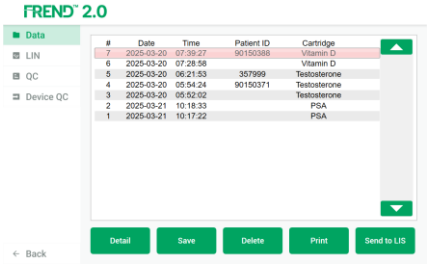
19. The test is complete. If another sample is to be run, repeat again steps 34–36.

• The results are stored automatically. If the **DATA** button on the main screen is tapped, more information is visible.

FREND™ 2.0 Data management

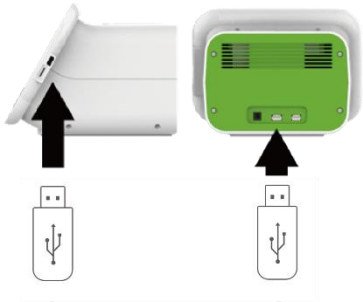
Tap the **DATA** button on the main screen to check, delete, and perform data backup.

Data selection

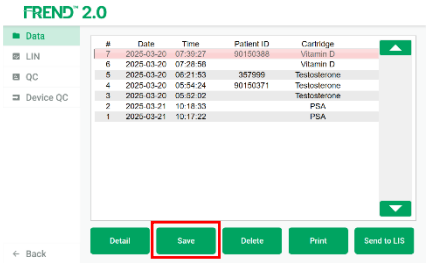


Drag the screen up or down to check the data. You can select the desired data by tapping the list.

Data backup



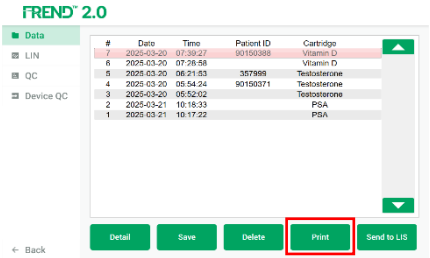
Connect the USB drive that will receive the data backup to a USB port on the side and back of the device.



Tap the **Save** button to store all data on the USB drive.

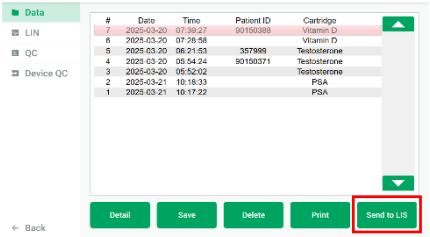
FREND™ 2.0 Data management

Data print



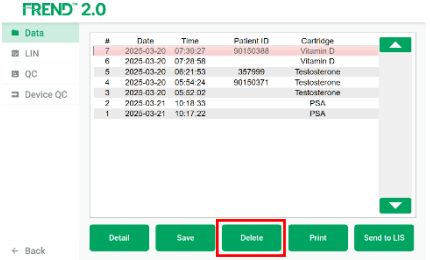
Tap the **PRINT** button to be printed the selected data from the built-in Print.

Data transfer to LIS



Tap the **Send to LIS** button for sending the selected data to the connected LIS.

Data deletion



The chosen data can be removed from tap the **DELETE** button.

Maintenance

FREND™ 2.0 Maintenance

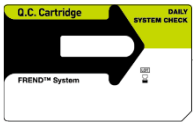
The FREND™ 2.0 checks

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

- Observe the external appearance and screen of the FREND™ 2.0 every time you use the device.
- Start by scrutinizing the signal input section of the FREND™ 2.0 on a monthly basis, irrespective of device usage. Employ the QC Cartridge and the QC code chip to conduct precise optical testing.
- Halt device usage immediately and reach out to the supplier's customer support if any issues are detected in the results following the checkup.

The FREND™ 2.0 maintenance supplies

QC Cartridge



QC Code Chip

The FREND™ 2.0 checklist are:

1. Laser Power
2. Laser Alignment
3. Calculate Ratio

FREND™ 2.0 Maintenance

1. Press the power button for 3 seconds.

2. Tap the **SETTING** button on the main screen.

3. Tap the **Codechip** button.

4. Select the way to install the code chip.

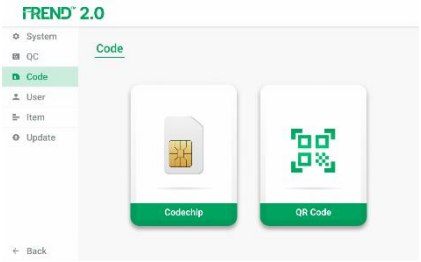
- Code chip

: Insert the QC Code chip into the code chip slot in the direction of the arrow

: Remove the code chip after the installation

- QR code

: Scan the QR code on the barcode reader

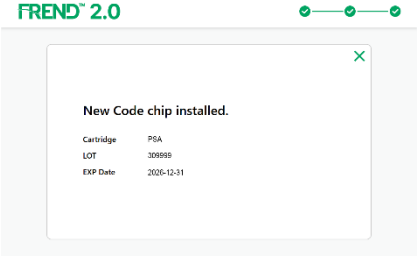


Warning:

Please check the inserting direction for the QC Code chip. The QC Pouch contains one QC Code chip, which is used with the QC Cartridge to do instrument validation

FREND™ 2.0 Maintenance

5. When the QC Code chip installation is complete. Tap the **X** button to go to the setting screen.

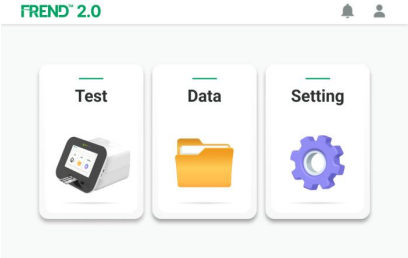


6. Tap the **ITEM** button on the setting screen.

7. Check the QC Cartridge lot number and the installed date.

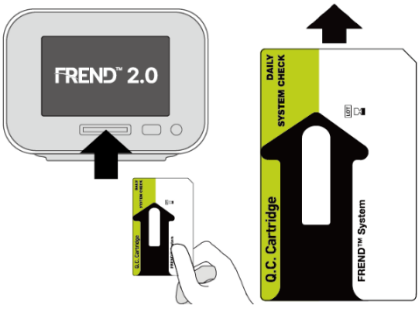
8. If the QC Code chip installation is complete, tap the ← **Back** button to go to the main screen.

9. Tap the **TEST** button on the main screen.



10. Tap the **Device QC** button on the TEST screen.

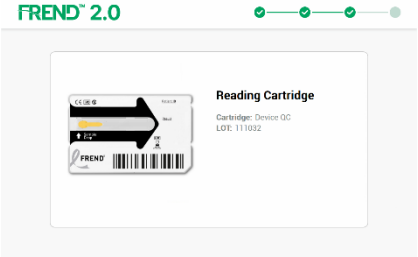
11. Insert the QC cartridge into the cartridge slot.



Warning:

Please check the direction of the QC Cartridge before insertion.

12. The QC check that the instrument is operating correctly will complete automatically and the QC Cartridge will be expelled.



The system automatically checks three steps while reading.
Step1. Laser power
Step2. Laser alignment
Step3. Calculate ratio

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

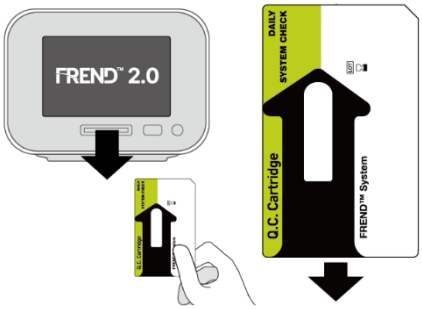
Warning:

If all results is not pass, try steps 9–12 again. If the device does not pass all three steps, please contact customer support via email.

FREND™ 2.0 Maintenance

14. Tap the **X** button and move to the main screen.

15. Remove the QC Cartridge.

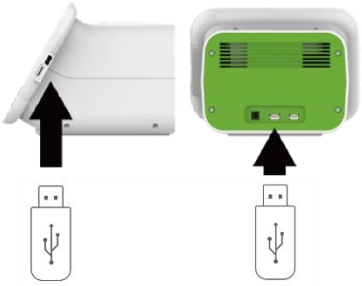


The FREND™ 2.0 setup is complete.

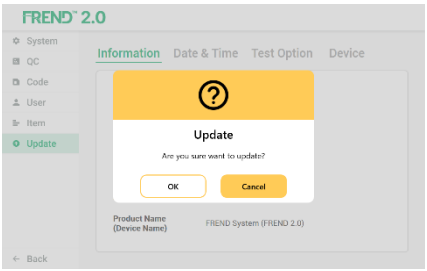
FREND™ 2.0 Update

1. Tap the **SETTING** button on the main screen and select the **SYSTEM** button.

2. Connect the **USB drive** with update file to a USB port on the side and back of the device.



3. Tap the **OK** button to proceed with the SW update.



Caution:

Do not perform updates through unauthorized personnel or devices. If verification cannot be confirmed, contact the manufacturer.
Operate the USB connection only with software designated by the manufacturer.
If any unverified activity is recorded in the log, contact the manufacturer or inspect the device before operation.

Maintenance

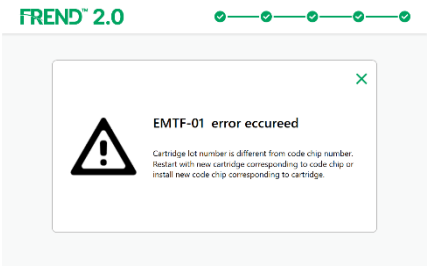
Cleaning and storage

- Do not clean the FREND™ 2.0 with strong or caustic cleansing agents, chemicals or cleansing tissues impregnated with chemicals.
- Use a soft and dry cloth to clean the FREND™ 2.0.
- For safety reasons, disconnect the power supply from the main outlet and remove the power adapter device from the FREND™ 2.0.
- If you want to store for a lengthy period, keep the FREND™ 2.0 covered in a dry place.
- Do not expose the device to direct sunlight.
- Recommended storage conditions are as follows:
  - Temperature: 10–40 °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.
- Maintain device cleanliness for its next use.
- Operate the device by lifting it cautiously and placing it down gently to prevent any impact.
- Refrain from placing heavy materials on the device.
- In storage, envelop or shield the device to safeguard it from dust.

Trouble-shooting

If the FREND™ 2.0 malfunctions, please check the following before you contact Customer Support.

Error window on the FREND™ 2.0



Error list

■ **Cartridge insertion issues**

Error code	Cause	Solution
EMCI-01	You did not insert the cartridge in 30 seconds.	Insert the cartridge.
EMCI-02	The motor started to run after inserting the cartridge, but it was not fully inserted.	Insert the cartridge completely.
EMCI-03 EMCI-04	The cartridge is inserted upside down or reversed.	Re-insert the cartridge correctly. After insertion, check to make sure the cartridge is properly and correctly inserted.

■ **Barcode issues**

Error code	Cause	Solution
EMBR-01	The barcode printed on the cartridge may have been damaged so the reader is unable to interpret the code correctly.	Manually enter the LOT number of the cartridge using the keypad or replace it with a new one.
EMBR-02	The barcode information related to the cartridge lot number printed on the cartridge is not readable by the system reader.	
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.

Trouble-shooting

Update issues

Error code	Cause	Solution
EMUF-01	There is no executable file on the USB drive.`	Save the executable file, “Frend2Update_X.X.X.fndpkg”, transfer it to the USB drive and then retry the update process.
EMUF-02	Update failed during the process.	The update file may be damaged. Try again with using a new flash drive and update file.

Data backup issues

Error code	Cause	Solution
EMDB-01	Update failed during the process	Please check whether the flash drive meets the requirements of the FREND™ 2.0. Also, ensure that the flash drive is properly connected to the device.
EMDB-02	A problem has been detected when attempting to transfer data from the FREND™ 2.0 to the USB drive.	Check the connection of the USB port and USB. If the same problem occurs, contact your dealer or the manufacturer.

Data save issues

Error code	Cause	Solution
EMDS-01	The storage capacity of the FREND™ 2.0 to store the data has been exceeded.	Back up the data stored in the FREND™ 2.0 to a USB drive. Then, delete the data stored in the FREND™ 2.0.

Code chip install issues

Error code	Cause	Solution
EMCC-01	The code chip is not inserted properly.	Make sure that the code chip is inserted correctly in the direction of the arrow and push the code chip in until it sounds ‘click’.
EMCC-02	The FREND™ 2.0 does not recognize the code chip.	Check that the code chip is correctly inserted, and restart the code chip installation. If the same problem occurs, contact your dealer or the manufacturer.

Trouble-shooting

■ Test result issues

Error code	Cause	Solution
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.
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 insert the cartridge into the system. If the problem is repeated, try a sample from a different source (different patient). If the problem continues, contact your dealer or the manufacturer.
EMTF-03	Unable to output a test result because the reference signal is stronger than the baseline.	
EMTF-04	The system cannot detect any signal.	The sample may not be loaded or the sample may not be flowed due to air bubbles. After checking, restart the test with the new cartridge.
EMTF-05	The system detects more than five signals.	Foreign substance (dust) inside the cartridge may cause unintentional signals. Restart the test with the new cartridge. If the same problem occurs, contact your dealer or the manufacturer.
EMTF-06	The lateral flow of the sample within the cartridge is incomplete.	
EMTF-07	The lateral flow is not completed after the specified time. (Time-out error)	Check if there is insufficient sample volume, air bubbles in the sample, whether the pipette is defective, or if the specimen is loaded in the wrong place.
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.

■ Test mode matching issues

Error code	Cause	Solution
EMMF-01	Different type of cartridge is read in QC Cartridge Mode	Read QC Cartridge in QC Cartridge Mode.
EMMF-02	QC Cartridge is read in the different mode	Use the QC Cartridge in the designated Mode.

General specification –normal environmental conditions

Electrical rating	Voltage	AC 100–240 , 1.7A
	Frequency	50 / 60 Hz
Electric input (Adaptor)	Voltage	DC 12 V
	Current	5.0 A
Dimensions	276 mm x 263 mm x 202 mm (W x L x H) 10.9 inch X 10.3 inch X 7.9 inch	
Weight	3.4kg (7.5 lb.)	
Optical Power (Laser)	Class 1 laser product (IEC 60825-1:2014)	
	Wavelength	635 nm
	CW Out Power	Max. 25 mW
User interface	Active screen size	8.0 inches diagonal dimension
	Pixel format	1920 x 1080, Capacitive Touch
Printer	Printing speed	50 mm/sec
Environmental suggestions for optimal performance	Do not place the unit in direct sunlight.	
	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.	
	Operating condition: Temperature: 10–40 °C, Humidity: 10 %–80 %	
	Storage condition: Temperature: 10–40 °C, Humidity: 10 %–80 %	

Installation Condition

1.1 Indoor use (For outdoor use, a protective case must be manufactured and attached inside to use)
1.2 Altitude : 2,000m or less
1.3 Ambient temperature: 10–40 degrees or less (When used outdoors, the temperature control device inside the protective case should be designed to be within the appropriate temperature range)
1.4 For a temperature below 31°C, which decreases linearly from an ambient temperature of 40°C to a relative humidity of 50%, the maximum relative humidity should be 80%
1.5 Mains supply voltage fluctuations Nominal voltage must be less than ±10%
1.6 Transient overvoltage should be below the overvoltage category I
1.7 Temporary overvoltage from mains supply equipment
1.8 The degree of pollution in the intended condition (in most cases, the degree of pollution is 2)

Maintenance

Customer support information

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As this product is distributed globally, please be aware that customer support services differ based on geographical regions. Upon shipping the FREND™ 2.0, you will receive information containing the relevant telephone numbers, fax numbers, and email addresses for obtaining support specific to your geographical region.

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FREND™ 2.0

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NanoEntek

NanoEntek, Inc.
851-14, Seohae-ro, Paltan-myeon, Hwaseong-si
Gyeonggi-do, 18531, Korea
Tel: +82-2-6220-7940 / Fax: +82-2-6220-7999

US Corporation
NanoEntek America, Inc.
220 Bear Hill Road, Suite 102, Waltham, MA 02451, USA
Tel: +1-781-472-2558 / Fax: +1-781-790-5649

European Corporation
NanoEntek Europe I mts med-tech supplies GmbH
Lochhamerstr. 4a, 82152 Martinsried, Germany
Tel: +49-89-21-55-38-43 / Fax: +49-89-99-95-46-60

EC REP
MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

UK Representative
MT Promedt Consulting Ltd.
First Floor, Park Central, 40-41 Park End Street
Oxford OX1 1JD, United Kingdom

E-mail
ivdst@nanoentek.com

Website
www.nanoentek.com