



CHR-631W

Rapid Test Reader

User Manual

V2.0 (EN)

Published: 2023/12/28



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Document Amendment History

Revision Date	Version	Description
2020/06/01	1.6	Add feature toggling for qualitative and quantitative
2023/12/28	2.0	1.Add Lithium Battery Hazard Description and Reporting of Serious Incidents 2.Add Instructions for Using Calibration Device 3.Renew intended use 4.Add WIFI settings (WIFI version only) 5.Add verification 6.Add analysis process 7.Add electronic version of instruction for use download link 8.Add UDI barcode paste area

1. Introduction

1.1 Precautions

DANGER

Inappropriate use of electronic reader can cause electrocution, burns, fire and other hazards. Basic safety precautions should always be taken, including all those listed below. Close supervision is necessary when reader is used by, on, or near, handicapped persons or invalids.

This device contains a pack of 18650 lithium batteries. Lithium batteries can overheat and release flammable gases if they are punctured, crushed, or overcharged. To prevent fire or explosion, do not: expose the batteries to heat or fire, puncture, crush, or disassemble the batteries, overcharge the batteries, and dispose of the batteries in a fire or in a conventional trash receptacle.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Read Before Using the Reader

1. Check that the voltage setting matches the supply voltage referring to chapter 8 (7).
2. Unplug the reader immediately after use.
3. Do not place the reader in liquid, nor put it where it could fall into liquid. If the reader becomes wet, unplug it before touching it.
4. Use the reader only for the purpose described in the instructions for use.
5. Do not use accessories which are not supplied or recommended by the manufacturer.
6. Do not use the reader if it is not working properly, or if it has suffered any damage.

NOTE: Examples of typical defects include:

- 6.1. Damage to the flexible supply cord or its plug;
 - 6.2. Damage caused by dropping the reader;
 - 6.3. Damage caused by dropping the reader into water or splashing water onto it.
7. Do not let the reader or its flexible cord come into contact with surfaces which are too hot to touch.
 8. Do not block air openings or place reader on a soft surface which might block them, and keep air openings free from lint, hair, fluff, etc.
 9. Do not place anything on top of the reader.

10. Do not use the reader where aerosol sprays are being used, or where air is being administered.
11. While using the reader, it may be affected by the static electricity and cause the screen to flicker temporarily, but it is only a temporary phenomenon and will not affect the use and function of the reader.
12. Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base units, and walkie-talkies, may affect this product. Therefore, this product should be kept at least 30 cm away from these devices.
13. The calibrators for the reader are intended for use with a specific instrument and should not be used with any other instrument. The calibrators for the reader have a shelf life of 12 months. Please follow the instructions on 4.6.6 Camera Calibration and 4.6.10 Machine Calibration when using the calibrators for the reader.
14. This product has passed RoHS testing and complies with relevant regulatory requirements. To dispose of used reagents or this product, follow the local regulations for the disposal or recycling of in vitro diagnostic medical waste. Do not dispose of it casually, as it may lead to environmental pollution.

WARNING

FCC ID: **VGG-KWCHR006**

This device complies with Part 15 FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are

designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

When using the product, maintain a distance of **20 cm** from the body to ensure compliance with RF exposure requirements.
















1.2 Intended Use

The CHR-631W Rapid Test Reader can grab and store reaction photos of lateral flow immunochromatography reagents, perform image analysis with numerical calculations based on the parameters provided by the reagent manufacturer, and deliver calculation results in qualitative, semi-quantitative, or quantitative formats depending on the intended use of the reagent. This versatile device finds application in various fields, including disease diagnostics, drug abuse testing, fertility assessment, and food safety analysis. In essence, the Rapid Test Reader serves as a comprehensive detection platform for a wide range of rapid test applications.

The intended users of this device are medical laboratory scientists, doctors, health care professionals or other professionals.

This model is suitable for reading the color results for single test strip style colloidal gold fast screening reagent cassette. This model has built-in Android operating system and battery, belong to portable handheld reader.

1.3 Symbols description

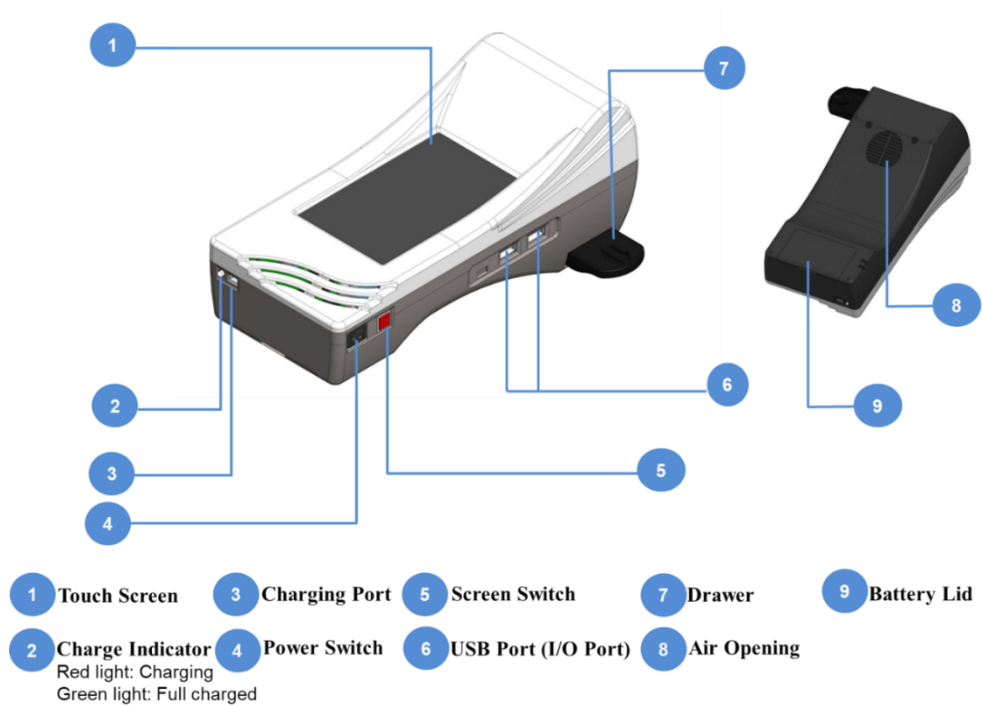
	Caution, consult accompanying documents		Manufacturer
	in vitro diagnostic device		Temperature Limitation
	European Authorized Representative		CE mark
	FCC declaration of conformity		This side up
	Handle with care		Keep dry
	Fragile		Keep away from sunlight
	Date of manufacture		Refer to instruction manual/booklet before use
	The symbol indicating separate collection for electrical reader consists of the crossed-out wheeled bin. When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.		

2. General Description

2.1 Principles of analysis

This reader captures the reaction results (color image) of rapid test reagent by a camera followed by using the image analyzing technology to distinguish the color information of the reaction area (C line and T line) and background area. The preset geometric position parameters are used to predict the positions of C and T lines of the rapid test reagent. Within the region of possible positions of the C and T lines, find out the most suitable coloring position of the reaction line by using image analysis method. The values of gray scale (color information) of C and T lines are then analyzed, averaged, and shown as RLU (Relate Light Unit). Using the preset valid/invalid threshold parameters, RLU cutoff parameters, and concentration cutoff parameters providing by the reagent manufacturer, the test data can be interpreted as negative/positive/invalid. Using parameters such as product name, batch number, and expiration date, the batch number management of reagents can be performed. These parameters, even the concentration curve table (RLU vs. concentration of the analyte), are stored in the QR code. If further concentration conversion is required, the measured RLU value is substituted into the concentration curve table for interpolation, and the corresponding concentration value can be obtained.

2.2 Hardware



2.3 Software

- 1) . The software is designed to run and control the reader, perform testing, save the results, print the results, upload the results, and download the QR code information. Client Management APP is designed to manage test result via PC.
- 2) . Software version: 1.7.0.0

2.4 Calibration Device Set

The calibration device set consist of 3 plastic cassettes with different colors printed on them. The colors printed on the calibration devices have been confirmed by a color analyzer. This analyzer is calibrated every year by the reference white board (S/N 18733112) in National Measurement Laboratory, R.O.C..

2.5 Contents of the package

Item	Quantity
CHR-631W Rapid Test Reader Device	1
CHR-631W User Manual	1
CD-ROM with Client Management App	1
Power Supply	1
Calibration Device Set	1 Contents: Camera Calibration x1 Machine Calibration 1 x1 Machine Calibration 2 x1
Battery	18650 Lithium battery pack x1

3. Installation

3.1 Environment

3.1.1 Operation environment

Prevent to operate CHR-631W under sunlight or near the places with high temperature because strong sunlight or high temperature might influence tests and cause more deviation of test results.

3.2 Preparation

3.2.1 Unpacking

Unpack the box and take the reader out of the inner air bag and place it on a stable and flat desk or surface.

3.2.2 Power supply options

- Battery powered: Install rechargeable batteries referring to chapter 3.3. Charge the batteries till the charging indicator turns to green before first testing.
- External power: Connect external 5V power supply to the charging port. (Refer to chapter 2.2.)

3.2.3 Connecting Accessories (Optional)

- Thermal Printer: Press power button of thermal printer for 2 seconds to power it on. Connect it to the USB Port of CHR-631W or by Bluetooth connection. (Refer to chapter 2.2)
- External barcode reader: Connect the USB barcode reader to the USB port to scan the sample ID. (Refer to chapter 2.2.)
- USB- RS232 cable: Connect USB-RS232 cable to the USB port (Refer to chapter 2.2)

3.2.4 Language Setting

Refer to 4.6.1.

3.2.5 Time setting

Refer to 4.6.3.

3.2.6 Station setting

Refer to 4.6.4.

3.3 Batteries Installation

The reader has provided with a rechargeable battery pack. When user needs to replace the battery, please follow the steps below:

Step 1: Place the bottom of the reader face up on the table (be careful not to place it on a rough table to avoid scratching the surface of the reader). Remove the battery lid. (Figure 1)

Step 2: Connect the connector of battery to the connector from the reader. (Figure 2)

Step 3: Store the cable in the side space of the reader. (Figure 3)

Step 4: Put the battery into the reader and make sure to put it in the correct direction. (Figure 4)

Step 5: Put the battery lid on. (Figure 5)



Figure 1

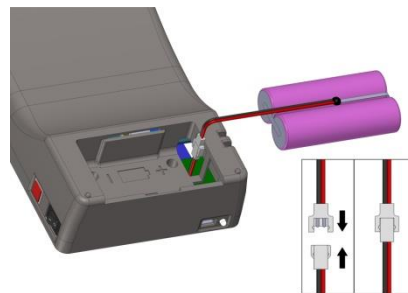


Figure 2

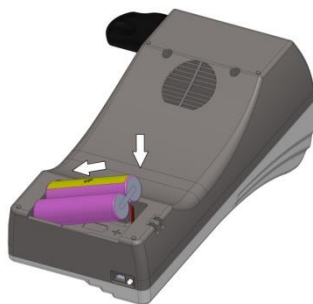


Figure 3



Figure 4



Figure 5

WARNING:

1. The battery is a consumable product. If the electric power storage time is too short after the battery is fully charged, please contact your supplier to purchase and replace the lithium battery pack with a new one.
2. If this reader is unlikely to be used for a period of time, please remove the battery pack from the reader.

4. Operation of CHR-631W

4.1 Turn on the reader

To turn on the reader please press power switch.

4.2 Check battery power status





4.2.1 First time usage:

Suggest plug in power supply to charge the battery till charge indicator turns to green.

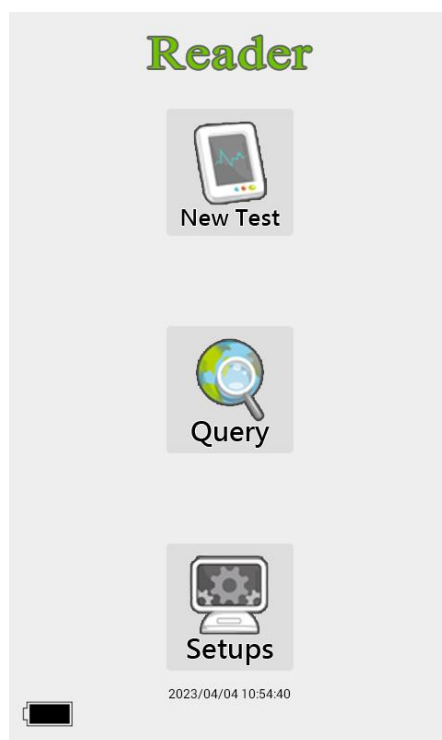
4.2.2 Operating:


Suggest plug in power supply to charge the battery if battery power is under 25%.



Mode	Reference
	Around 100% battery power
	Around 50 % battery power
	Around 25% battery
	Empty

4.3 Main Menu

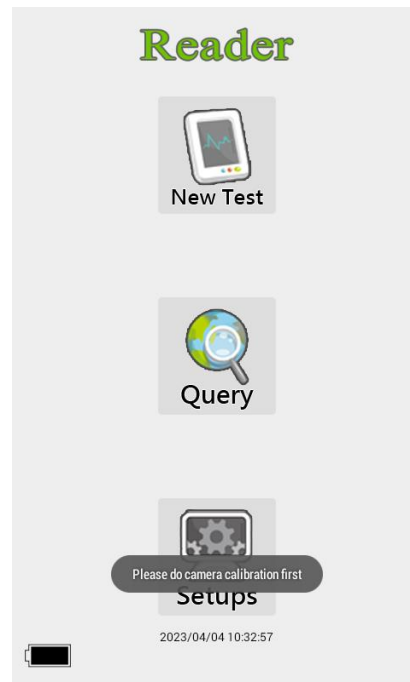


Mode	Reference
New Test	See Chapter 4.4
Results	See Chapter 4.5
Setup	See Chapter 4.6
	See Chapter 4.2

4.4 New Test

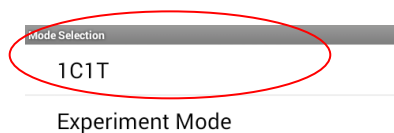
In the case of calibration is passed, the button of “New Test” will turn green, press “New Test” to run test.

Attention: In the case of calibration is failed or the calibration performed last time has already over 24 hours, the button of “New Test” is disable, need to be corrected.



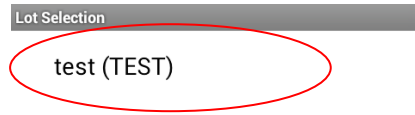
4.4.1 Read Mode

1) . Mode Selection



2) . Lot Selection

Existing Lot numbers are listed in the screen. Please choose the number in accordance with the one on foil pouch or plastic case of test cassette.



Attention:

- In the case of you cannot find proper lot number, please add new lot referring to chapter 4.4.2.
- In the case of some lot numbers are useless, press "Delete lot", and choose useless lot number and press "Delete" to delete it.

Lot Selection	Lot Selection
DEMO (A)	DEMO (A) <input type="checkbox"/>
DEMO (B)	DEMO (B) <input type="checkbox"/>



3) . Key in test information and press “OK”.

Test Informations:

ID

Name

OK Back Home

4) . Result will be shown out, please choose “Print” or “New Test” to get report or process next analysis. Press “Home” to go back to Main menu.

Analysis (ID:, Name:)

Test now

Message

Analyzing...

57%

Cancel

CHR-631

2023-11-27 15:06:31

ID:
Name:
SN device: CHR-6311
ID/LOT: TEST/Demo
Exp. Date: 2023-11-16
Location:

T1-1: 37.08 RLU Positive(+)

Cutoff:
C1: 10.0 RLU
T1-1: 10.0 RLU

OK Back Home Print New Test Home

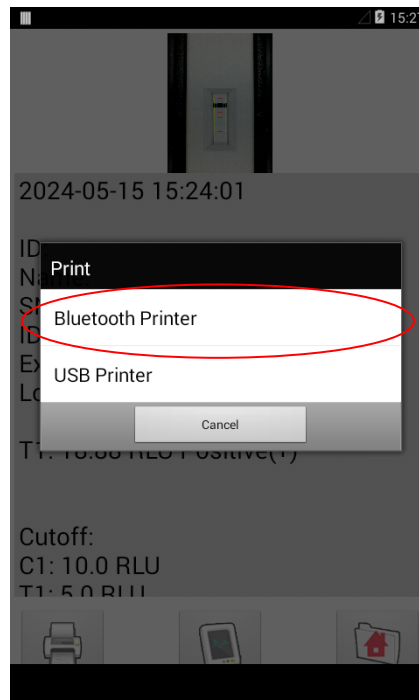
5) . USB printer printing (Optional)

Press the power button to turn on the printer. Connect the printer and the reader with a USB cable, then select "USB Printer" and print.

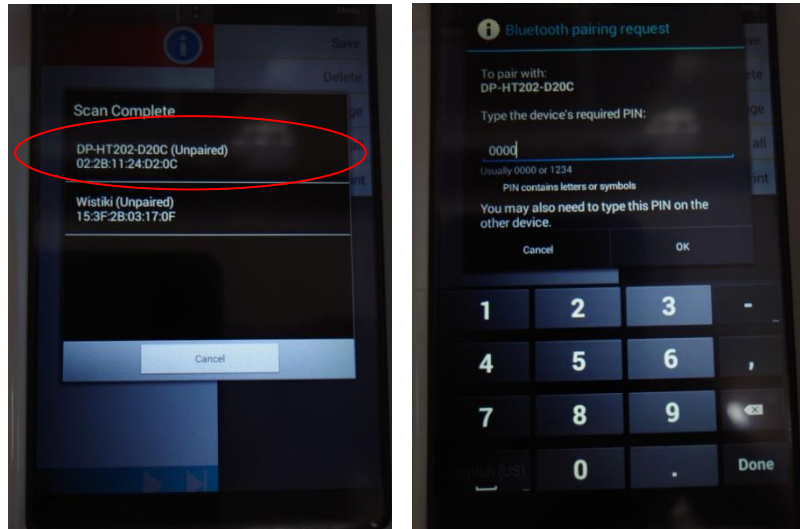


6) .Bluetooth printer printing (Optional)


Press "Print" and select "Bluetooth Printer". The reader will start searching for the printer.



The reader will scan for nearby Bluetooth devices. Select "DPHT202-XXXX" and enter "0000" to start pairing. Once paired successfully, the screen will return to the previous menu. Select "Bluetooth Printer" again and print.



4.4.2 Add New Lot Mode

- 1) . Put QR code into the drawer, press “ New Test”, then press “” in the bottom right, make sure QR code is in the square frame, the frame will turn to green from red and directly go into choose cassette model while reading is successful.

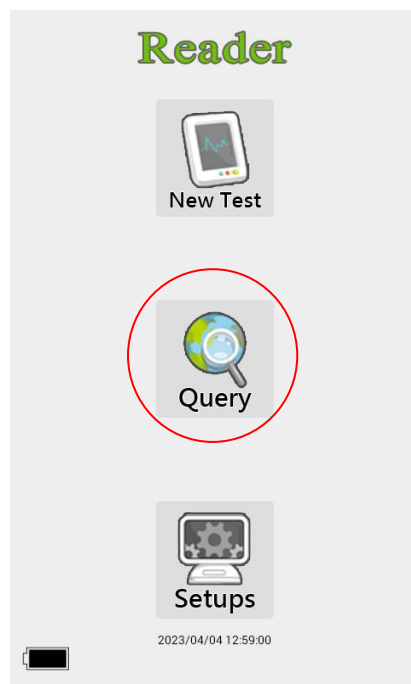





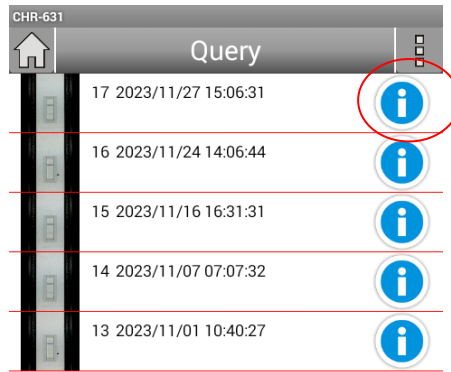
4.5 Results

4.5.1 View results.

1) . Press "Query".

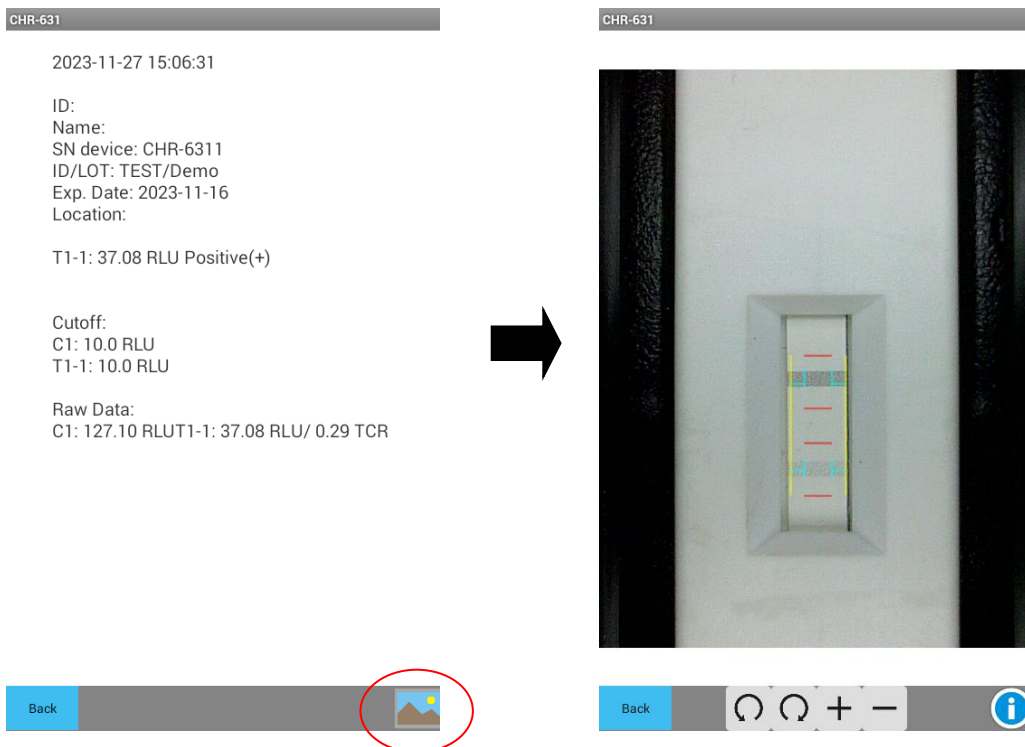


2) . Press " " to view the measure result of the single selected data.

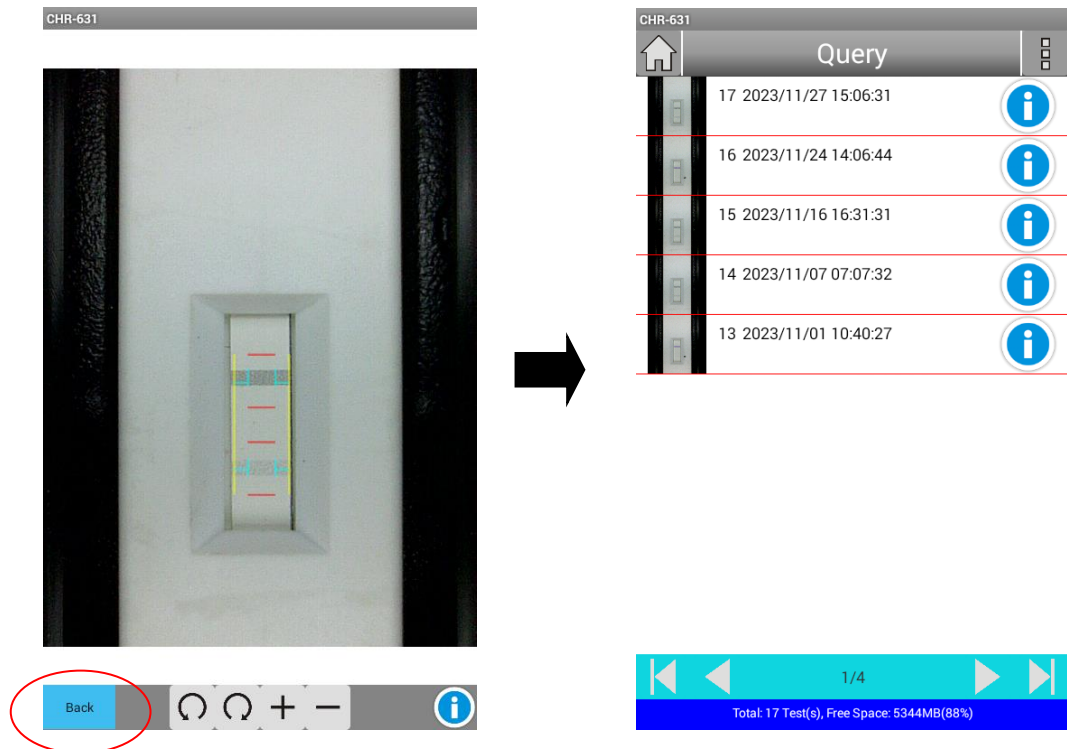


3) . The measurement result of the selected data will be presented on the screen.

Press “Show Photo” to view photo of test.



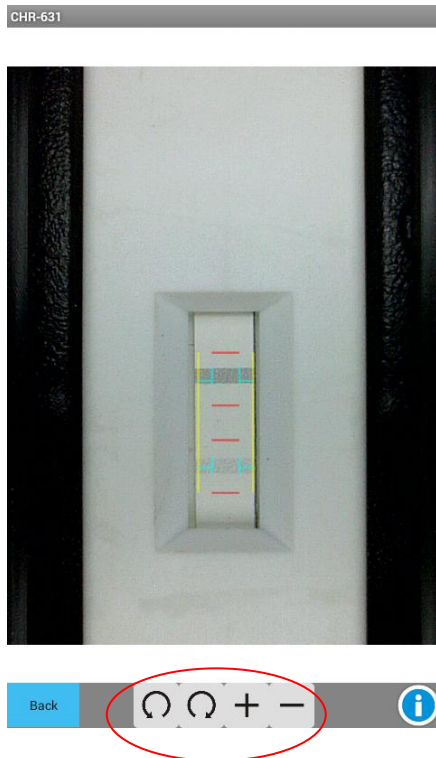
4) . Press “Back” to return to the previous page.







5) . Press “ ” to view measurement result.



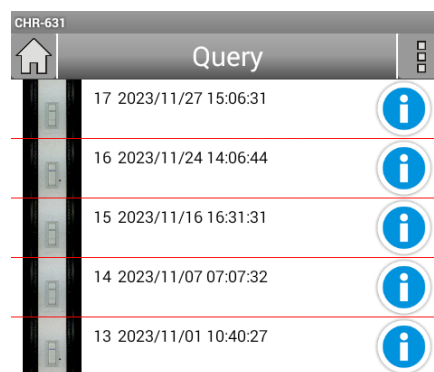
6) . Press function bar under the photo to view the photo in different ways.




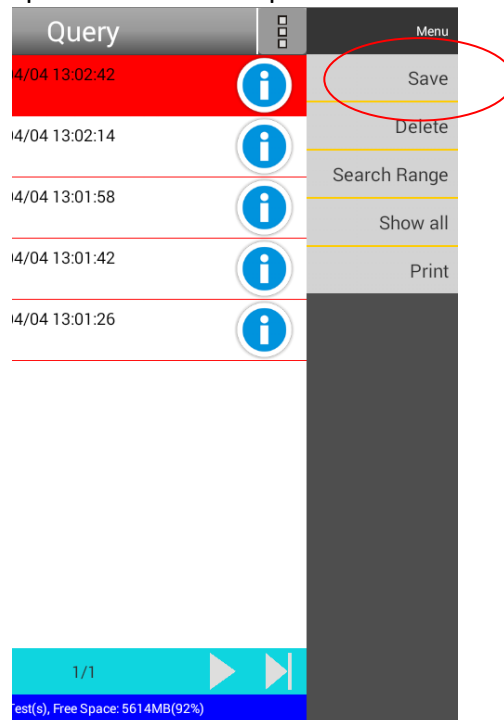
	Rotate left
	Rotate right
	Enlarge
	Downsize

4.5.2 Save result.

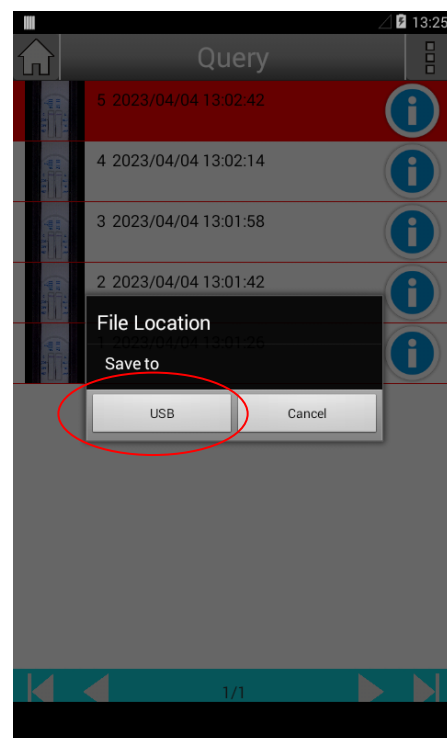
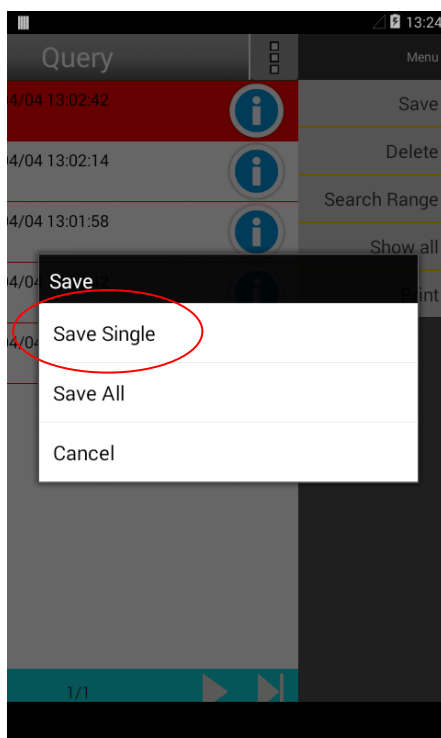
- 1) . Save single data.
 1. Press single data.



2. Press  to drop down menu and press “Save”.

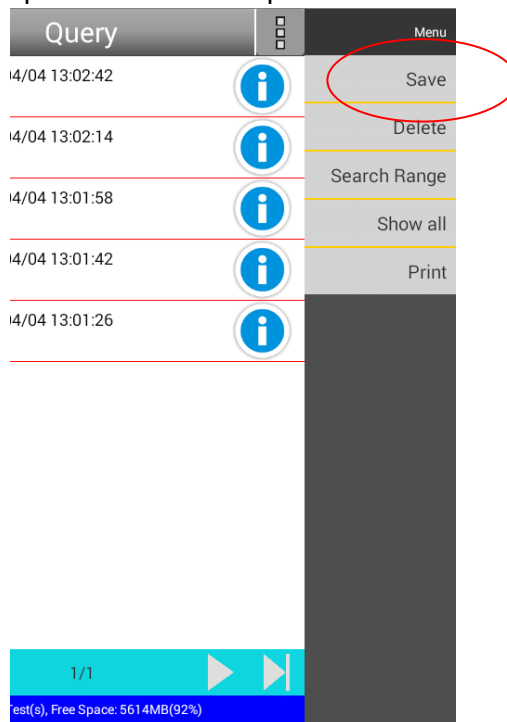


3. Press “Save Single” and then press “USB” to save selected data to USB flash device.

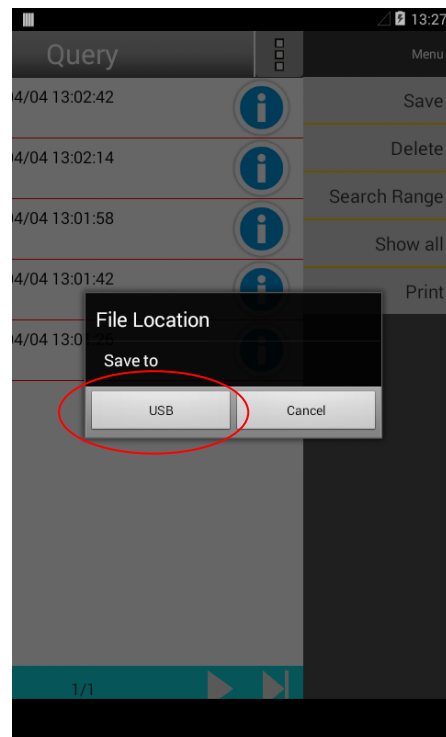
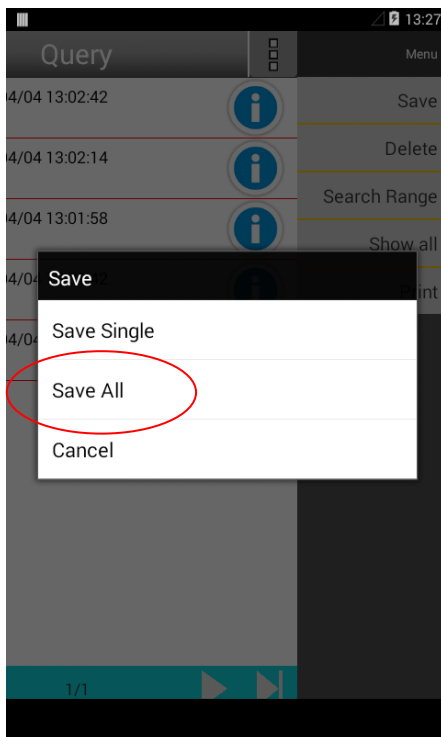


2) . Save all data.

1. Press  to drop down menu and press “Save”.



2. Press “Save All” and then press “USB” to save all data to USB flash device.

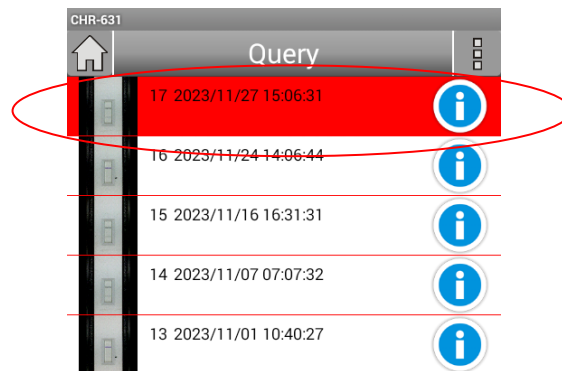


Attention: To analyze the saved data in USB flash device, you can use “Client Management APP” which is provided in the CD-ROM. For instruction, please refer to chapter Appendix A (Client Management App).

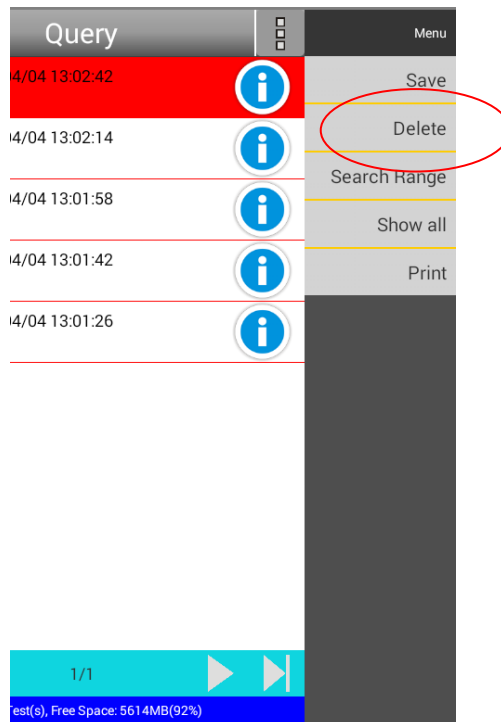
4.5.3 Delete result.

1) . Delete single data.

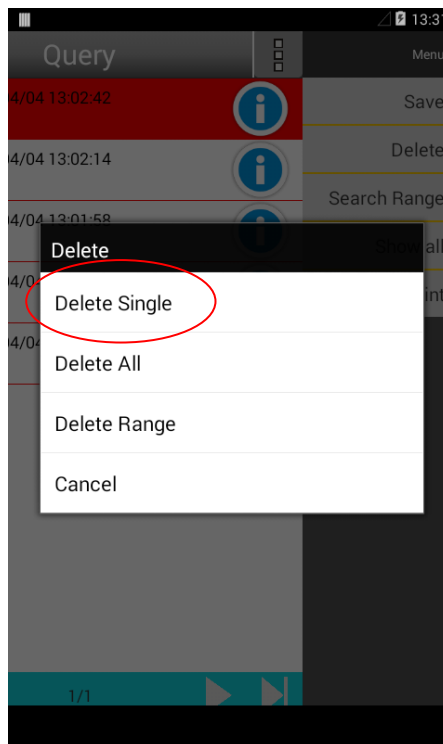
1. Press single data.




2. Press  to drop down menu and press “Delete”.

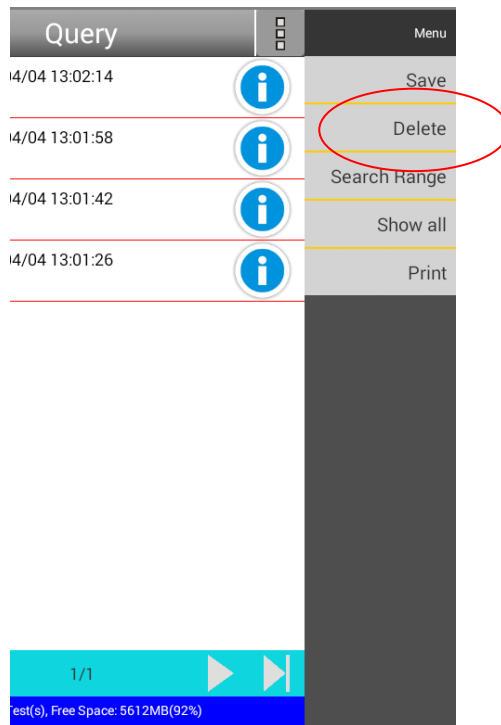


3. Press “Delete Single” to delete selected data.

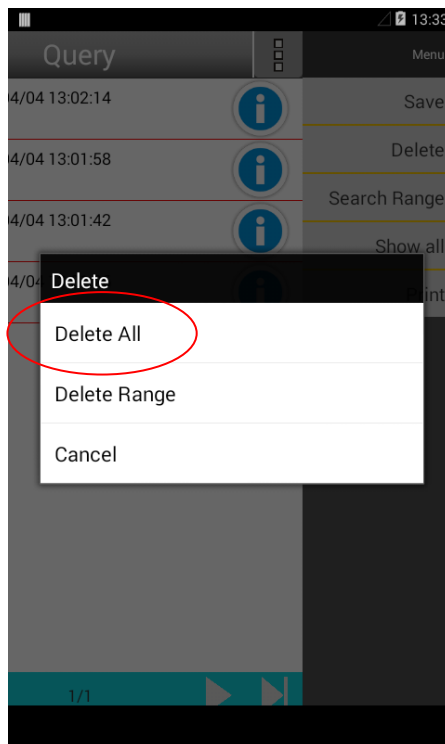


2) . Delete all data.


1. Press  to drop down menu and press “Delete”.

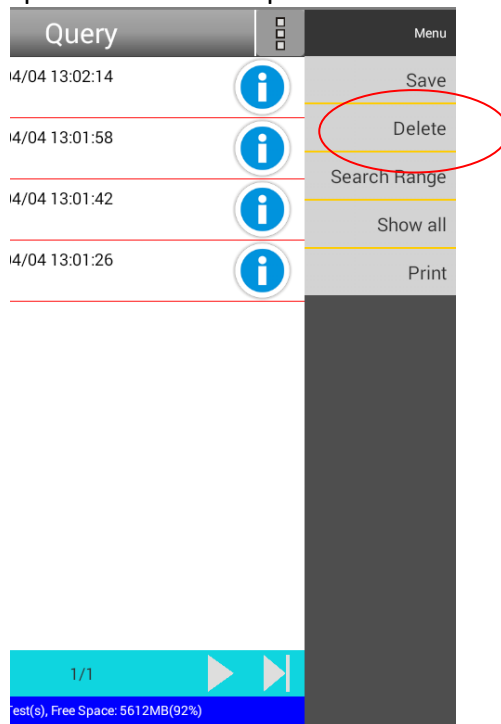


2. Press “Delete All” to delete all data.

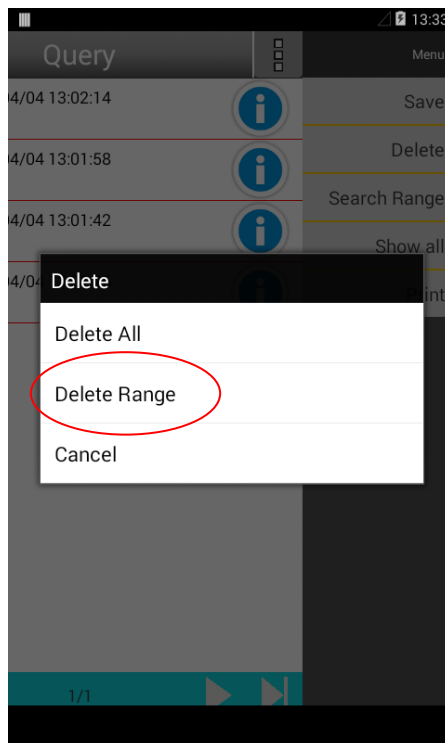


3) . Press "Delete Range" to delete a range of data.

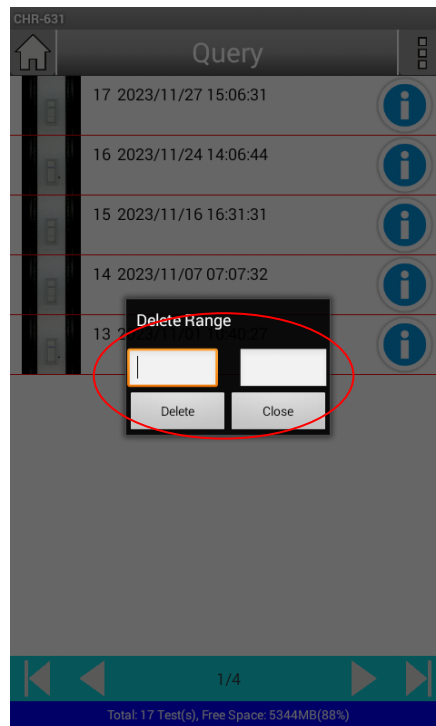
1. Press  to drop down menu and press "Delete".




2. Press "Delete Range".

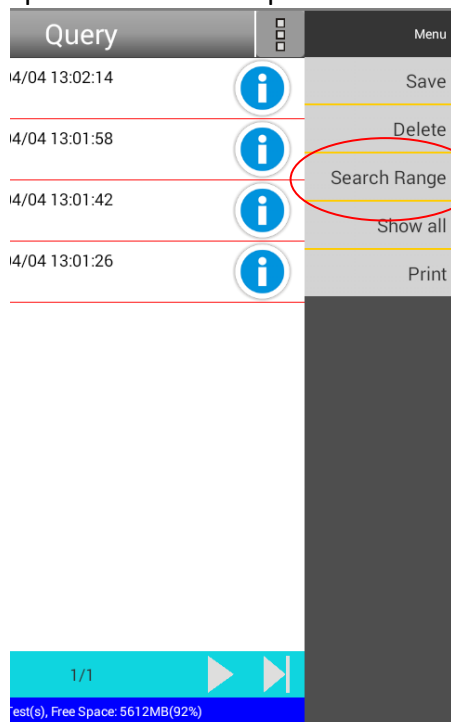


3. Key in serial number to set a sequence of data to delete.

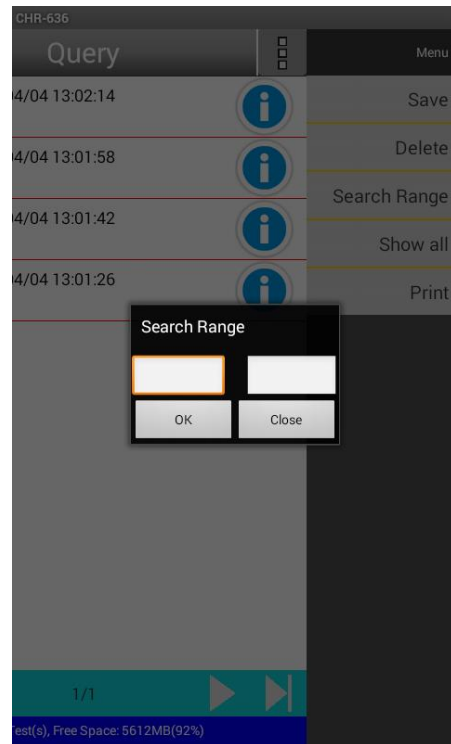
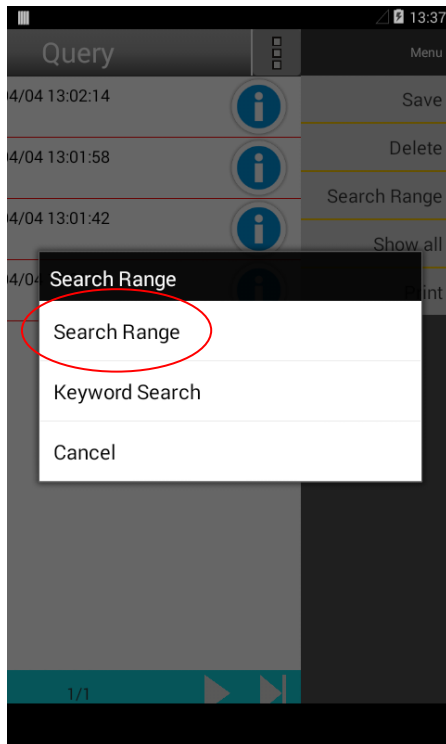


4.5.4 Search result.

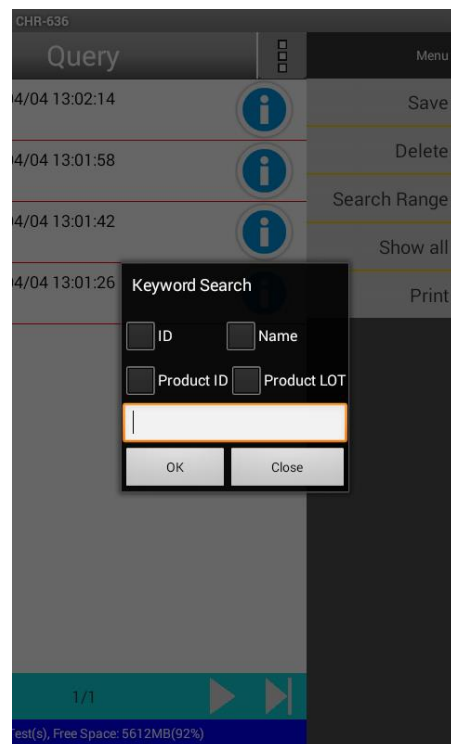
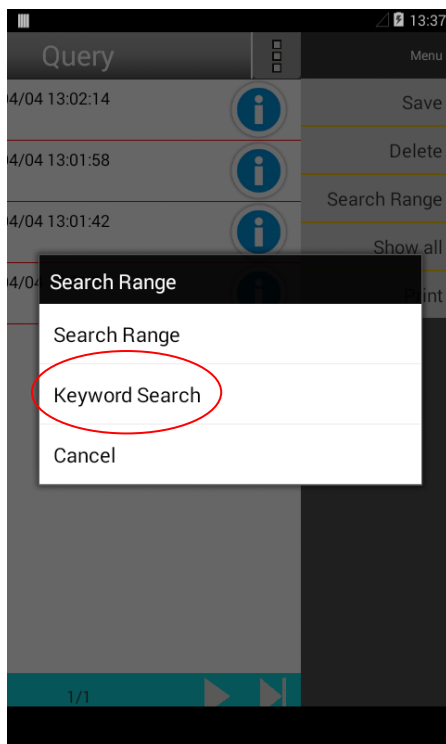
1) . Press  to drop down menu and press “Search Range”.



2) . Press “Search Range” to search data in a sequence by key in serial number of data.

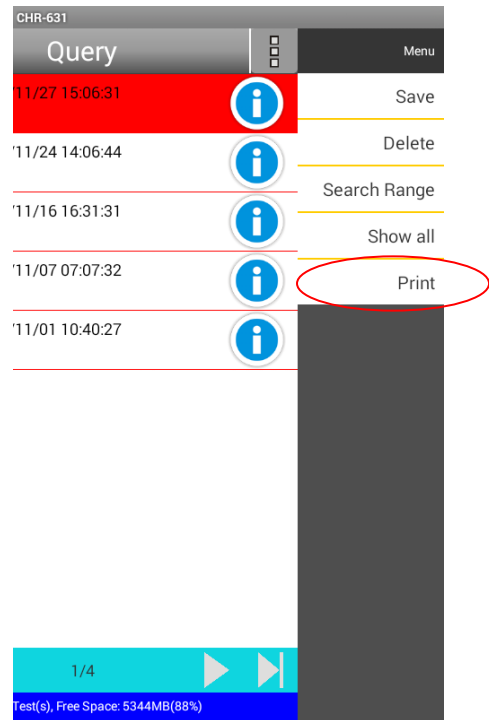
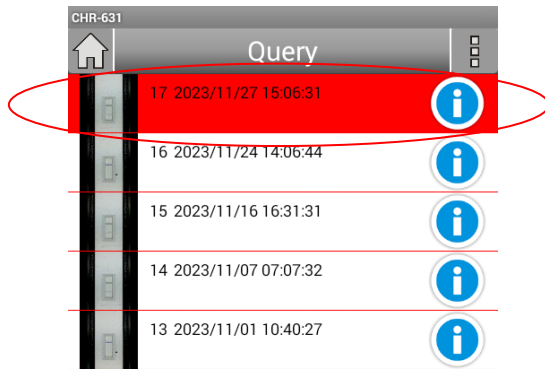


3) . Press “Keyword Search” to search data by keyword.



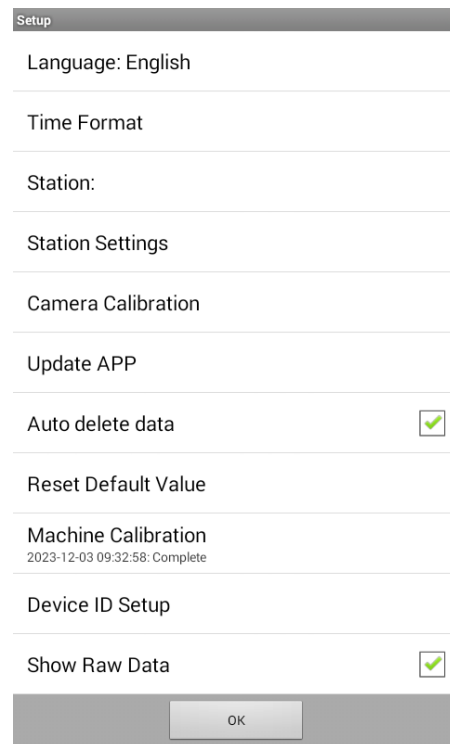
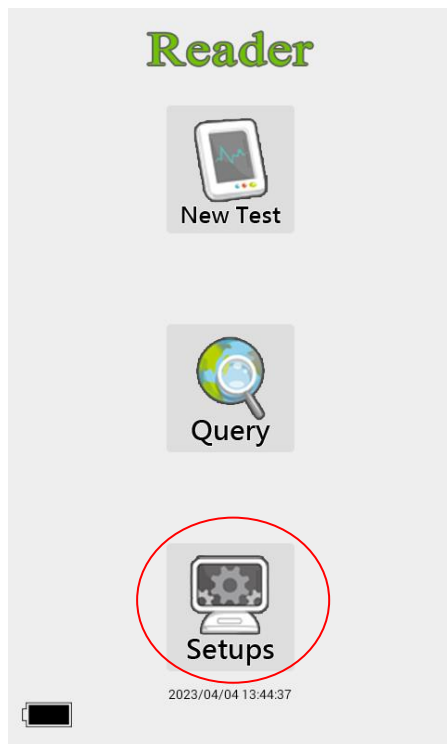
4.5.5 Print result (Optional)

Connect USB or Bluetooth printer and press “Print” to print out the result.



4.6 Setup

1) . Press “Setup” to set up basic functions.



Mode	Reference
Language	See Chapter 4.6.1
WIFI Settings (WIFI version only)	See Chapter 4.6.2
Time Format	See Chapter 4.6.3
Station	See Chapter 4.6.4
Station setting	See Chapter 4.6.5
Camera Calibration	See Chapter 4.6.6
Update APP	See Chapter 4.6.7
Auto delete data	See Chapter 4.6.8
Reset Default Value	See Chapter 4.6.9
Machine Calibration	See Chapter 4.6.10
Device ID Setup	See Chapter 4.6.11

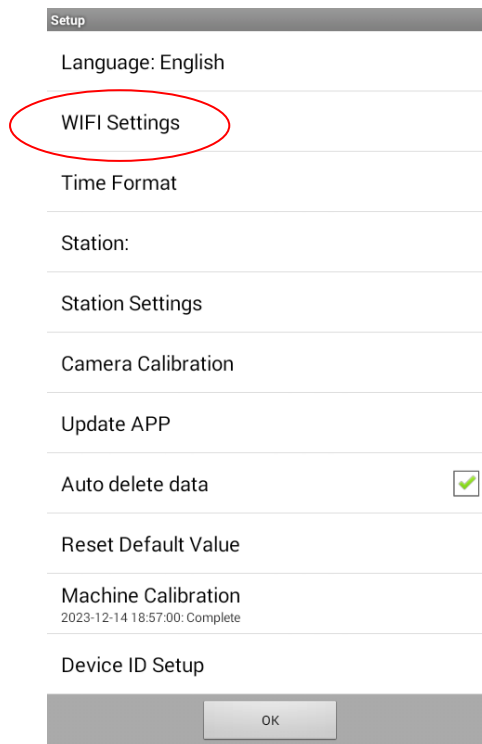
4.6.1 Language Format

1) . Default language: English.



4.6.2 WIFI Settings (WIFI version only)

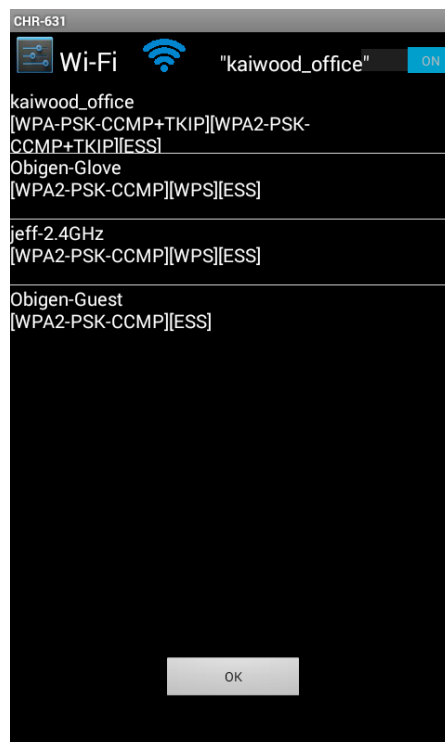
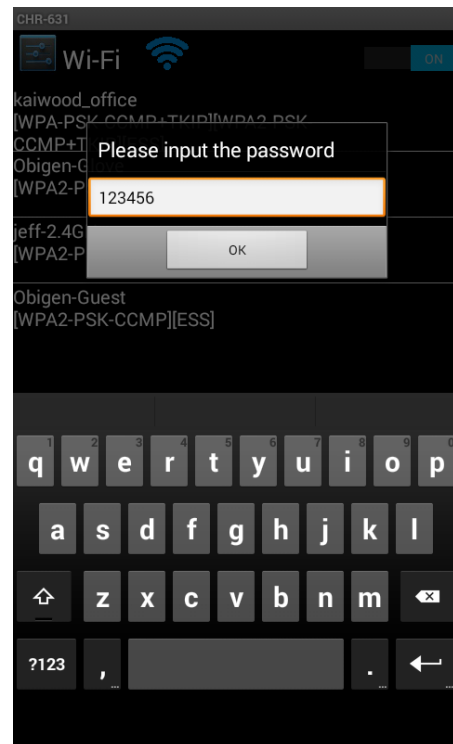
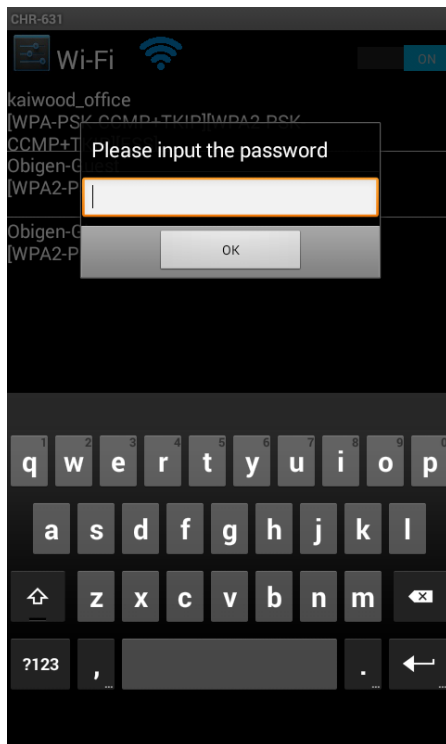
1) . Press “WIFI Settings”.



2) . Switch button “OFF” to “ON”.

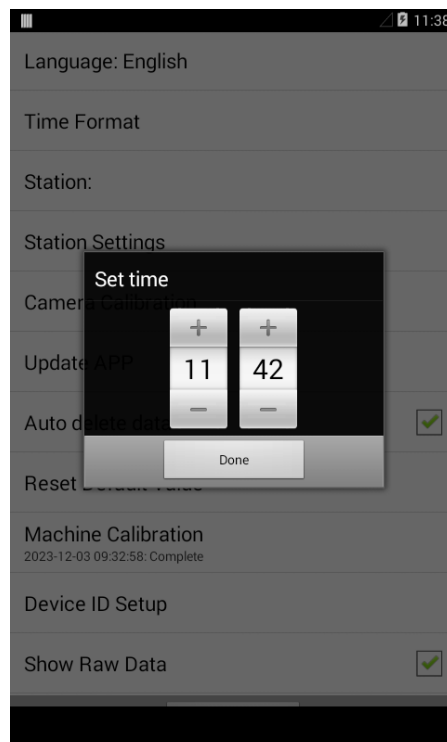
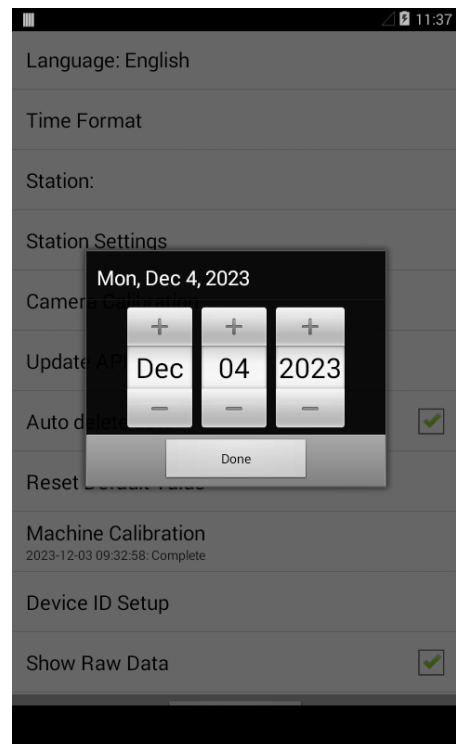
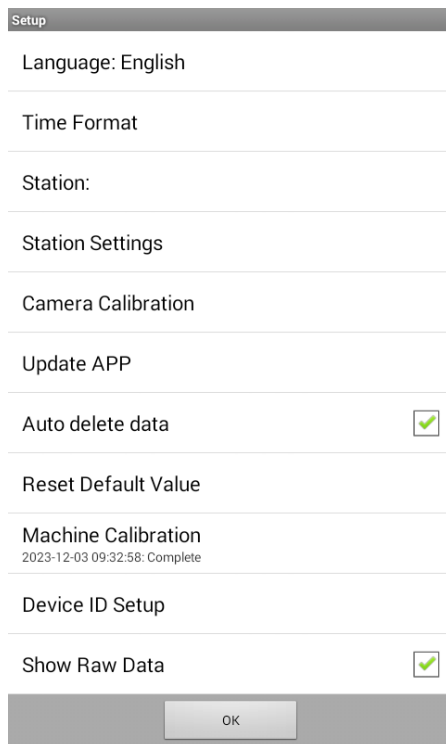


3) . Select WIFI to connect and input the password.



4.6.3 Time Format

1) . Press “Time Format”.

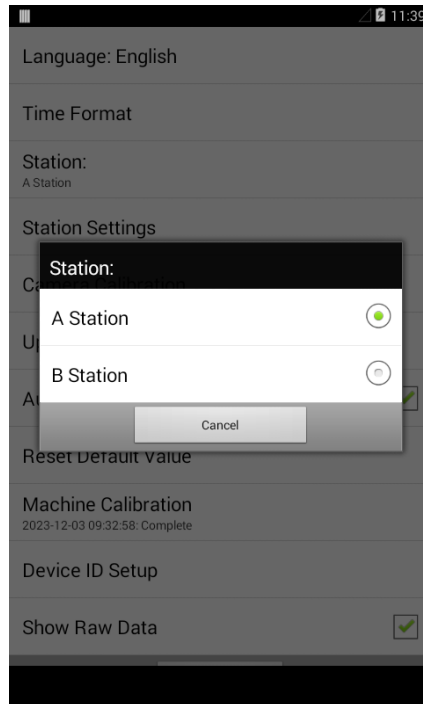


4.6.4 Station

Testing station information will be listed in the test report if station is selected.

If there's no existed station, please go to "Station setting" to key in station information.

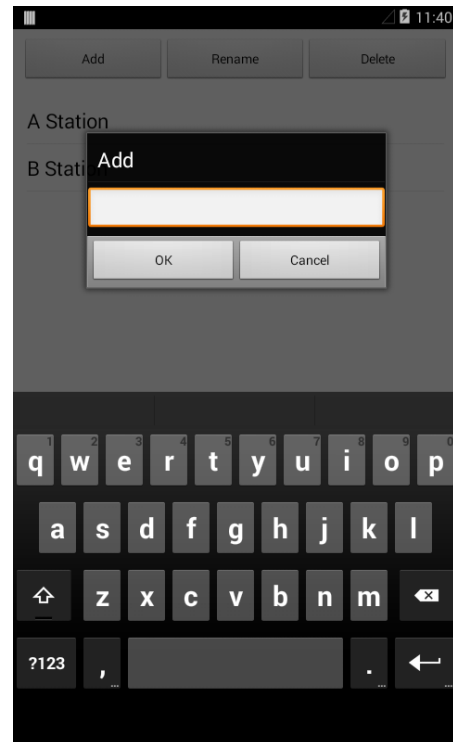
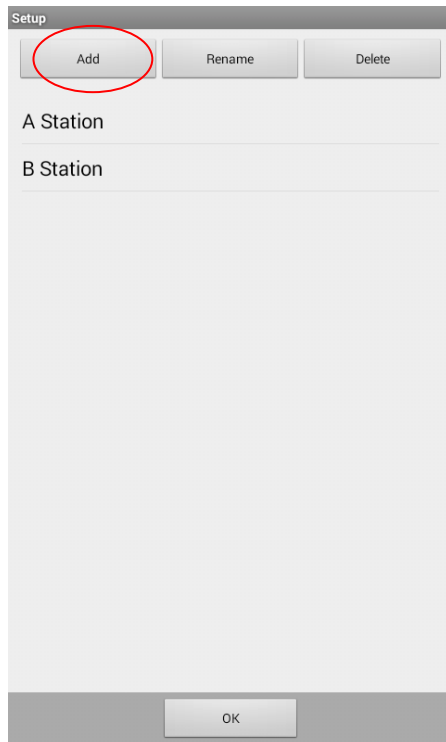
- 1) . Press "Station" to select testing station.
- 2) . Select an existing station if it has been created before.



4.6.5 Station setting

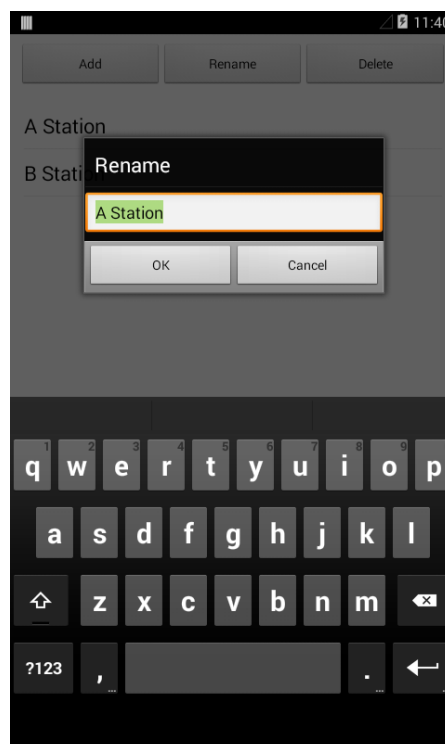
- 1) . Press "Station setting".
- 2) . Add new station.

Press "Add" and key in station name. You can set the station as department or clinical name or location or address, etc.



3) . Rename station.

Select existed station and rename it.

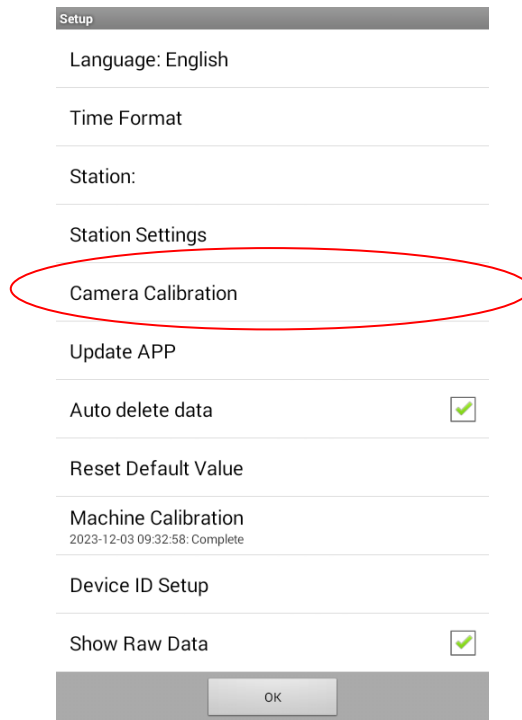


4) . Delete station.

Select existed station and delete it.

4.6.6 Camera Calibration

- 1) . Press “Camera Calibration”.



- 2) . Insert calibration Camera Calibration into the drawer of reader following the direction shown below.
- 3) . Check the yellow line according to the instruction. Make sure the gray rectangle is within the rectangle yellow line.
- 4) . Press “Apply”.

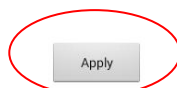
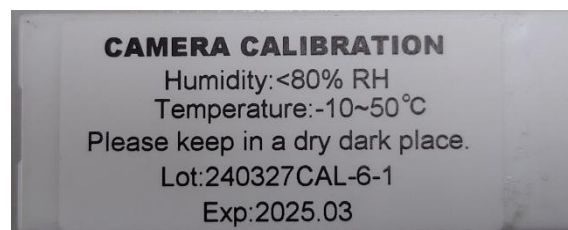


The yellow line should around the Gray Level rectangle!



Reminder:

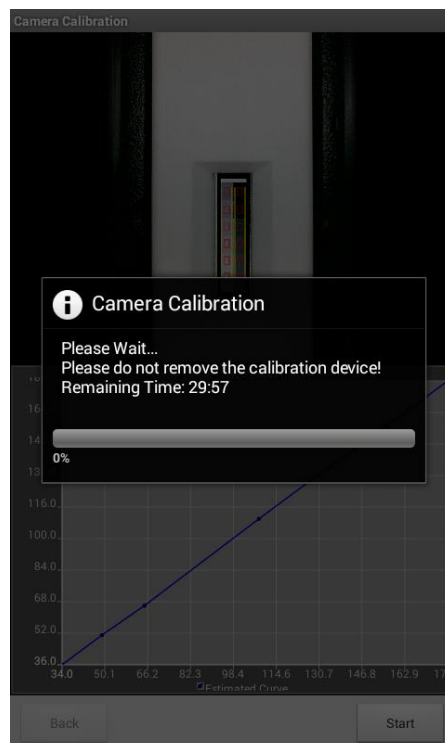
Back of Camera Calibration



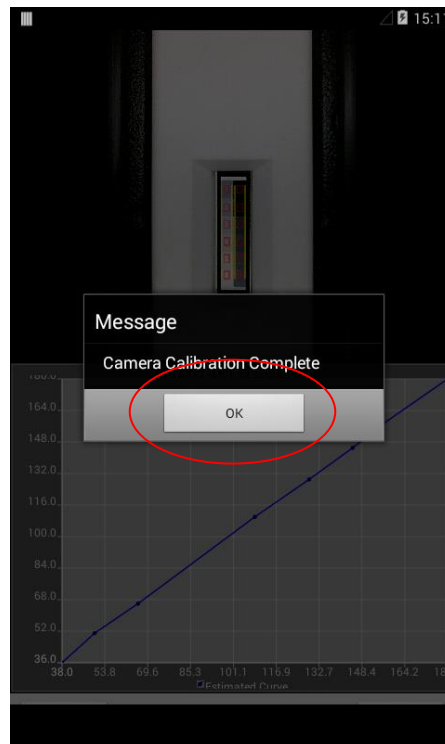
- 5) . Press “Start” to start reader calibration. Or press “Back” to go back to the previous screen.



- 6) . Do not remove Camera Calibration during calibrating.
7) . Wait for Camera Calibration completing.



8) . In the case of Camera Calibration complete, press “OK”.



9) . Press “Back” and “Close” go back to setting page.

4.6.7 Update APP

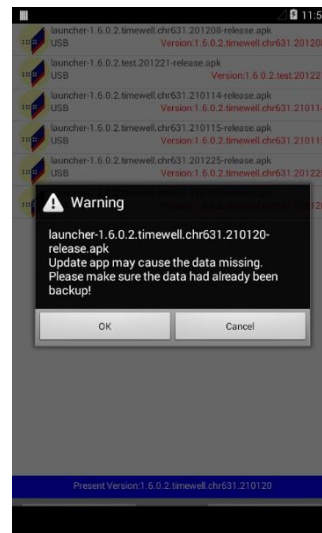
- 1) . Press “Update APP”.
- 2) . Check the up-to-date APP version in the bottom of the screen.

Update APP



3) . Update APP when necessary

1. Save APP file in USB flash device (Do not change name of APP).
2. Connect USB flash device to the USB port of reader.
3. Press “Refresh”, the reader will automatically search APP file from USB flash device.
4. Press the targeted APP, a warning message will pop up on the screen.
5. Press “OK” to update APP.



Attention: Basically, updating APP does not influence analysis data which are already in reader before. However, please back up your data as it may be lost due to an unexpected problem.

4.6.8 Auto delete data

Tick the check box if necessary. The reader will delete the oldest data in the case that reader's memory is full.

Setup

Language: English

Time Format

Station:

Station Settings

Camera Calibration

Update APP

Auto delete data ☒

Reset Default Value

Machine Calibration
2023-12-03 09:32:58: Complete

Device ID Setup

Show Raw Data ☒

OK

4.6.9 Reset Default Value

If reader shutdown abnormally or calibration value abnormal, please press “Reset Default Value” and press “OK” to reset default value.

Setup

Language: English

Time Format

Station:

Station Settings

Camera Calibration

Update APP

Auto delete data ☒

Reset Default Value

Machine Calibration
2023-12-03 09:32:58: Complete

Device ID Setup

Show Raw Data ☒

OK

13:08

Language: English

Time Format

Station:
A Station

Station Settings

Camera Calibration

Update APP

Auto delete data ☒

Reset Default Value

Machine Calibration
2023-12-03 09:32:58: Complete

Device ID Setup

Show Raw Data ☒

Message
Reset Default Value
OK Cancel

4.6.10 Machine Calibration

1) . Press “Machine Calibration”.

Setup

Language: English

Time Format

Station:

Station Settings

Camera Calibration

Update APP

Auto delete data ☒

Reset Default Value

Machine Calibration
2023-12-03 09:32:58: Complete

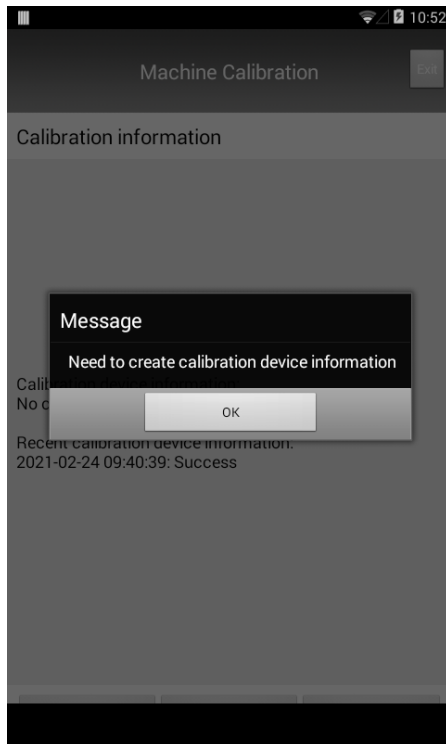
Device ID Setup

Show Raw Data ☒

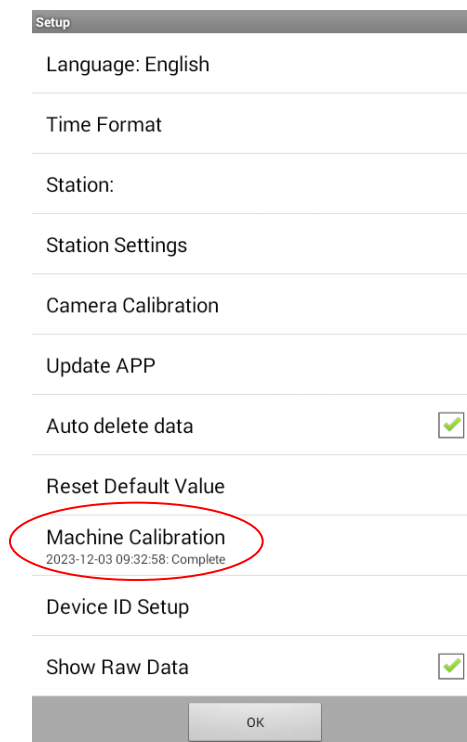
OK

2) . Calibration information shall already be installed in the reader.

However, in the case that reader cannot find Calibration Device information, please insert the Machine Calibration 1 with the back side up. The reader will scan the QR code in the back side of the devices and input Calibration Device information automatically.

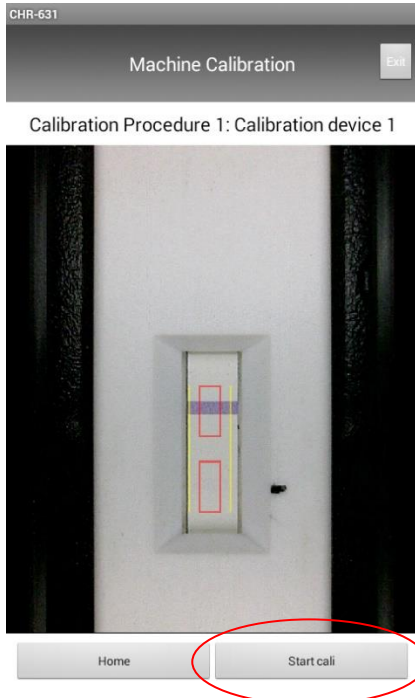


- 3) . Press “Machine Calibration. “Machine Calibration 1 and 2” shall be performed within 30 minutes after “Camera Calibration” is completed.



Insert Machine Calibration 1 into the drawer of reader following the direction shown below.

- 4) . Make sure the two red rectangles are covering each line, and then press "Start cali".

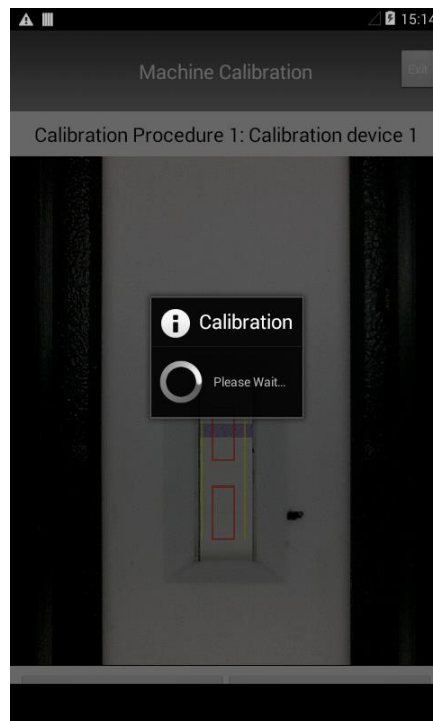


Reminder:

Back of Machine Calibration 1



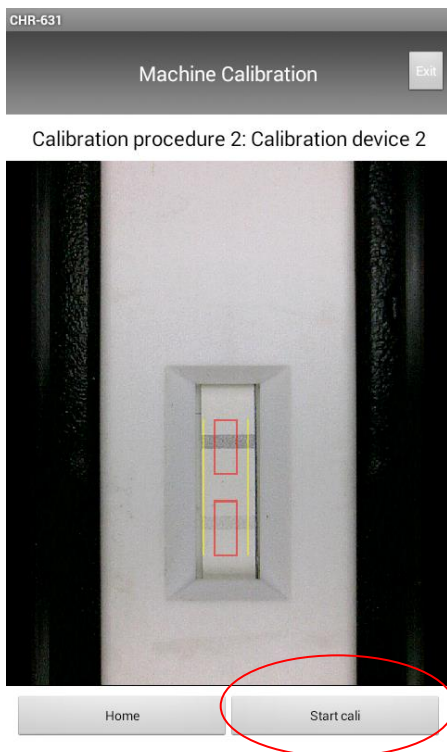
- 5) . Wait for calibration. Do not remove Machine Calibration 1 during calibrating.



- 6) . After Machine Calibration 1 is finished. Insert Machine Calibration 2 into the drawer of reader following the direction shown below.

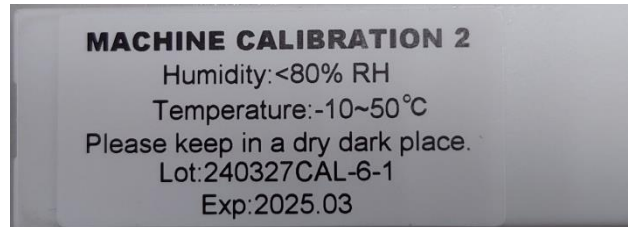
- 7) . Make sure the two red rectangles are covering each line, and then press

“Start cali”.

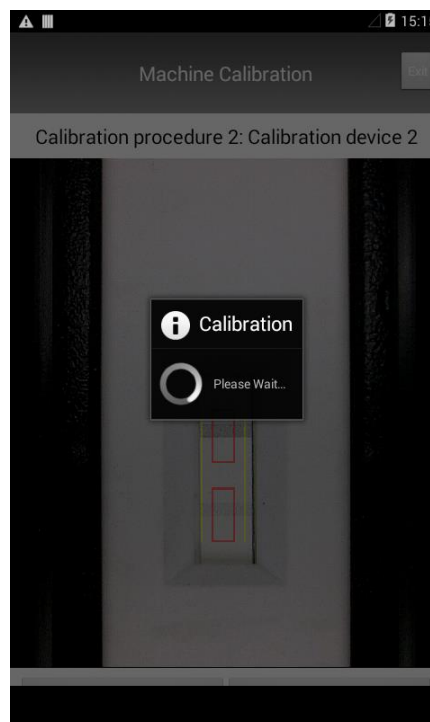


Reminder:

Back of Machine Calibration 2

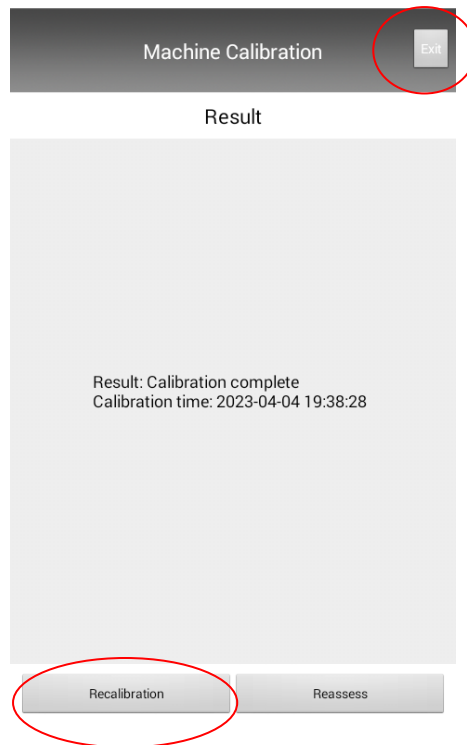


8) . Wait for the calibration to end. Do not remove Machine Calibration 2 during measuring.



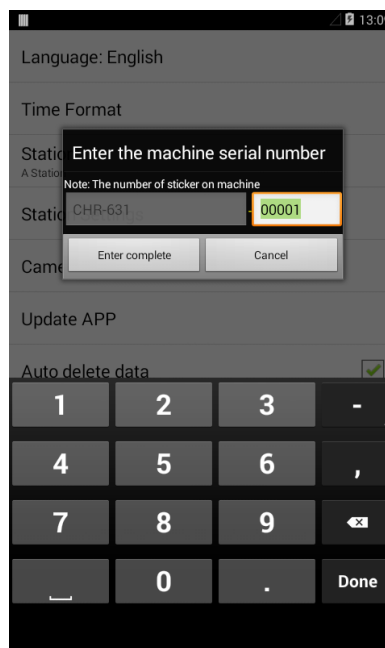
9) . Check calibration result.

1. In the case of “Calibration Passed”, press “Exit” to run setting.
2. In the case of “Calibration Failed”, press “Recalibration” to run calibration again. Proceed to 4.6.7) and conduct.



4.6.11 Device ID Setup

It is suggested that the serial number of the reader is remained. Make sure to keep the original number if it has to be changed.



4.7 Verification

1. Read the device manual to understand the device's functions and operating methods.
2. Install the device according to the instructions in the manual.

3. Calibrate the device using calibration devices.
4. Test the device using samples to verify the device's performance.

5. Troubleshooting

Troubleshooting
<p>ERROR 1: The reader cannot power on normally.</p> <p>A1: Please make sure the battery pack is inserted.</p> <p>A2: Please make sure the battery pack is not dead.</p> <p>A3: Please plug in power cord and make sure the charge indicator is lighting.</p> <p>A4: Plug in power cord for 30-60 minutes and reboot the reader again.</p>
<p>ERROR 2: If reader cannot go into main screen.</p> <p>A: Please make sure the battery is dead or not.</p>
<p>ERROR 3: If touch screen cannot be operated.</p> <p>A1: Please reboot the reader.</p> <p>A2: Press 4 corners of the screen.</p>
<p>ERROR 4: "Camera Init Err. PLEASE RESTART DEVICE".</p> <p>A: Please reboot reader.</p>
<p>ERROR 5: When the detected position wasn't correct.</p> <p>A1: Make sure the direction of cassette is correct.</p> <p>A2: Please make sure the drawer is closed.</p>
<p>ERROR 6: When you got unusual test result.</p> <p>A1: Please make sure the target item consists with the cassette you put in.</p> <p>A2: Please run Camera Calibration and Machine Calibration 1 & 2.</p>
<p>ERROR 7: If Calibration 1 & 2 fails for several times.</p> <p>A: Please make sure to put Camera Calibration in the right order. Insert Calibration 1 & 2.</p>

Please contact provider if above ERRORS cannot be solved.

6. Maintenance

1. This product is an in-vitro diagnostic device and does not directly contact with the patient's samples, hence there is no need for regular sterilization or disinfection. Keep the device appearance clean by using soft towel; it is not necessary to clean inside.
2. Carefully maintain the reader, otherwise the warranty is invalid if the QA label is tear down or ruined.

3. When the device needs to be scraped, please refer to 4.5.3 Delete result to clear all the records in the reader.
4. Please check the expiration date marked on the back of the calibration device (18 months after manufacture) regularly. If user needs to renew the calibration device, please contact with the supplier for purchases.

7. Package, Storage and Transportation

Package	There should be a whole set of accessories, documentation within the Reader box. Moisture proof and shock proof measures should be taken as well. The Reader transport box should be corrugated box with moisture proof, shock proof and reliable fixed measures.
Storage	The packaged Reader should be stored in a room where the temperature is between -10°C and 50°C, the maximum relative humidity is 80%, no corrosive gas and good air circulation.
Transportation	The packaged Reader can be transported by general transportation means. However, severe shock, vibration, and exposure under the rain or snow should be avoided.

8. Hardware Specifications

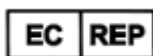
1. Detector: CMOS Sensor
2. Display: 5" resistive type touch panel
3. Accuracy: Around 8 RLU, CV value <10%; around 160 RLU, CV value <5%
4. Precision: Around 8 RLU, CV value <10%; around 150 RLU, CV value <5%
5. Lowest Detection Limit: 5.5 RLU
6. Measurement Range: 5.5 ~ 380 RLU
7. Power: DC 5V 3A
8. Battery: 18650 Lithium battery pack x1
9. Type A USB Port x2: 5V 500mA
10. Type B USB Port: For charge
11. Weight: 740g ± 20g
12. Size: 236mm * 104mm * 96.5mm
13. Wi-Fi: IEEE 802.11 b/g/n, 2.4 GHz (optional)
14. Bluetooth: Bluetooth V4.0 (optional)
15. Print: Portable Bluetooth/USB Thermal Printer (Optional)
16. Environment:
 - 16.1 Operation: 5°C ~ 40°C, < 80% RH
 - 16.2 Storage and Transportation: -10°C ~ 50°C, < 80% RH
 - 16.3 Atmospheric pressure: 80~106 kPa
 - 16.4 Away from high radio frequency interference (such as base station, etc.)
17. Other:
 - 17.1 Life time of reader: 2 years
 - 17.2 Shelf life of calibration device: 12 months
 - 17.3 Date of manufacture: Marked on the device label
 - 17.4 Side effect: No
 - 17.5 Storage: At least 5,000 results.

9. Contact Information

Company Kaiwood Technology Co., Ltd.
5F, No.12&16, Lane 31, Sec. 1, Huandong Rd.,
Xinshi District, Tainan City 74146, Taiwan
www.kaiwood.com.tw
+886-6-5050766 +886-6-6006000
<https://www.kaiwood.com.tw/en/contact.html>



Kaiwood Technology Co., Ltd.
5F, No. 12 & 16, Lane 31, Sec. 1, Huandong Rd.,
Xinshi District, Tainan City 74146, Taiwan
www.kaiwood.com.tw



Obelis S.A.
Bd. Général Wahis, 53
1030 Brussels, Belgium
Tel: +(32) 2 732-59-54
Fax: +(32) 2 732-60-03
mail@obelis.net

Where the UDI barcode
is pasted

e-User Manual <https://www.kaiwood.com.tw/en/download.html>

Appendix

Appendix A (Client Management App)

1. How to use Client Management App (only for use on a personal computer)

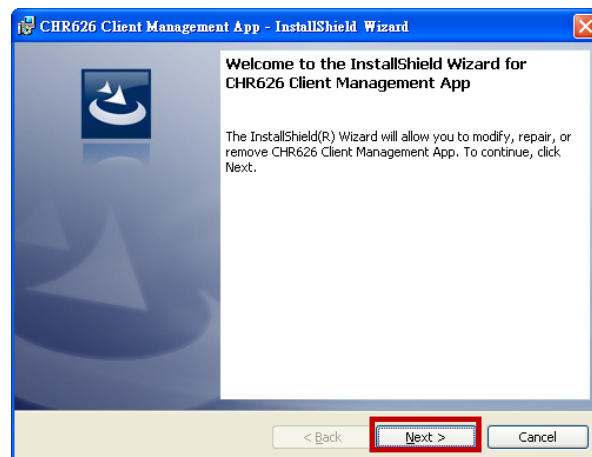
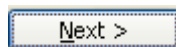
1.1 Installation

1.1.1 Put CR-ROM in computer.

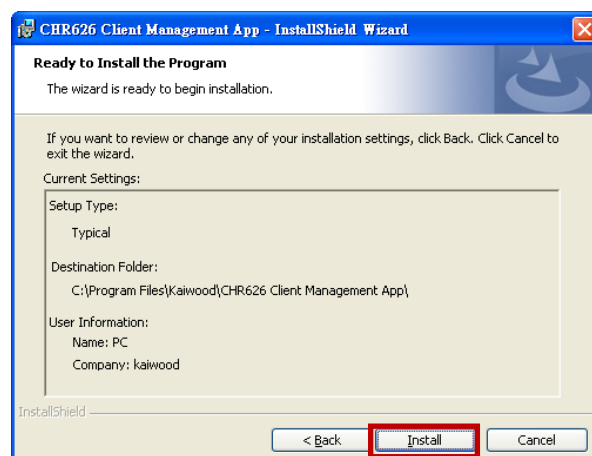
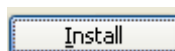
1.1.2 Click on the client installation file setup.exe



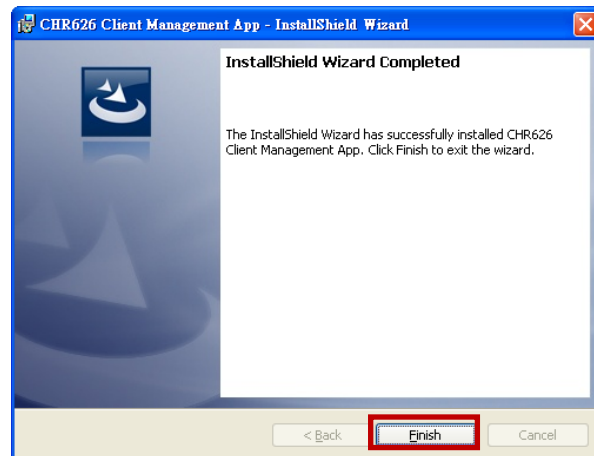
1.1.3 Click on



1.1.4

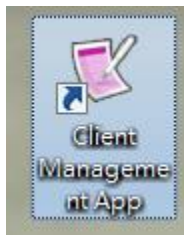


1.1.5

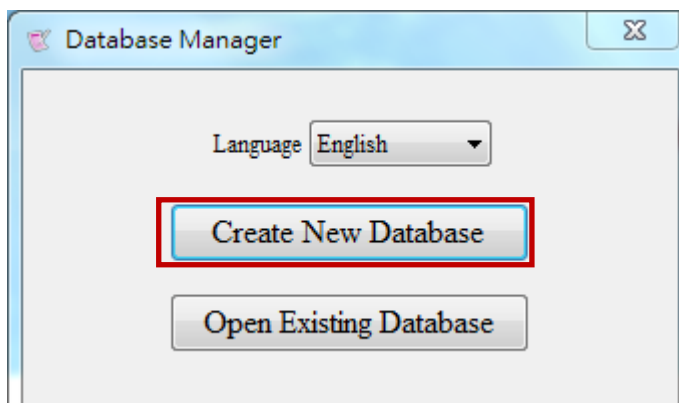


2. USE & OPERATION

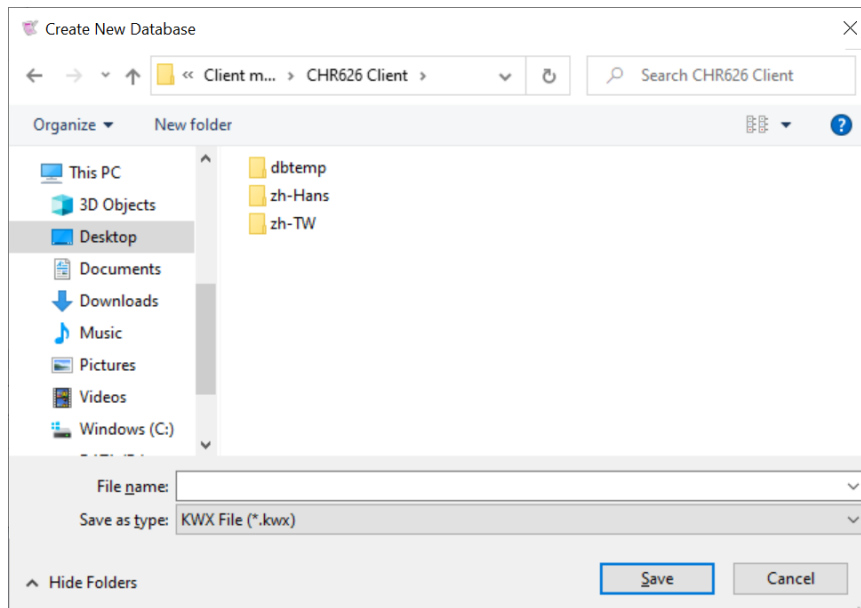
2.1 Click on the shortcut on the desktop



2.2 Establish new database file to manage your test data by clicking on

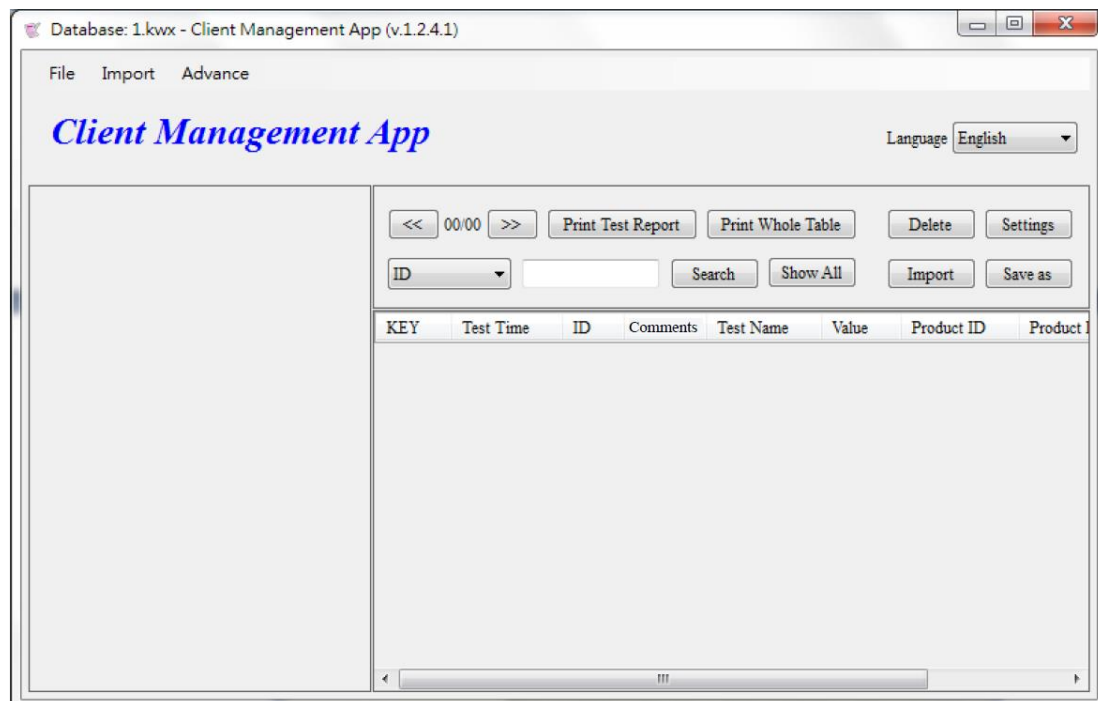


2.3 Press "Save" after named the file. (The file name can be named by yourself)



*Recommended to save the file under C:\Program Files\Kaiwood\ Client Management App

2.4 Execute client management APP



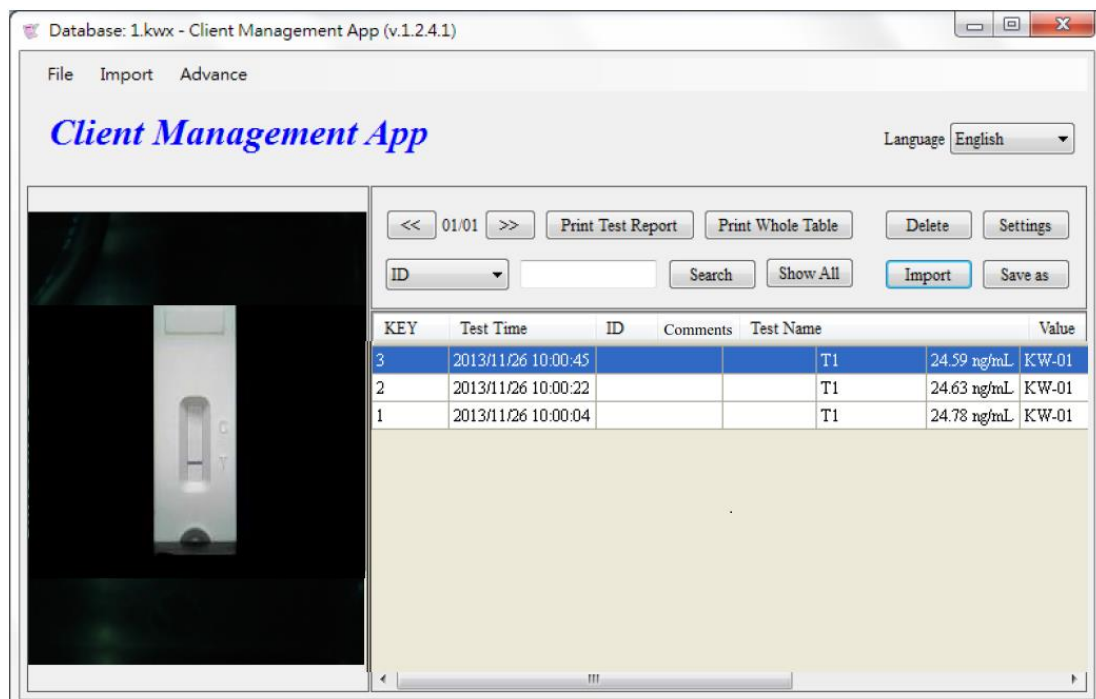
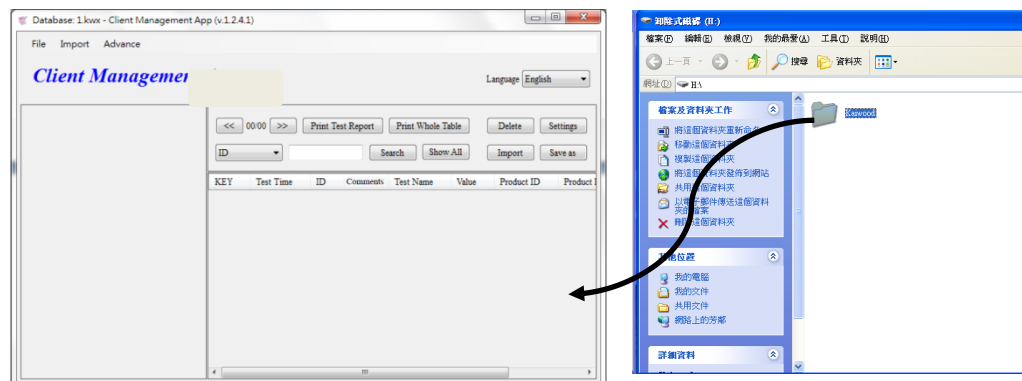
2.5 Import data

2.5.1 Save data from reader firstly.

Open the “Results” section of reader and save the test data to the USB flash device.
(Please refer to “User manual of CHR-631W”.)

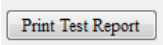
2.5.2 Insert the USB flash device to your personal computer

2.5.3 Import data from USB flash device by choosing the folder named “Kaiwood”. You can drag the entire Kaiwood folder onto the programming interface or drag the data you need by choosing them.

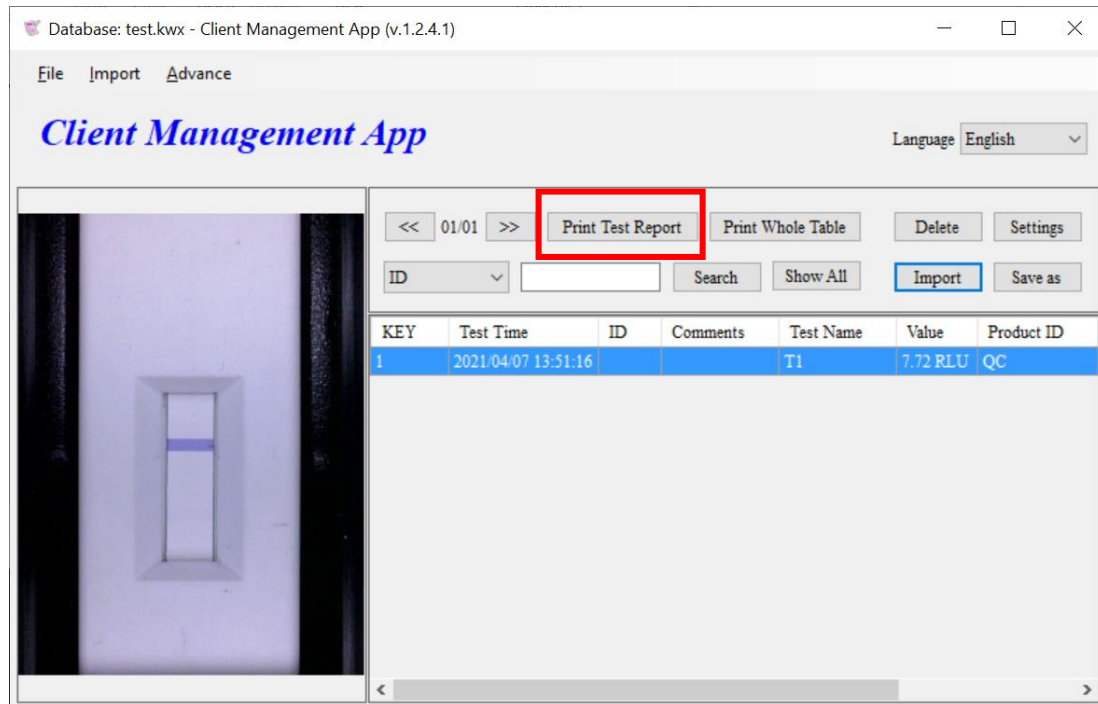


3. Printing

3.1 Print single analysis report.

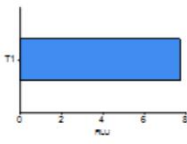

3.1.1 Select the data and press .

The preview window will pop up for checking.



Reader
TEST REPORT

(1) IMAGES AND GRAPHICS




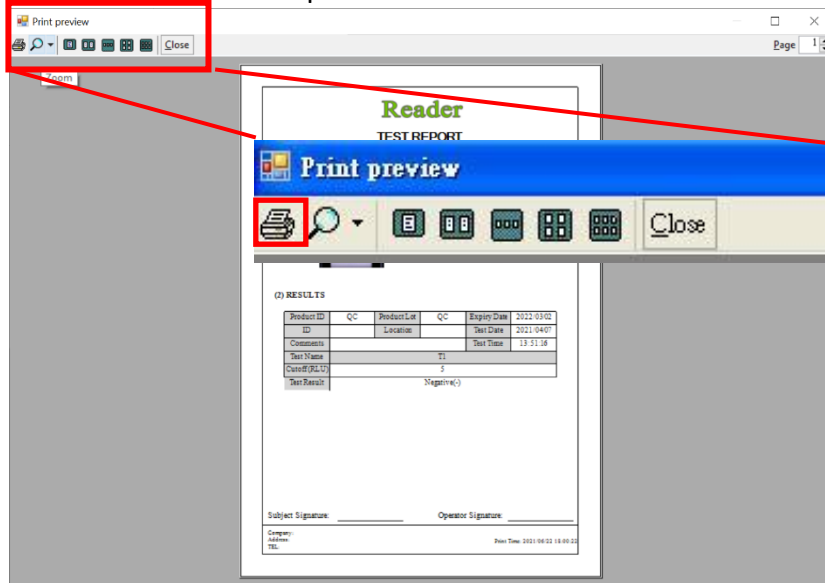
(2) RESULTS

Product ID	QC	Product Lot	QC	Expiry Date	2022/03/02
ID		Location		Test Date	2021/04/07
Comments				Test Time	13:51:16
Test Name	T1				
Cutoff (RLU)	S				
Test Result	Negative(-)				

Subject Signature: _____ Operator Signature: _____

Company: _____ Address: _____ TEL: _____ Print Time: 2021/04/22 18:00:22

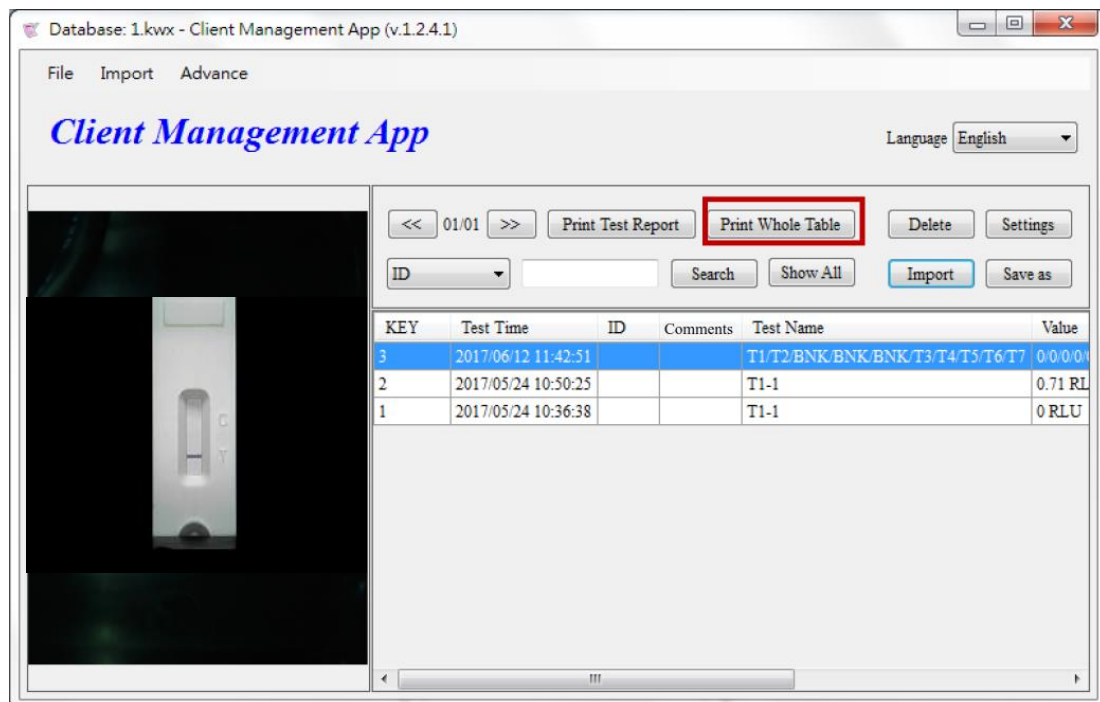
3.1.2 Click on  to print



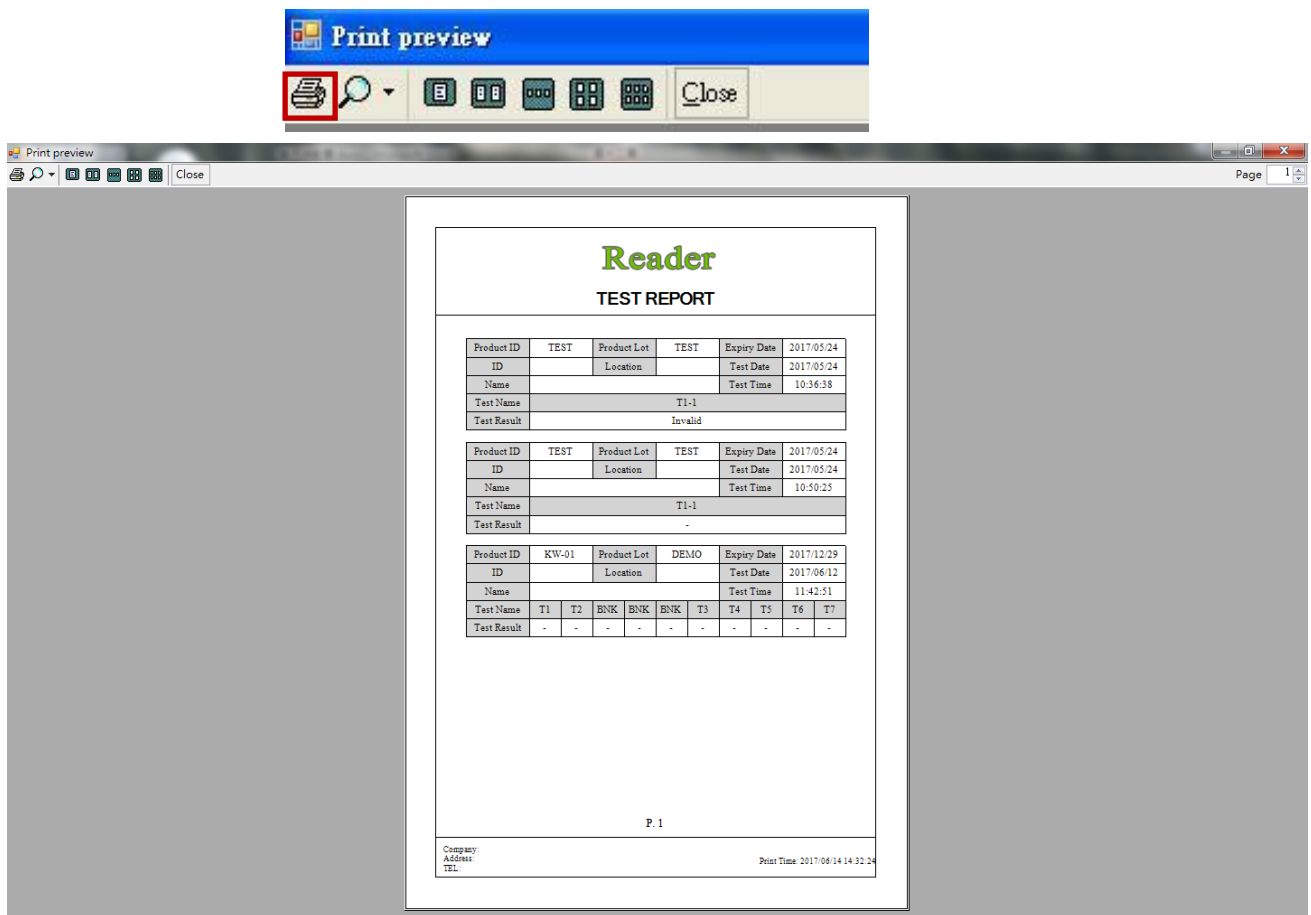
3.2 Print whole analysis reports

3.2.1 Click on

Print Whole Table

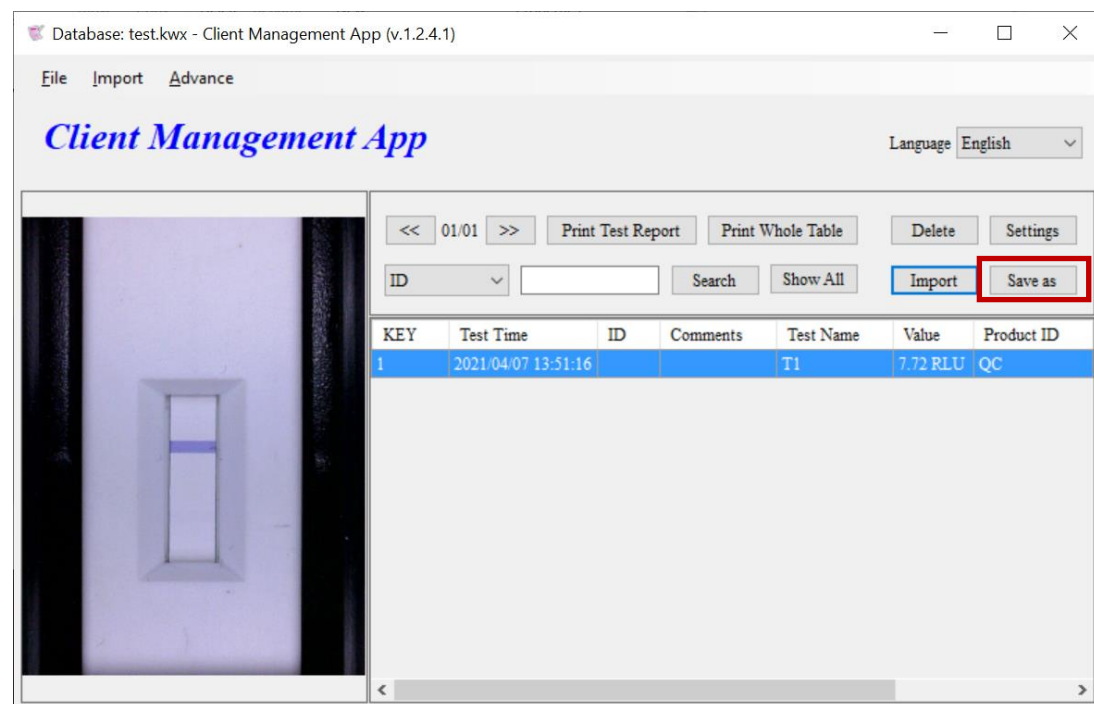


3.2.2 Click on  to print data

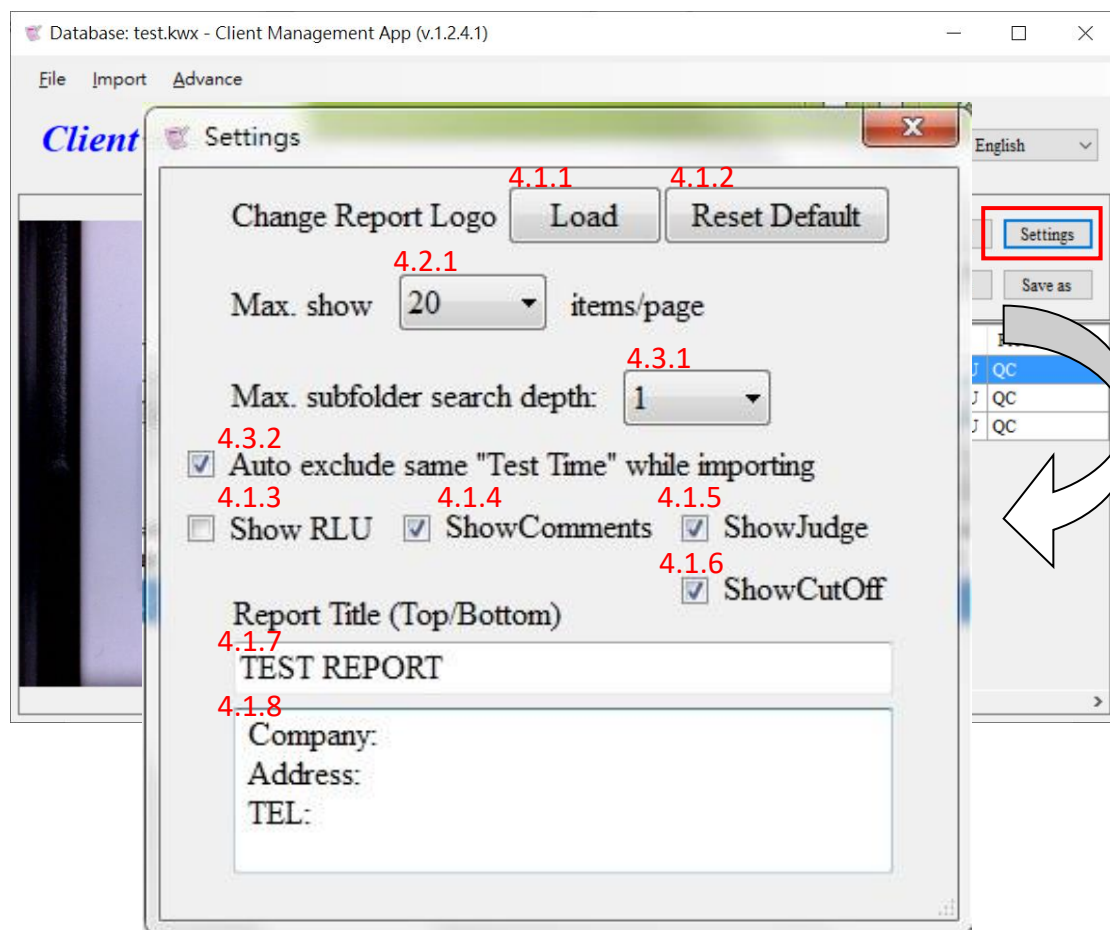


3.3 Data analysis

Export all data to an Excel file.



4. Settings



4.1 Report settings

- 4.1.1 Change the logo displayed above when printing the analysis report.
- 4.1.2 Reset the set brand to the default value, and the default value is the green Reader typeface.
- 4.1.3 Whether to display RLU when printing the analysis report.
- 4.1.4 Whether to display comments when printing the analysis report.
- 4.1.5 Whether to display the negative/positive interpretation result when printing the report.
- 4.1.6 Whether to display the cutoff reference value when printing the analysis report.
- 4.1.7 Change the title of the header when printing the analysis report.
- 4.1.8 Change the content of the footer when printing the analysis report.

4.2 Display settings

- 4.2.1 Set the maximum number of items displayed on each page.

4.3 Import data settings

4.3.1 When importing data, to set the level of subfolder search depth.

4.3.2 Whether to automatically exclude the records with the same test time when importing.

5 Advance

5.1 Reset Database

Reset the current database. When resetting, all currently imported information will be cleared.