

LensHOOKE™

Semen Quality Analyzer

User Manual

















X1 PRO



Please read this user manual carefully first to ensure proper use of the product. This user manual is also available at www.LENSHOOKE.com.

Symbols

The following icons may appear in the content of this user manual.

-  Symbol for "NOTICE"
-  Symbol for "CAUTION"
-  Symbol for "PAGE NUMBER"
-  Symbol for "DO NOT REUSE"
-  Symbol for "USE BY"
-  Symbol for "BATCH CODE"
-  Symbol for "SERIAL NUMBER"
-  Symbol for "DATE OF MANUFACTURE"
-  Symbol for "MANUFACTURER"
-  Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
-  Symbol for "IN VITRO DIAGNOSTIC DEVICE"
-  Symbol for "TEMPERATURE LIMITATION"
-  Symbol for "CONSULT INSTRUCTIONS FOR USE"
-  Symbol for "WEEE WASTE RECYCLING"
-  CE mark
-  Symbol for "FOLLOW INSTRUCTIONS FOR USE"

The package includes

- Semen Quality Analyzer
- Power Adaptor (for analyzer)
- User Manual

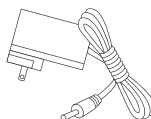
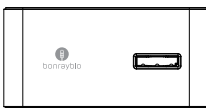


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I. Introduction

LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) is in vitro diagnostic only. User should read this User Manual first to get familiar with the device and its proper operation procedure prior to use the analyzer.

If you have any questions about the product or require any assistance, please feel free to contact Bonraybio by calling the Service Hotline (+886-4-2491-2385) or contact your local distributor.
Service Hotline time : Mon~Fri 08:30~17:30 (GMT+8)

II. Intended use

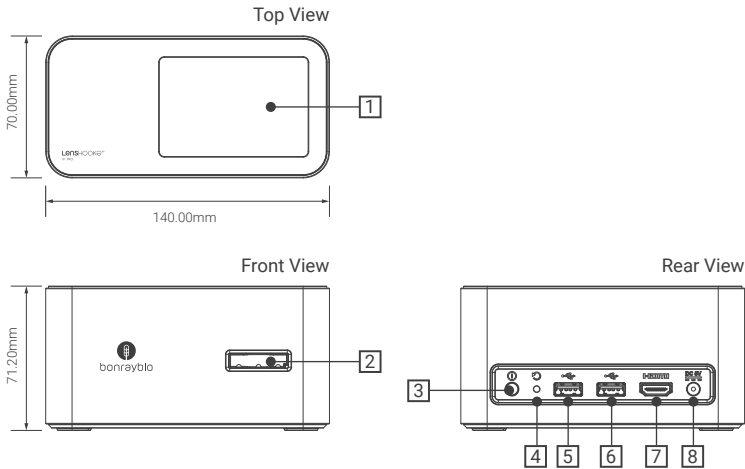
The LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) used with LensHooke™ Semen Test Cassette is an easy-to-use, optical device for human semen analysis which provides direct and calculated measurements for:

- (1) Sperm concentration (10^6 per ml)
- (2) Total motility (PR+NP, %)
 - Progressive motility (%)
 - Non-Progressive motility (%)
 - Immotility (%)
 - Other parameters from CASA assessment (MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, and BCF)
- (3) Sperm morphology (normal forms, %)
- (4) pH value

The LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro diagnostic use only. For Professional use.

III. Product Overview

LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic)



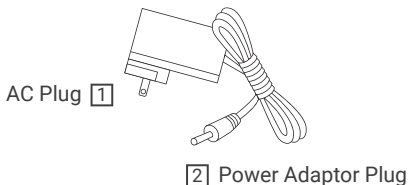
- 1 Touch Screen
- 2 Test Cassette Insert Slot
- 3 Power Key
- 4 Reset Key
- 5 USB Port
- 6 USB Port
- 7 HDMI Port
- 8 Power Adaptor Port

NOTE

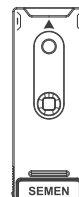
- **USB Port** : High-speed USB 2.0
- **Reset Key** : If the analyzer crashes, please use a pin to press the reset button.
- **HDMI Port** : The analyzer allows an HDMI cable connection to a high definition monitor to review the images and data.

Accessories

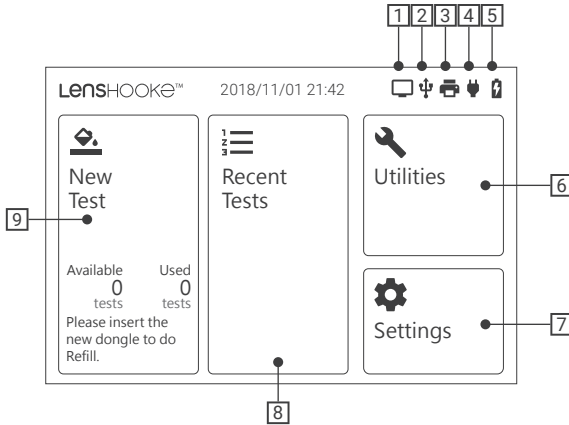
- **Power Adaptor**



- **LensHooke™ Semen Test Cassette**



Touch Screen Icon



- 1** **HDMI connection icon:** This analyzer is connected to monitor by a HDMI port.
- 2** **USB connection icon:** This analyzer is connected to USB Device by a USB port.
- 3** **Thermal Printer connection icon:** This analyzer is connected to Portable Thermal Receipt Printer.
- 4** **Power Adaptor connection icon:** This analyzer is connected to power adaptor to charge the battery.
- 5** **Battery icon:** It shows the battery capacity.

NOTE

- **USB connection icon:** If you insert the other device by USB port, such as keyboard, mouse, dongle...etc, this icon will not appear on the screen.

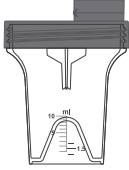
The icons below are functional

- 6** **Utilities icon:** It includes the functions of:
 - Quality Control: To check the quality of the analyzer/device
 - Backup All Records: To backup the data for all results
 - System Update: To update the system of the analyzer/device
 - About: To get the detail information of the analyzer/ device
 - Delete All Records: To delete all results
- 7** **Settings icon:** It includes the functions:
 - WHO Standard: To select WHO edition of 4th or 5th.
 - Date & Time: To set up the Date and Time
 - Language: To select the language preference
 - LAN Password: To get or change the LAN password to access into the analyzer/device through network
 - Brightness: To adjust the brightness of the screen
- 8** **Recent Tests icon:** To review the previous test results
- 9** **New Test icon:** To start testing

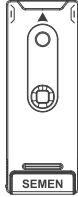
IV. Consumables

The consumables for LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) is as below:

- C-KUP™
Liquefaction Test Cup



- LensHooke™
Semen Test Cassette



- LensHooke™
Cleaning Wipe



- LensHooke™
X QC Beads (For Semen)



- The result will be inaccurate, if you DO NOT use a LensHooke™ Semen Test Cassette.

NOTE

- C-KUP™ Liquefaction Test Cup is for semen sample collection.
- LensHooke™ Semen Test Cassette is used to hold semen sample for analysis with the analyzer.
- LensHooke™ Cleaning Wipe is used to clean the test cassette insert slot.
- LensHooke™ X QC Beads (For Semen) is used for quality control of the analyzer.

V. Major Function

LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic)

Turn on / off

1 Turn the analyzer on:

Push the power key for around 2 seconds to turn on the analyzer (as Image 1).

When the touch screen lights up (as Image 2), the analyzer is ready to operate.

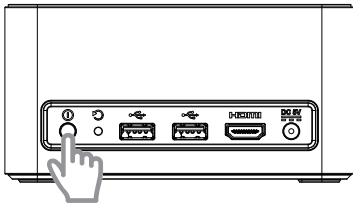


Image 1

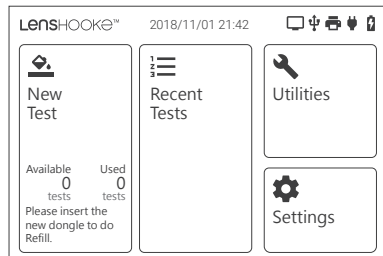



Image 2

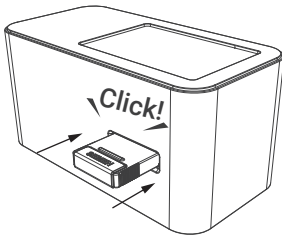
2 Turn the analyzer off:

Hold the power key for around 10 seconds until the touch screen shows  Power off and tap the icon to turn off the analyzer.

Insert / Remove the Test Cassette

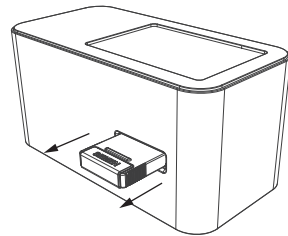
1 Insert the Test Cassette:

With the “arrow” side of this cassette facing up, insert it into the “Insert Slot” according to the direction of the arrow until you hear a “Click” sound.




2 Remove the Test Cassette:

After the test, remove the test cassette in the opposite direction of the “arrow”.



Charging the battery

1 When the “Low Battery” message shows on the touch screen (Image 3), it means the battery power is low. Use the power adaptor to charge the battery immediately. The “plug” symbol will appear on the touch screen (as the  of Image 4) during charging. If the “plug” symbol fails to show on the screen, check to make sure the adaptor is properly connected to the analyzer and socket.

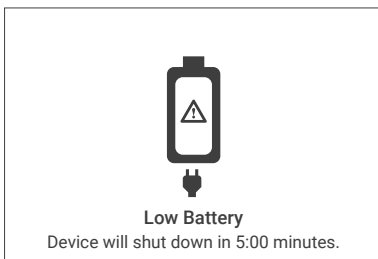


Image 3

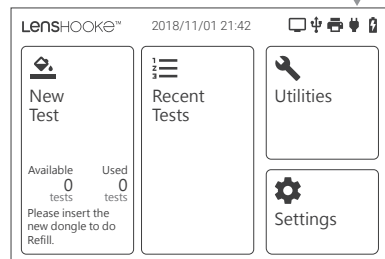


Image 4



- Analyzer is equipped with a built-in Lithium-ion polymer batteries with a battery capability of 2500 mA.
- The battery can not be removed or changed. If you have battery problem, please contact us.


NOTE

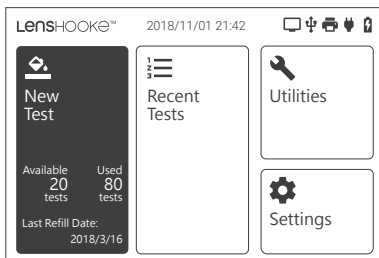
- If you want to enter to the power saving mode, please press the power button quickly. If you want to wake up the analyzer, please press the power button again quickly.
If there is no operation for 10 minutes, the system will automatically enter to the power saving mode.
- * **Power Saving Mode:** To turn off the touch screen to reduce battery power consumption.
- For the purpose to extend the build-in Lithium-ion polymer battery's life time, please keep charging the battery by using the adaptor even you don't use the analyzer.
- If the analyzer is not operated over 3 months, please use the power charger before using.
- The date and time of the analyzer might be back to the default setting, if it ran out of battery. Please check and set up the date & time properly (refer to Page 16).
- If the warning messages of "Battery overheating" or "Battery Temperature is too Low" show on the screen, the analyzer will shut down automatically in 5 minutes to protect itself. When you see this warning message, please turn off the analyzer, connect the power adaptor to the analyzer, and then return on it after 10 minutes.

Test the Sample


1 New Test

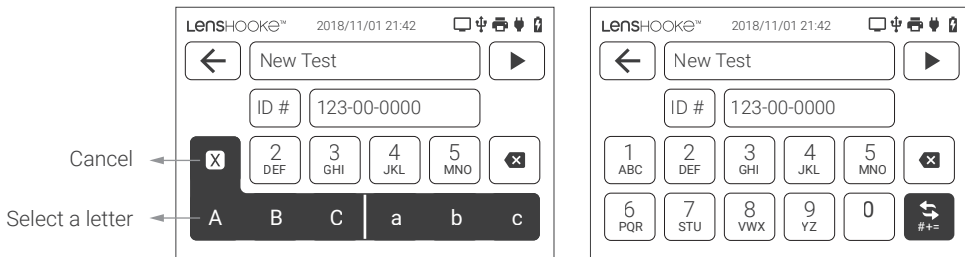
Step 1. Click the icon "New Test".

Step 2. Please Enter the ID number and click  to go to the next step.

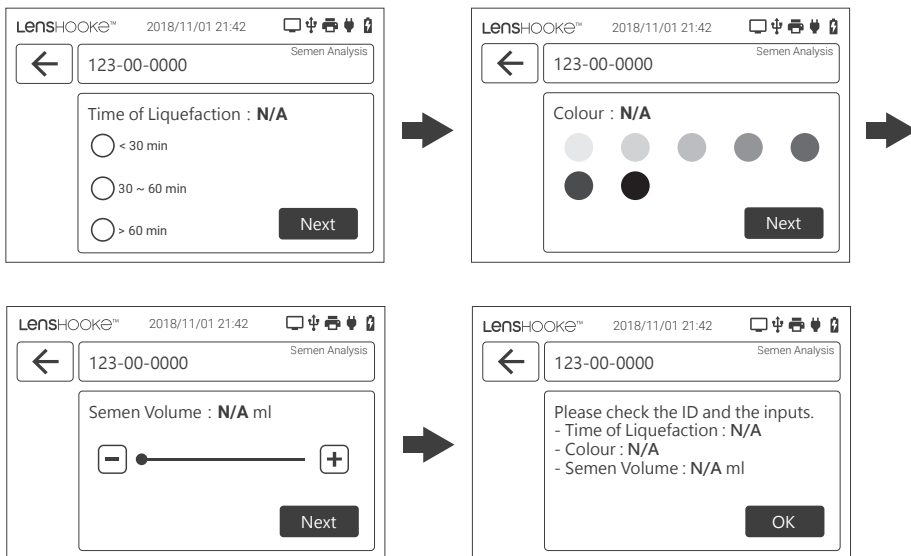


NOTE

- DO NOT use over 15 characters and symbols for the patient ID#.
- If you want to enter a character, please press the icon for 0.5 to 1 second and select the letter. If you want to enter a symbol, please click the icon "  " to switch the keyboard.
- You could also use barcode scanner to scan the barcode of patient ID#. (Please refer to page 23 to connect the barcode scanner to the analyzer.)



Step 3. Please click the Liquefaction Time, Semen Colour, Semen Volume and click **“Next”** to go to the next step to check if the information you enter is correct.



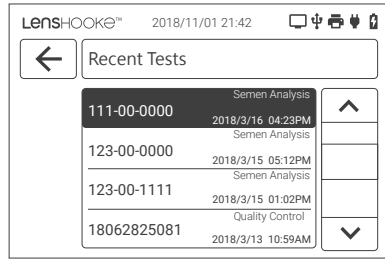
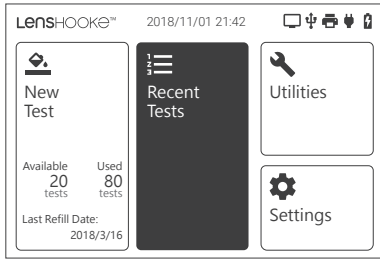
NOTE



- Follow the indication to operate the test cassette. If you are familiar with the semen test cassette operation, please click **“Skip”** to do the next step.
- Please click and to adjust the semen volume.

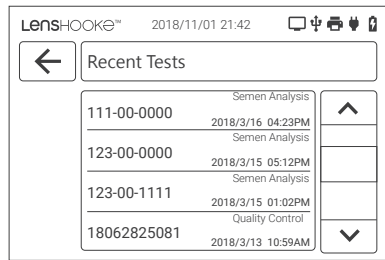
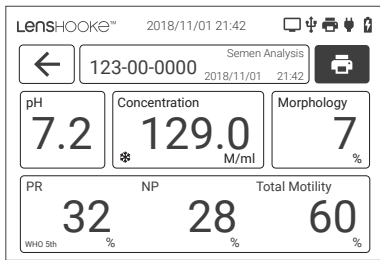
Review the Test Result

1 Recent Tests

(1) Click the icon **“Recent Tests”** and then click the record you want to review by patient’s ID.



(2) The record will appear on the screen. If you want to print out this record, click the icon “”. If not, click the icon “” to return to the previous page.



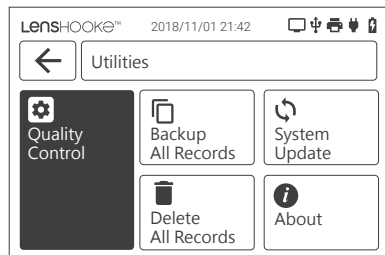
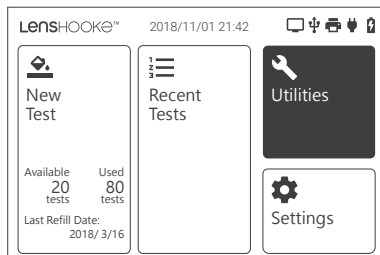
NOTE

- ONLY the Blue icons can be clicked.

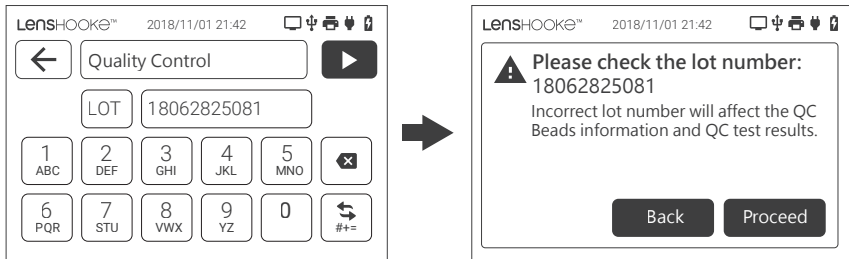
The functions of Quality Control, Backup All Records, System Update, About & Delete All Records

1 Quality Control

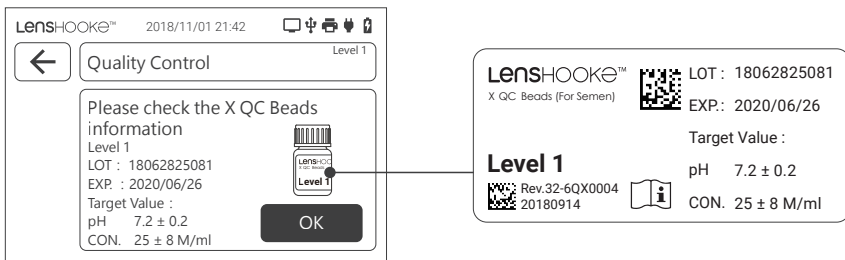
(1) Click the icon of “Utilities” and then click the icon of “Quality Control”.



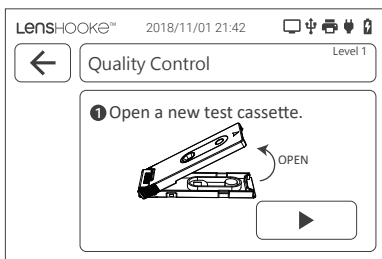
(2) Please enter the LOT number and click “▶” to go to the next step, and then check the lot number. If it is the same as the lot number of the X QC Beads, please click “Proceed” to go to the next step.



(3) Please check the X QC Beads information of the screen. If this information is completely the same as the label on the X QC Beads, please click “OK” to go to the next step.



(4) Please open the test cassette.



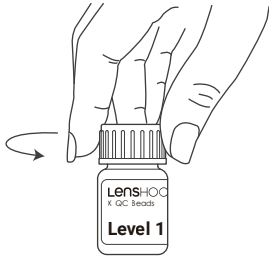
(5) Flip the bottle for 8-10 times until there is no white precipitate in the bottom. Please do it gently to avoid the bubble.



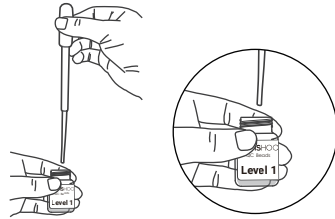
NOTE

- DO NOT place the opened cassette on any unstable surface when adding the X QC Beads.
- The test cassette is only for single use. DO NOT reuse it.
- DO NOT touch the window and drip area of the test cassette.
- Insert the cassette into analyzer within 30 seconds after adding X QC Beads.

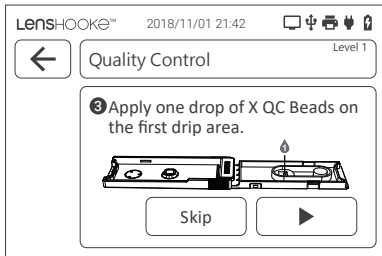
(6) Open the screw cap of bottle.



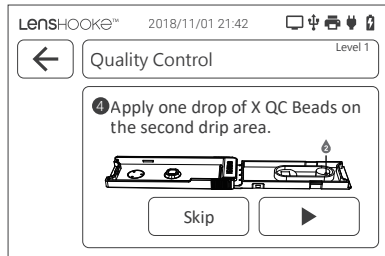
(7) Please place a new dropper into the bottle of X QC Beads and repeat pipetting for 3-5 times. After that please press the dropper by fingers to suck the liquid.



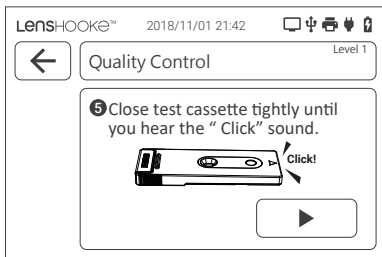
(8) Squeeze the dropper to apply a drop of the X QC Beads on the first drip area of test cassette to test the pH value.



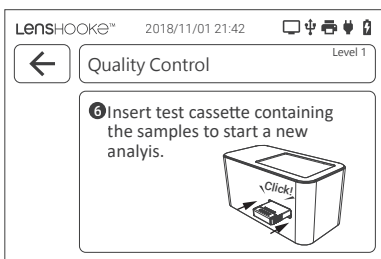
(9) Squeeze the dropper to apply another drop on the second drip area of the test cassette to test the concentration.



(10) Close test cassette tightly until you hear the "Click" sound.



(11) Insert the cassette (with X QC Beads) into the "Insert Slot" until you hear the "Click" sound to start the Quality Control test. After 2-5 minutes the result will appear on the screen automatically.

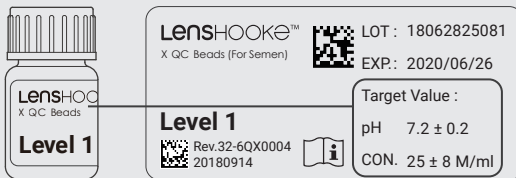


(12) Please check the test result with the information of the label.



NOTE

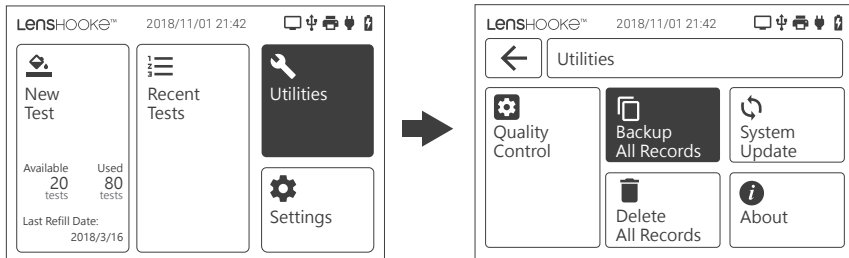
- Once you have opened the LensHooke™ X QC Beads (For Semen), please keep it in the refrigerator at 2-8 °C (36-46 °F) (DO NOT freeze), and finish it in 90 day. Please write down the discard date on the label to remind you the expiry date. DO NOT use if it is expired.(Shelf-life: 2 years, Opened vial: 90days)
- If you want to redo the Quality Control test, please make sure to use the new dropper, new test cassette and new drop of X QC Beads .
- Please make sure to mix the LensHooke™ X QC Beads (For Semen) every time when you want to get a drop of the beads.
- Please mix the LensHooke™ X QC Beads (For Semen) gently. If there is too much bubble inside the bottle, please place it on a flat surface and wait for 10 minutes until the bubble disappear. After that, please mix LensHooke™ X QC Beads (For Semen) gently again.
- DO NOT use if LensHooke™ Semen Test Cassette or LensHooke™ X QC Beads (For Semen) is expired. If they are expired, please use the new one to do the Quality Control test.
- Please screw up the cap of LensHooke™ X QC Beads bottle immediately after use. If the LensHooke™ X QC Beads is spilled out, the concentration will be changed.
- Please make sure to screw up the cap tightly, because the beads might be stuck into the bottle tread if there is a gap between the bottle neck and cap.
- Please compare the test result with the target value (on the label).The test result of real sample might be incorrect if the result of quality control is out of the range from target value.



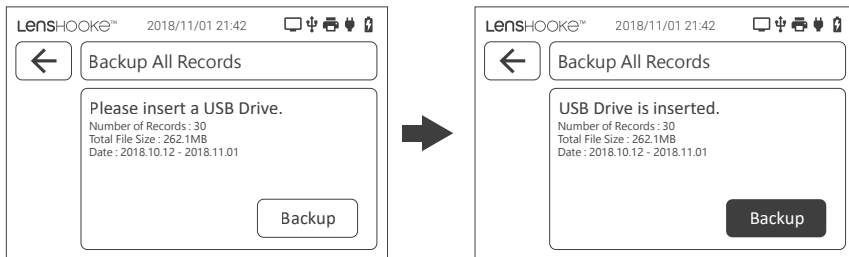
- Please keep the child away from the LensHooke™ Semen test cassette and LensHooke™ X QC Beads (For Semen). Please contact with the doctor if someone swallow it.

2 Backup All Records

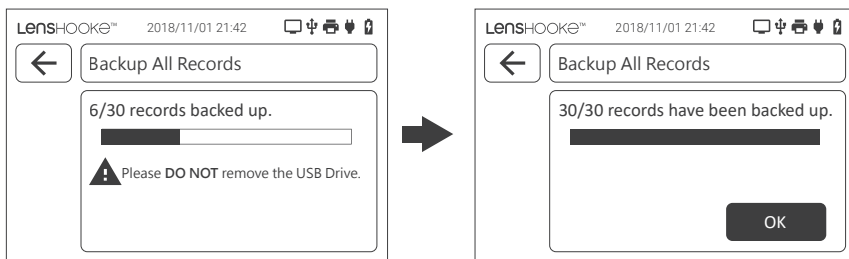
- (1) Prepare a USB Drive in advance. (Capacity: 1GB or more)
- (2) Click the icon of “Utilities” and then click the icon of “Backup All Records”.



- (3) Insert the USB Drive. When the icon of “Backup” turns blue, click it to backup the records.



- (4) When the records have been backed up to your USB Drive successfully, click the icon “OK” to return to the home page.

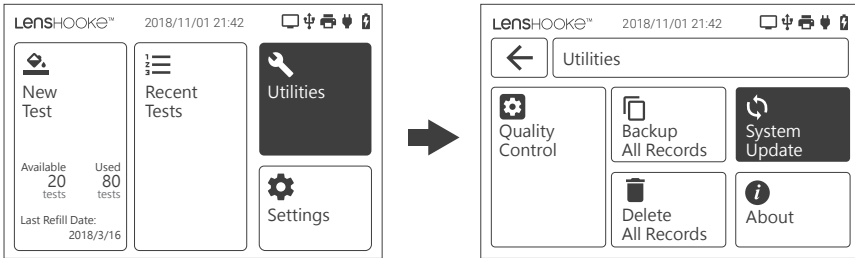


NOTE

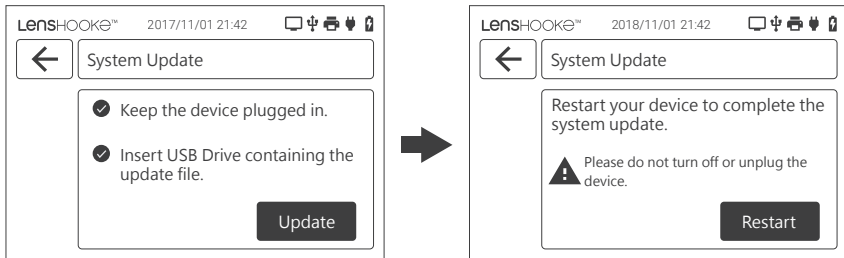
- DO NOT remove the USB Drive when the records still back up.
- There is the “Insufficient Storage Available” warning message will appear on the screen, if the memory capacity of analyzer is insufficient. Please back up all records before you delete records to release the capacity.
- If the memory capacity of the USB Drive is insufficient, please remove the USB Drive and delete the files by computer/laptop to release capacity or use another USB Drive.

3 System Update

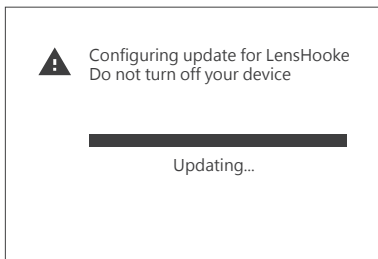
- (1) Prepare a USB Drive with system update software. (The Capacity of USB Drive : 1GB or more)
(Please contact with your local distributor for the system update software).
- (2) Click the icon **“Utilities”** and then click the icon **“System Update”**.



- (3) Please connect power and the USB Drive with the updated file into the analyzer. Click the **“Update”** icon to update the system. After that click the **“Restart”** icon to restart the analyzer and complete the system update.



- (4) The system will configure updates automatically, and restart the analyzer when the system update is completed.



NOTE

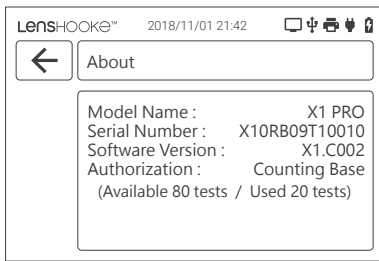
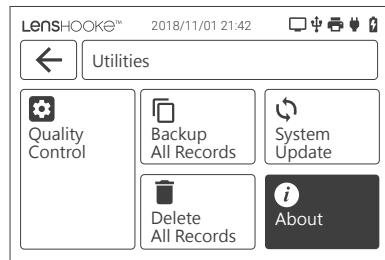
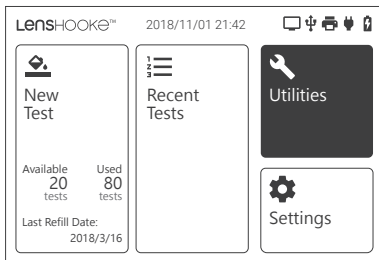
- DO NOT turn off or unplug the device during the update process. Make sure to plug in the power adaptor and insert the USB Drive with system update file when updating the system.

NOTE

- If the **“Update File is Corrupted”** warning message appear on the screen which means you did not download the complete file. Please download the system update file again to the USB Drive and redo the system update.
- If the **“Update Failed”** warning message appear on the screen which means the USB Drive for system update has been removed, please insert the USB Drive with system update file again to redo the system update.

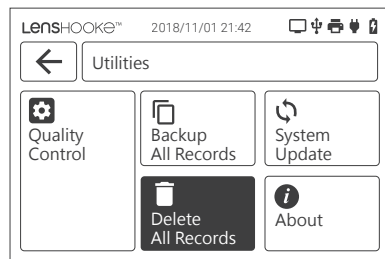
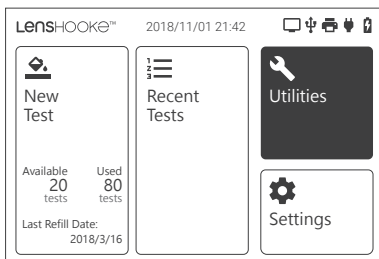
4 About

Click the icon “Utilities” then click the icon **“About”** to know about the analyzer’s information.

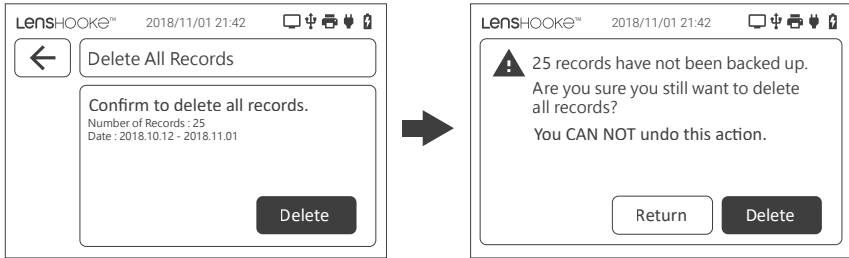


5 Delete All Records

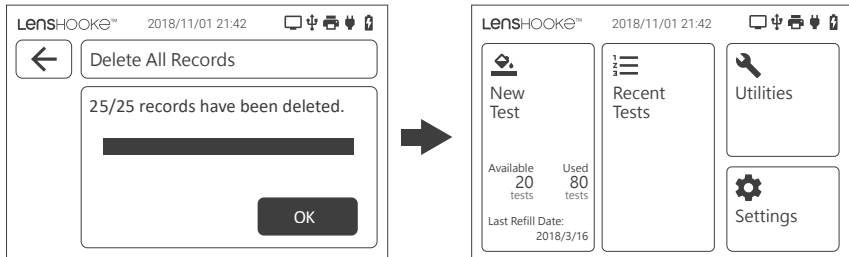
(1) Click the icon **“Utilities”** and then click the icon **“Delete All Records”**.



(2) Click the yellow icon **“Delete”** to confirm and delete all the records.



(3) Click the icon **“OK”** to return to the home page.



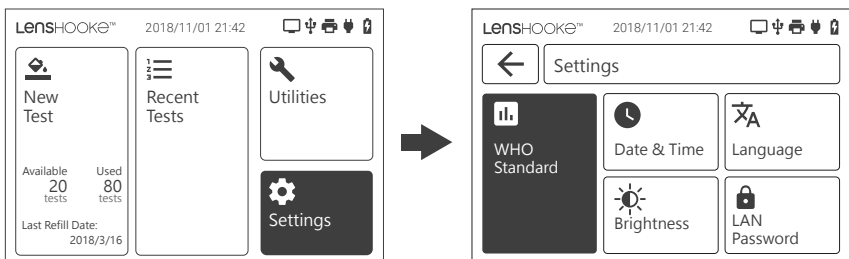
NOTE

- The records cannot be recovered after you delete them. Make absolutely sure you want to delete them permanently before clicking the icon **“Delete”**.

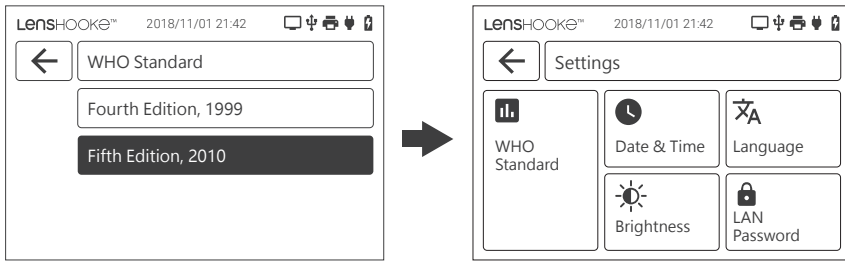
The Setting of WHO Standard, Date & Time, Language, LAN Password, & Brightness

1 WHO Edition

(1) Click the icon **“Settings”** and then click the icon **“WHO Standard”**.

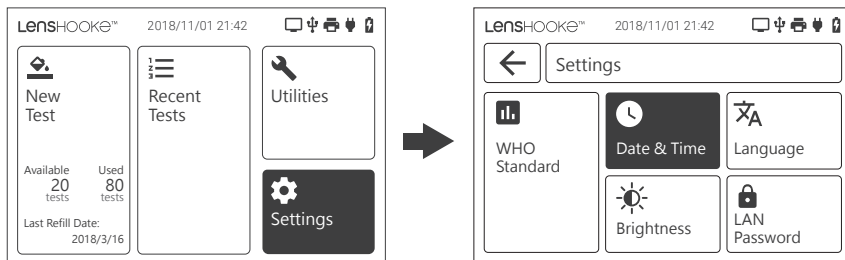


(2) Select the preference edition and click the “←” to return to the previous page.



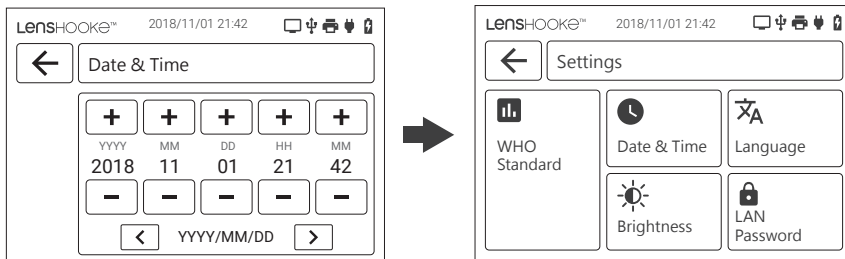
2 Date & Time

(1) Click the icon “Settings” and then click the icon “Date & Time”.



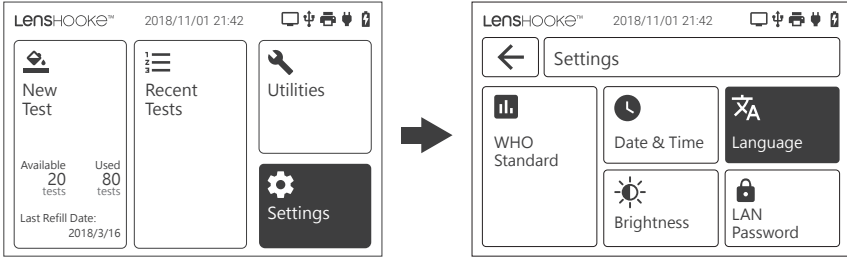
(2) You can select the format of DD/MM/YYYY, MM/DD/YYYY or YYYY/MM/DD by clicking the icon “<” or “>”, and adjust date & time by clicking the icon “+” or “-”.

After setting the Date & time, click the “←” to return to the previous page.

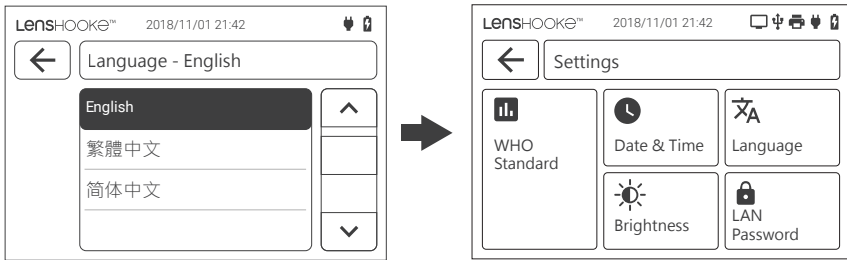


3 Language

(1) Click the icon “Settings” and then click the icon “Language”.

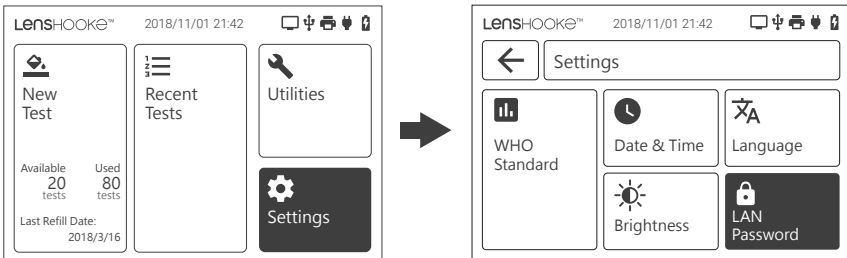


(2) Select your language preference and then click the icon of “←” to return to the previous page.

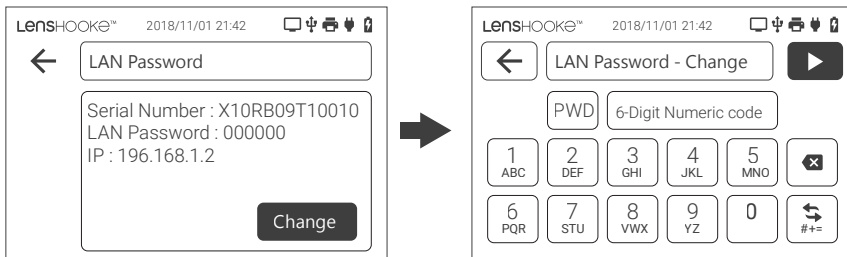


4 LAN Password

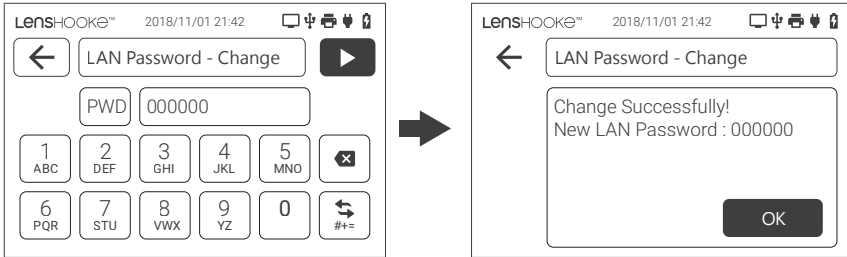
(1) Click the icon “Settings” and then click the icon “LAN Password”.



(2) The password will appear on the screen. If you want to change this password, you could click the icon of “Change” and then enter any 6 digit numeric code as your new password.



(3) After you enter the new password, please click “▶” to go to the next step. Please click “OK” to return to the previous page.

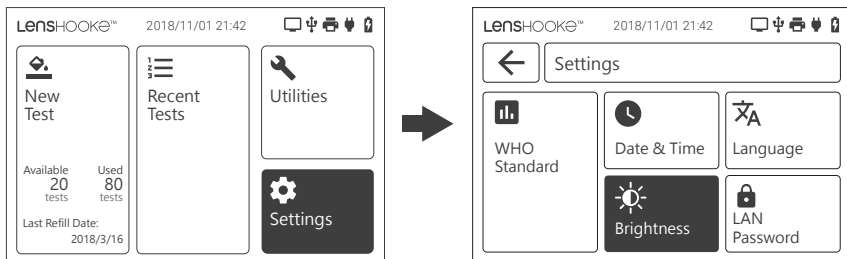


NOTE

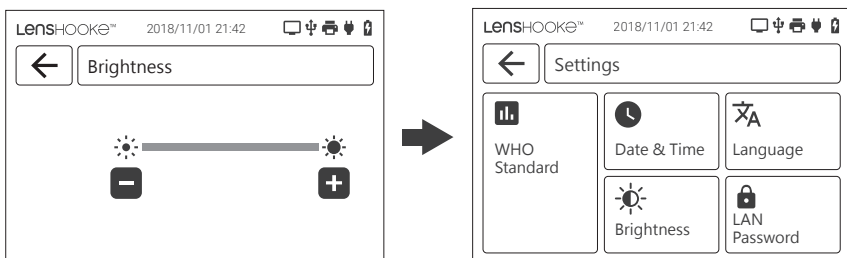
- If you want to access into the analyzer to read or download the results by other devices, you have to enter the LAN password.
- If you don't enter enough 6 digit numeric codes to set up the new password, the icon of ▶ won't turn blue to let you click.
- Please use USB to RJ45 Gigabit Ethernet Adapter to connect the analyzer to the LAN (Local Area network) by cable. (Please refer to page 20 for more detail)

5 Screen Brightness Setting

(1) Click the icon “Settings” and then click the icon “Brightness”.



(2) Adjust the brightness of the screen by clicking the icon “+” or “-”, and then click the icon “◀” to return to the previous page.

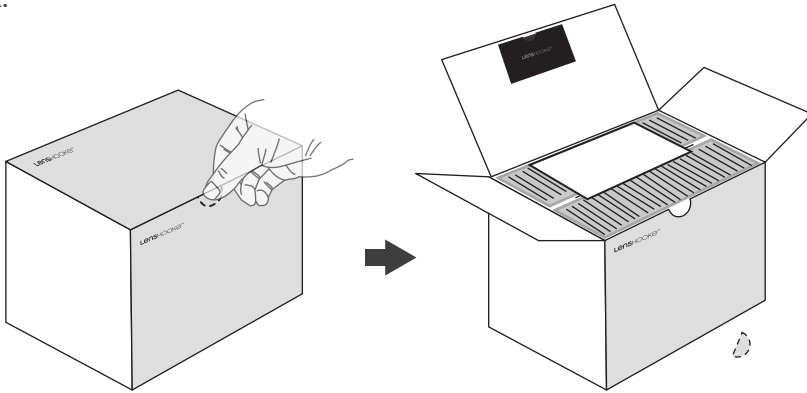


VI . Accessories

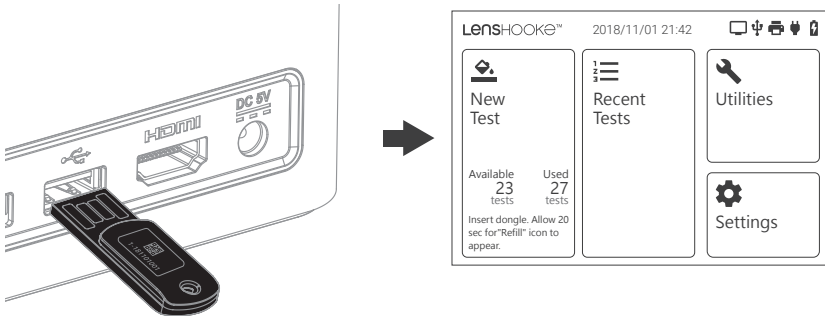
License Dongle

1. To Refill the License

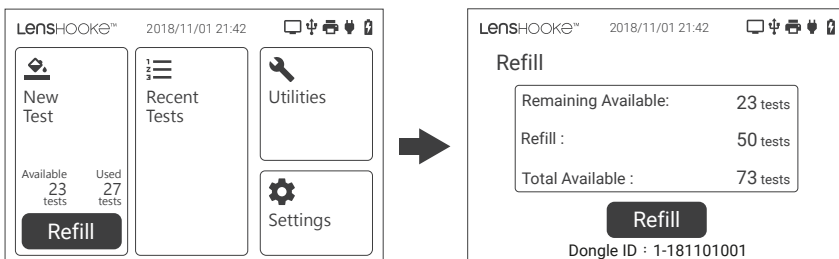
(1) When you unpack the LensHooke™ Test Cassette box, you will find the license dongle on top of the box.



(2) Please insert this license dongle to the USB Port of the analyzer and wait for 20 seconds until the "Refill" icon appear on the screen.

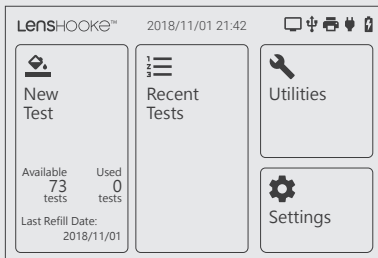


(3) Please click the "Refill" icon to refill the licenses. After that, please check if the fill information is correct, and then click "Refill" icon. If you refill successfully, please remove the license dongle.



NOTE

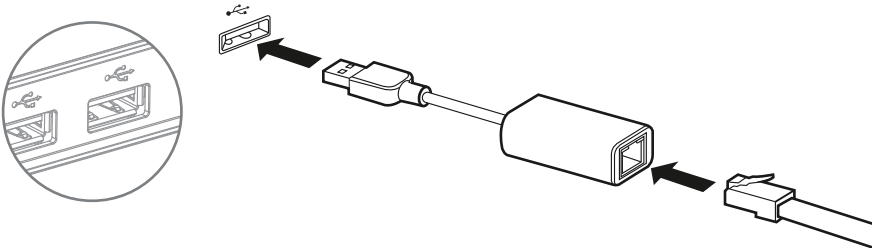
- If the license dongle is not offered by BONRAYBIO Co., LTD., the “Refill” icon will not appear on the screen.
- Once the license dongle has been refilled to the analyzer, it cannot be refilled again. If you insert this dongle again, the dongle error message will appear on the screen.
- Please insert the dongle to refill the license immediately when you unpack the box of the LensHooke™ Semen Test Cassette.
- Please return to the home page to refill the license.
- When you insert a new dongle to refill the license, the calculation of “Used” will return to zero and the calculation of “Available” will be added by the license of dongle to the remaining available.



USB to RJ45 Gigabit Ethernet Adapter

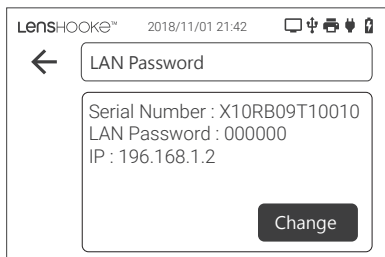
1. Analyzer : Connect to LAN (Local Area Network)

(1) Please use USB to RJ45 Gigabit Ethernet Adapter to connect the analyzer to the LAN (Local Area network) by cable.



2. Other Device: Access into the Analyzer

- (1) Please open the browser of your computer/Laptop and then enter the IP. (You could check this information from the analyzer by clicking the icon of Settings & LAN Password.)



- (2) Please Login by entering the LAN Password. (You could check this information from the analyzer by clicking the icon of Settings & LAN Password.)
- (3) You could preview PDF or MP4 files.

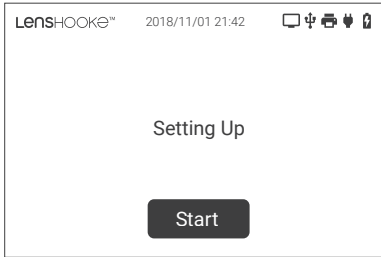
NOTE

- If there are too many people accessing into the same analyzer at the same time, it might affect the performance of the analyzer.
- Please use the following browsers to activate the access page.
 - FireFox, Chrome, Microsoft Edge for Windows 10...etc.
 - (Please refer to www.LensHooke.com for more details.)
- Please plug in power for the analyzer if you want to connect it to the LAN.
- Status of all records on the LAN is only for analyzer status.

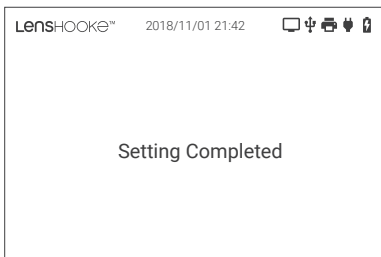
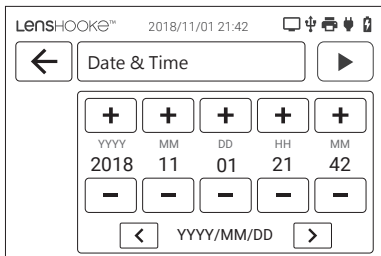
VII. Getting Started

Setup the analyzer:

- (1) Click the icon "Start" and then select the Language preference. After that, please click the icon "▶" to set up the Date & Time.



- (2) Setup the format of DD/MM/YYYY, MM/DD/YYYY or YYYY/MM/DD by clicking the icon "◀" or "▶", and adjust date & time by clicking the icon "+" or "-". After that, please click the icon "▶" to select the edition of WHO. When you select the edition of WHO, please click the icon "▶" to complete the setting. After that, the message of "Setting Completed" will show on the screen.

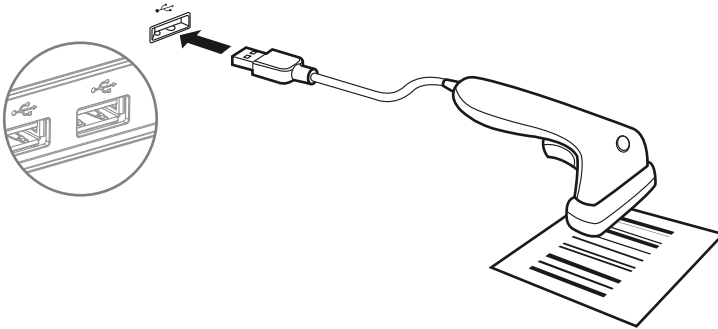


- The analyzer could **ONLY** read the following letters, numbers, and symbols.

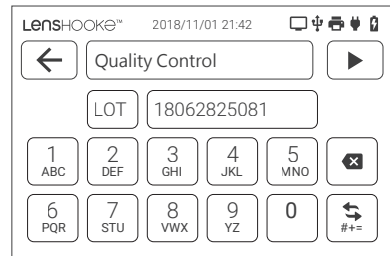
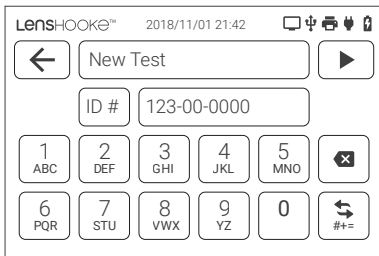
Barcode Scanner

1. To connect the Barcode Scanner with Analyzer

(1) Please connect the barcode scanner with the analyzer by USB Port.

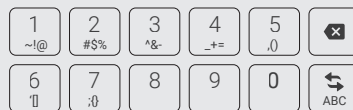


(2) You could use the barcode scanner to enter the patient's ID# for the real sample test or the LOT# of X QC Beads for the quality control test.



NOTE

- The analyzer could ONLY connect with the barcode scanner by USB port.
- The analyzer could ONLY read the following letters, numbers, and symbols.



Prepare the Test Analyzer

1. Please put the analyzer on a flat surface, ex. desk.
2. Check if the analyzer is under the normal operating status.
3. Check battery status. If the battery is low, connect the power adaptor before testing.



- Refer to “Turn on/off” on page 4 for normal operating status. Refer to “Charging the battery” (Page 5) for battery status.

Testing

1 Semen sample collection

Refer to the C-KUP™ Liquefaction Test Cup user manual for details.



- **Interference:** Refer to the user manual of LensHooke™ Semen Test Cassette.

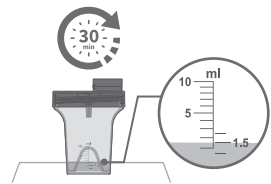


- **For the purposes of preventing cross infection, please wear gloves when performing the test.**

2 Check the liquefaction status, colour, and volume for the semen sample.

Step 1. Put the C-KUP™ Liquefaction Test Cup (with the semen) on the desk and wait 30 minutes for liquefaction.

Step 2. Check the semen sample colour and volume
(graduation mark of the C-KUP™ Liquefaction Test Cup)



Step 3. Flip the C-KUP™ Liquefaction Test Cup for 8~10 times to mix the sample.

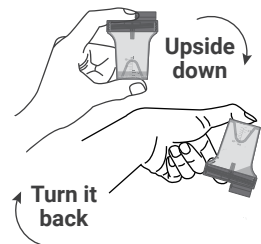
Invert
8~10 times
Mix the Sample



Before

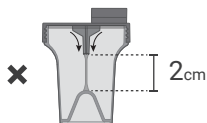


After

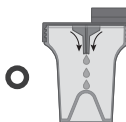




- Incomplete liquefaction: the sample drop will form a thread more than 2 cm long.



- Completed liquefaction: the sample drop is in small discrete drops. (Please refer to the images at right hand side for the difference.)



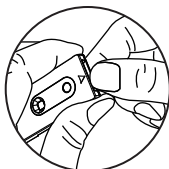
NOTE

- Semen analysis should begin with a simple inspection soon after liquefaction, preferably at 30 minutes, but no longer than 1 hour after ejaculation, to prevent dehydration or changes in temperature from affecting semen quality, please refer to **"WHO laboratory manual for the Examination and processing of human semen"** for more detail.
- If the sample had not completed liquefaction, please wait for another 30 minutes and check the liquefaction status again.
If the sample still had not liquified, DO NOT use the sample. (It will affect the test result.)
According to the treatment for **"Delayed liquefaction"**, please refer to **"WHO laboratory manual for the Examination and processing of human semen"** for more detail.
- If the sample completed liquefaction, please use this sample to do the test immediately. Please remix the sample again to ensure all of the sample has been mixed well before testing. Unmixed samples may lead to inaccurate results.
- Please follow the standard medical waste procedure to dispose the test sample. Please wear gloves or personal protection equipment to handle the test sample.

3 Open the cassette and drip the sample

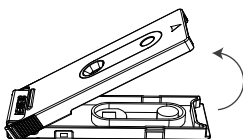
Step 1.

Remove one semen test cassette from the package.



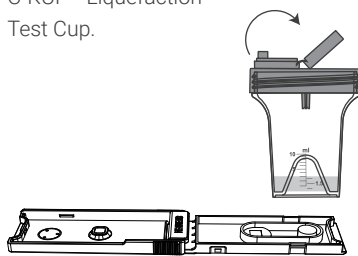
Step 2.

Open a test cassette cover by using your thumb. After that please place the opened test cassette on a flat and stable surface.



Step 3.

Open the tip cap of the C-KUP™ Liquefaction Test Cup.



Please open the cover from Δ area.

NOTE

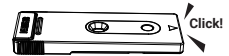
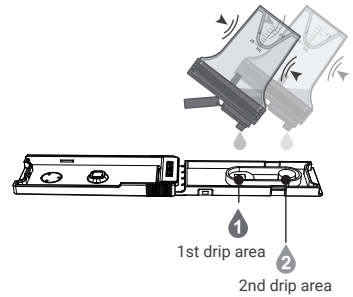
- DO NOT use expired test cassettes.
- DO NOT place the opened cassette on any unstable surface when adding the sample.

Step 4. Squeeze the body of the cup to apply a drop of the sample on the 1st drip area of the cassette to test the pH value.

Step 5. Squeeze the body of the cup to apply another drop of the sample on the 2nd drip area of the cassette to test the sperm concentration, motility, and morphology.

Step 6. Cover up the drip cover of the C-KUP™ Liquefaction Test Cup.

Step 7. Cover up the test cassette until you hear the “Click” sound.




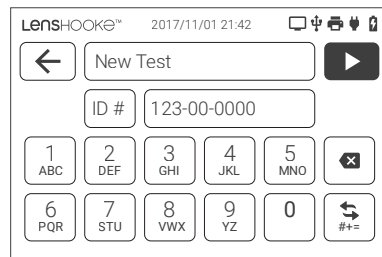
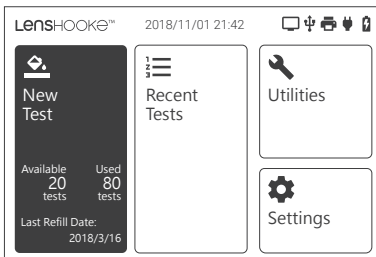
NOTE

- Insert the cassette into the analyzer within 30 seconds after adding the sample.
- The test cassette is only for single use. Please throw away after use. DO NOT reuse.
- DO NOT touch the window and drip area of the test cassette.

4 The test cassette is now ready for testing.

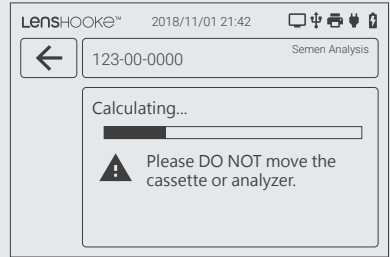
Step 1. Click the icon “New Test”.

Step 2. Please Enter the ID number and click  to go to the next step.



NOTE

- If a “❄” symbol appears next to the concentration result, it means that the sample has aggregation of spermatozoa, sperm crystals, or bubbles that may impact the result. We will suggest you to note the result or redo the test.
- DO NOT move the cassette or analyzer during the calculation.
- The analyzer will not calculate the pinhead, since it is not considered a sperm by the clinic as it has no chromatin. If you want to use our analyzer to exam for the vasectomy patient, please use the manual exam method to double confirm.



VIII. Cleaning and Maintenance

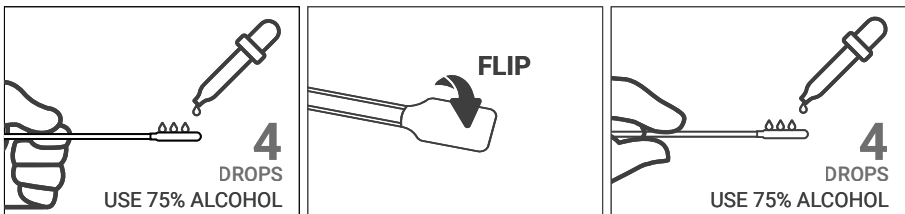
1 Suggestion for Routine Clean

- (1) Test Cassette Insert Slot could only be cleaned by “LensHooke™ Cleaning Wipe”.
- (2) Please DO NOT use other materials to clean the Test Cassette Insert Slot.
- (3) LensHooke™ Cleaning Wipe is disposable. DO NOT reuse.
- (4) Keep LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) away from dust, water or any liquids.
- (5) Clean the body of LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) every day when you finish the tests.

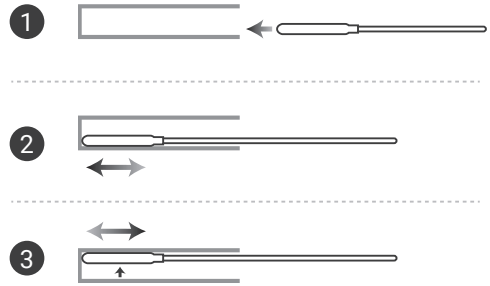
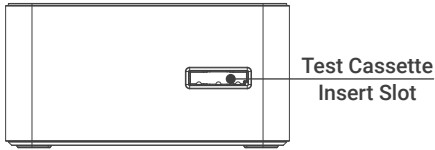
2 Steps for Cleaning

I. Test Cassette Insert Slot:

- (1) Turn off the analyzer before cleaning.
- (2) Prepare 2 pcs of LensHooke™ Cleaning Wipe.
- (3) Please drop 4 drops of the 75% alcohol for each 2 sides of a LensHooke™ Cleaning Wipe.



- (4) Please insert this LensHooke™ Cleaning Wipe into the test cassette insert slot, and follow the instruction to clean.



(5) Please use another new dry LensHooke™ Cleaning Wipe (without alcohol or any liquid) to clean the insert slot again.

(6) Throw away the used cleaning wipe.

(For USA market, please use **CaviWipes** to disinfect the insert slot first before you start to use the LensHooke cleaning wipe to clean.)

II. Analyzer Body:

(1) Use the alcohol swab to clean the body of analyzer.

(2) Throw away the used alcohol swab.

(For USA market, please use **CaviWipes** to disinfect & clean the body of analyzer instead of using the alcohol swab.)

NOTE

- Use LensHooke™ Cleaning Wipe to clean the LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic).

Cleaning and Disinfection Procedure (For USA, CANADA)

(1) CaviWipes® DISINFECTING TOWELETTES has been tested and may be used to clean and disinfect the meter. Users may purchase the disinfecting wipes from the manufacturer (METREX), distributors or major on line retail sites such as amazon.com.

Please follow the prepared wipes product label manufacturer's instructions for cleaning and disinfecting the Meter.

To clean the analyzer:

(1) Clean and wipe the all surface of the analyzer.

To disinfect the analyzer:

(2) Take another disinfecting wipe and wipe the analyzer thoroughly. (Note: analyzers should be cleaned with a fresh wipe before performing disinfecting procedure)

(3) Allow surface to remain wet for 2 minute.

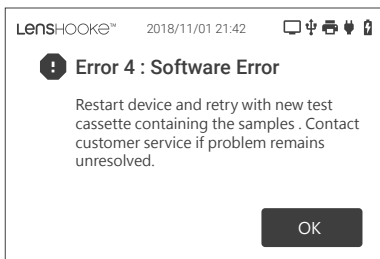
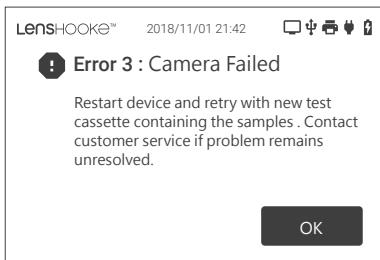
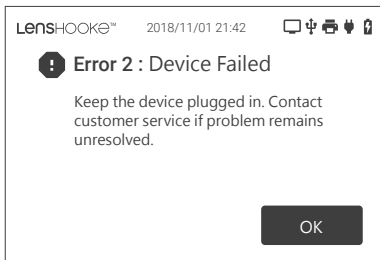
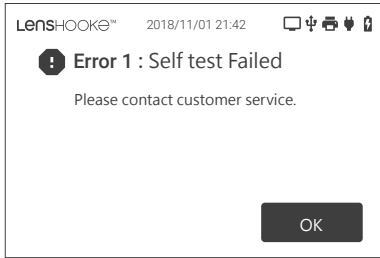
(4) Allow to air dry.

NOTE

- Your LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) has been tested to ensure that there is no change in performance or external materials of the analyzer after 10,950 cleaning cycles and 10,950 disinfecting cycles. This testing simulates 10 cleaning and disinfecting cycles per day over the typical life of the analyzer (3 years).

IX. Error Messages

Error Messages



Solution

Error 1:

Self test failed. It might be a start up failure.

Please contact our customer service.

Error 2:

Device failed. It might be an analyzer problem.

Please remove the test cassette and click the icon "OK" to return to home page then turn the analyzer off. (Refer to "Turn on/off" on Page 4 for normal operation status.) If this message still appears, contact our customer service.

Error 3:

Camera failed. It might be a camera problem.

Please remove the test cassette and click the icon "OK" to return to home page.

Please insert another new test cassette redo the action. If this message still appears, contact our customer service.

*Make sure you're using correct LensHooke™ Semen Test Cassette.

Error 4:

Software Error. It might be a software problem.

Please remove the test cassette and click the icon "OK" to return to home page then turn the analyzer off. (Refer to "Turn on/off" on Page 4 for normal operation status.)

X. Analyzer Specification

Analyzer name

LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic)

Control panel

3.5-in resistive touch screen

External power input

AC 100-240V / 50~60 Hz; Output DC 5V / 2A

Battery durability

2500 mA (embedded re-chargeable lithium polymer battery, DC3.7V / 2.5Ah)

Internal storage capacity

30 records including data and images

Detection time

2~5 minutes (depends on the sample condition)

Power adaptor:

Input: 100~240 Vac, 50~60 Hz, 0.5 A

Output: 5 Vdc, 2 A Max

Operation environment

Temperature 15°C~38°C (59°F~100°F)

Humidity <70%

Storage environment

Temperature 15°C~38°C (59°F~100°F)

Humidity <70%

Transportation environment

Temperature -10°C~60°C (14°F~140°F)

Measurements Range

pH 6.0~8.0 (Each Scale Range:0.2)

Concentration <0.1-300 (10⁶/ml)

Total Motility <1-100%

Morphology (Normal forms) <1-100%

XI. Reference

Reference of Parameter from WHO Laboratory Manual for the Examination and Processing of Human Semen.

Reference	WHO 5th Low Reference	WHO 4th Low Reference
Concentration	15 x 10 ⁶ (12-16)/ ml	≥ 20 x 10 ⁶ / ml
Motility	40% (38-42%)	a + b ≥ 50% or a ≥ 25%
PR (Progressive Motility)	32% (31-34%)	
Morphology(Normal)	4% (3-4%)	≥ 15%

a : Rapid Progressive Motility (≥25μm/s)

b : Slow or Sluggish Progressive Motility

XII. Statement

All relevant contents of the user manual related to this product is not allowed to be reproduced, distributed, duplicated or stored in any kind of retrieval system without permission in writing from Bonraybio Co., LTD. Bonraybio reserves all rights to change the description of the hardware and software's technical specifications in this manual at any time without prior notice. We will try our best to ensure the content. If there are any mistakes or unclear information, please contact your local distributor. We highly appreciate any feedback for this manual.

XIII. Warnings and Precautions

1. Overvoltage Category: Level II
2. Pollution Degree: Level 2
3. Altitude: < 2000 meters
4. Relative humidity (RH%): < 70%
5. Indoor Use
6. While installing and operating this transmitter, the radio frequency exposure limit of 10 W/m² may be exceeded at distances close to the transmitter. Therefore, the user must maintain a minimum distance of 20 cm from the analyzer at all time.
7. The IP code is IP21 is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically dripping water.
8. Avoid strangulation resulting from baby or child entanglement in monitoring cables.
9. Avoid choking resulting from a child swallowing a small part.
10. The test result is followed WHO Laboratory Manual for the Examination and Processing of Human Semen. Please refer to the user manual of LensHooke™ Semen Test Cassette.

NOTE

- LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic), Semen Test Cassette, and C-KUP™ Liquefaction Test Cup

Manufacturer:

Bonraybio Co., LTD.

4F., No. 118, Gongye 9th Rd.,

Dali Dist., Taichung City 41280,

Taiwan (R.O.C.)

Product complied with In Vitro Diagnostic Medical Device Directive 98/79/EC. (CE)

- Electromagnetic compatibility, emission, and immunity, and the requirements of IEC 61326-2-6 apply.

XIV. Warranty

Bonraybio offers a one-year warranty from the day you purchase the LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic). During the warranty period, we will repair or replace the analyzer free of charge.

The warranty only applies to the original LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic) from Bonraybio. The warranty will be voided if the analyzer is modified or improperly used.



Manufacturer : Bonraybio Co., LTD.
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