LensHOOKe®

X1 PRO

Semen Quality Analyzer

English
User Manual ▶

Deutsche
Benutzerhandbuch ▶

日本語
ユーザーマニュアル ▶

Italiano
Manuale d'uso ▶

Português
Manual do usuário ▶

LensHOOKe®

Semen Quality Analyzer

User Manual

X1 PRO

Rev.29-0X10003 20210219X1E003

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 RE-USE"**

Symbol for **"USE-BY DATE"**

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 MEDICAL DEVICE"**

Symbol for **"TEMPERATURE LIMIT"**

Symbol for **"CONSULT INSTRUCTIONS FOR USE"**

Symbol for **"WEEE WASTE RECYCLING"**

CE mark

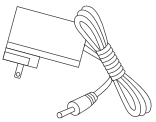
Symbol for **"FOLLOW INSTRUCTIONS FOR USE"**

Symbol for **"The intended use of a prescription IVD product"**

The package includes

- **LensHooke® X1 PRO Semen Quality Analyzer**

- **Power Adaptor** (for analyzer)



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I. Introduction

LensHooke® X1 PRO Semen Quality Analyzer is for in vitro diagnostic only. The user should read this User Manual first, to get familiar with the device and its proper operation procedure prior to use the analyzer. "LensHooke® Semen Test Cassette" is the general description for "LensHooke® CS0 Semen Test Cassette" and "LensHooke® CS1 Semen Test Cassette".

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 used with LensHooke® Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated quantitative measurements for:

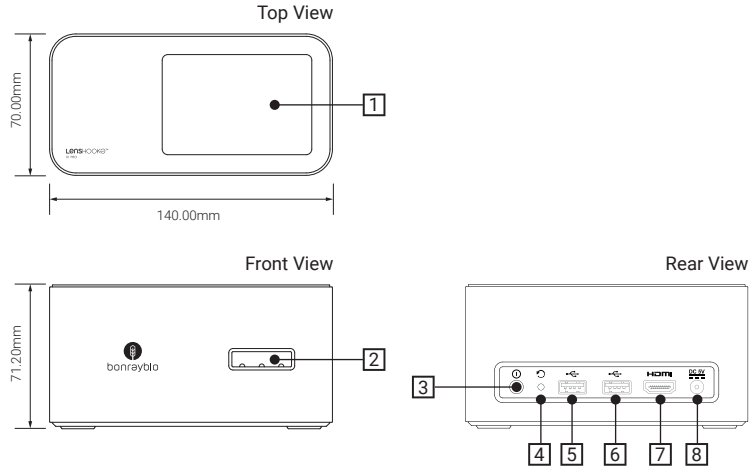
(1) Sperm concentration (10^6 per ml)
(2) Total motility (PR+NP, %)
- Progressive motility (%)
- Non-Progressive motility (%)
- Immotility (%)
- Other parameters from CASA assessment (MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, and BCF)

(3) Sperm morphology (normal forms, %)
(4) pH value

The LensHooke® X1 PRO Semen Quality Analyzer 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



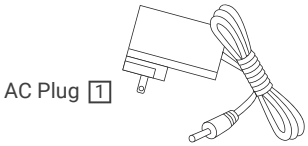
1 Touch Screen
2 Test Cassette Insert Slot
3 Power Button
4 Reset Button
5 USB Port
6 USB Port
7 HDMI Port
8 Power Adaptor Port

NOTE

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

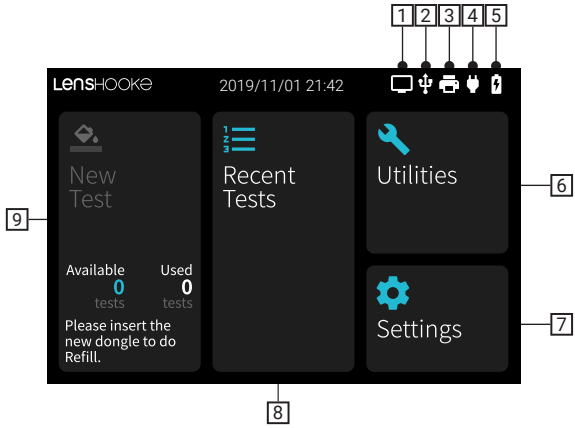
Accessories

- **Power Adaptor**



Dongguan Shilong Fuhua Electronic Co., Ltd;
UES12LCP-050200SPA

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 a USB Drive.
3 **Thermal Receipt Printer connection icon:** This analyzer is connected to a Thermal Receipt Printer.
4 **Power Adaptor connection icon:** This analyzer is connected to a power adaptor.
5 **Battery icon:** It shows the battery status.

NOTE

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

The icons below are functional

6 **Utilities icon:** Functions include:
- 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.
- About: To get the informations of the analyzer/device.
- Delete All Records: To remove/delete all results.
- Insert Logo: To Insert logo on the top of the PDF report.

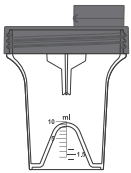
7 **Settings icon:** Functions include:
- WHO Standard: To select WHO edition of 4th or 5th.
- Date & Time: To set up the Date and Time.
- Network Connection: To select the IP preference.
- Access Password: To get or change the password to access into the anaylzer.
- Brightness: To adjust the brightness of the screen.
- Language: To select the language preference.

8 **Recent Tests icon:** To review the previous test results.
9 **New Test icon:** To start testing.

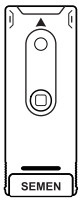
IV. Consumables

The consumables for LensHooke® X1 PRO Semen Quality Analyzer are as below:

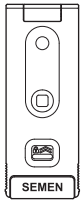
- **C-KUP™ Liquefaction Test Cup**



- **LensHooke® CS0 Semen Test Cassette**



- **LensHooke® CS1 Semen Test Cassette**



- **LensHooke® Cleaning Wipe**

- **LensHooke® X QC Beads (For Semen)**

- **LensHooke® X QC Reticle (For Semen)**

- **LensHooke® X QC Video (For Semen)**

The result might be inaccurate, if you DO NOT use the LensHooke® Semen Test Cassette or LensHooke® X QC series products.

NOTE

- Product pictures are schematic diagrams only. Please refer to the actual products.
- C-KUP™ Liquefaction Test Cup is for semen sample collection.
- LensHooke® Semen Test Cassette is a specific counting chamber only for LensHooke® semen analyzer.
- LensHooke® Cleaning Wipe is used to clean the test cassette insert slot.
- LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) and LensHooke® X QC Video (For Semen) are used for quality control of the analyzer.

V. Major Function

LensHooke® X1 PRO Semen Quality Analyzer

Turn on / off

1 Turning on the analyzer:

Push the power button down for 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.

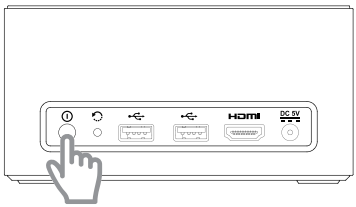


Image 1

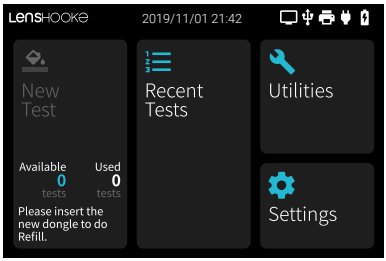


Image 2

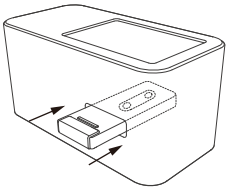
2 Turning off the analyzer:

Hold down power button for 10 seconds to directly turn off the analyzer, or you can also push the power button for 2 seconds until the touch screen shows **"Power Off"** and select the icon to turn it off.

Insert / Remove the Test Cassette

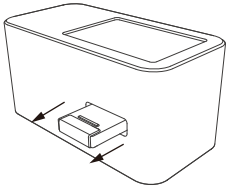
1 Insert the Test Cassette:

Insert the test cassette into the slot and push it to the end.



2 Remove the Test Cassette:

After the test, take the test cassette out of the slot.



Charging the battery

1 When the battery power is low, the **"Low Battery"** message will show on the screen (Image 3). 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.

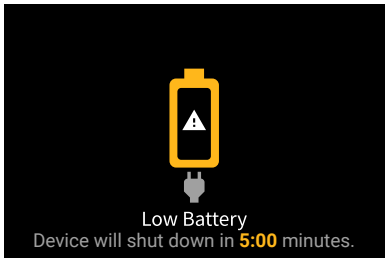


Image 3

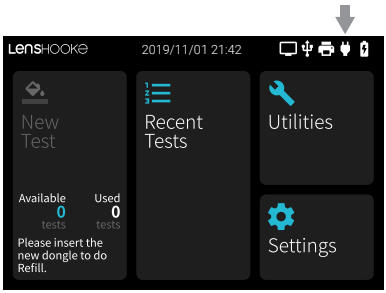


Image 4

- Analyzer is equipped with a built-in 2500 mAh Lithium-ion polymer battery.
- The battery can not be removed or changed. If you have battery related problems, please contact us.

NOTE

- If you want to enter power saving mode, please press the power button. If you want to wake up the analyzer, please press the power button again.
- If the device had idled for 10 minutes, the system will automatically enter Power Saving Mode.

  * **Power Saving Mode:** Turns off the touch screen to reduce battery consumption.
- For the purpose of extending the built-in Lithium-ion polymer battery life, please keep the adaptor plugged in even while not using the analyzer.
- If the analyzer has not been used for over 3 months, please charge before using.
- If the analyzer runs out of battery, the date and time indicator might be reset to the default settings. Please check and set up the date & time properly (refer to Page 17).
- If the warning messages **"Battery overheating"** or **"Battery Temperature is too Low"** show on the screen, the analyzer will shut down automatically within 5 minutes to protect itself. When you see the above warning message, please turn off the analyzer, then place the Analyzer under the operation environment as 15°C ~ 38°C (59°F ~ 100°F), Humidity <70% for more than 1 hour, then connect the power adaptor to the analyzer and turn on the analyzer for use.

Prepare the Test Analyzer

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

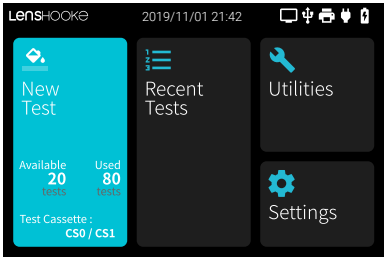
Prepare the Sample

1. Refer to the LensHooke® Semen Test Cassette user manual to prepare the sample.

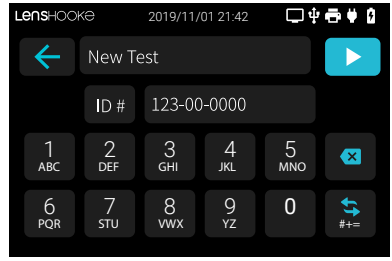
Test the Sample

1 New Test

Step 1. Select the **"New Test"** icon.

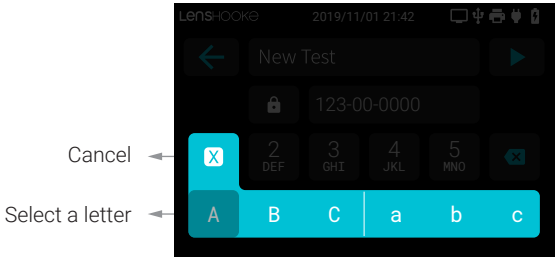


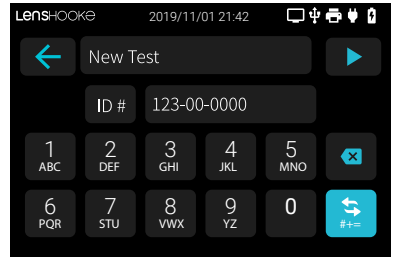
Step 2. Please input the patient ID number and select the " ▶ " icon to go to the next step.



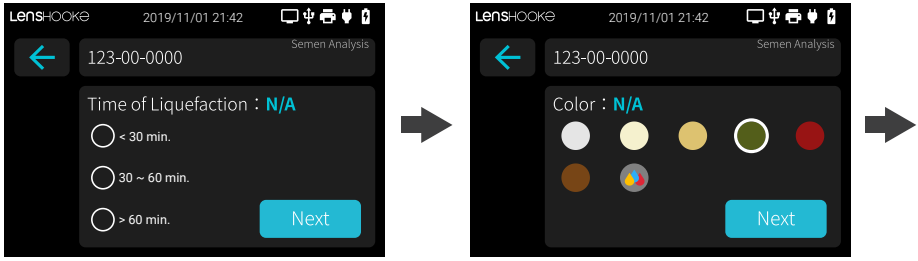
NOTE

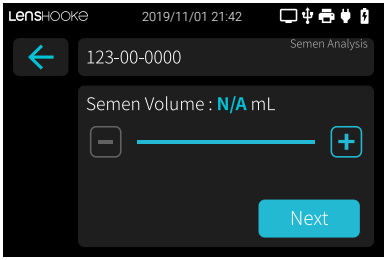
- DO NOT exceed 20 characters and symbols for the patient ID#.
- If you want to input a letter, please hold the icon for around 1 second and select the letter. If you want to input a symbol, please select the " ⇆ " icon to switch the keyboard.
- You can also use a barcode scanner to scan the bar or QR code of patient ID#. (Plese refer to page 25 to connect the barcode scanner to the analyzer.)
- Please refer to Page 22 of this user manual for refill.

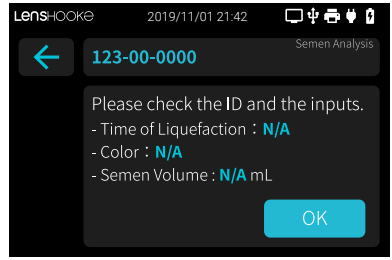




Step 3. Please select the Liquefaction Time, Semen Colour, Semen Volume, and then select **"Next"** to go to the next step. Select the **"OK"** icon if the information is correct.







NOTE

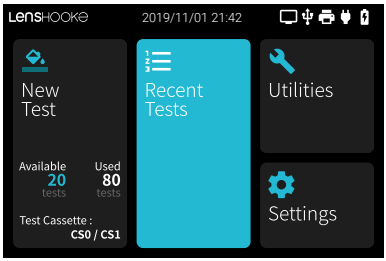
- Please select ⊖ and ⊕ to adjust the semen volume.
- DO NOT move the cassette or analyzer during the results calculation.

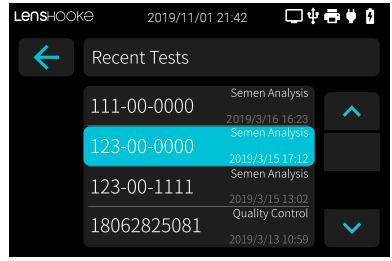
Step 4. Insert the test cassette (with sample) into the slot and push it to the end.

Review the Test Result

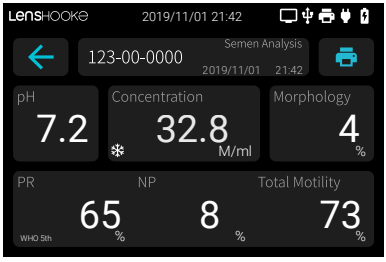
1 Recent Tests

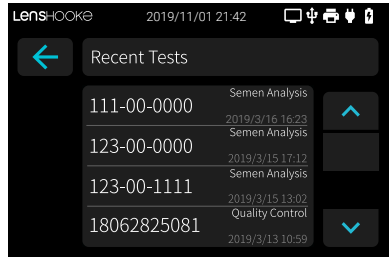
(1) Select the **"Recent Tests"** icon and then select the record you want to review by patient's ID.





(2) The record will appear on the screen. If you want to go back to the record list, please select the "⟵" icon to return to the previous page.





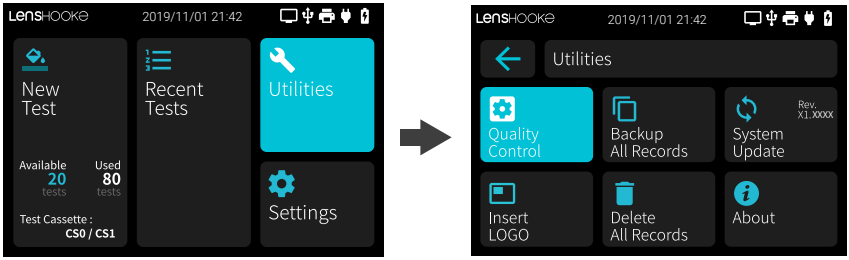
NOTE

- ONLY the icon that turn blue can be selected.
- You can also connect the analyzer to the LAN to print out the result. (Please refer to page 24 to connect the analyzer to the LAN.)
- 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 or seek professional assistance.
- If a " ▨ " symbol appears next to the motility result, it means that the device detects the sperms move by push rather than swim that may impact the result. We will suggest you to note the result or redo the test or seek professional assistance.
- 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.
- If you didn't apply the sample to the pH drip area, the result of pH value will show < 6.0. Therefore, please check the pH drip area of the test cassette, if the result shows < 6.0.

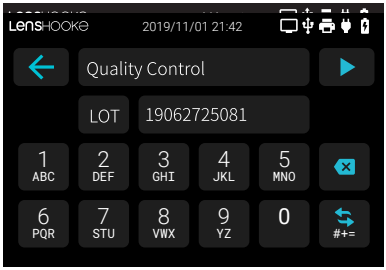
Utilities

1 Quality Control

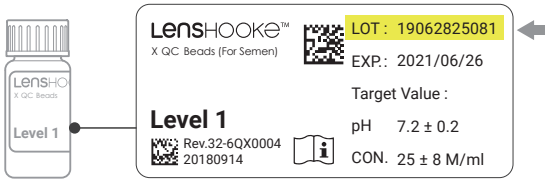
(1) Select **"Utilities"** and then select the **"Quality Control"** icon.



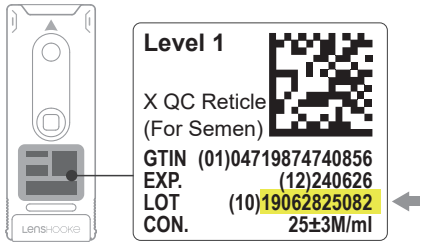
(2) Please input the LOT number on the label of the LensHooke® X QC Beads (For Semen) or LensHooke® X QC Reticle (For Semen) or LensHooke® X QC Video (For Semen). Please confirm the LOT number and then select **"▶"** to go to the next step.



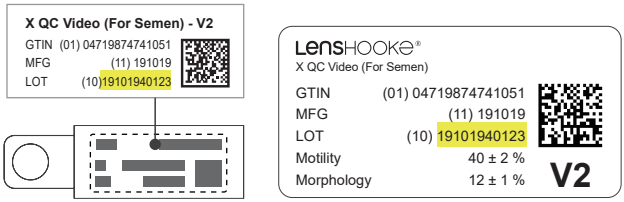
• LOT number of X QC Beads (For Semen)



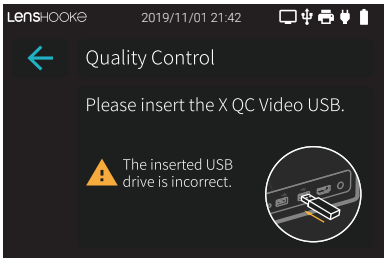
• LOT number of X QC Reticle (For Semen)



• LOT number of X QC Video (For Semen)

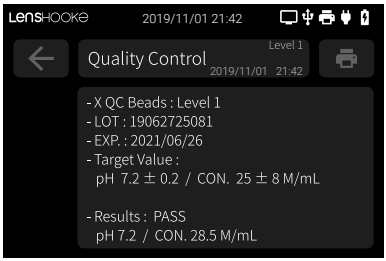


(3) Please follow up the instructions of LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) or LensHooke® X QC Video (For Semen) to operate and then insert the cassette into the **"Insert Slot"** or insert the LensHooke® X QC Video USB into USB Port.

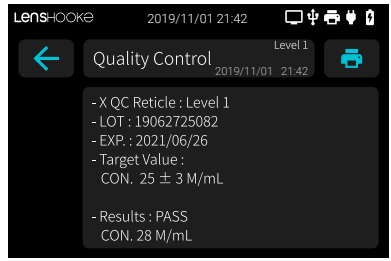


(4) After 2-5 minutes, the result will appear on the screen automatically.

• Result of X QC Beads



• Result of X QC Reticle

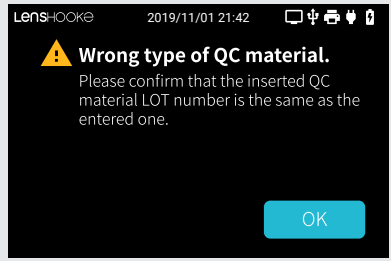


• Result of X QC Video

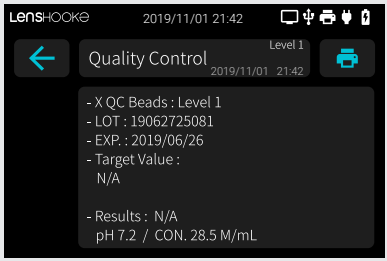
NOTE

- LensHooke® X QC Beads (For Semen) exams pH value and concentration.
  LensHooke® X QC Reticle (For Semen) ONLY exams concentration.
  LensHooke® X QC Video (For Semen) ONLY exams motility and morphology.

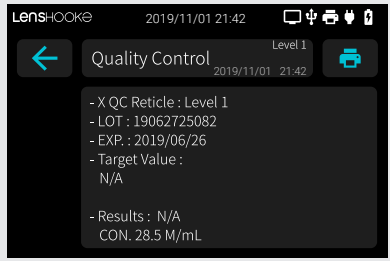
- If you input the LOT number of LensHooke® X QC Beads (For Semen) but insert the cassette of LensHooke® X QC Reticle (For Semen), the analyzer will show the message as below to warn you, and vice versa.



- If N/A shows on the result screen, it means that the LensHooke® X QC Beads (For Semen) or LensHooke® X QC Reticle (For Semen) is expired. Please use another new one or contact customer service.



X QC Beads

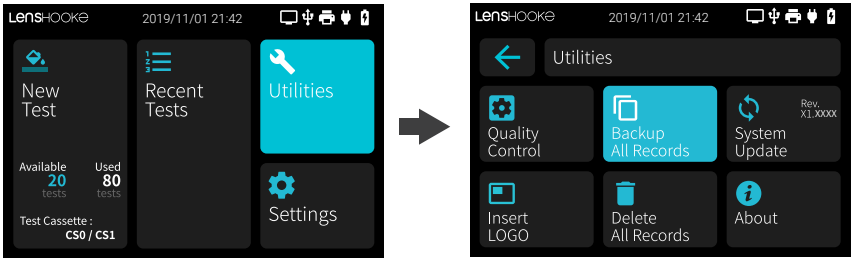


X QC Reticle

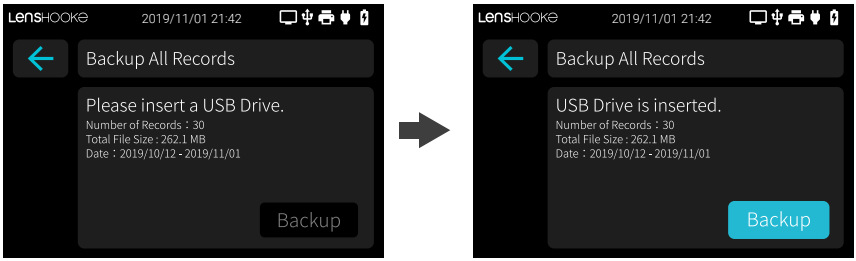
2 Backup All Records

(1) Prepare a USB Drive in advance. (Capacity : 1GB or more)

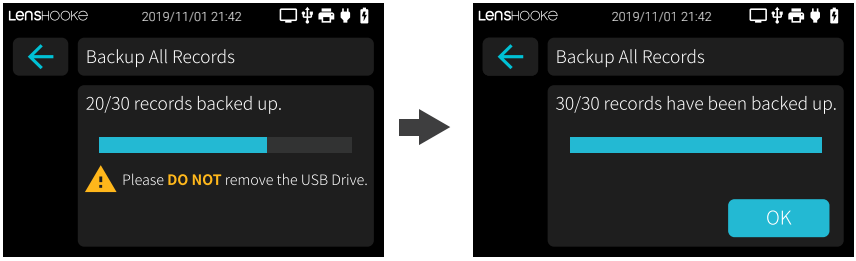
(2) Select **“Utilities”** and then select **“Backup All Records”**.



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



(4) When the records have been backed up to your USB Drive successfully, select the **“OK”** icon to return to the previous page.



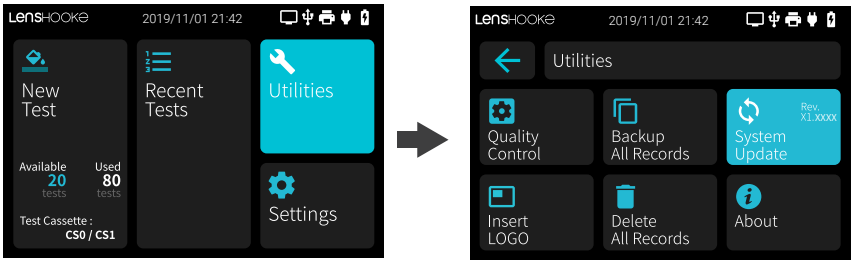
NOTE

- DO NOT remove the USB Drive during back up.
- If the memory capacity of analyzer is insufficient, the **“Insufficient Storage Available”** warning message will appear on the screen. Please back up all records before you delete them to free up capacity.
- If the memory capacity of the USB Drive is insufficient, please remove the USB Drive and delete the files using a computer/laptop, or using another USB Drive.
- After backed up the records, you will get the PDF, MP4, and CSV files at the same time.

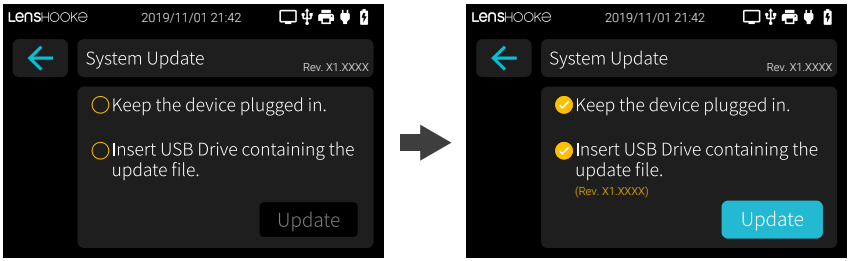
3 System Update

(1) Prepare the a USB Drive with system update software. (Capacity : 1GB or more)
(Please contact with your local distributor for the system update software).

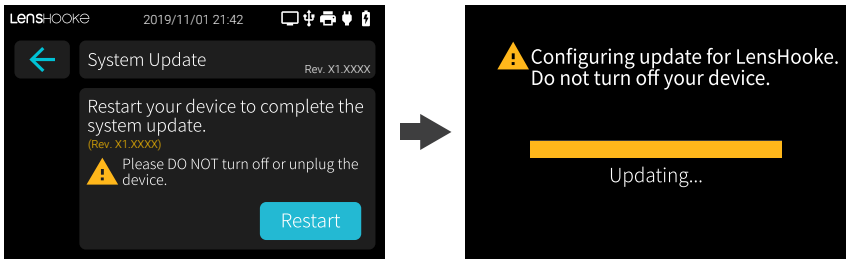
(2) Select **"Utilities"** and then select the **"System Update"** icon.



(3) Please connect the device with the power adaptor, and plug the USB Drive with the update file into the analyzer. Select the **"Update"** icon to update the system.



(4) Select the **"Restart"** icon to restart the analyzer and complete the system update. The system will configure updates automatically, and restart the analyzer when the system update is completed.



NOTE

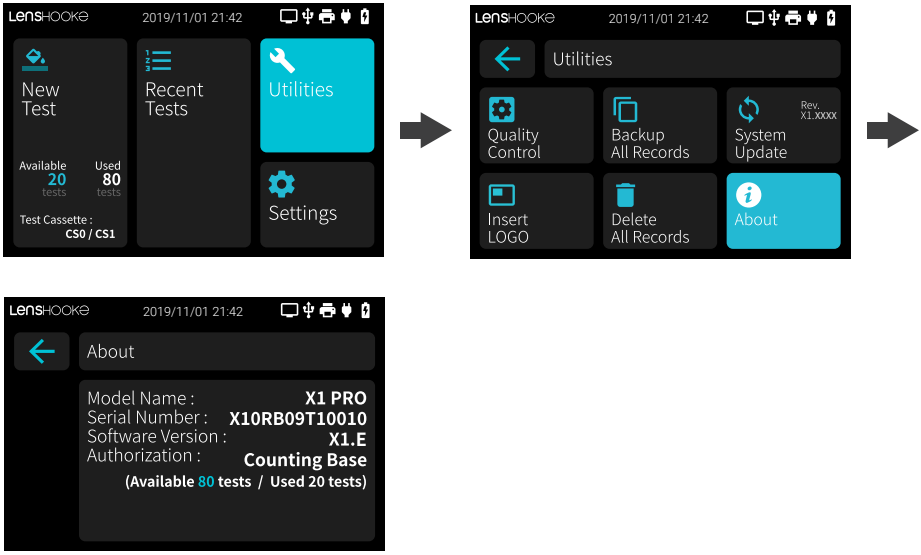
- Please back up all records before system update.
- DO NOT turn off or unplug the device during the update process. Make sure to plug in the power adaptor and insert the USB Drive with system update file when updating the system.

NOTE

- If the **"Update File is Corrupted"** warning message appears on the screen, it 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 appears on the screen, it 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.

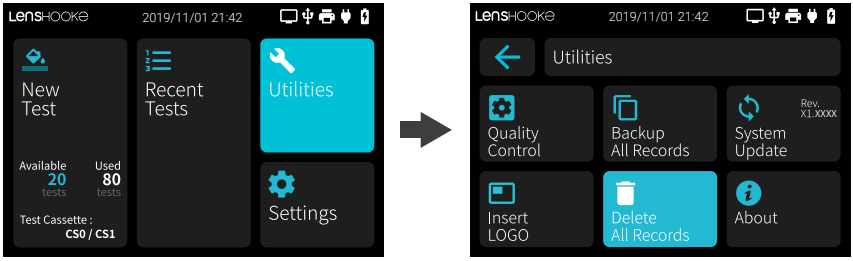
4 About

Select **"Utilities"** and then select the **"About"** icon to read about the analyzer's information.

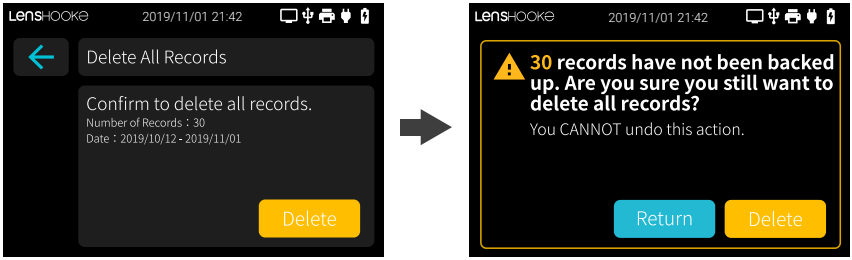


5 Delete All Records

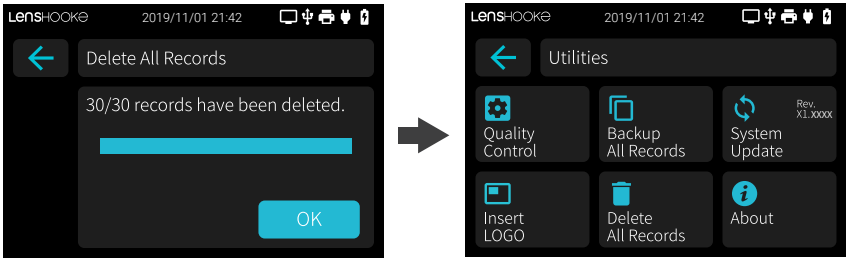
(1) Select **"Utilities"** and then select the **"Delete All Records"** icon.



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



(3) Select the **“OK”** icon to return to the previous page.

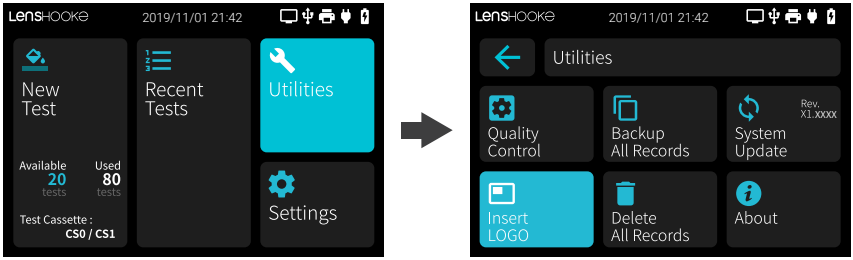


NOTE

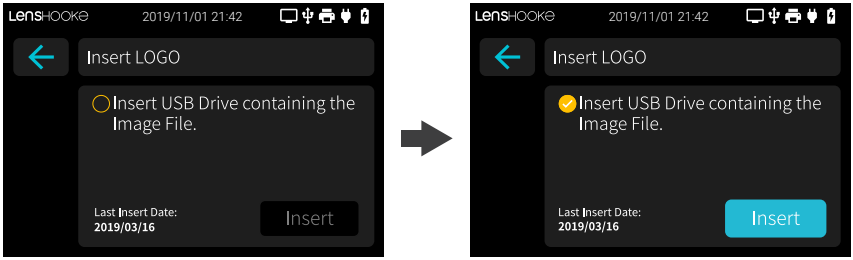
- The records cannot be recovered after you delete them. Make sure you want to delete them permanently before selecting the **“Delete”** icon.

6 Insert LOGO

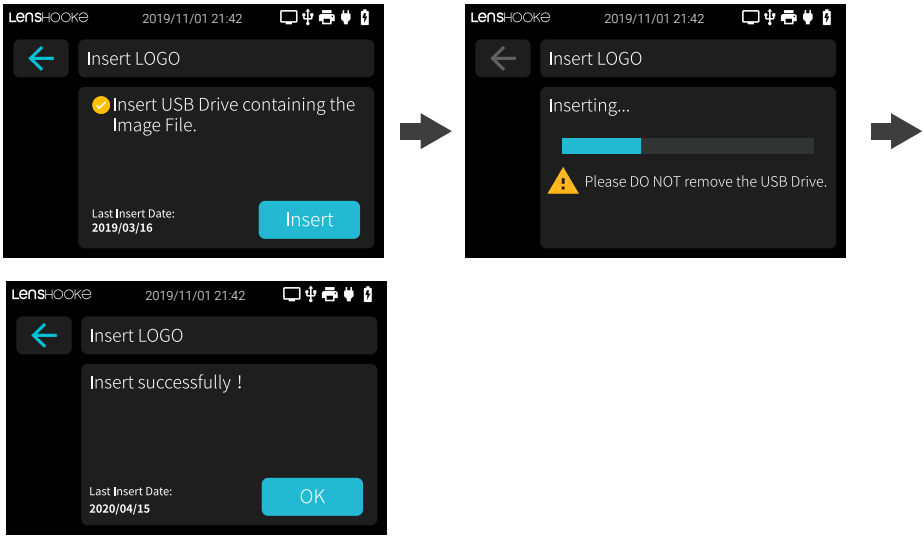
(1) Select the icon **“Utilities”** and then select the icon **“Insert LOGO”**.



(2) Insert the USB Drive.



(3) Select the **“Insert”** icon and wait until the message of **“Insert successfully!”** appears on the screen.



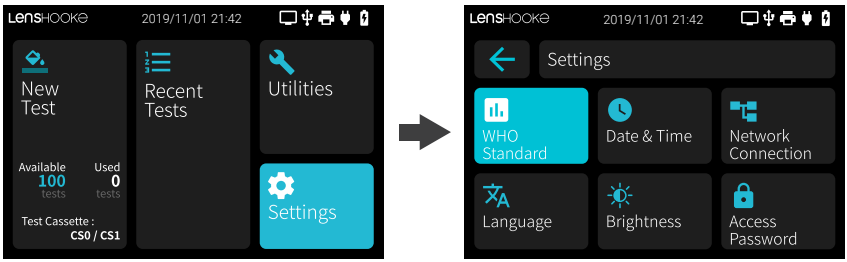
NOTE

- The LOGO image must be in PNG format by 2040x168 pixels, and file has to be named **“lenshooke_X1_pdf_logo.png”**.
- Just save the file to the USB drive directly. Please do not save it to the folder.

Settings

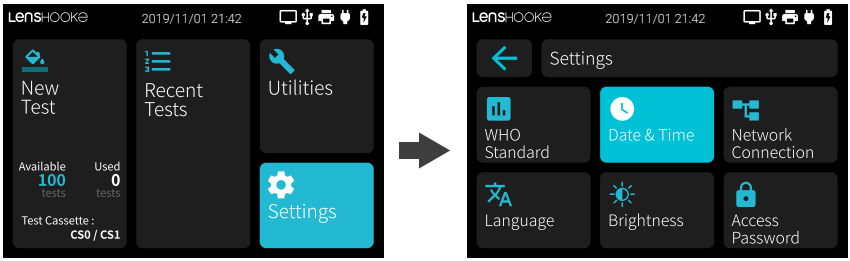
1 WHO Edition

(1) Select **“Settings”** and then select the **“WHO Standard”** icon, and select the preference edition.



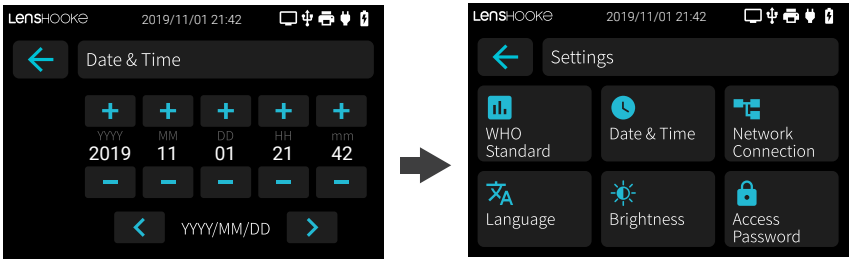
2 Date & Time

(1) Select **“Settings”** and then select the **“Date & Time”** icon.



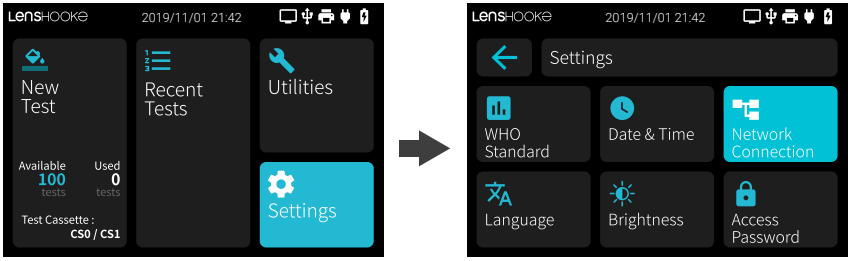
(2) You can select the format of the date by selecting the icon “ < ” or “ > ”, and adjust date & time by selecting “ + ” or “ − ”.

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

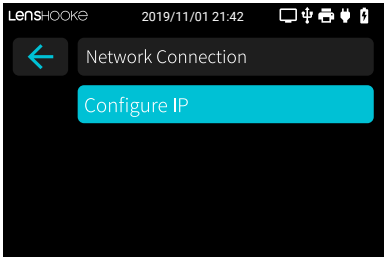


3 Network Connection

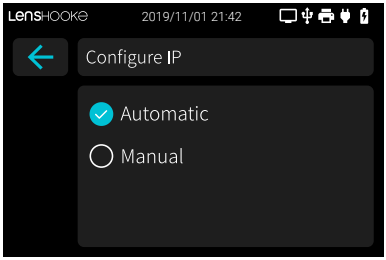
(1) Select **“Settings”** and then select **“Network Connection”** icon.



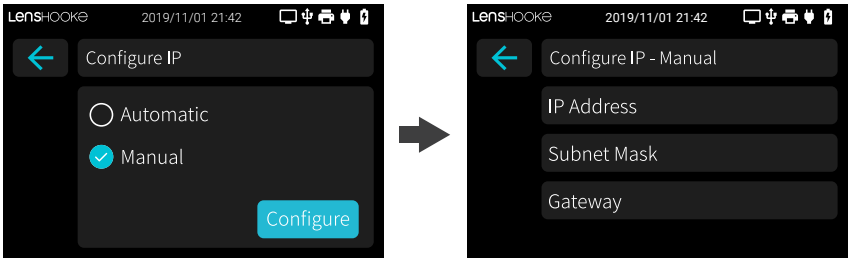
(2) Select **“Configure IP”**.



(3) The default setting is **“Automatic”**. When you choose this icon, the device use dynamic IP address, which is assigned when the network is connected and changes over time.



(4) If you want to change to the static IP address, please select **“Manual”** and then select **“IP address”**, **“Subnet Mask”**, **“Gateway”** and fill in the information respectively.

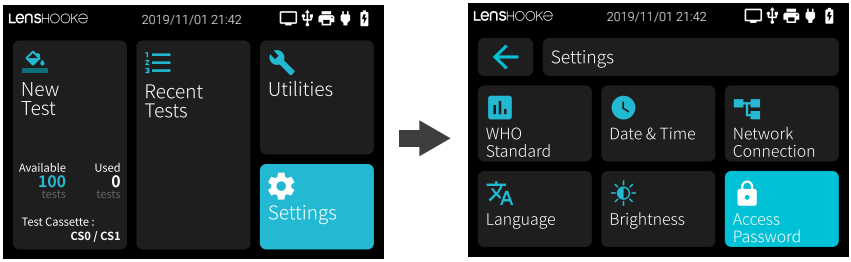


NOTE

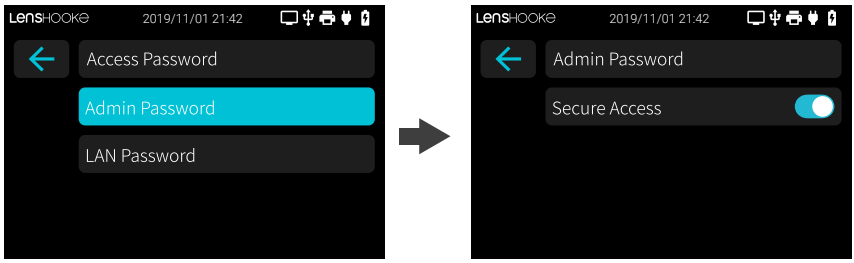
- If you don’t enter the completed information for IP address, Subnet Mask, and Gateway, the configure IP status will stay in **“Automatic”**.

4 Access Password

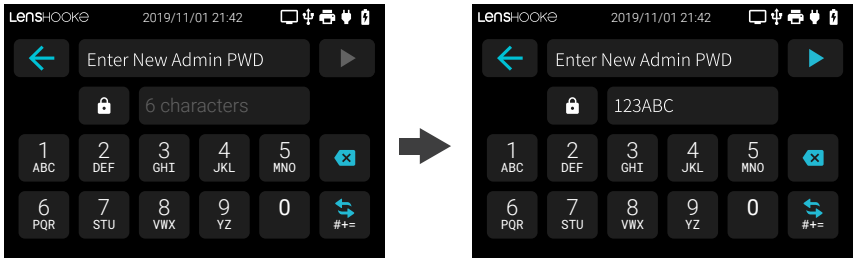
(1) Select **“Settings”** and then select the **“Access Password”** icon.



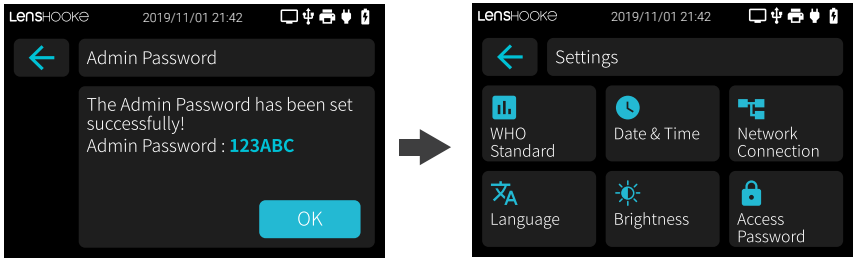
(2) Select **"Admin Password"** icon. Switch on " ◯ " of Admin Password to secure your access.



(3) Input any six characters as your new Admin Password, and then select the " ▶ " icon to go to the next step. Please input the six characters again to verify the new Admin Password.



(4) After you verify the new Admin Password, and then select the " ▶ " icon to go to the next step. Please select **"OK"** to return to the previous page.

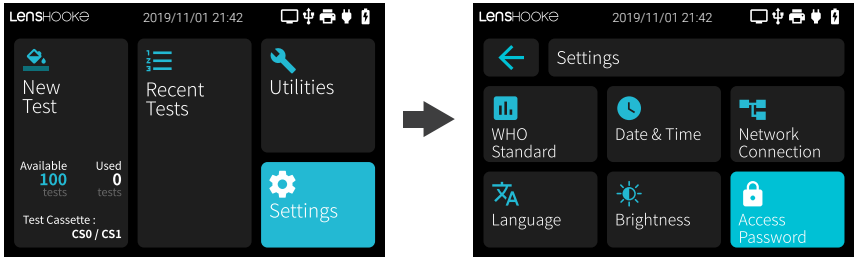


NOTE

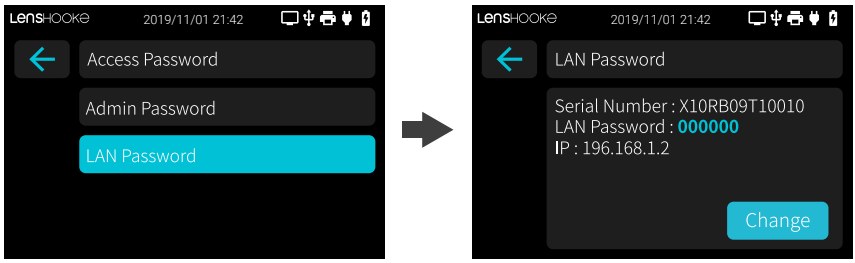
- The default password for the Admin Password is **"000000"**.
  Once the icons " ◯ " has been selected, it means your access is secured.
- If you want to access into the analyzer, you have to input the Admin Password to wake up the analyzer from the power saving mode.

5 LAN Password

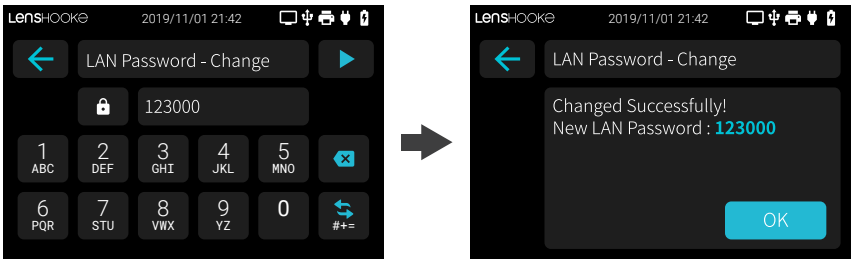
(1) Select **“Settings”** and then select the **“Access Password”** icon.



(2) Select the **“LAN Password”** icon, and the password will appear on the screen. If you want to change this LAN Password, you can select **“Change”**.



(3) Input any six-digit numeric code to set up the new password. After you input the new password, please select the **“** ▶ **”** icon to go to the next step. Please select the **“OK”** icon to return to the previous page.

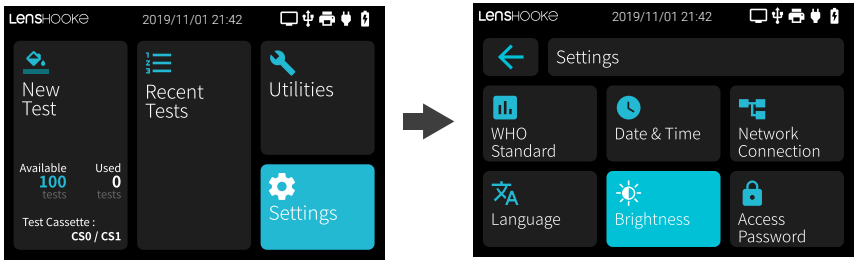


NOTE

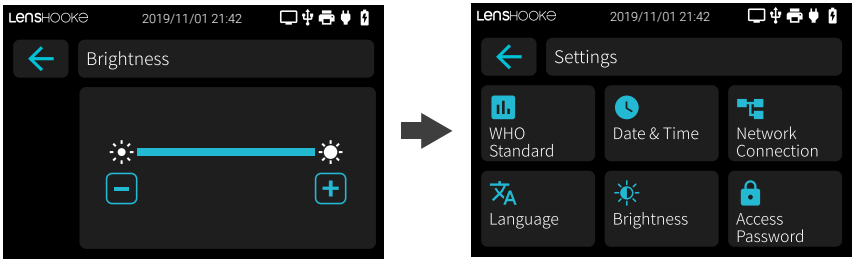
- The default password for the LAN Password is **“000000”**.
- If you want to access into the analyzer to read or download the results by other devices, you have to input the LAN password.
- If you don’t input a complete six-digit numeric code to set up the new password, the **“** ▶ **”** icon won’t turn blue for you to select.
- Please use a USB to RJ45 Gigabit Ethernet Adaptor to connect the analyzer to the LAN (Local Area network) using a cable. (Please refer to page 24 for more detail)

6 Brightness

(1) Select **“Settings”** and then select the **“Brightness”** icon.

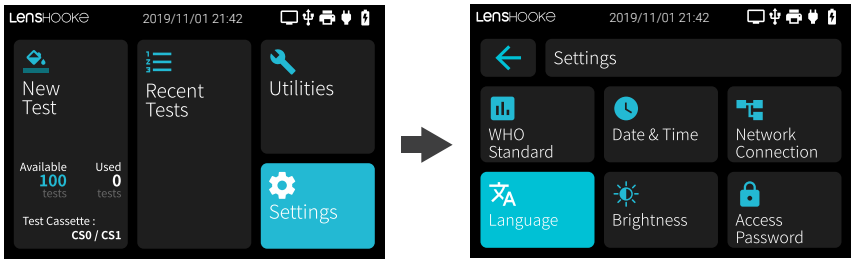


(2) Adjust the brightness of the screen by selecting “ [+] ” or “ [−] ”, and then select the “ [←] ” icon to return to the previous page.



7 Language

(1) Select **“Settings”** and then select the **“Language”** icon, and select your language preference.

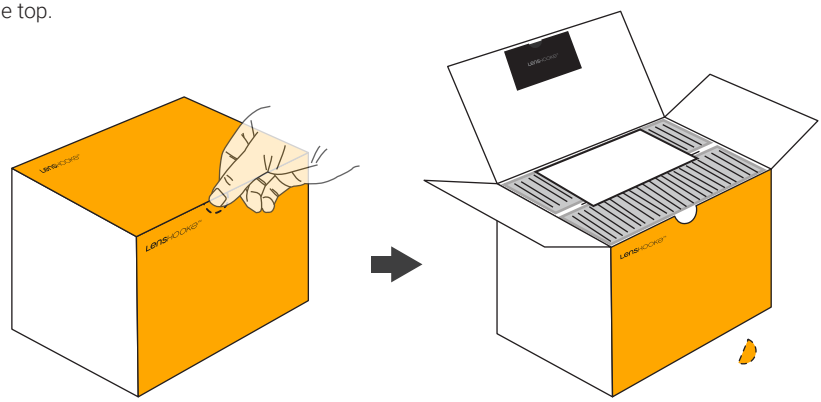


VI . Accessories

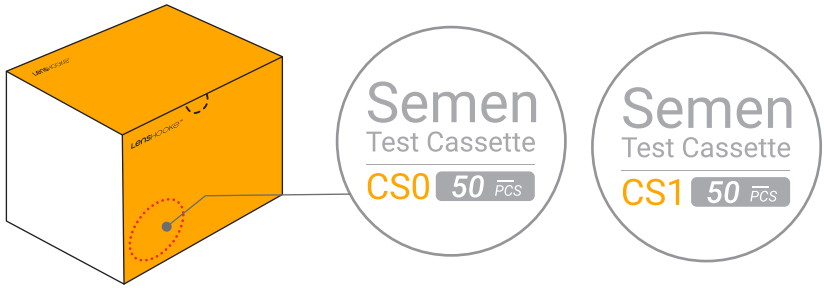
License Dongle

1 To Refill the License

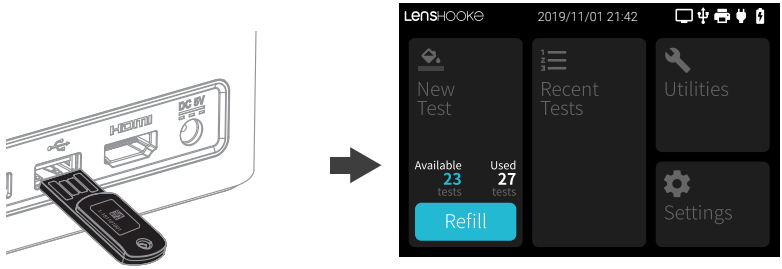
(1) When you unpack the LensHooke® Semen Test Cassette box, you will find the license dongle on the top.



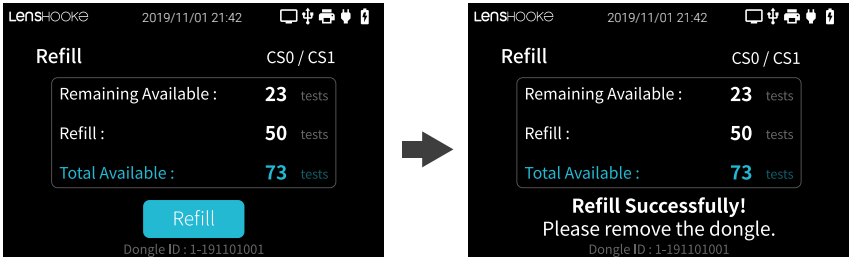
(2) Please check if the test cassette type is correct before you insert the dongle to refill the license.



(3) Please insert this license dongle into the USB Port of the analyzer.

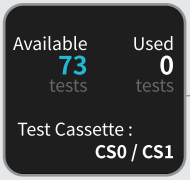


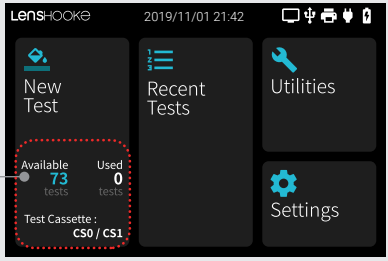
(4) Please select the **"Refill"** icon to refill the licenses. Please check if the refill information is correct, and select the **"Refill"** icon. If you refill successfully, please remove the license dongle.



NOTE

- If the license dongle is not distributed by BONRAYBIO Co., LTD., the **"Refill"** icon will not appear on the screen.
- Once the license dongle has been used with the analyzer, it cannot be used 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 after unpacking the box of the LensHooke® Semen Test Cassette.
- When you insert a new dongle to refill the license, the number of the **"Used"** tests will return to zero. The number of the **"Available"** tests in the dongle will be added on to the remaining tests in the analyzer.

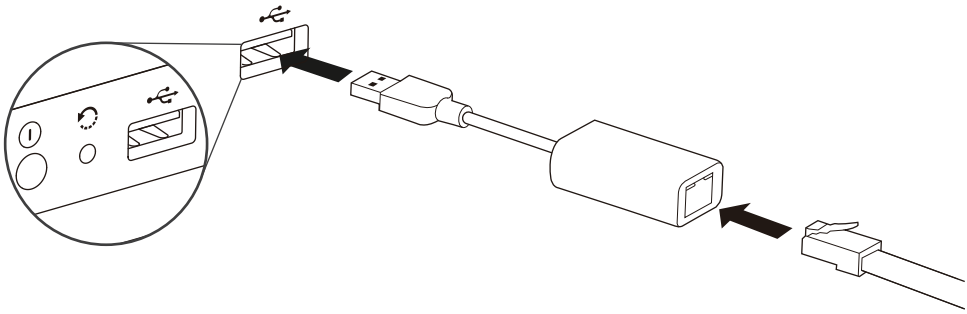




USB to RJ45 Gigabit Ethernet Adaptor

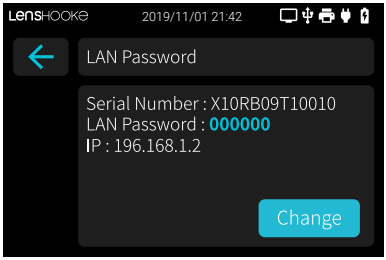
1 Analyzer : Connect to the LAN (Local Area Network)

(1) Please use USB to RJ45 Gigabit Ethernet Adaptor to connent the analyzer to the LAN (Local Area network) with a cable.



2 Other Device: Access the Analyzer

(1) Please open a browser from your computer/laptop/ipad, and then input the IP Address of the device. (You can check this information from the analyzer by selecting the LAN Password.)



(2) Please Login by input the LAN Password. (You can check this information from the analyzer by selecting the LAN Password.)

(3) You can preview PDF or MP4 files.

(4) You can download PDF, MP4, and CSV files.

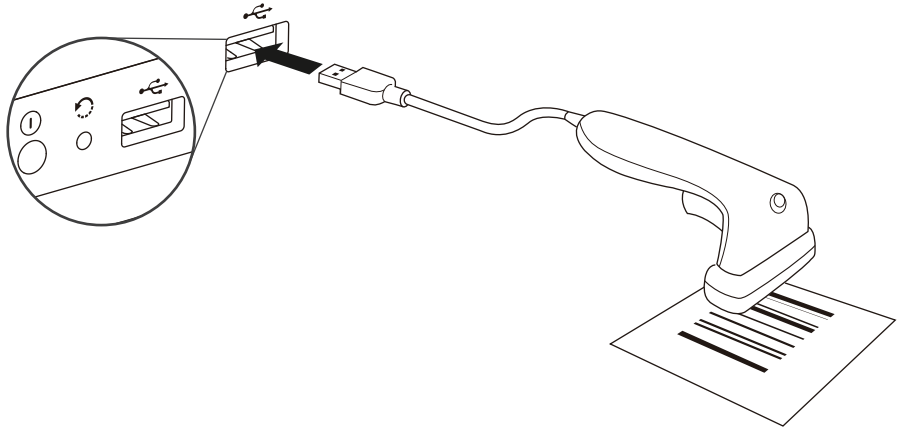
NOTE

- 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 one of the following browers to access the login page.
  - Firefox (Ver: 62 or more), Chrome (Ver: 69 or more), Microsoft Edge for Window 10, and Safari...etc. (Please refer to www.LensHooke.com for more details.)
- Only support iPad, PC or laptop.
- It is suggested to keep the power plugged in while connected to the LAN.

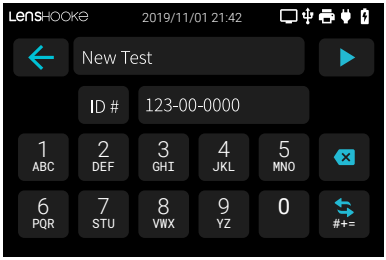
Barcode Scanner

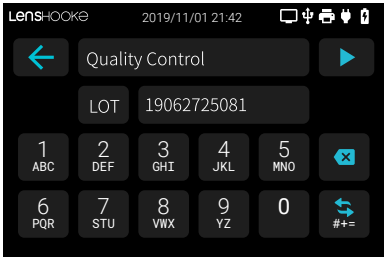
1 To connect the Barcode Scanner to the Analyzer

(1) Please connect the barcode scanner to the the analyzer using the USB Port.



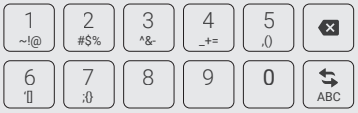
(2) The barcode scanner to input the patient's ID or the LOT of LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen), and LensHooke® X QC Video (For Semen) for the test.





NOTE

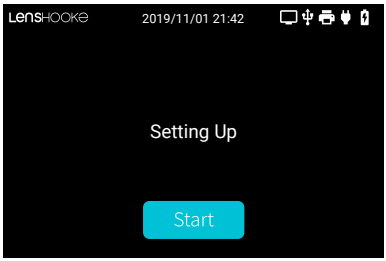
- The analyzer can ONLY connect to the barcode scanner using the USB port.
- The analyzer can ONLY read the following letters, numbers, and symbols.



VII. Getting Started

Setup the analyzer:

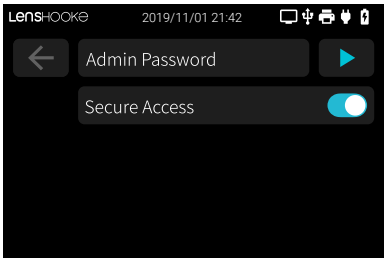
(1) Select **"Start"** and then select your language preference.

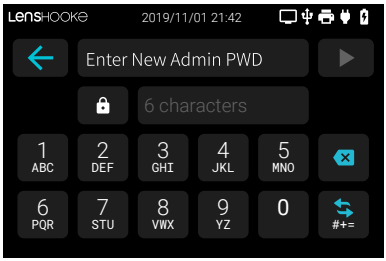


(2) Set up the Date & Time. Please select the " < " or " > " to adjust the date format, and use the " + " or " − " icon to adjust the values.

(3) Select the WHO edition. Select " ▶ " to proceed to the WHO edition selection.

(4) Secure Access. If you want to secure the analyzer access, please slide the icon to turn blue, and then input any six characters as your new Admin Password.





Please charge the battery of the analyzer for 3 hours before you start to use it in the first time.

VIII. Cleaning and Maintenance

1 Suggestion for Cleaning Routine

(1) Test Cassette Insert Slot can only be cleaned by **"LensHooke® Cleaning Wipe".**

(2) Please DO NOT use other tools to clean the Test Cassette Insert Slot.

(3) LensHooke® Cleaning Wipe is single-use only. DO NOT reuse.

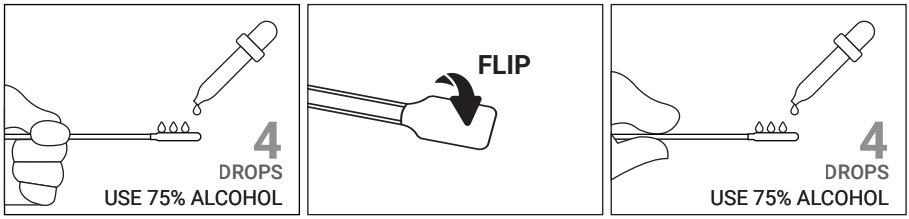
(4) Keep LensHooke® X1 PRO Semen Quality Analyzer away from dust, water or any liquids, and extreme environment (which is beyond the operation or storage environment stated in the specification).

(5) Clean the body of LensHooke® X1 PRO Semen Quality Analyzer every day after test completion.

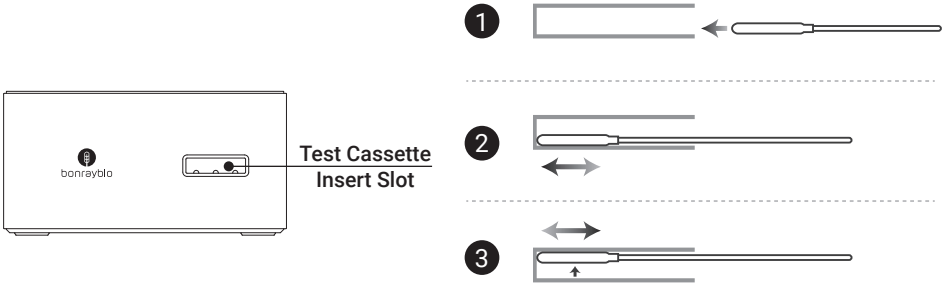
2 Steps for Cleaning

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 Test Cassette 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) Turn off the analyzer before cleaning.
(2) Use the alcohol swab to clean the analyzer body.
(3) 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.)

III. Power adaptor:

(1) Please use the soap without alcohol to soak the cloth.
(2) Wring out the cloth and gently clean the power adaptor.
(3) Clean the area again with a cloth soaked in clean water.

NOTE

- Use LensHooke® Cleaning Wipe to clean the LensHooke® X1 PRO Semen Quality Analyzer.

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:

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

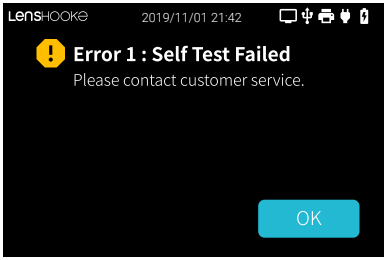
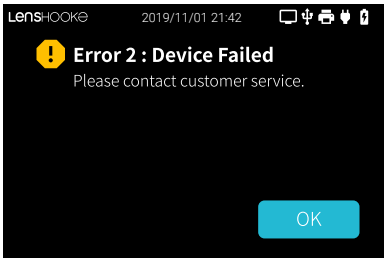
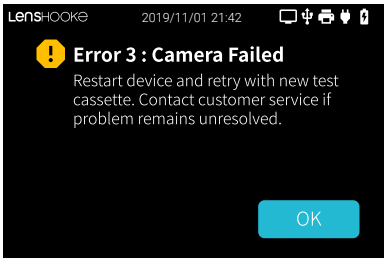
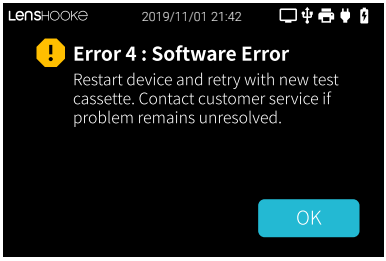
(2) Allow surface to remain wet for 2 minute.

(3) Allow to air dry.

NOTE

- Your LensHooke® X1 PRO Semen Quality Analyzer 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 Message

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 select the **"OK"** icon to return to home page then turn the analyzer off. (Refer to **"Turn on/off"** on Page 5 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 select the **"OK"** icon 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 select the **"OK"** to return icon to home page then turn the analyzer off. (Refer to **"Turn on/off"** on Page 5 for normal operation status.)

X. Analyzer Specifications

Analyzer name
LensHooke® X1 PRO Semen Quality Analyzer

Control panel
3.5-in resistive touch screen

External power input
AC 100 ~ 240V / 50 ~ 60 Hz; Output DC 5V / 2A

Battery durability
2500 mAh (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 (10^6/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 5th edition.

Reference	WHO 5th Low Reference	WHO 4th Low Reference
Concentration	15 x 10^6 (12-16)/ ml	≧ 20 x 10^6 / ml
Total 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 kid 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. 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.
7. Avoid strangulation resulting from baby or child entanglement in monitoring cables.
8. Avoid choking resulting from a child swallowing a small part.
9. 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, LensHooke® Semen Test Cassette, C-KUP™ Liquefaction Test Cup, LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen), and LensHooke® X QC Video (For Semen).
  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.

Manufacturer:
Bonraybio Co., LTD.
4F., No. 118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280,
Taiwan (R.O.C.)

XIV. Warranty

Bonraybio offers a one-year warranty from the day you purchase the LensHooke® X1 PRO Semen Quality Analyzer. 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 from Bonraybio. The warranty will be voided if the analyzer is modified or improperly used.

Manufacturer : Bonraybio Co., LTD.
Address : 4F., No.118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280, Taiwan(R.O.C.)
Tel : +886-4-2491-2385
Fax : +886-4-2491-2885
Email : support@bonraybio.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

CE

LensHOOKe®

LensHOOKe®

Semen Quality Analyzer

Benutzerhandbuch

X1 PRO

Rev.29-0X10300 20210226X1E003DE

Bitte lesen Sie sich diese Bedienungsanleitung sorgfältig durch, um die optimale Funktionalität des Gerätes zu gewährleisten. This user manual is also available at **www.LENSHOOKE.com**.

Symbole

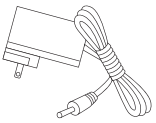
Folgende Symbole können in dieser Bedienungsanleitung verwendet werden:

	Hinweis
	Vorsicht
	Seitenzahl
	Nicht zur Wiederverwendung
	Verwendbar bis
LOT	Chargenbezeichnung
SN	Seriennummer
	Herstellungsdatum
	Hersteller
EC REP	Autorisierter Vertreter in der Europäischen Gemeinschaft
IVD	In-vitro Diagnostikum
	Temperaturbegrenzung
	Gebrauchsanweisung beachten
	Getrennt entsorgen
CE	CE Konformitätszeichen
	Gebrauchsanleitung beachten
Rx	Verschreibungspflichtig

Lieferumfang

- **LensHooke® X1 PRO Semen Quality Analyzer**

- **Netzteil (für Analysegerät)**



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I. Einführung

Der LensHooke® X1 PRO Semen Quality Analyzer ist ausschließlich für die In-vitro-Diagnostik bestimmt. Lesen Sie zuerst diese Bedienungsanleitung, um sich mit dem Gerät und seiner ordnungsgemäßen Funktionsweise vertraut zu machen, bevor Sie das Analysegerät benutzen.

Der Begriff „LenseHooke® Semen Test Cassette" beinhaltet sowohl die Bezeichnung für die LenseHooke® CS0 Semen Test Cassette als auch für die LensHooke® CS1 Semen Test Cassette.

Wenn Sie Fragen zum Produkt haben oder Hilfe benötigen, wenden Sie sich bitte an Bonraybio über die Service-Hotline (+886-4-2491-2385, Mo-Fr 08:30-17:30, GMT+8) oder Ihren lokalen Vertriebspartner nal von minden GmbH (+49-941-29010-0, Mo-Fr 08:00-17:00, MEZ).

II. Verwendungszweck

Der LensHooke® X1 PRO Semen Quality Analyzer, wird zusammen mit der LenseHooke® Semen Test Cassette verwendet und ist ein einfach zu bedienendes, optisches Gerät für die Analyse von menschlichem Samen, das direkte und berechnete Messungen liefert zu:

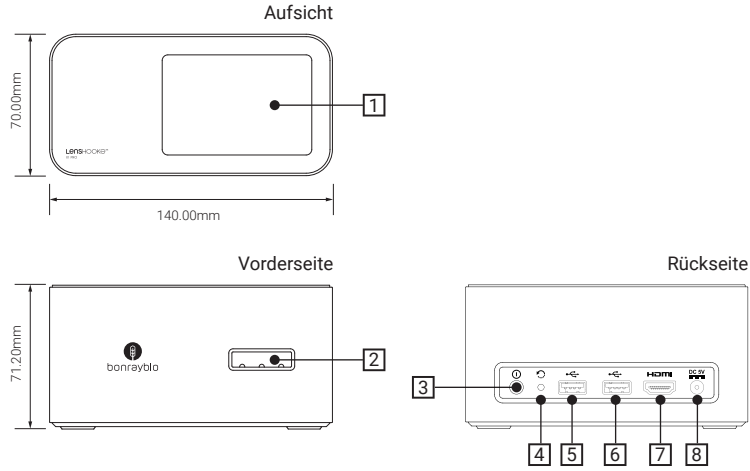
(1) Spermienkonzentration (10^6 pro mL)
(2) Gesamtmotilität (PR+NP, %)
- Progressive Motilität (%)
- Nicht-progressive Motilität (%)
- Immotilität (%)
- Weitere Parameter aus der CASA-Bewertung (MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, und BCF)

(3) Spermienmorphologie (Normalformen, %)
(4) pH-Wert

Der LensHooke® X1 PRO Semen Quality Analyzer bietet keine umfassende Bewertung des Fruchtbarkeitsstatus eines Mannes und ist nur für den professionellen Gebrauch in der In-vitro-Diagnostik bestimmt.

III. Produktübersicht

LensHooke® X1 PRO Semen Quality Analyzer



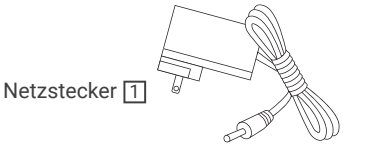
1 Touchscreen
2 Einschub für Testkassette
3 Netzschalter
4 Reset-Taste
5 USB-Anschluss
6 USB-Anschluss
7 HDMI-Anschluss
8 Netzteilanschluss

HINWEIS

- **USB-Anschluss:** USB 2.0
- **Reset-Taste:** Wenn das Analysegerät abstürzt, verwenden Sie bitte eine Nadel, um die Reset-Taste zu drücken.
- **HDMI-Anschluss:** Das Analysegerät ermöglicht eine HDMI-Verbindung zu einem hochauflösenden Monitor, um die Bilder und Daten zu überprüfen.

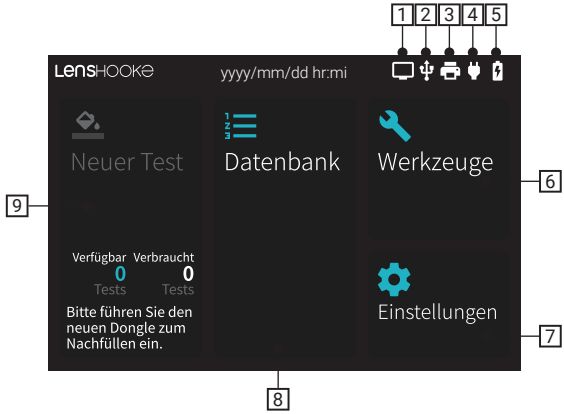
Zubehör

- **Netzteil**



Dongguan Shilong Fuhua Electronic Co., Ltd;
UES12LCP-050200SPA

Touch Screen Icon



1 **Symbol für die HDMI-Verbindung:** Dieses Analysegerät ist über einen HDMI-Anschluss mit dem Monitor verbunden.

2 **Symbol für die USB-Verbindung:** Dieses Analysegerät ist über einen USB-Anschluss mit dem USB-Laufwerk verbunden.

3 **Symbol für die Verbindung des Thermodruckers:** Dieses Analysegerät ist an einen tragbaren Thermodrucker angeschlossen.

4 **Symbol für den Anschluss des Netzteils:** Dieses Analysegerät ist an das Netzteil angeschlossen, um den Akku aufzuladen.

5 **Batteriesymbol:** Zeigt die aktuelle Akkukapazität an.

HINWEIS

- **Symbol für die USB-Verbindung:** Wenn Sie Geräte wie z.B. Tastatur, Maus, Dongle, etc. über den USB-Anschluss einstecken, erscheint dieses Symbol nicht auf dem Bildschirm.

Die folgenden Symbole sind funktionsbezogen:

6 **Werkzeuge:**
- QC-Test: Überprüfung der Qualität des Analysegerätes
- Datensätze sichern: Datensicherung aller Messergebnisse
- System Update: Aktualisierung des Analysegerätes
- Logo einfügen: Hinzufügen eines Logos auf dem Ergebnis-PDF
- Geräteinformation: Detailinformationen des Analysegerätes
- Datensätze löschen: Löschen aller gespeicherten Messergebnisse

7 **Einstellungen:**
- WHO-Standard: Auswahl 4. oder 5. WHO-Standard
- Datum & Zeit: Einstellung von Datum und Uhrzeit
- Netzwerkverbindung: Auswahl zwischen manueller und automatischer Konfiguration, Einstellmöglichkeit für IP Adresse, Subnetzmaske und Gateway
- Sprache: Spracheinstellung
- Helligkeit: Helligkeit des Bildschirms anpassen
- Passwort: Admin-Passwort aktivieren und vergeben, LAN-Passwort ändern

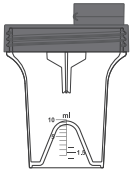
8 **Datenbank:** Zur Überprüfung der gespeicherten Testergebnisse

9 **Neuer Test:** Einen neuen Test starten

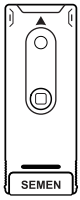
IV. Verbrauchsmaterial

Verbrauchsmaterialien für den LensHooke® X1 PRO Semen Quality Analyzer:

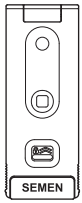
- **C-KUP™**
  Liquefaction Test Cup



- **LensHooke® CS0**
  Semen Test Cassette



- **LensHooke® CS1**
  Semen Test Cassette



- **LensHooke®**
  Cleaning Wipe

- **LensHooke®**
  X QC Beads (For Semen)

- **LensHooke®**
  X QC Reticle (For Semen)

- **LensHooke®**
  X QC Video (For Semen)

⚠

- **Das Ergebnis ist fehlerhaft, wenn Sie KEINE LensHooke® Samen Test Cassette oder LensHooke® X QC Produkte verwenden.**

HINWEIS

- Bei den Abbildungen der Produkte handelt es sich um schematische Darstellungen.
- Der C-KUP™ Probenverflüssigungsbecher dient zur Aufnahme von Samenproben.
- Die LensHooke® Semen Test Cassette beinhaltet eine spezielle Zählkammer für den LensHooke® X1 PRO Semen Quality Analyzer
- Die LensHooke® Cleaning Wipe werden zur Reinigung des Einschubschachts der Testkassette verwendet
- LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) und LensHooke® X QC Video (For Semen) werden zur Qualitätskontrolle des Analysegerätes verwendet.

V. Hauptfunktionen

LensHooke® X1 PRO Semen Quality Analyzer

Ein- und Ausschalten

1 Einschalten des Analysegeräts:

Drücken Sie die Ein-/Aus-Taste für ca. 2 Sekunden, um das Gerät einzuschalten (wie in Abbildung 1). Wenn der Touchscreen aufleuchtet (wie in Abbildung 2), ist das Gerät betriebsbereit.

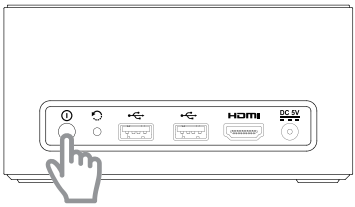


Abbildung 1

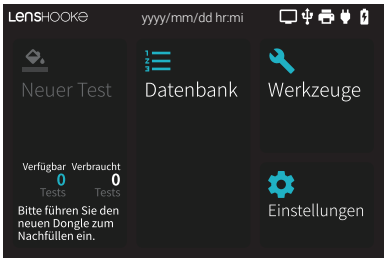


Abbildung 2

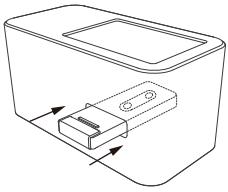
2 Ausschalten des Analysegeräts:

Halten Sie die Ein-/Aus-Taste ca. 10 Sekunden lang gedrückt, bis der Touchscreen **„Power Off“** anzeigt. Anschließend tippen Sie auf **„Power Off“**, um das Analysegerät auszuschalten.

Einlegen / Entfernen der Testkassette

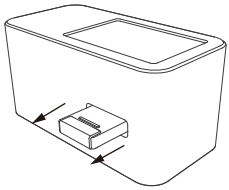
1 Einlegen der Testkassette:

Testkassette bis nach hinten in den Einschub einstecken.



2 Entfernen der Testkassette:

Ziehen Sie nach dem Test die Testkassette aus dem Einschub.



Aufladen des Akkus

1 Wenn die Meldung **„Low Battery“** (Abbildung 3) auf dem Touchscreen angezeigt wird, verbinden Sie das Analysegerät unverzüglich mit dem Stromnetz. Während des Ladevorgangs erscheint das **„Stecker“**-Symbol auf dem Touchscreen (Abbildung 4). Wenn das **„Stecker“**-Symbol nicht auf dem Bildschirm erscheint, vergewissern Sie sich, dass der Adapter ordnungsgemäß mit dem Analysegerät und der Buchse verbunden ist.

Abbildung 3

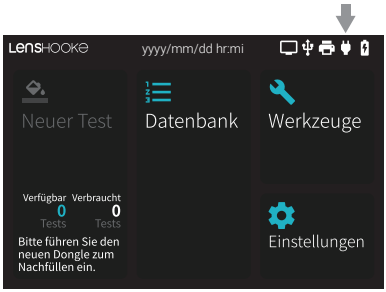


Abbildung 4

- Das Analysegerät ist mit einer eingebauten Lithium-Ionen-Polymer-Batterie mit einer Akkukapazität von 2500 mA ausgestattet.
- Der Akku kann nicht entnommen oder ausgetauscht werden. Wenn Sie ein dauerhaftes Problem mit der Batterie haben, kontaktieren Sie uns bitte.

HINWEIS

- Wenn Sie in den Energiesparmodus wechseln möchten, drücken Sie bitte kurz den Netzschalter. Wenn Sie das Analysegerät wieder aktivieren möchten, drücken Sie bitte erneut kurz den Netzschalter.
- Wenn 10 Minuten lang keine Bedienung erfolgt, wechselt das System automatisch in den Energiesparmodus. *Energiesparmodus: Ausschalten des Touchscreens, um den Stromverbrauch der Batterie zu reduzieren.
- Um die Lebensdauer der eingebauten Lithium-Ionen-Polymer-Batterie zu verlängern, laden Sie die Batterie bitte weiterhin mit dem Adapter auf, auch wenn Sie das Analysegerät nicht verwenden.
- Wenn das Analysegerät 3 Monate lang nicht in Betrieb ist, laden Sie es vor Gebrauch auf.
- Das Datum und die Uhrzeit des Analysegeräts könnten wieder auf die Standardeinstellung zurückgesetzt worden sein, wenn die Batterie leer ist. Bitte überprüfen Sie dies und stellen Sie Datum und Uhrzeit gegebenenfalls richtig ein (siehe Seite 17).
- Wenn die Warnmeldungen **„Battery overheating“** (Batterieüberhitzung) oder **„Battery Temperature is too low“** (Batterietemperatur ist zu niedrig) auf dem Bildschirm erscheinen, schaltet sich das Analysegerät zum Selbstschutz automatisch innerhalb von 5 Minuten ab. Wenn Sie diese Warnmeldung sehen, schalten Sie bitte das Analysegerät aus und stellen es für mehr als eine Stunde unter folgenden Umgebungsbedingungen auf: 15 - 38 °C und Luftfeuchtigkeit < 70 %. Schließen Sie das Netzteil an das Analysegerät an und schalten Sie dieses wieder ein.

Analysegerät vorbereiten

1. LensHooke® X1 PRO Semen Quality Analyzer auf eine ebene, glatte Oberfläche stellen.
2. Die empfohlenen Umgebungsbedingungen einhalten.
3. Batteriestatus überprüfen. Bei niedrigem Batteriestand das Gerät vor dem Testen an das Stromnetz anschließen.

Probe vorbereiten

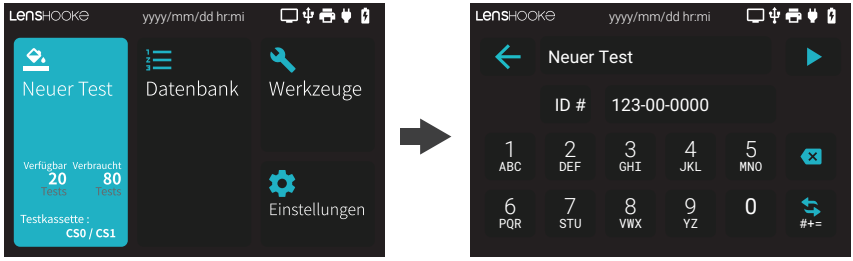
1. Bitte beachten Sie die Packungsbeilage der LensHooke® Semen Test Cassette.

Testen der Probe

1 Neuer Test

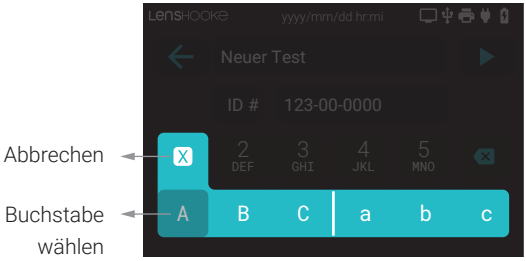
Schritt 1. Klicken Sie auf das Symbol **“Neuer Test”**.

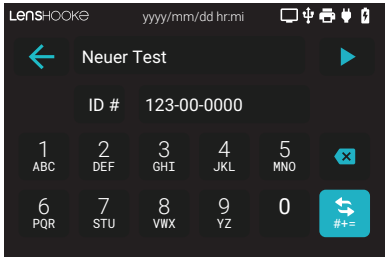
Schritt 2. Bitte geben Sie die Patienten ID ein und klicken Sie auf [▶], um zum nächsten Schritt zu gelangen.



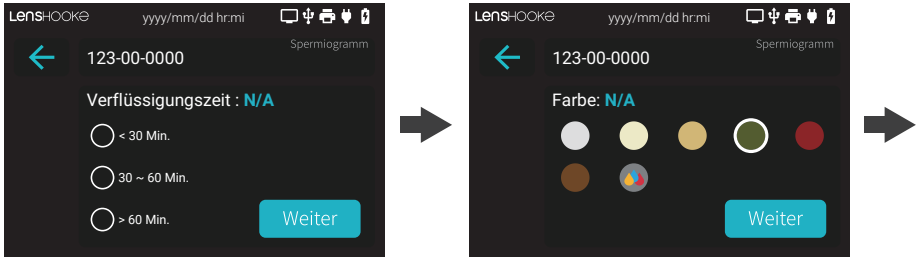
HINWEIS

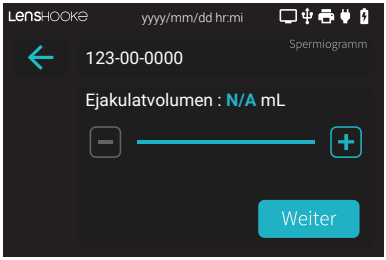
- Verwenden Sie NICHT mehr als 20 Zeichen und Symbole für die Patienten-ID-Nummer.
- Wenn Sie einen Buchstaben eingeben möchten, drücken Sie bitte etwa 1 Sekunde auf das entsprechende Feld und wählen Sie den Buchstaben aus. Wenn Sie ein Symbol einfügen möchten, drücken Sie die Schaltfläche „ [⇆] “, um die Tastatur zu wechseln ändern.
- Sie können die Patienten ID auch mit einem Barcode Scanner über einen Barcode oder QR Code eingeben. (Bitte beachten Sie dazu Kapitel VI des Handbuchs).
- Zum Auffüllen der Lizenzen **„Nachfüllen”**, beachten Sie bitte Kapitel VI des Handbuchs.

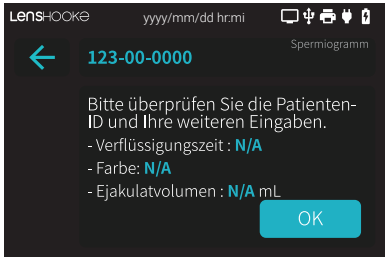




Schritt 3. Bitte geben Sie Verflüssigungszeit, Samenfarbe und Samenvolumen ein und klicken Sie auf **„Weiter”** um zum nächsten Schritt zu gelangen und die von Ihnen eingegebenen Informationen zu prüfen.







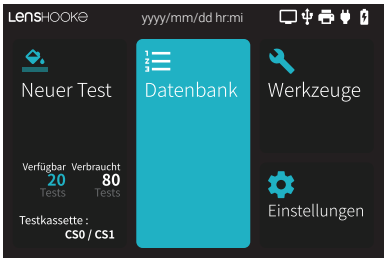
HINWEIS

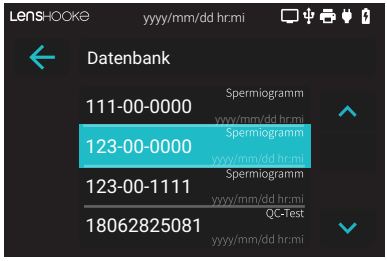
- Bitte klicken Sie auf ⊖ und ⊕ , um das Samenvolumen einzustellen.
- Die Testkassette bzw. das Analysegerät während der Messung nicht bewegen.

Schritt 4. Führen Sie die Testkassette bis zum hinteren Ende in den Einschub ein.

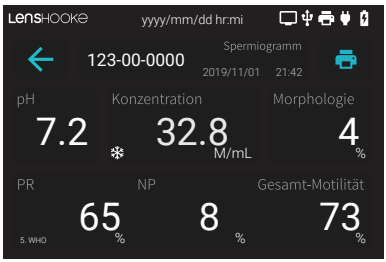
2 Datenbank

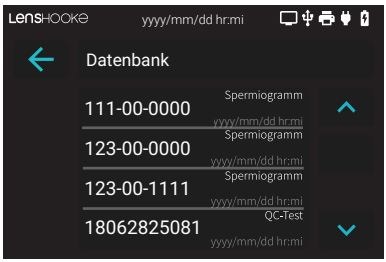
(1) Klicken Sie auf das Symbol **„Datenbank"** und dann auf den Datensatz, den Sie anhand der Patienten-ID überprüfen möchten.





(2) Der Datensatz wird auf dem Bildschirm angezeigt. Klicken Sie auf das Symbol „ ← ", um zur vorherigen Seite zurückzukehren.





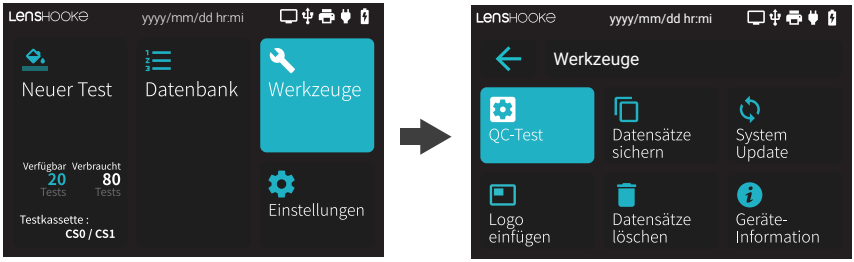
HINWEIS

- Es können nur BLAUE Symbole angeklickt werden.
- Messergebnisse können über einen Netzwerkdrucker ausgedruckt werden. Zur Anbindung des Analysegeräts an das lokale Netzwerk siehe Kapitel Netzwerk Einstellungen.
- Ein " ❄ " neben einem Messergebnis weist darauf hin, dass Konzentrationsergebnisse möglicherweise durch Aggregation von Spermatozoen, Spermien-Kristallen oder Luftblasen beeinflusst wurden.
- Ein " ▨ " neben einem Motilitäts-Parameter weist darauf hin, dass das Ergebnis beeinträchtigt sein könnte. Das Gerät erkennt, dass die Spermien sich eher durch äußere Einflüsse als selbstständig fortbewegen.
- Das Analysegerät bezieht keine Pinhead-Spermien mit in die Berechnung ein, da diese Form auf Grund fehlenden Chromatins klinisch nicht als Spermien betrachtet werden.
- Bei einer Analyse nach einer Vasektomie sollte das Ergebnis nochmals mit einer manuellen Analyse bestätigt werden.
- Wurde keine Probe auf den Tropfbereich für den pH-Wert aufgebracht, wird ein pH-Wert < 6.0 angezeigt. Bei einem pH-Wert < 6 bitte den Tropfbereich für die Messung des pH-Werts der Testkassette überprüfen.

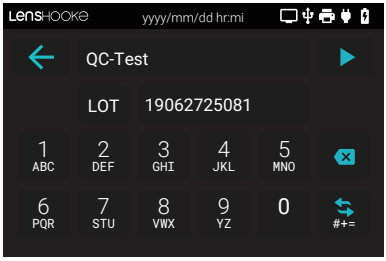
Zubehör

1 Qualitätskontrolle

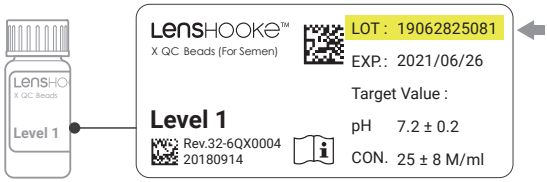
(1) Klicken Sie auf das Symbol **„**Werkzeuge**"** und dann auf das Symbol **„QC-Test"**.



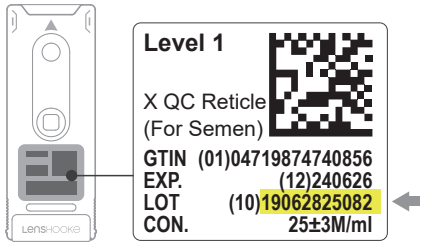
(2) Bitte geben Sie die LOT-Nummer auf dem Etikett der LensHooke® X QC Beads (Samenkontrollkit), des LensHooke® X QC Reticles (Samenkontrollkit) oder des LensHooke® X QC Videos ein. Bestätigen Sie die LOT-Nummer und klicken auf „ ▶ ", um zum nächsten Schritt zu gelangen.



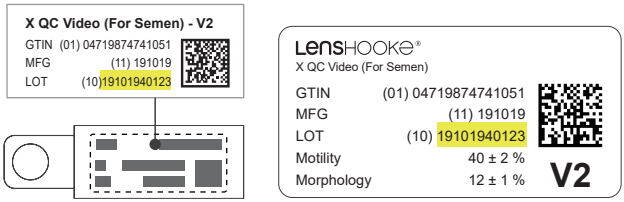
• Lot Nummer auf den X QC Beads (For Semen)



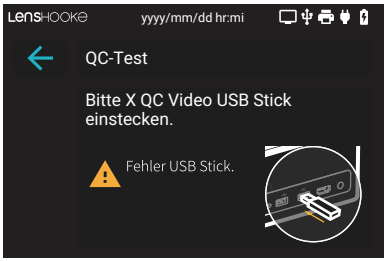
• Lot Nummer auf den X QC Reticle (For Semen)



• Lot Nummer auf den X QC Video (For Semen)

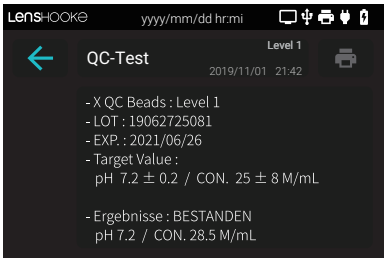


(3) Folgen Sie den Anweisungen der Packungsbeilage der LensHooke® QC Beads, des Lenshooke® X QC Reticles oder des LensHooke® X QC Videos. Führen Sie die Kassette bis ganz hinten in den Einschub ein bzw. stecken den Video USB Stick in die USB Buchse.



(4) Nach 2-5 Minuten erscheint das Ergebnis auf dem Bildschirm.

• Ergebnis des X QC Beads (For Semen)

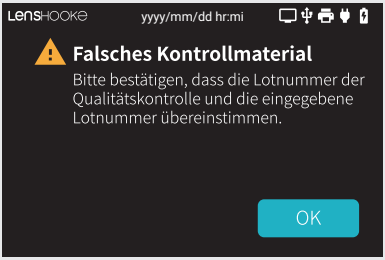


• Ergebnis des X QC Reticle

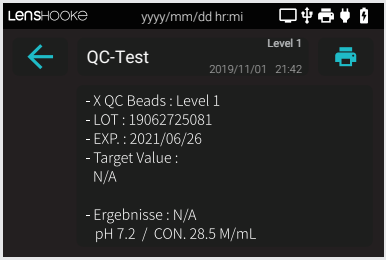
• Ergebnis des X QC Video

HINWEIS

- LensHooke® X QC Beads (For Semen) misst pH-Wert und Konzentration.
  LensHooke® X QC Reticle (For Semen) misst NUR die Konzentration.
  Das LensHooke® X QC Video misst NUR die Motilität und Morphologie.
- Wenn eine Lot Nummer der LensHooke® X QC Beads eingegeben wird, aber ein LensHooke® X QC Reticle verwendet wird (oder umgekehrt), erscheint eine Warnung auf dem Bildschirm.



- Falls N/A auf dem Ergebnisbildschirm angezeigt wird, ist das Haltbarkeitsdatum der Lot der LensHooke® X QC Beads oder LensHooke® X QC Reticle abgelaufen. Bitte eine neue Lot verwenden oder den Kundendienst kontaktieren.



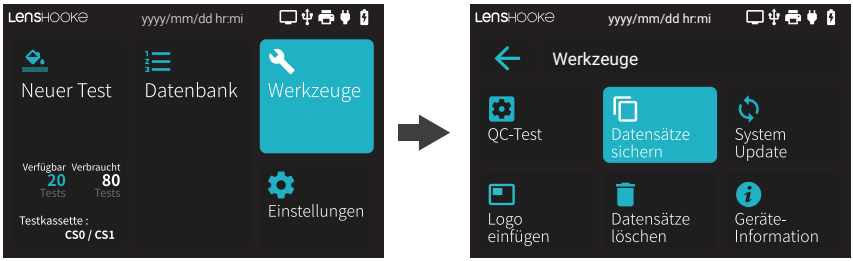
X QC Beads

X QC Reticle

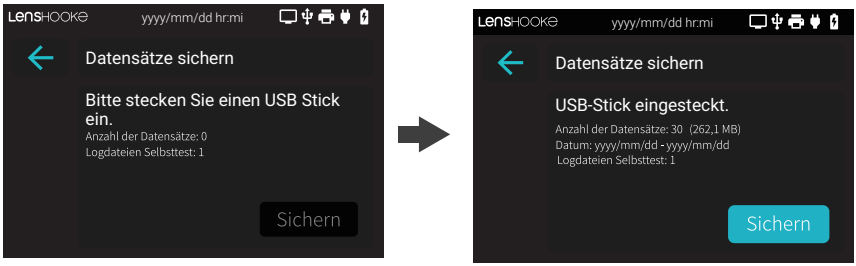
2 Datensätze sichern

(1) Bereiten Sie einen USB-Stick vor (Kapazität: ≥ 1GB).

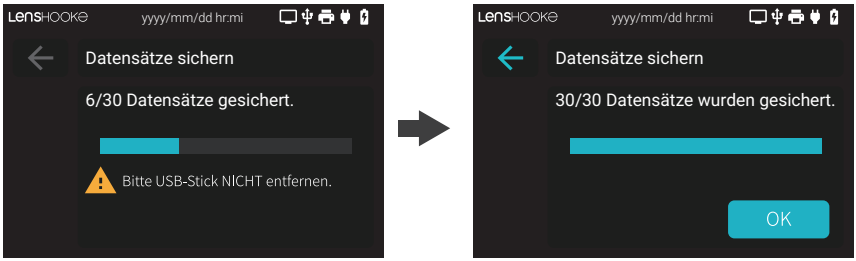
(2) Klicken Sie auf das Symbol **„Werkzeuge"** und dann auf das Symbol **„Datensätze sichern"**.



(3) Stecken Sie den USB-Stick ein. Wenn das Symbol **„Sichern"** blau wird, klicken Sie darauf, um die Datensätze zu sichern.



(4) Wenn die Datensätze erfolgreich auf Ihrem USB-Stick gesichert wurden, klicken Sie auf **„OK"**, um zur Startseite zurückzukehren.



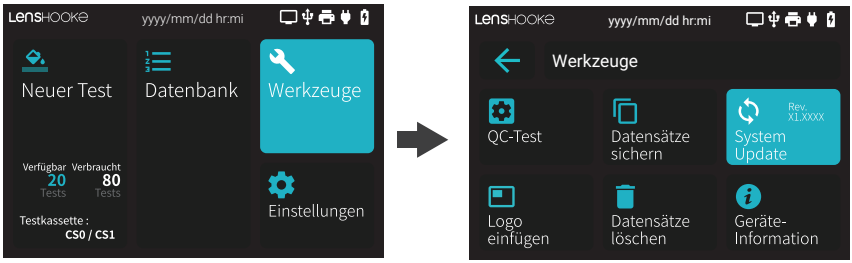
HINWEIS

- Entfernen Sie den USB-Stick NICHT, solange die Datensicherung noch nicht abgeschlossen ist.
- Die Warnmeldung **„Nicht genügend Speicher"** erscheint auf dem Bildschirm, wenn die Speicherkapazität des Analysegeräts nicht ausreicht. Bitte sichern Sie alle Datensätze, bevor Sie sie löschen, um Speicherplatz freizugeben.
- Wenn die Speicherkapazität des USB-Sticks unzureichend ist, entfernen Sie ihn bitte und löschen Sie die Dateien per Computer/Laptop, um den Speicherplatz freizugeben oder verwenden Sie einen anderen USB-Stick.
- Nach dem Backup stehen PDF, MP4 und CSV Dateien zur Verfügung.

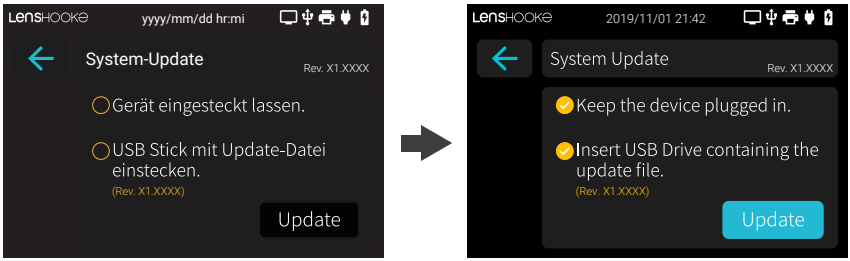
3 System Update

(1) Bereiten Sie den USB-Stick mit der System-Update-Software vor. (Speicherplatz des USB-Sticks: ≥ 1 GB). Bitte wenden Sie sich an Ihren lokalen Händler, um die System-Update-Software zu erhalten.

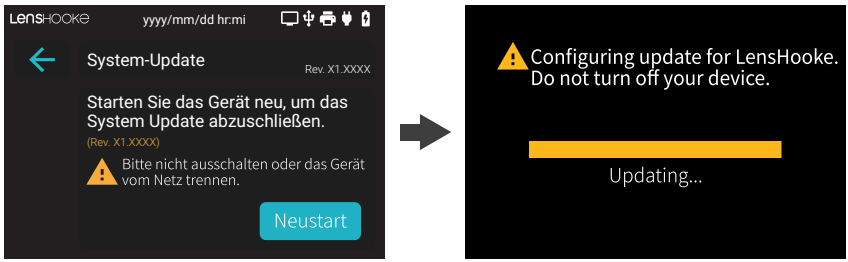
(2) Klicken Sie auf das Symbol **„Werkzeuge"** und dann auf das Symbol **„System Update"**.



(3) Bitte verbinden Sie das Analysegerät mit dem Stromnetz und stecken den USB-Stick mit der System-Update-Datei ein. Klicken Sie auf das Symbol **„Update"**, um das System zu aktualisieren.



(4) Klicken Sie anschließend auf das Symbol **„Neustart"**, um das Analysegerät neu zu starten und das Systemupdate abzuschließen. Das System konfiguriert die Updates automatisch und startet das Analysegerät neu, wenn das System-Update abgeschlossen ist.



HINWEIS

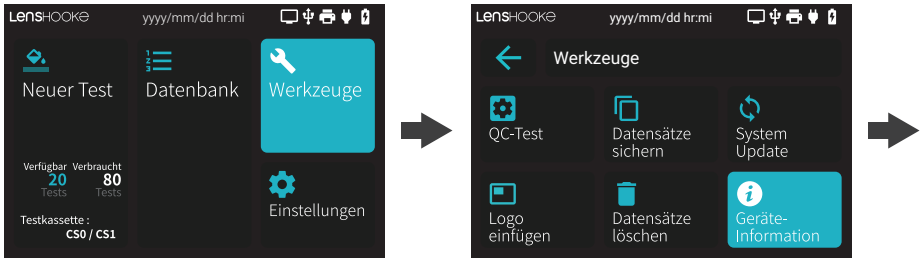
- Sichern Sie alle Daten vor einem System Update.
- Schalten Sie das Gerät während des Aktualisierungsvorgangs NICHT aus oder ziehen Sie den Netzstecker. Achten Sie darauf, dass Sie das Netzteil anschließen und den USB-Stick mit der System-Update-Datei einstecken, wenn Sie das System aktualisieren.

HINWEIS

- Wenn die Warnmeldung **„Aktualisierungsdatei ist beschädigt“** auf dem Bildschirm erscheint, wurde nicht die gesamte Datei heruntergeladen. Bitte laden Sie die System-Update-Datei erneut auf den USB-Stick herunter und führen Sie das System-Update nochmals durch.
- Wenn die Warnmeldung **„Aktualisierung fehlgeschlagen“** auf dem Bildschirm erscheint, wurde der USB-Stick für das System-Update entfernt. Bitte stecken Sie den USB-Stick mit der System-Update-Datei erneut ein, um das System-Update durchzuführen.

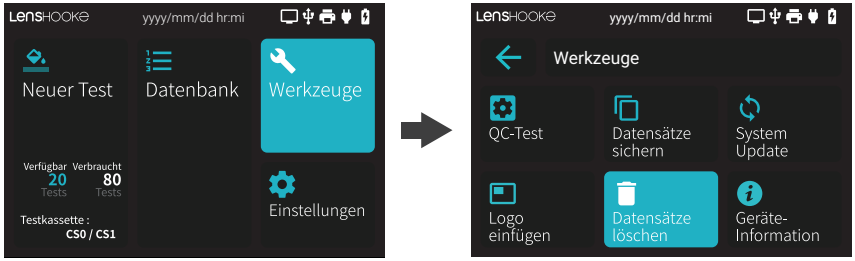
4 Geräteinformation

Klicken Sie auf das Symbol **„Werkzeuge”** und dann auf das Symbol **„Geräteinformation”**, um mehr Informationen über des Analysegeräts zu erhalten.



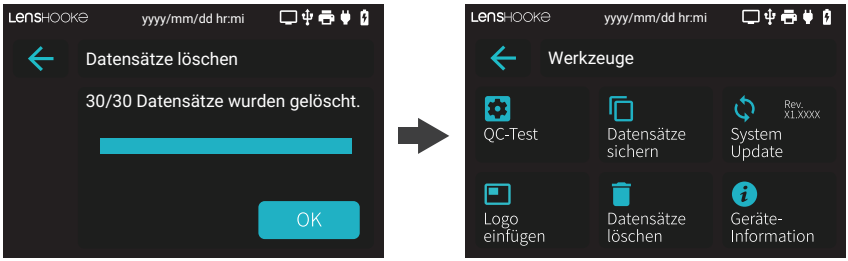
5 Alle Datensätze löschen

(1) Klicken Sie auf das Symbol **„Werkzeuge”** und dann auf das Symbol **„Datensätze löschen”**.



(2) Klicken Sie zur Bestätigung auf das gelbe Symbol **„Löschen“** und löschen Sie alle Datensätze.

(3) Klicken Sie auf das Symbol **„OK“**, um zur Startseite zurückzukehren.

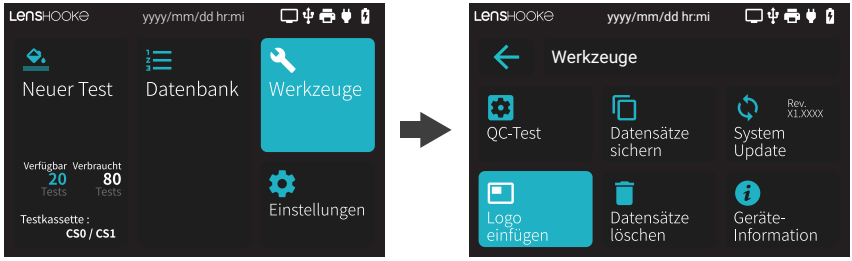


HINWEIS

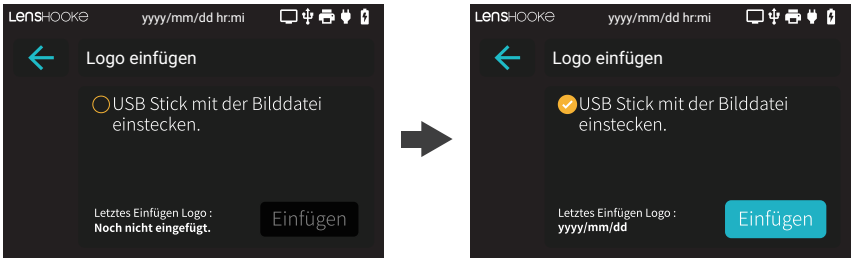
- Die Datensätze können nach dem Löschen nicht wiederhergestellt werden. Stellen Sie sicher, dass Sie diese wirklich dauerhaft löschen möchten, bevor Sie auf das Symbol **„Löschen“** drücken.

6 Logo einfügen

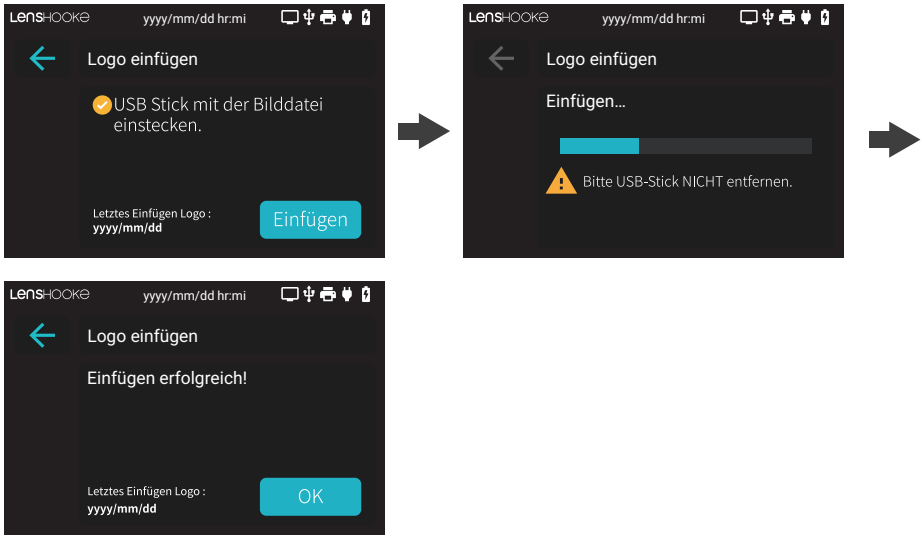
(1) Klicken Sie auf das Symbol **„Werkzeuge”** und dann auf das Symbol **„Logo einfügen”**.



(2) Stecken Sie den USB Stick mit der Logo-Datei ein.



(3) Klicken Sie auf **„Einfügen“** und warten Sie, bis die Nachricht **„Einfügen erfolgreich!“** auf dem Bildschirm erscheint.



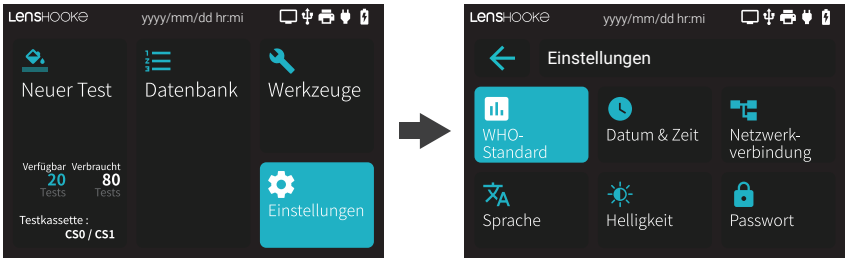
HINWEIS

- Die Bilddatei für das Logo muss **“lenshooke_X1_pdf_logo.png“** benannt werden und im png Format mit 2040 x 168 px abgespeichert sein.
- Die Datei muss im Hauptverzeichnis des USB Sticks liegen. Bitte nicht in einem Unterordner speichern.

Einstellungen

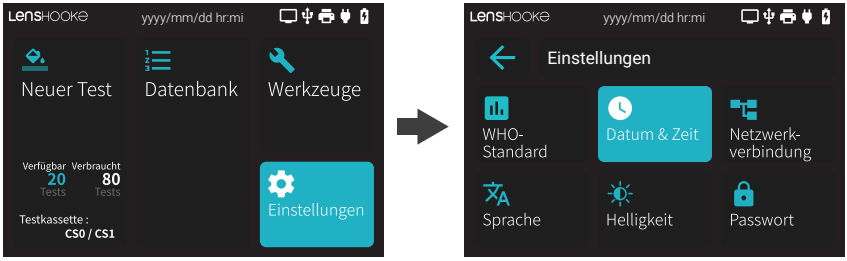
1 WHO Edition

(1) Klicken Sie auf das Symbol **„Einstellungen“** und dann auf das Symbol **„WHO Standard“**, um die bevorzugte Edition auszuwählen.

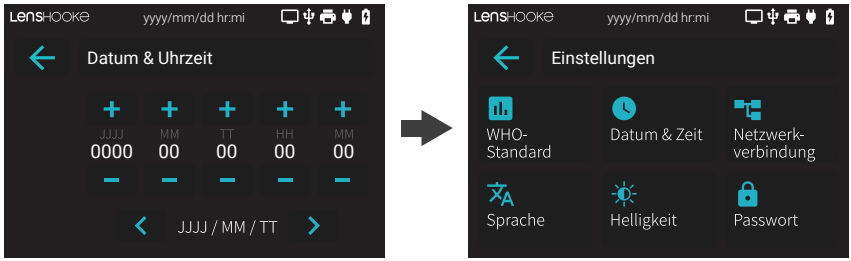


2 Datum und Uhrzeit

(1) Klicken Sie auf das Symbol **„Einstellungen"** und dann auf das Symbol **„Datum & Zeit"**.

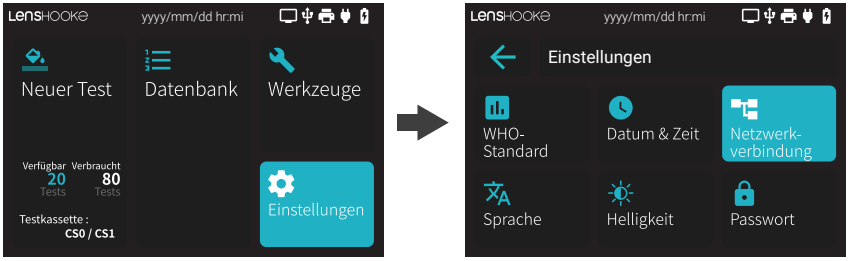


(2) Sie können das Format durch Anklicken der Symbole „ < " oder „ > " auswählen und können Datum und Uhrzeit durch Anklicken des Symbols „ + " oder „ − " anpassen. Nachdem Sie Datum und Uhrzeit eingestellt haben, klicken Sie auf „ ← ", um zur vorherigen Seite zurückzukehren.

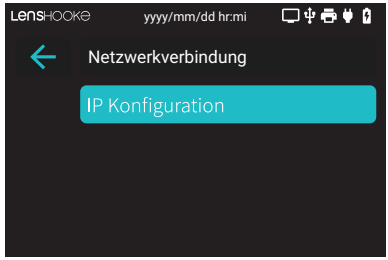


3 Netzwerk Einstellungen

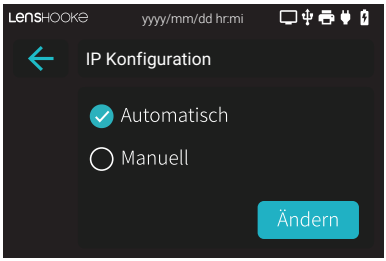
(1) Klicken Sie auf das Symbol **„Einstellungen"** und dann auf das Symbol **„Netzwerkverbindung"**.



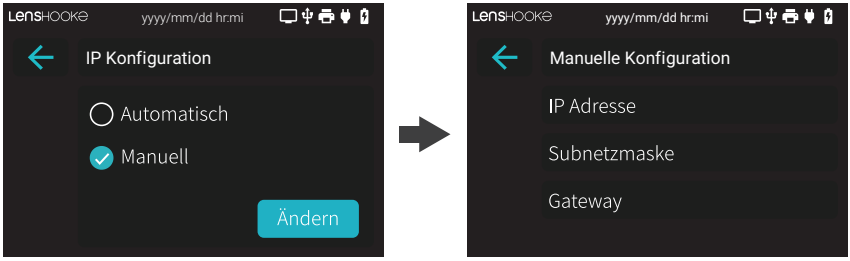
(2) „IP konfiguration" auswählen.



(3) Die Standardeinstellung ist **“Automatisch”**. Dabei benutzt das Analysegerät eine dynamische IP-Adresse, die beim Anschluss an ein Netzwerk automatisch zugewiesen wird und sich ändern kann.



(4) Soll eine statische IP-Adresse verwendet werden, muss **“Manuell”** ausgewählt werden. Nun können die Einstellungen für **“IP Adresse”**, **“Subnetzmaske”** und **“Gateway”** entsprechend angepasst werden.

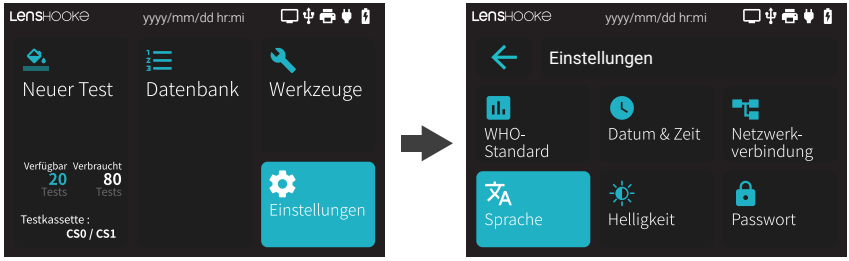


HINWEIS

- Werden die Informationen für IP Adresse, Subnetzmaske und Gateway nicht vollständig eingegeben, bleibt die Konfiguration auf **„Automatisch“**.

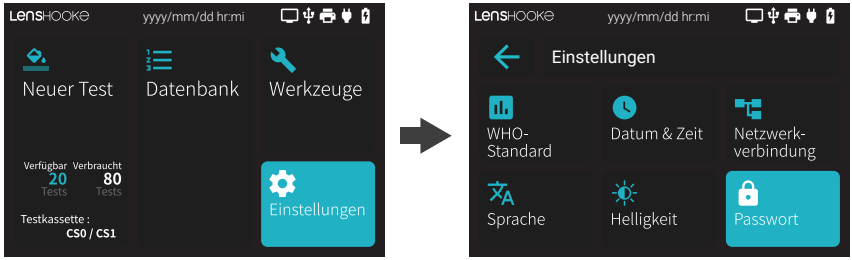
4 Sprache

(1) Klicken Sie auf das Symbol **„Einstellungen”** und dann auf das Symbol **„Sprache”** . Wählen Sie Ihre bevorzuge Spracheinstellung.

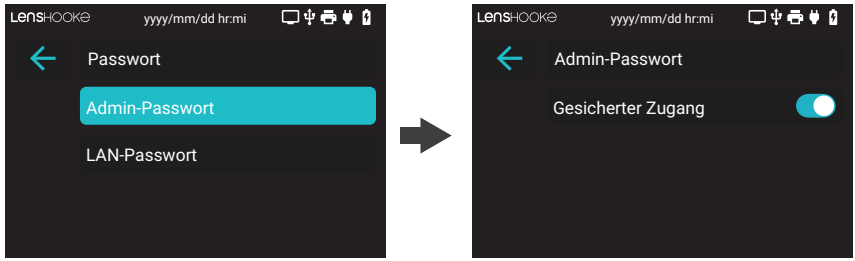


5 Passwörter

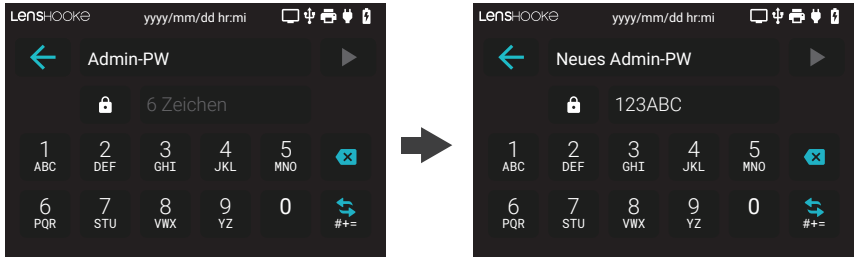
(1) Klicken Sie auf das Symbol **„Einstellungen"** und dann auf das Symbol **„Passwort"**.



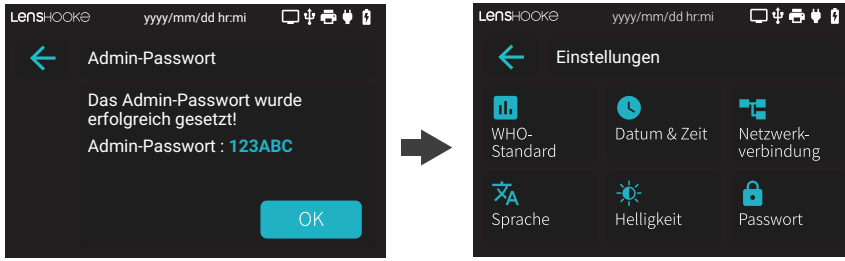
(2) Wählen Sie die Schaltfläche **„Admin-Passwort"**. Aktivieren Sie **„Gesicherter Zugang"**, um den Zugang zu beschränken.



(3) Geben Sie ein sechsstelliges Passwort ein und fahren mit " ▶ " fort. Bitte wiederholen Sie Ihr Passwort, um die Eingabe des neuen Admin Passwortes zu bestätigen.



(4) Nach der Überprüfung des neuen Admin Passwortes bestätigen Sie dies mit „ ▶ " und gelangen zum nächsten Schritt. Mit **„OK"** kehren Sie zur vorigen Seite zurück.

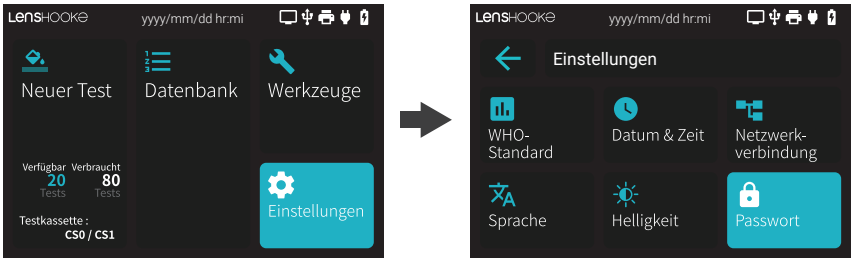


HINWEIS

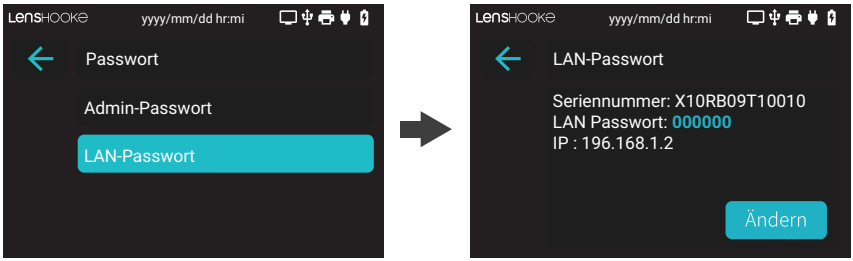
- Das Standard Admin Passwort lautet **„000000“**.
- Wurde die Schaltfläche „ ⬭ “ ausgewählt, ist der Zugang gesichert.
- Für den Zugriff auf das Analysegerät aus dem Energiesparmodus muss das Admin Passwort eingegeben werden.

6 LAN Passwort

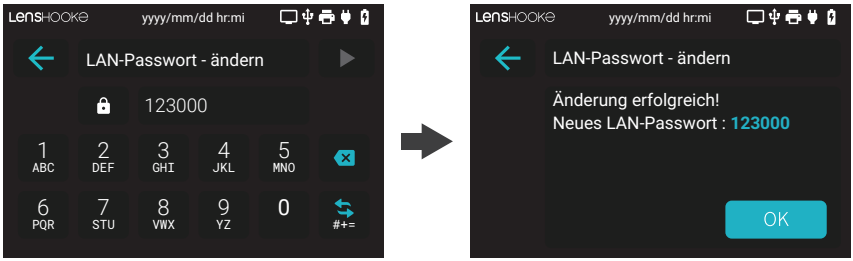
(1) Klicken Sie auf das Symbol **„Einstellungen”** und dann auf das Symbol **„Passwort”**.



(2) Wählen Sie **„**LAN-Passwort**”**, um das Passwort anzeigen zu lassen. Möchten Sie das Passwort ändern, klicken Sie auf die Schaltfläche **„Ändern”**.



(3) Geben Sie als Passwort eine beliebige sechstellige Zahl ein. Bestätigen Sie die Eingabe mit “ ▶ ”, um zum nächsten Schritt zu gelangen. Schließen Sie die Änderung des Passworts mit **„OK”** ab.

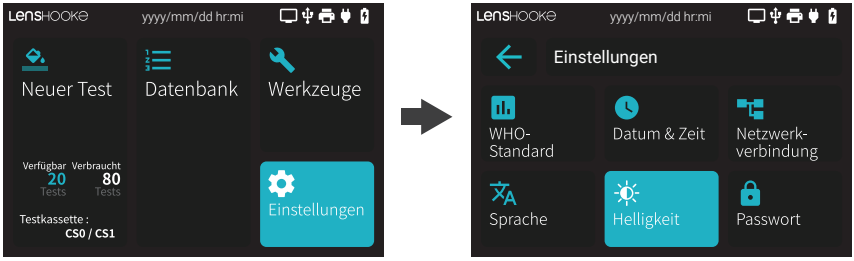


HINWEIS

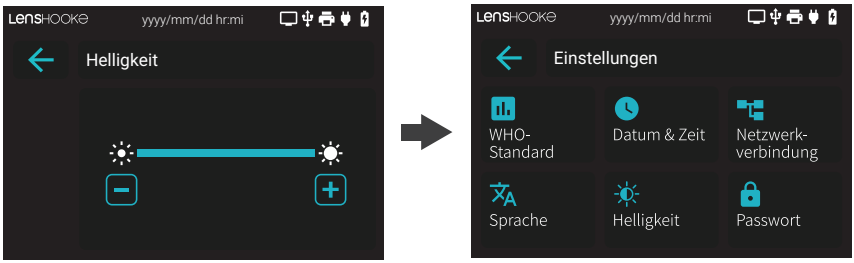
- Das Standard LAN Passwort lautet **„000000“**.
- Wenn Sie Zugang zum Analysegerät über ein Netzwerk möchten, um Ergebnisse zu lesen bzw. herunterzuladen, müssen Sie das LAN Passwort eingeben.
- Erst wenn Sie eine sechsstellige Zahl komplett eingegeben haben, wird die Schaltfläche **„** ▶ **“** blau und kann bestätigt werden.
- Bitte verwenden Sie einen RJ45-USB Adapter (Artikel 1830307), um das Analysegerät über ein Netzwerk-kabel mit dem lokalen Netzwerk LAN (LAN - Local Area Network) zu verbinden. (Weitere Informationen in Kapitel VI)

7 Einstellung der Bildschirmhelligkeit

(1) Klicken Sie auf das Symbol **„Einstellungen”** und dann auf das Symbol **„Helligkeit”**.



(2) Passen Sie die Helligkeit des Bildschirms an, indem Sie auf das Symbol **„** + **”** oder **„** − **”** klicken. Klicken Sie anschließend auf das Symbol **„** ← **”**, um zur vorherigen Seite zurückzukehren.

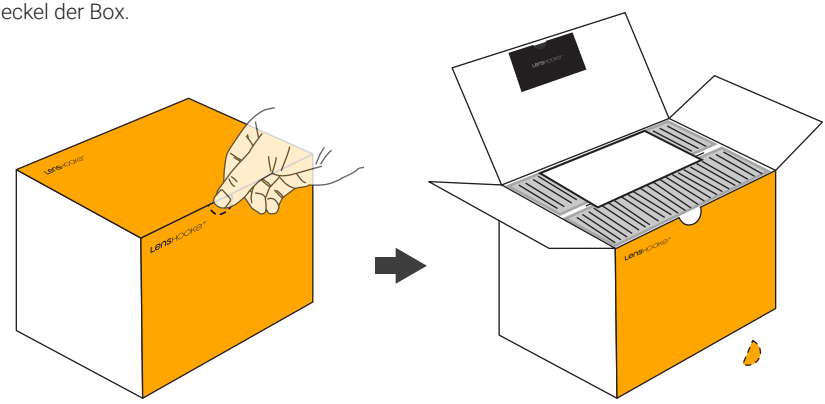


VI . Zubehör

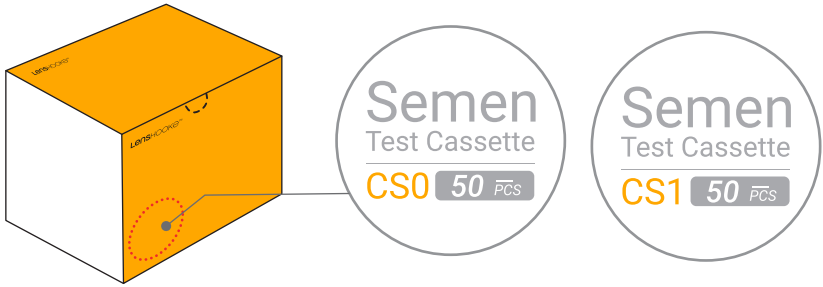
Lizenz-Dongle:

1 Lizenz auffüllen

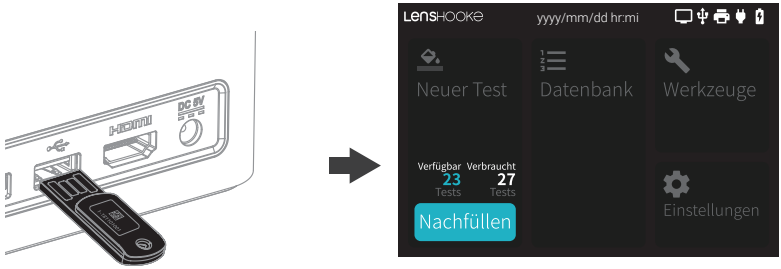
(1) Wenn Sie die LensHooke® Semen Test Cassette Box auspacken, finden Sie den Lizenz-Dongle im Deckel der Box.



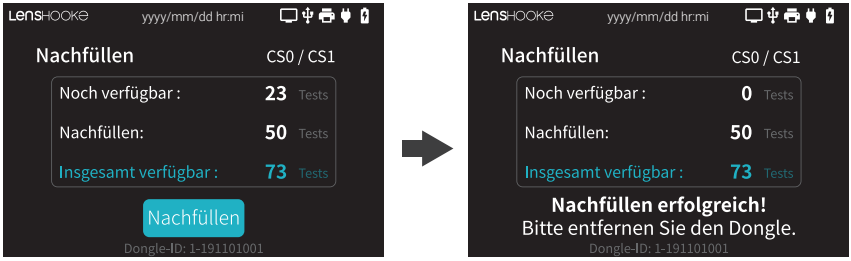
(2) Überprüfen Sie den Typ der Testkassette, bevor Sie den Dongle zum Auffüllen der Lizenz einstecken.



(3) Bitte stecken Sie diesen Lizenz-Dongle in den USB-Anschluss des Analysegeräts.

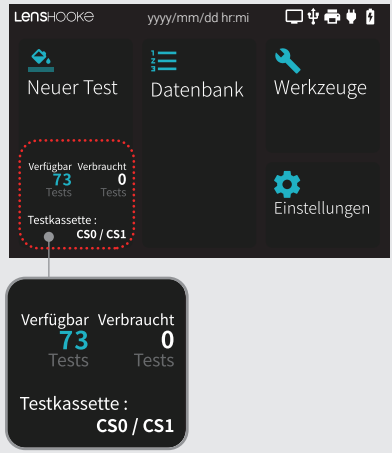


(4) Bitte klicken Sie auf das Symbol **„Nachfüllen”**, um die Lizenzen aufzufüllen. Überprüfen Sie anschließend, ob die Füllinformationen korrekt sind und klicken Sie dann auf das Symbol **„Nachfüllen”**. Wenn Sie erfolgreich aufgefüllt haben, entfernen Sie bitte den Lizenz-Dongle.



HINWEIS

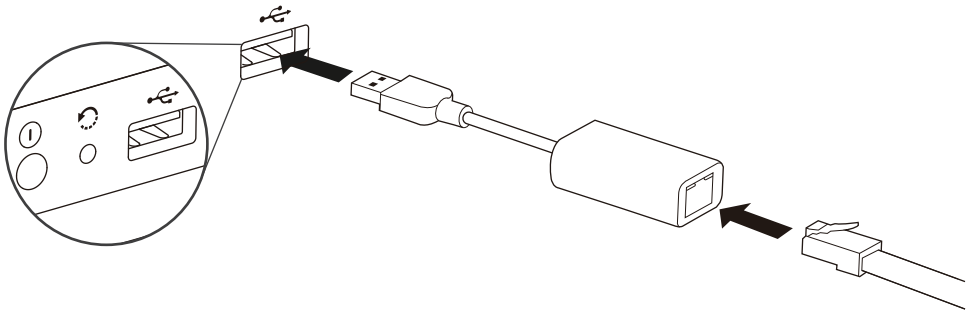
- Nur mit einem Lizenz-Dongle von BONRAYBIO Co., LTD. erscheint das Symbol **„Nachfüllen”** auf dem Bildschirm.
- Jeder Lizenz-Dongle kann nur einmal verwendet werden. Wenn Sie diesen Dongle erneut verwenden, erscheint eine Dongle-Fehlermeldung auf dem Bildschirm.
- Bitte stecken Sie den Dongle unmittelbar in das Gerät, sobald Sie die Box der LensHooke® Semen Test Cassette auspacken, um die Lizenz sofort wieder aufzufüllen.
- Wenn Sie mit einem neuen Dongle die Lizenz wieder aufzufüllen, wird die Zahl von **„Verbraucht”** Tests auf Null zurückgesetzt. Die Anzahl verfügbarer Tests des Lizenz-Dongles wird zu den **„Verfügbar”** Tests hinzugefügt.



RJ45-USB Adapter (Artikel 1830307)

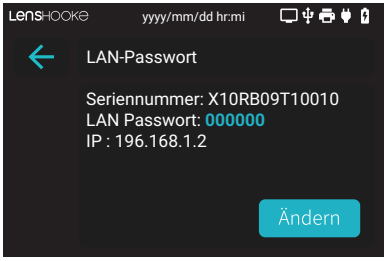
1 Analysegerät : Verbindung mit LAN (Local Area Network) herstellen

(1) Bitte verwenden Sie den RJ45-USB Adapter (Artikel 1830307), um das Analysegerät per Kabel mit dem LAN (Local Area Network) zu verbinden.



2 Andere Geräte: Zugriff auf das Analysegerät

(1) Öffnen Sie bitte den Browser Ihres Computers/Laptops/iPad und geben Sie dann die IP des Gerätes ein. Sie können die Informationen des Analysegerätes überprüfen, indem Sie auf das Symbol **„Netzwerkverbindung“** in den Einstellungen klicken.



(2) Bitte loggen Sie sich ein, indem Sie das LAN-Passwort eingeben. Sie können die Informationen des Analysegerätes überprüfen, indem Sie auf das Symbol **„LAN-Passwort“** im Einstellungsbereich klicken.

(3) Sie können sich PDF und MP4-Dateien ansehen.

(4) Sie können PDF, MP4 und CSV-Dateien speichern.

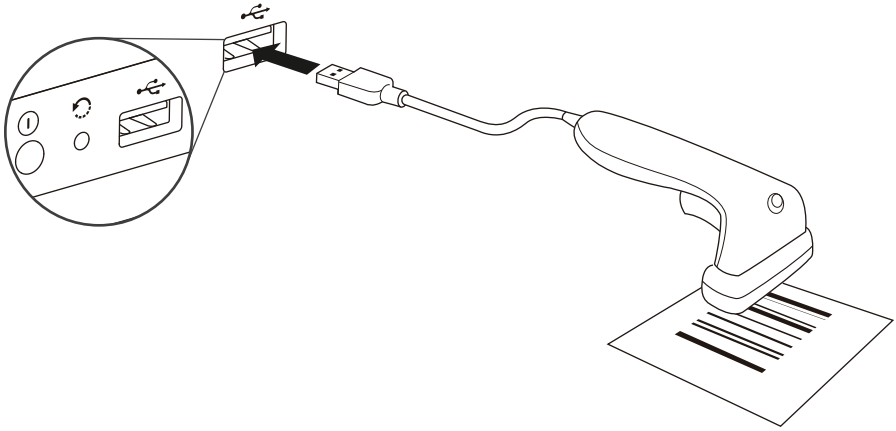
HINWEIS

- Wenn zu viele Personen gleichzeitig auf denselben Analyzer zugreifen, kann dies die Leistung des Analysegerätes beeinträchtigen.
- Bitte verwenden Sie die folgenden Browser, um den Login Bereich zu öffnen: Firefox (Version: 62 oder höher), Chrome (Version: 69 oder höher), Microsoft Edge für Windows 10 oder Safari. (Weitere Details finden Sie unter www.LensHooke.com.)
- Unterstützung für iPad, PC oder Laptop
- Solange das Analysegerät mit dem lokalen Netzwerk verbunden ist, wird empfohlen, das Gerät ans Stromnetz anzuschließen.

Barcode Scanner

1 To connect the Barcode Scanner to the Analyzer

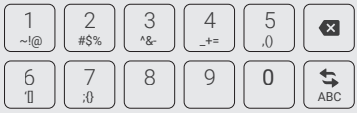
(1) Bitte den Barcode Scanner mit einem USB Port des Anylaysegerätes verbinden.



(2) Der Barcode Scanner kann zur Eingabe der Patienten ID oder LOT der LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) und LensHooke® X QC Video (For Semen) verwendet werden.

HINWEIS

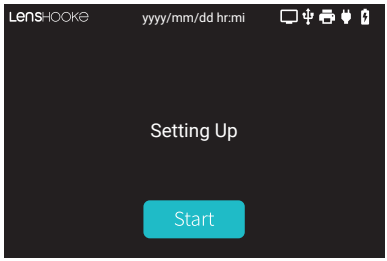
- Ein Barcode Scanner kann nur über USB mit dem Analysegerät verbunden werden.
- Das Analysegerät kann nur folgende Buchstaben, Zahlen und Symbole lesen:



VII. Erste Schritte

Das Analysegerät einrichten:

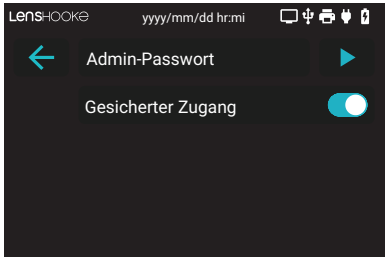
(1) Klicken Sie auf das Symbol **„Start"** und wählen Sie dann die Spracheinstellung aus.

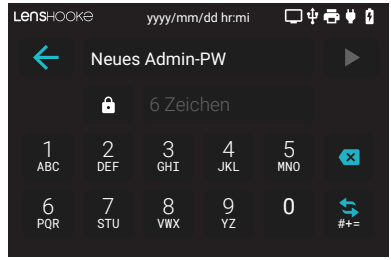


(2) Datum und Uhrzeit einstellen. Mit „ < " und „ > " das Format auswählen und mit „ + " und „ − " Datum und Uhrzeit anpassen.

(3) Klicken Sie bitte auf das Symbol „ ▶ ", um die Ausgabe des WHO-Standards auszuwählen.

(4) Gesicherter Zugang. Möchten Sie den Zugriff auf das Analysegerät absichern, aktivieren Sie die Funktion mit dem Toggle Button (wird blau) und geben ein sechstelliges neues Admin Passwort ein.





Bitte laden Sie den Akku 3 Stunden vor der Inbetriebnahme auf.

VIII. Reinigung und Wartung

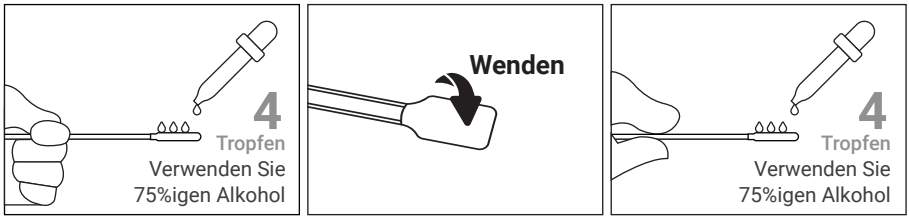
1 Hinweise für die Routinereinigung

(1) Der Testkassetteneinschub sollte nur mit LensHooke® Cleaning Wipe gereinigt werden.
(2) Bitte verwenden Sie KEINE anderen Materialien, um den Testkassetteneinschub zu reinigen.
(3) LensHooke® Cleaning Wipe sind für den Einmalgebrauch bestimmt. NICHT wiederverwenden.
(4) Halten Sie das LensHooke® X1 PRO Semen Quality Analyzer von Staub, Wasser, Flüssigkeiten und extremen Umweltbedingungen fern (siehe auch technische Daten für Lagerung und Betrieb).
(5) Reinigen Sie das Gehäuse des LensHooke® X1 PRO Semen Quality Analyzer täglich, wenn Sie die Testungen abgeschlossen haben.

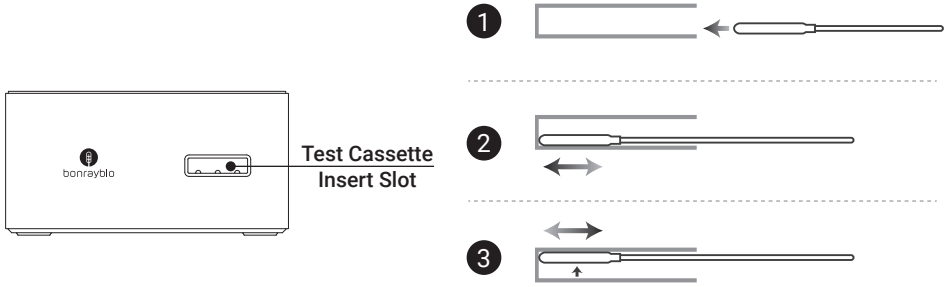
2 Reinigungsschritte

I. Schalten Sie das Analysegerät vor der Reinigung aus.

(1) Schalten Sie das Analysegerät vor der Reinigung aus.
(2) Bitte bereiten Sie 2 LensHooke® Cleaning Wipe vor.
(3) Bitte träufeln Sie vier Tropfen 75%igen Alkohols auf beide Seiten eines LensHooke® Cleaning Wipe.



(4) Führen Sie das LensHooke® Cleaning Wipe in den Einschubschacht der Testkassette und folgen Sie den Anweisungen zur Reinigung.



(5) Bitte verwenden Sie ein neues trockenes LensHooke® Cleaning Wipe (ohne Alkohol oder Flüssigkeit), um den Testkasssetteneinschub nochmals zu reinigen.
(6) Entsorgen Sie die gebrauchten LensHooke® Cleaning Wipe.

II. Gehäuse:

(1) Schalten Sie das Analysegerät vor der Reinigung aus.
(2) Säubern Sie das Gehäuse des Analysegerätes mit einem alkoholischen Desinfektionstuch.
(3) Entsorgen Sie das gebrauchte alkoholische Desinfektionstuch.

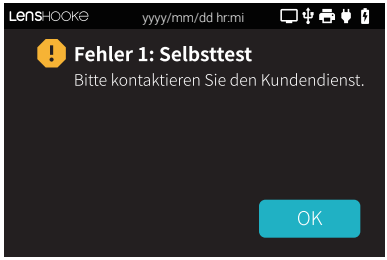
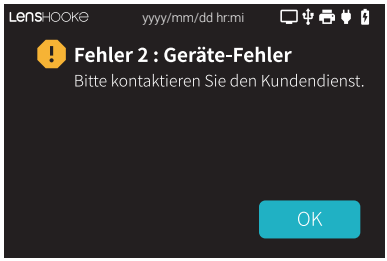
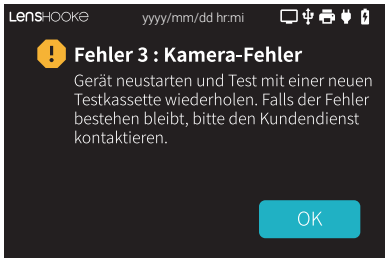
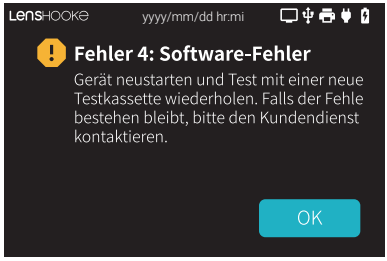
III. Netzteil:

(1) Verwenden Sie ein alkoholfreies Reinigungsmittel.
(2) Reinigen Sie das Netzteil vorsichtig mit einem feuchten Reinigungstuch.
(3) Reinigen Sie das Netzteil erneut mit einem feuchten Tuch ohne Reinigungsmittel.

HINWEIS

- Verwenden Sie die LensHooke® Cleaning Wipes, um das LensHooke® X1 PRO Semen Quality Analyzer zu reinigen.

IX. Fehlermeldungen

Fehlermeldung	Lösung
	**Fehler 1: „Selbsttest“** Fehler beim Starten, bitte kontaktieren Sie unseren Kundenservice.
	**Fehler 2: „Geräte-Fehler“** Gerätefehler, bitte entnehmen Sie die Testkassette und klicken Sie auf das Symbol **„OK”** um zur Startseite zurückzukehren und das Analysegerät auszuschalten (siehe „**Ein und Ausschalten**” auf Seite 5 für den normalen Betriebsstatus). Wenn diese Meldung weiterhin erscheint, wenden Sie sich an unseren Kundendienst.
	**Fehler 3: „Kamera-Fehler“** Kamerafehler, bitte entnehmen Sie die Testkassette und klicken Sie auf das Symbol **„OK”**, um zur Startseite zurückzukehren. Bitte legen Sie eine neue Testkassette ein und wiederholen Sie die Aktion. Wenn diese Meldung weiterhin angezeigt wird, wenden Sie sich an unseren Kundendienst. Vergewissern Sie sich, dass Sie die richtige LensHooke® Semen Test Cassette verwenden.
	**Fehler 4: „Software-Fehler“** Softwarefehler, bitte entnehmen Sie die Testkassette und klicken Sie auf das Symbol **„OK“**, um zur Startseite zurückzukehren und das Analysegerät auszuschalten (siehe Kapitel 1 Ein- und Ausschalten).

X. Spezifikationen

Name des Analysegerätes
LensHooke® X1 PRO Semen Quality Analyzer

Bedienfeld:
3,5 Zoll resistiver Touchscreen

Externe Spannungsversorgung:
Eingang: AC 100-240 V / 50-60 Hz / 0,5 A
Ausgang: DC 5V / 2A.

Batterielebensdauer:
2500 mA (eingebaute, wieder aufladbare Lithium-Polymer-Batterie; DC 3,7 V / 2,5 Ah)

Interne Speicherkapazität:
30 Datensätze mit Daten und Bildern

Erkennungszeit:
2-5 Minuten (abhängig von der Probenbeschaffenheit)

Netzteil:
Eingang: AC 100-240 V / 50-60 Hz / 0,5 A
Ausgang: DC 5 V / 2 A Max.

Betriebsbedingungen:
Temperatur: 15-38°C (59-100°F)
Luftfeuchtigkeit: <70 %

Lagerbedingungen:
Temperatur: 15-38°C (59-100°F)
Luftfeuchtigkeit: <70 %

Transportbedingung:
Temperatur: -10 bis 60°C (14-140°F)

Messbereich:
pH-Wert: 6,0 - 8,0 (jeder Skalenbereich: 0,2)
Konzentration: <0,1-300 (10^6/mL)
Gesamtmotilität: <1-100 %
Morphologie (Normalformen): <1-100 %

XI. Referenzen

Referenz der Parameter aus dem WHO-Laborhandbuch für die Untersuchung und Verarbeitung von menschlichem Sperma.

Referenz	WHO 5th Niedrige Referenz	WHO 4th Niedrige Referenz
Konzentration	15 x 10^6 (12-16)/ ml	≧ 20 x 10^6 / ml
Motilität	40% (38-42%)	a + b ≧ 50% or a ≧ 25%
PR (Progressive Motilität)	32% (31-34%)	
Morphologie (Normal)	4% (3-4%)	≧ 15%

a：Schnelle progressive Motilität (≧25μm/s)
b：Langsame oder träge progressive Motilität

XII. Erklärung /Rechtliche Hinweise

Alle relevanten Inhalte der Bedienungsanleitung zu diesem Produkt dürfen ohne schriftliche Genehmigung von Bonraybio Co., LTD. nicht reproduziert, verteilt, vervielfältigt oder in irgendeiner anderen Art von Abrufsystemen gespeichert werden. Bonraybio behält sich das Recht vor, die Beschreibung der technischen Daten der Hard- und Software in diesem Handbuch jederzeit und ohne vorherige Ankündigung zu ändern. Wir werden unser Bestes tun, um einen vollständigen und korrekten Inhalt sicherzustellen. Bei Fehlern oder unklaren Informationen wenden Sie sich bitte an Ihren lokalen Händler. Wir freuen uns über jedes Feedback zu diesem Handbuch.

XIII. Warnhinweise und Vorsichtsmaßnahmen

1. Überspannungskategorie: Stufe II
2. Verschmutzungsgrad: Stufe 2
3. Einsatzhöhe: < 2000 meter
4. Relative Luftfeuchtigkeit (RH%): < 70%
5. Verwendung ausschließlich in Räumen
6. Das Gerät hat den Code IP21, damit ist es gegen das Einführen von Fingern geschützt und wird bei einem genormten Test, bei dem er vertikalem Tropfwasser ausgesetzt ist, nicht beschädigt oder beeinträchtigt.
7. Gerät und Zubehör außerhalb der Reichweite von Kindern aufbewahren, um ein Strangulieren durch Netz- und Verbindungkabel Erstickung durch Verschlucken von Kleinteilen zu verhindern.
8. Das Testergebnis folgt dem WHO-Laborhandbuch für die Untersuchung und Verarbeitung von menschlichem Sperma. Bitte beachten Sie das Benutzerhandbuch der LensHooke® Semen Test Cassette.

HINWEIS

- LensHooke® X1 PRO Semen Quality Analyzer, LensHooke® Semen Test Cassette, C-KUP™ Liquefaction Test Cup, LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) und LensHooke® X QC Video (For Semen).

Hersteller:
Bonraybio Co., LTD.
4F., No. 118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280,
Taiwan (R.O.C.)

Distributor:
nal von minden GmbH
Friedenstrasse 32
93053 Regensburg
Deutschland

Das Produkt entspricht der Richtlinie 98/79/EG über In-vitro-Diagnostika für Medizinprodukte (CE).

- Es gelten die elektromagnetische Verträglichkeit, Emission und Störfestigkeit sowie die Anforderungen der IEC 61326-2-6.

XIV. Garantie

Bonraybio bietet eine einjährige Garantie ab dem Tag, an dem Sie den LensHooke® X1 PRO Semen Quality Analyzer erworben haben. Während der Garantiezeit wird das Analysegerät kostenlos repariert oder ersetzt.

Die Garantie gilt nur für das original LensHooke® X1 PRO Semen Quality Analyzer von Bonraybio. Bei Änderungen oder unsachgemäßer Verwendung des Analysegeräts erlischt die Garantie.

Hersteller : Bonraybio Co., LTD.
Adresse : 4F., No.118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280, Taiwan(R.O.C.)
Tel : +886-4-2491-2385
Fax : +886-4-2491-2885
Email : support@bonraybio.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

CE

LensHOOKe®

LensHOOKe®

Semen Quality Analyzer

ユーザーマニュアル

X1 PRO

Rev.29-0X10900　20210317X1E003JP

製品を適切に使用するために、最初にこのユーザーマニュアルをよくお読みください。このユーザーマニュアルは **www.LENSHOOKE.com** でも入手できます。

記号

このユーザーマニュアルの内容には、次のアイコンが表示される場合があります。

「注記」

「注意」

「ページ番号」

「再使用禁止」

「使用期限」

「ロット番号」

「シリアル番号」

「製造年月日」

「製造元」

「EU欧州代理人」

「IN VITRO DIAGNOSTIC DEVICE」

「管理温度」

「使用説明書を参照」

「WEEE司令の適用表示」

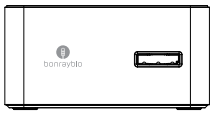
CEマーク

「使用説明書を参照」

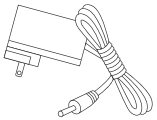
このアイコンは米国専用です。

パッケージに含まれるもの

- **LensHooke® X1 PRO Semen Quality Analyzer**



- 電源アダプター（アナライザー用）



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I. はじめに

LensHooke® X1 PRO Semen Quality Analyzerは、in vitro診断専用です。ご使用前には必ず本取扱説明書を読み、機器の使用方法を理解した上で機器の使用を行ってください。
ここで言う"LensHooke® Semen Test Cassette"は"LensHooke® CS0 Semen Test Cassette"、"LensHooke® CS1 Semen Test Cassette"のことを意味します。

製品に関するご質問やご不明な点がございましたら、サービスホットライン（+886-4-2491-2385）までお電話頂くか、販売代理店 までお気軽にお問い合わせください。
サービスホットライン：月~金 8:30~17:30(GMT+8)

II. 使用目的

光学機器を用いたLensHooke® X1 PRO Semen Quality AnalyzerではLensHooke® Semen Test Cassetteとともに使用することで、以下の値を簡単に測定することができます:

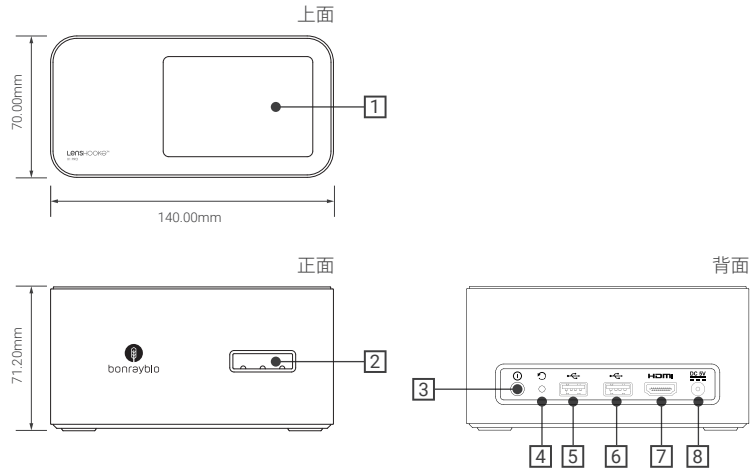
(1) 精子濃度 (10^6 per ml)
(2) 総運動性 (前進運動精子+非前進運動精子, %)
- 前進運動率%)
- 非前進運動率 (%)
- 不動 (%)
- その他のパラメーター(MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, and BCF)

(3) 正常形態率 (normal forms, %)
(4) pH 値

LensHooke® X1 PRO Semen Quality Analyzerは男性の妊娠可能性の包括的な評価をするものではなく、体外診断での使用のみを目的としています。

III. 製品の概要

LensHooke® X1 PRO Semen Quality Analyzer



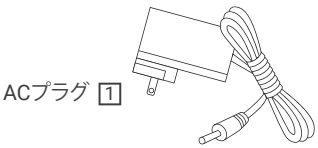
1 タッチスクリーン
2 テストカセット挿入スロット
3 電源スイッチ
4 リセットボタン
5 USB ポート
6 USB ポート
7 HDMI ポート
8 電源アダプター接続口

注意

- **USB** ポート: USB 2.0
- リセットボタン : 本体がフリーズ等した際には、ピン等で背面のリセットボタンを押します。
- **HDMI** ポート : このアナライザーでは、HDMIケーブルを高解像度モニターに接続して、画像とデータを確認することができます。

アクセサリー

- 電源アダプター



2 電源アダプタープラグ

Dongguan Shilong Fuhua Electronic Co., Ltd;
UES12LCP-050200SPA

タッチスクリーンアイコン

1 **HDMI** 接続アイコン: アナライザーは、HDMIポート経由で外部モニターと接続されていることを示します。
2 **USB**接続アイコン: アナライザーはUSBポート経由でUSBドライブと接続されています。
3 サーマルレシートプリンター接続アイコン: アナライザーはサーマルレシートプリンターに接続されています。
4 電源アダプター接続アイコン: このアナライザーは電源アダプターに接続されています。
5 バッテリーアイコン: バッテリーの残量を示します。

注意

- **USB**接続アイコン: キーボードやマウス、ドングル等のその他の機器をUSBポート経由で接続した際、このアイコンはスクリーン上に表示されません。

タッチスクリーンからは以下の機能を行うことができます。

6 **ユーティリティ:** 機能が含まれます:
- **品質管理**: アナライザー/デバイスの品質を確認します。
- **全ての検査データのバックアップ:** 全検査のデータのバックアップを行います。
- **システムの更新**: アナライザーのソフトウェアの更新を行います。
- **情報**: アナライザーの情報を確認します。
- **全ての検査データの削除:** 全ての検査データを削除します。
- **ロゴの挿入:** PDF形式のレポート上部に指定のロゴを挿入します。

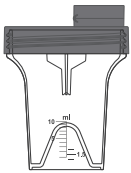
7 **設定:** 以下の機能を含みます:
- **WHO スタンダード:** WHOスタンダード 4版か 5版を選択できます。
- **日付と時刻**: アナライザーの日付と時刻を設定します。
- **ネットワーク接続:** ネットワークへの接続方法を選択します。
- **アクセスコード: アナライザーにアクセスする際のパスワードを確認・変更できます。**
- **輝度:** 画面の輝度の調整をします。
- **言語:** アナライザーの言語設定を選択します。

8 **検査履歴:** 過去の検査履歴の閲覧ができます。
9 **新規検査:** 検査を開始します。

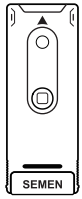
IV. 消耗品

LensHooke® X1 PRO Semen Quality Analyzerの消耗品は次のとおりです。

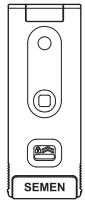
- **C-KUP™ Liquefaction Test Cup**



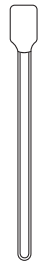
- **LensHooke® CS0 Semen Test Cassette**



- **LensHooke® CS1 Semen Test Cassette**



- **LensHooke® Cleaning Wipe**



- **LensHooke® X QC Beads (For Semen)**

- **LensHooke® X QC Reticle (For Semen)**

- **LensHooke® X QC Video (For Semen)**

⚠ 正確な測定を行うためには必ずテストカセット等の消耗品は純正の製品**(LensHooke® Semen Test Cassette** や **LensHooke® X QC)**をご使用ください。

注意

- 上記画像はイメージですので実際の商品とは異なる場合があります。
- C-KUP™ Liquefaction Test Cupは、精液の採取に使用します。
- LensHooke® Semen Test Cassetteは、アナライザー本体とともに採取した精液の分析に使用します。
- LensHooke® Cleaning Wipeはテストカセット挿入スロットのクリーニングに使用します。
- LensHooke® X QC Beads (For Semen)やLensHooke® X QC Reticle (For Semen)、LensHooke® X QC Video (For Semen)はアナライザーの品質管理に使用します。

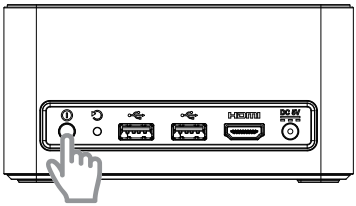
V. 主な機能

LensHooke® X1 PRO Semen Quality Analyzer

電源のon/off

1 アナライザーの電源を入れる:

図 1 の様に電源ボタンを2秒間押し続けるとアナライザーの電源が入ります。
タッチスクリーンが点灯すると、アナライザーの操作準備が整います（図 2）。



画1

画2

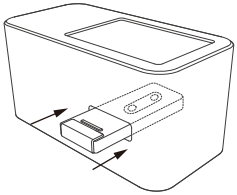
2 アナライザーの電源を切る:

電源を切る際には電源ボタンを10秒間押し続けてアナライザーを直接オフにするか、電源ボタンをタッチスクリーンに「電源オフ」が表示されるまで2秒間押し続け、アイコンを選択してオフにします。

テストカセットの挿入/取り外し

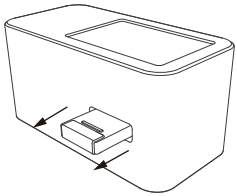
1 テストカセットの挿入:

テストカセットはスロットの一番奥まで挿入します。



2 テストカセットを取り出し:

検査後、下記の図の様にテストカセットを矢印の方向に引き、取り出します。



バッテリーの充電

1 バッテリー残量が少なくなると、「ローバッテリー」のメッセージが画面に表示されます（図3）。使用すぐに電源アダプターを使いバッテリーの充電を行ってください。充電中は「電源アダプター接続」アイコンがタッチスクリーンに表示されます（図4）。「電源アダプター接続」アイコンが画面に表示されない場合はアダプターがアナライザー背面のソケットに正しく接続されていることを確認してください。

画像3

画像4

- 本アナライザーには2500 mAリチウムイオンポリマーバッテリーが内蔵されています。
- バッテリーの交換や取り外しはできません。バッテリーに問題がある際には販売店までお問い合わせください。

注意

- 機器を省電力モード（スリープモード）にする場合には機器背面の電源ボタンを素早く押します。通常動作に戻す際には再度電源ボタンを素早く押します。機器を10分間放置すると自動的に省電力モードに入ります。

  * 省電力モード: バッテリー消費を抑えるためにタッチスクリーンの表示を一時的に切ります。

- 搭載のリチウムイオンバッテリーの寿命を保つためには、機器を使用しない際でも充電ケーブルと接続し、常に充電している状態にします。
- アナライザーを3ヶ月以上使用しない場合には必ず使用する前に充電を行ってください。
- バッテリーが空になると日付と時間がデフォルト設定に戻る可能性があります。必ず確認をしてから使用してください（17ページ参照）。
- 画面に "バッテリーが過熱しています" または "バッテリーの温度が低すぎます" という警告メッセージが表示された場合、アナライザーは安全のため 5分以内に自動的に電源を落として機器を保護します。上記の警告メッセージが表示された場合は、機器の電源を切り、15℃～38℃、湿度70%以下の環境下に1時間以上置いた後、電源アダプターを接続し、機器の電源を入れて使用してください。

テストアナラ イザーを準備する

1. アナライザーを平らな面に置いてください。
2. アナライザーが通常の動作環境にあるかどうかを確認します。
3. バッテリーの状態を確認します。バッテリー残量が少ない場合は、テストする前に電源アダプターを接続してください。

精液サンプルの採取

1. 詳細については、LensHooke® CS0 Semen Test Cassetteのユーザーマニュアルを参照してください。

検査を始める

1 新しいテスト

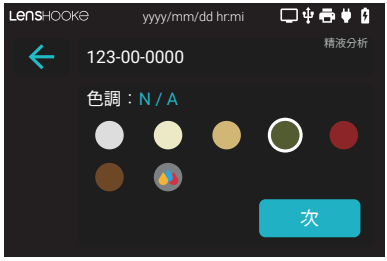
ステップ1. 「新規検査」アイコンを選択します。

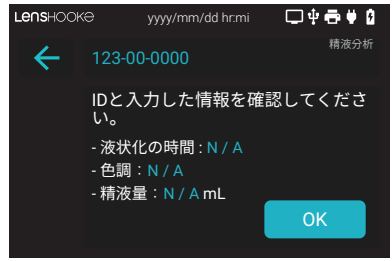
ステップ2. 患者ID番号を入力し、「 ▶ 」アイコンを選択して次のステップへ進みます。

注意

- 患者IDには20桁以上を超えての文字または記号は入力しないでください。
- 文字を入力する場合は、アイコンを0.5〜1秒間押し続けて、文字を選択してください。記号を入力するには、「 ⇆ 」アイコンを選択してキーボードを切り替えてください。
- バーコードリーダーを使用することで患者IDを読み込むこともできます。（25ページ「バーコードスキャナー」を参照してください。）
- リフィルに関しては22ページを参照ください。

ステップ3. 精液サンプルの採取後、完全に液化したのち、液化時間、精液色、精液量を選択してください。「次」を選択して次のステップに進みます。入力した情報が正しいことを確認し「OK」アイコンから次のステップに進みます。





注意

- 「⊖」と「⊕」を使用して、精液量を入力します。
- 測定結果の計算中にはテストカセットやアナライザーを動かさないで下さい。

ステップ**4.** 検体を滴下したカセットをスロットの奥まで挿入します。

検査結果の確認

1 検査履歴

(1)「検査履歴」アイコンから、患者IDから閲覧したい検査 を選択します。

(2) 検査結果が画面に表示されます。リストのに戻るには “ ← ” を選択して前のページに戻ります。

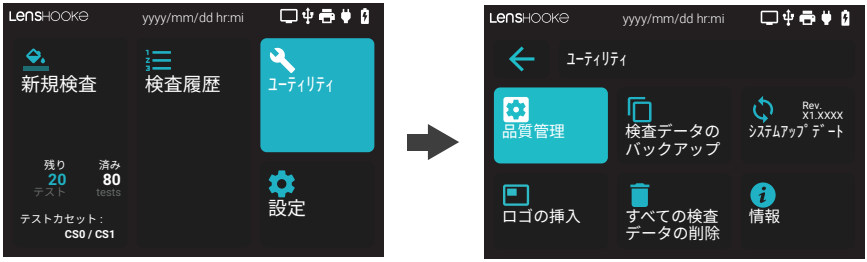
注意

- 青色で表示されているアイコンのみ選択が可能です。
- アナライザーをLANに接続して、結果を印刷することもできます。(接続するには24ページUSB-RJ45ギガビットイーサネットアダプターの項を参照して下さい)
- 濃度の表示の隣に「 ❄ 」が表示された場合、それは凝集や結晶、気泡が混入し検査結果に影響を与えてることを意味します。記録をしておくか再検査を行うことを推奨します。
- 運動率の表示の隣に「⁂」が表示された場合、自身の運動以外で動いた精子も運動精子と機器に検知され、検査結果に影響を与えていることを意味します。このシンボルが表示された際には検査結果を記録するか再検査を推奨します。
- 尾部(鞭毛)のない精子はクロマチンの欠損が見られるためにカウントされません。
- 精管切除をした患者の検査を行う際にはマニュアルでのカウントと二重で行うことが推奨されます。
- pH値の測定部にサンプルを滴下しなかった場合には結果には < 6.0と表示されます。pH値が < 6.0と表示された場合にはテストカセット上のpH値測定部を確認します。

ユーティリティ

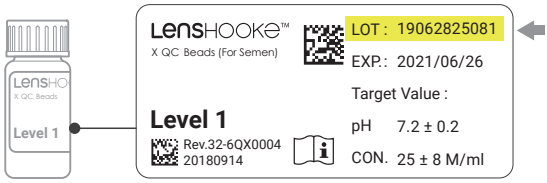
1 品質管理

(1) 「ユーティリティ」アイコンから「品質管理」を選択します。

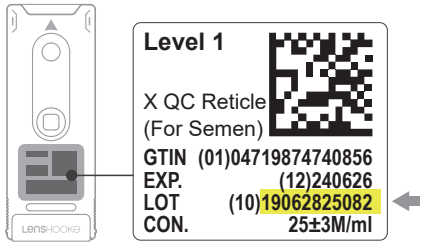


(2) LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen), LensHooke® X QC Video (For Semen)のラベル上に記載のロット番号を入力します。入力したロット番号を確認し、"▶"を選択し次のステップに進みます。

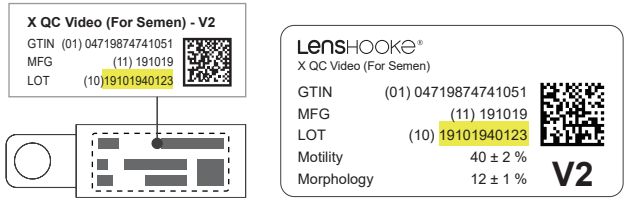
• X QC Beads (For Semen)のロット番号の記載場所



• X QC Reticle (For Semen)のロット番号の記載場所



• X QC Video (For Semen)のロット番号の記載場所



(3) LensHooke® X QC Beads (For Semen)、LensHooke® X QC Reticle (For Semen)、LensHooke® X QC Video (For Semen)の説明書に従って操作し、カセットを " 挿入スロット" に挿入するか、LensHooke® X QC Video USB を USB ポートに挿入します。

(4) 2〜5分後に結果は自動的に画面に表示されます。

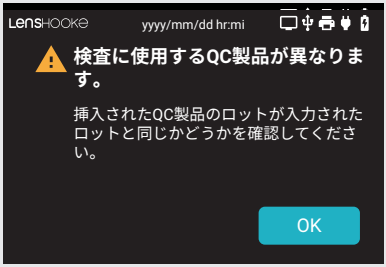
• X QC Beads の検査結果

• X QC Reticle の検査結果

• X QC Videoの検査結果

注意

- LensHooke® X QC Beads (For Semen) では検体のpH値、濃度が測定できます。
  LensHooke® X QC Reticle (For Semen) では 検体の濃度のみ測定できます。
  LensHooke® X QC Video (For Semen) では、精子の運動率と形態率のみを検査します。
- LensHooke® X QC Beads (For Semen) のロット番号を入力し、LensHooke® X QC Reticle (For Semen) のカセットを挿入した場合、右図の様なメッセージが表示されます。
  また、その逆も同様のメッセージが表示されます。



- LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen)の使用期限が過ぎている場合には検査結果に N/A と表示がされます。使用期限の残っている新しい 製品を使用してください。

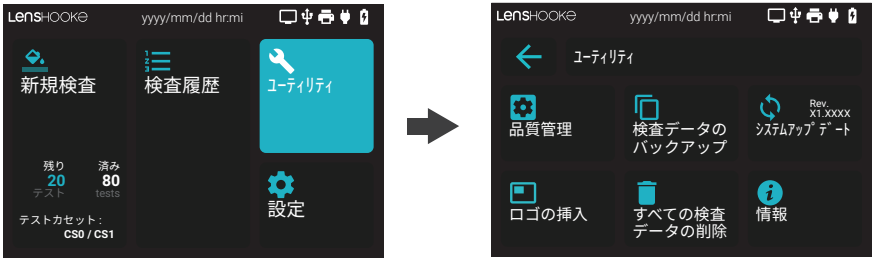
X QC Beads

X QC Reticle

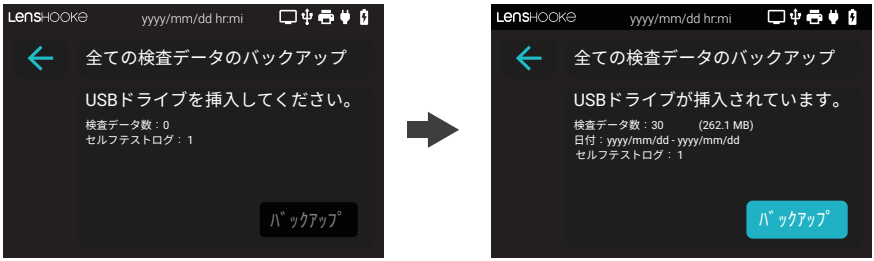
2 全ての検査結果をバックアップする

(1) 容量が 1 GB以上空きのあるUSBメモリーを用意します。

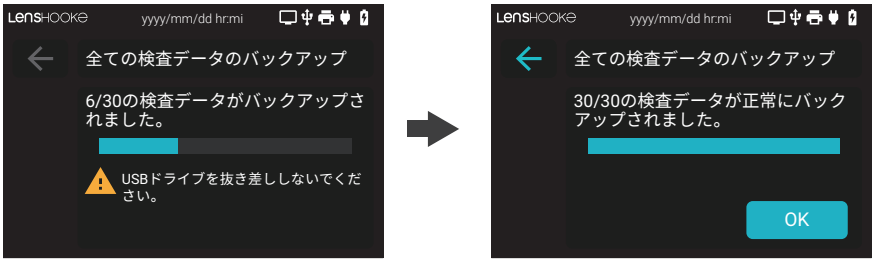
(2)「ユーティリティ」を選択し、「検査データのバックアップ」を選択します。



(3) USBメモリーを機器背面のUSBドライブ挿入口に挿します。「バックアップ」アイコンが青く変わったら、ボタンを押し、バックアップを開始します。



(4) 検査データのバックアップが正常に完了したら、「OK」を選択しホームページへ戻ります。



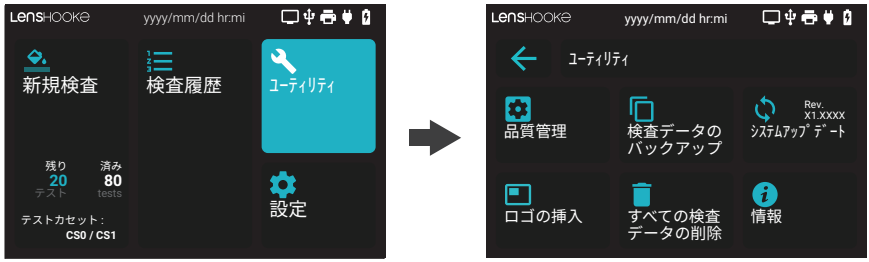
注意

- バックアップ中にUSBドライブの抜き差しはしないで下さい。
- “利用可能なストレージが不足しています。”とメッセージ時が表示された際には、検査結果の バックアップと削除を行い、バックアップに十分な容量を確保して下さい。
- USBドライブ上のメモリ容量が不足している場合は、PC上で操作をし、十分な保存領域を確保します。
- バックアップでは検査履歴内にあるデータのPDF, MP4, CSVファイルが作成されます。

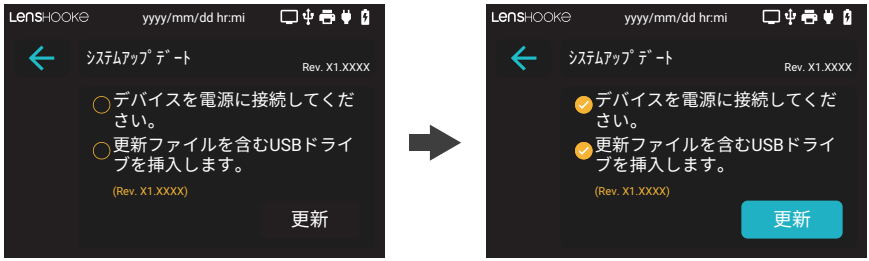
3 システムの更新

(1) システム更新のファイルが入ったUSBメモリーを準備します（空き容量 1 GB以上、システム更新については販売店までお問い合わせ下さい）。

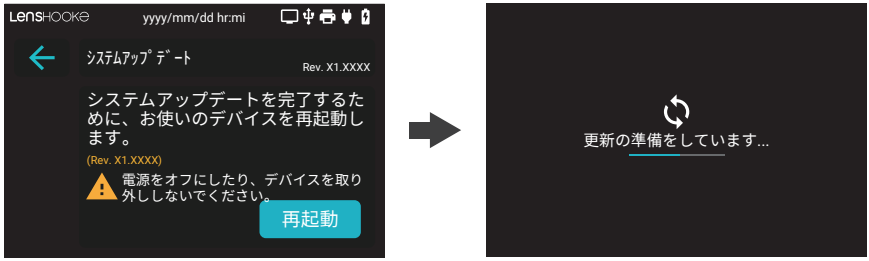
(2)「ユーティリティ」アイコンから、「システムアップデート」を選択します。



(3) 電源コードに接続し、更新ファイルの入ったUSBメモリーを機器に挿入します。「更新」アイコンが青く点灯したらボタンを選択しソフトウェアの更新を行います。



(4)「再起動」のボタンを選択し、機器を再起動します。完了後、再起動を行いシステムの更新が完了します。



注意

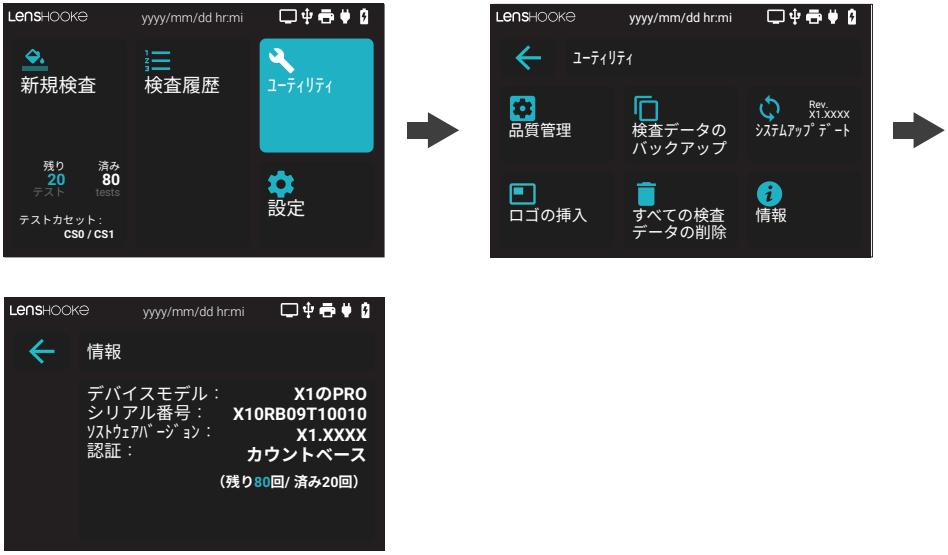
- システムを更新する前に、すべての検査データのバックアップを行ってください。
- システム更新中は電源アダプターを外したり、機器の電源を切ったりはしないでください。必ず電源アダプターとUSBドライブを接続した状態でアップデートを行います。

注意

- 「更新ファイルが破損しています」というメッセージが画面に表示された場合、ファイルのダウンロードが不完全だった可能性があります。システム更新ファイルを再度USBドライブにダウンロードして、 システムの更新をやり直して下さい。
- 「更新に失敗しました」というメッセージが画面に表示された場合にはUSBドライブが取り外された可能性があります。システム更新ファイルを含むUSBドライブを機器に挿入してシステムアップデートを再度実行してください。

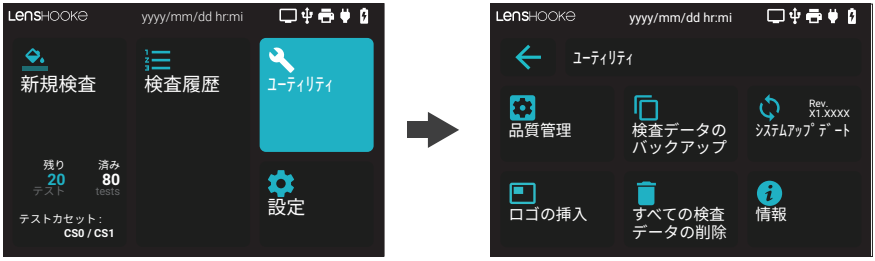
4 情報

[ユーティリティ]アイコンから、[情報]を選択して、アナライザーの情報を確認します。



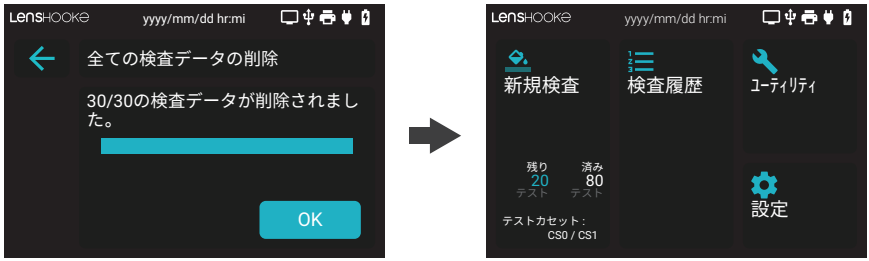
5 すべての検査データの削除

(1) 「ユーティリティ」アイコンから、「すべての検査データの削除」アイコンを選択します。



(2) 黄色の「削除」アイコンを選択して、すべての検査データの確認および削除を行います。

(3) 「OK」アイコンを選択してホームページに戻ります。

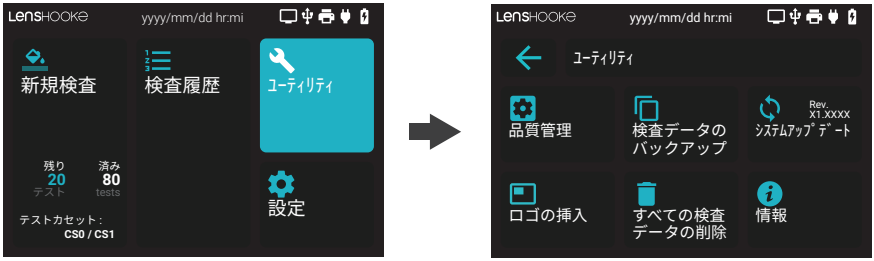


注意

- 一度削除した検査データは復元することはできません。「削除」ボタンを選択する前に、それらを完全に削除してもいいかを確認してください。

6 ロゴの挿入

(1) 「ユーティリティ」アイコンから「ロゴの挿入」を選択します。



(2) 機器背面のUSBポートにUSBドライブを挿入します。

(3)「挿入」ボタンを選択し、「挿入が正常に終了しました。」と表示されるまで待ちます。

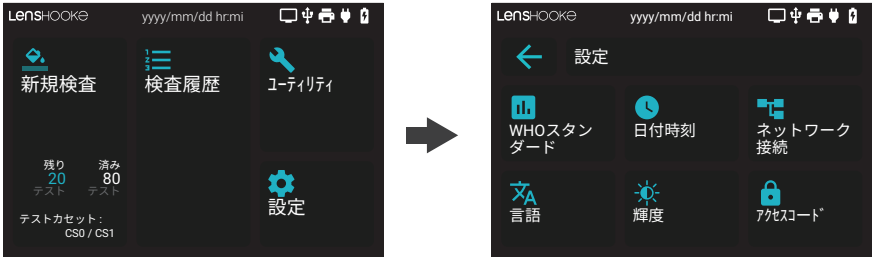
注意

- 挿入するロゴはサイズが2040 x 168ピクセル且つファイル名が **“lenshooke_X1_pdf_logo.png”** のPNGファイルである必要があります。
- ロゴファイルはフォルダ内等に保存せず、直接USBドライブの最上層に保存します。

設定

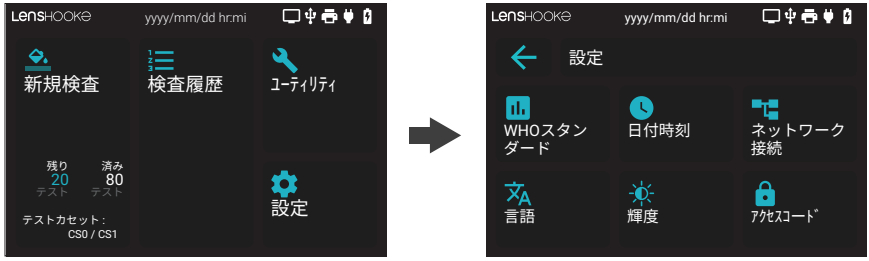
1 WHOスタンダード

(1)「設定」アイコンから、「WHOスタンダード」を選択します。



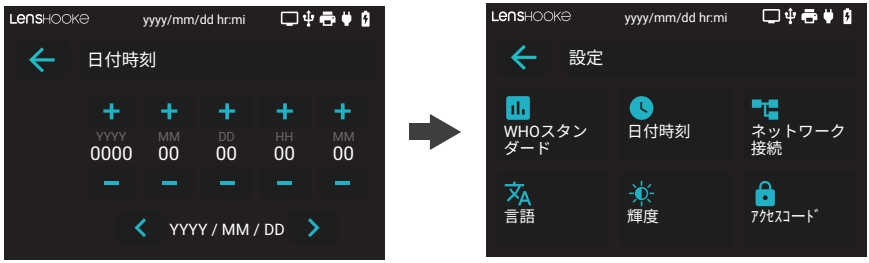
2 日付と時刻

(1)「設定」アイコンから、「日付時刻」を選択します。



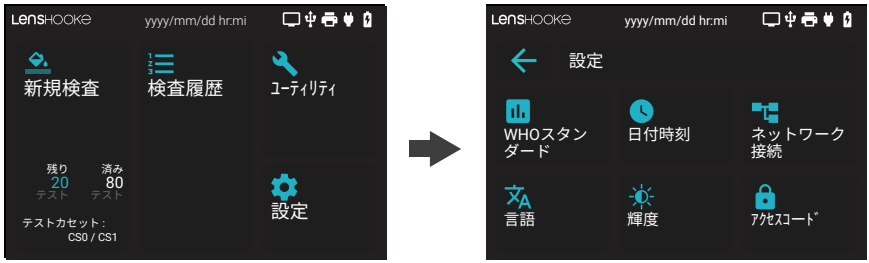
(2) 画面下部の「 ＋ 」または「 － 」ボタンで日付時刻の表示を選択します。また「 ＜ 」と「 ＞ 」ボタンで日時の変更をします。

設定後、「 ← 」から前の画面へ戻ります。



3 ネットワーク接続

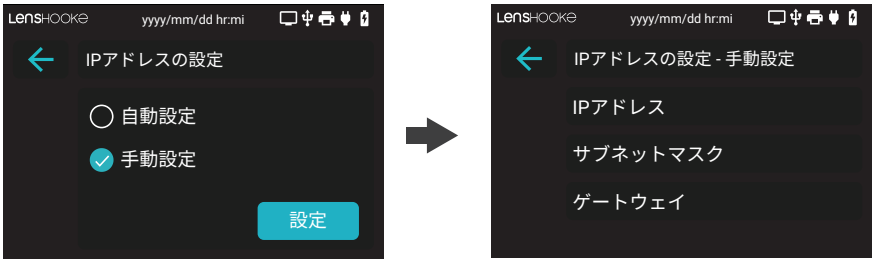
(1)「設定」アイコンから、「ネットワーク接続」を選択します。



(2) IPアドレスの設定を選択します。

(3) 初期設定は自動設定になっています。この設定を選択すると、デバイスは、ネットワークが接続されているときに割り当てられ、時間の経過とともに変化する動的なIPアドレスを使用します。

(4) 静的IPアドレスを使用する場合には手動設定を選択し、IPアドレス、サブネットマスク、ゲートウェイをそれぞれ選択肢、必要な情報を入力します。

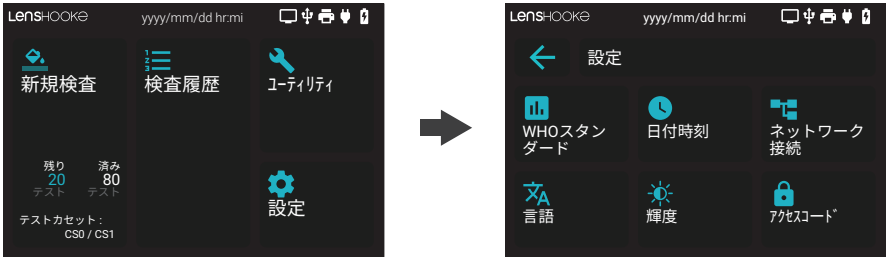


注意

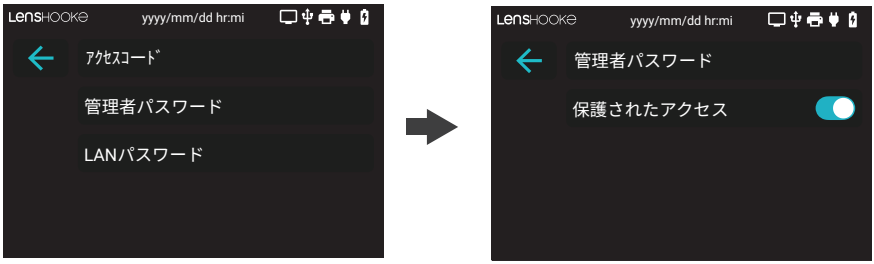
- IPアドレス、サブネットマスク、ゲートウェイのいずれかの情報を入力しない場合、IPアドレスの設定は自動設定になります。

4 アクセスパスワード

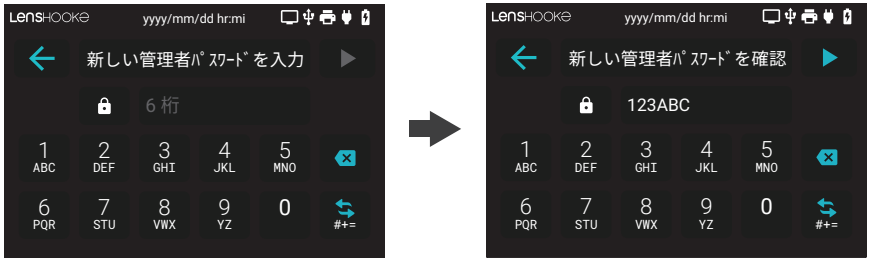
(1) 「設定」アイコンから、「アクセスコード」を選択します。



(2) 「管理者パスワード」アイコンを選択します。アクセスを保護するには、管理者パスワードの「保護されたアクセス」をオンにします。



(3) 新しい管理者パスワードとして6文字を入力し、「 ▶ 」アイコンを選択して、次のステップで新しい管理者パスワードを確認するため、パスワード6文字を再度入力します。



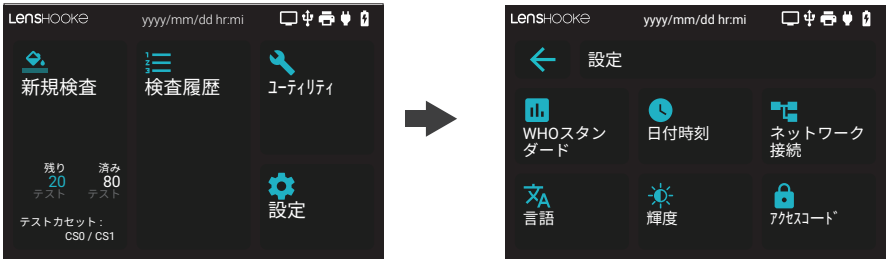
(4) 新しい管理者パスワードを確認したら、「 ▶ 」アイコンを選択して次の手順に進みます。
前のページに戻るには「OK」を選択してください。

注意

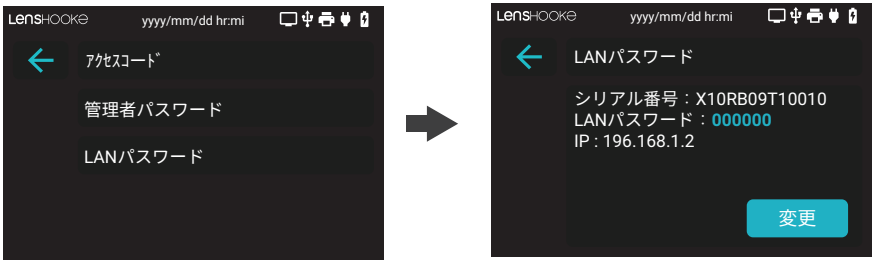
- 管理者パスワードのデフォルトのパスワードは「000000」です。
  アイコン「 ◯ 」の際にはアクセスが保護されていることを意味します。
- 一度省電力モードに入ったアナライザーにアクセスするには、管理者パスワードを入力して機器を立ち上げ直します。

5 LAN/パスワード

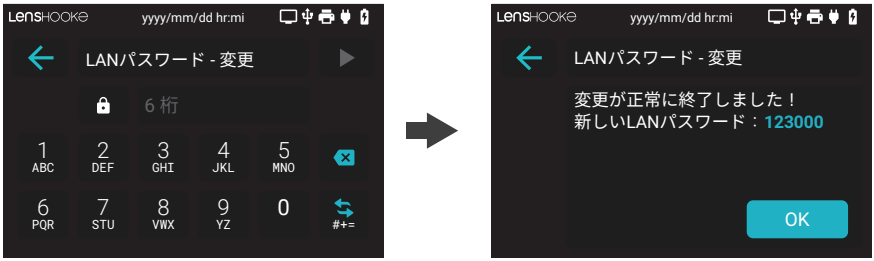
(1) 「設定」アイコンから、「アクセスコード」を選択します。



(2) 「LANパスワード」アイコンを選択すると、パスワードが画面に表示されます。変更したい場合「変更」ボタンからをパスワードを変更できます。



(3) 6桁の数字コードを入力して、新しいパスワードを設定します。新しいパスワードを入力したら、「 ▶ 」アイコンをクリックして、次のステップに進みます。「OK」を押して、前のページに戻ります。

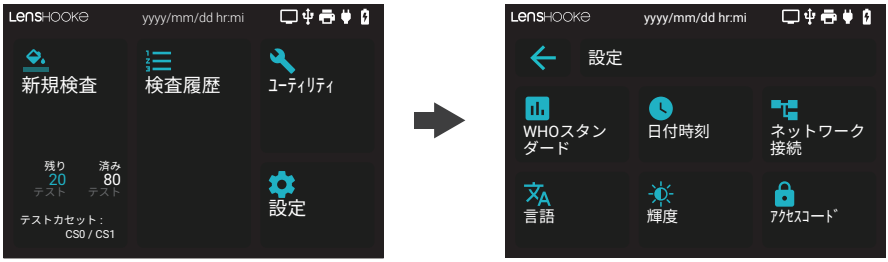


注意

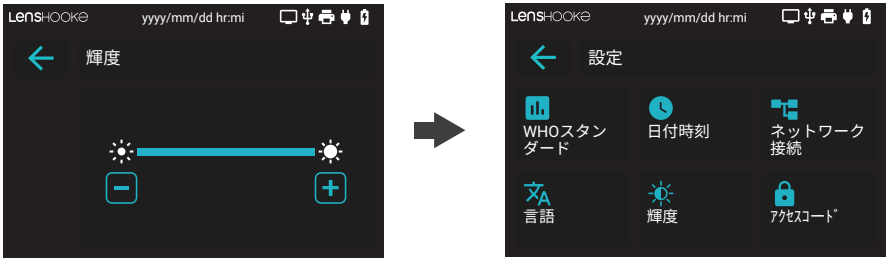
- デフォルトのLANパスワードは「000000」です。
- 外部のデバイスからアナライザーにアクセスして検査データの読み込みやダウンロードをする場合には、上記で設定したLANパスワードを入力する必要があります。
- パスワードを設定する際、入力した数字が 6 桁に満たない場合、「 ▶ 」のアイコンが青く点灯せず、変更ができません。
- ローカルエリアネットワーク(LAN)に接続するにはUSB-RJ45ギガビットイーサーネットアダプターを使用し、LANケーブルから接続ください（詳細は24ページを参照してください）

6 タッチスクリーンの輝度の調整

(1)「設定」アイコンから、「輝度」を選択します。

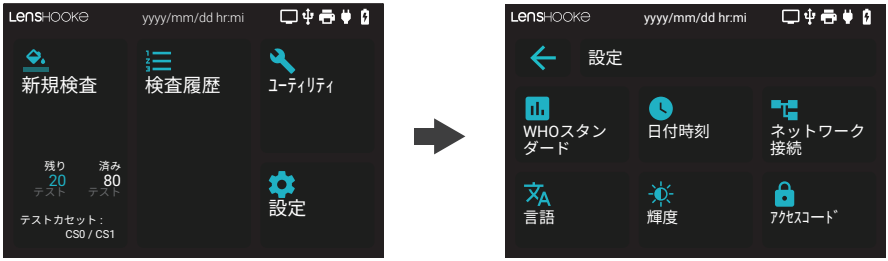


(2)「 − 」または「 + 」を使用して画面の明るさを調整します。「 ← 」アイコンをクリックして、前のページに戻ります。



7 言語

(1)「設定」アイコンから、「言語」を選択します。使用する言語を選択し、「 ← 」アイコンで前のページに戻ります。

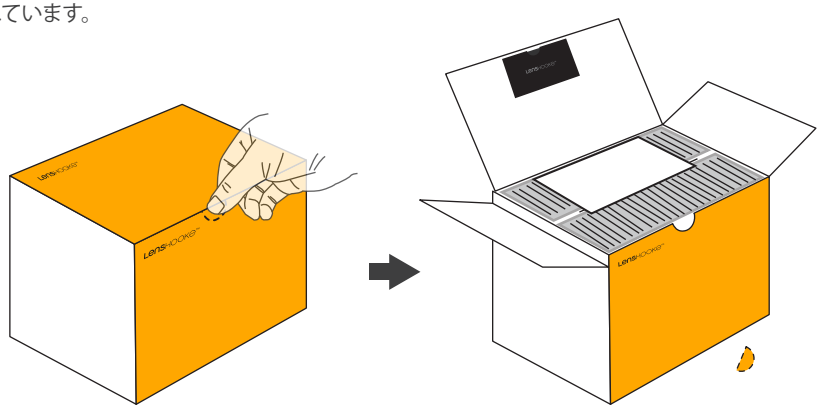


VI . アクセサリー

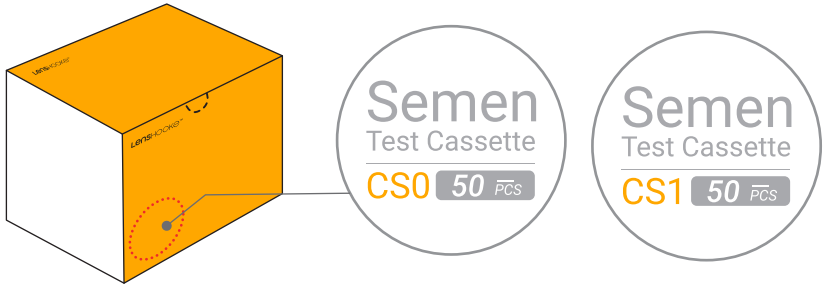
ライセンスドングル

1ライセンス（テスト回数）のリフィル

(1) LensHooke® Semen Test Cassetteボックスを開梱すると、箱の天井にライセンスドングルが同梱されています。

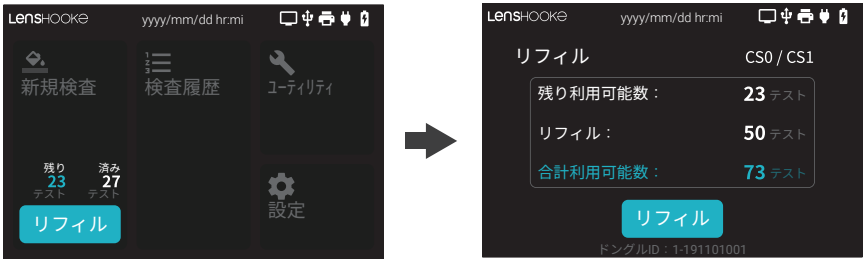


(2) ドングルを使用してリフィルを行う前に必ずテストカセットの型番が使用する製品の型番と合致しているかを確認します。



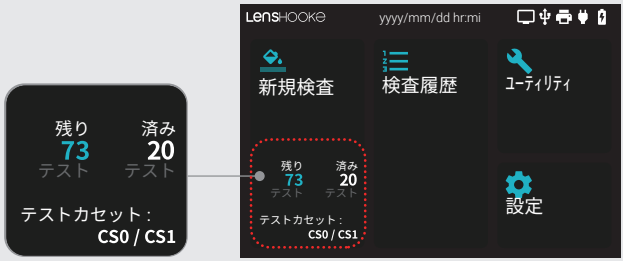
(3) ライセンスドングルを機器背面のUSBポートに挿入します。

(4) 「リフィル」ボタンを押して、画面に表示される情報を確認します。表示が正しければ「リフィル」ボタンを押します。正常にリフィルが終了した後、ライセンスドングルを機器から取り外します。



注意

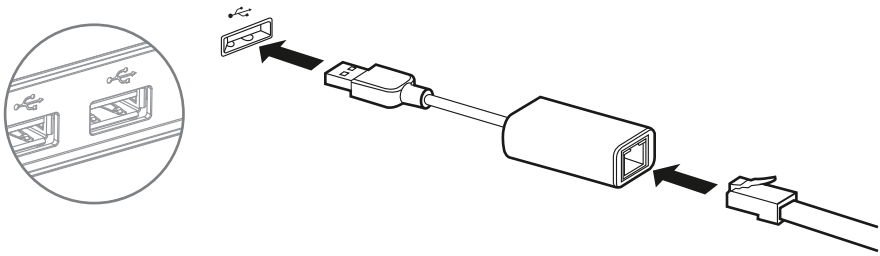
- メーカー純正ではないライセンスドングルを挿入した場合、「リフィル」アイコンは点灯しません。
- 一度リフィルに使用したライセンスドングルは再使用できません。使用済みドングルを機器に再度挿入すると、ドングルエラーメッセージが画面に表示されます。
- LensHooke® Semen Test Cassetteの箱を開梱したらすぐにライセンスドングルを挿入してライセンスを補充して下さい。
- 新しいドングルを挿入してライセンスを補充すると、「済み」の回数が 0 にリセットされ、「残り」の回数がその時点での残数に追加され表示されます。



USB-RJ45ギガビットイーサネットアダプター

1 アナライザー : ローカルエリアネットワーク(LAN)接続

(1) アナライザーをローエリアネットワークに接続するにはRJ45ギガビットイーサネットアダプターとLANケーブルを使用します。



2 その他のデバイス:アナライザーへのアクセス

(1) パソコンからインターネットブラウザを開き、機器に割り振られたIPアドレスを入力します。
（アナライザー上、「LANパスワード」からこの情報を確認できます。）

(2) LANパスワードを入力してログインしてください。(この情報も「LANパスワード」から確認ができます。)

(3) ログイン後、機器に保存されている検査データのレポート（PDFファイル）と動画（MP4ファイル）を閲覧できます。

(4) PDF, MP4, CSVファイルのダウンロードができます。

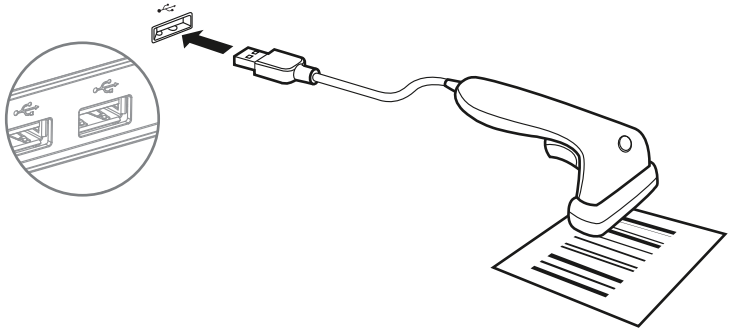
注意

- 同時に多数の外部機器から同一のアナライザーにアクセスすると機器のパフォーマンスに影響が出る場合があります。
- ログインページにアクセスするには、次のブラウザのいずれかを使用してください。
  - Firefox (Ver: 62 or more), Chrome (Ver: 69 or more), Microsoft Edge for Window 10, Safari等
  （詳細については、www.LensHooke.comを参照してください。）
- この機能は iPad, パソコン、ノートPCのみに対応しています。
- LANに接続する際には付属の電源ケーブルを機器に繋げてご使用ください。

バーコードスキャナー

1 バーコードスキャナーとアナライザーの接続

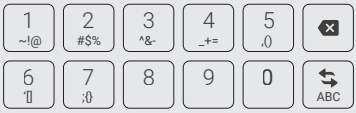
(1) 機器背面のUSBポートからバーコードスキャナーをアナライザーに接続します。.



(2) バーコードリーダーは患者IDの入力や品質管理時に使用するX QCビーズのロットを入力する際に使用できます。

注意

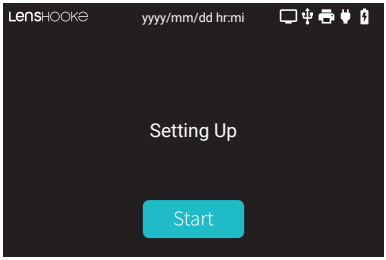
- バーコードスキャナーは機器背面のUSBポートから接続して使用下さい。
- 本機器では、以下の文字、数字、記号のみを読み取ることができます。



VII. 機器のセットアップ

アナライザーのセットアップ:

(1) 「Start」を選択し、使用する言語をリストから選択します。



(2) 日付時刻の設定:" ‹ " または " › "ボタンで日付時刻の表示を選択します。また " + " と " − " ボタンで日時の変更をします。

(3) WHOスタンダードの設定: " ▸ " ボタンで使用するWHOスタンダードの版を選択します。

(4) 保護されたアクセス: アナライザーのアクセス権を保護しながら使用する場合は、アイコンをスライドさせて青の状態にし、新しい管理者パスワードとして任意の6文字を入力します。

⚠ 初めて使用する前に、アナライザーのバッテリーを**3**時間充電してください。

VIII. クリーニングとメンテナンス

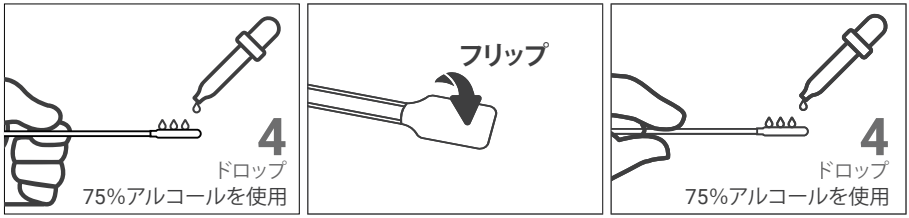
1 定期クリーニング

(1) テストカセット挿入スロットのクリーニングには、「**LensHooke® Cleaning Wipe**」を使用ください。
(2) 他の製品を使用してのテストカセット挿入スロットのクリーニングは行わないでください。
(3) LensHooke® Cleaning Wipeは単回使用品です。再利用はしないで下さい。
(4) LensHooke® X1 PRO Semen Quality Analyzer精子運動解析装置は、ほこりや水、液体を避けて、過酷な環境（仕様書に記載されている操作環境や保管環境を超えた環境）外で保管してください。
(5) LensHooke® X1 PRO Semen Quality Analyzerは日常的にクリーニングを行い、清潔に保つことをお勧めします。

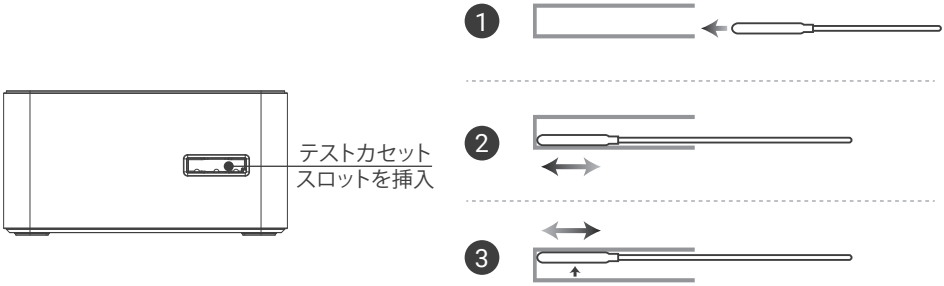
2 クリーニングの手順

I.カセット挿入スロットのクリーニング:

(1) クリーニングを行う前に機器の電源を切ります。
(2) LensHooke® Cleaning Wipe を2本準備します。
(3) LensHooke® Cleaning Wipe の両面に75%アルコールを4滴落とします。



(4) アルコールを垂らしたクリーニングワイプをテストカセット用スロットに挿入し、以下の手順に沿って洗浄します。



(5) もう1本のワイプを、アルコール製剤を使用せず、乾いたままテストカセット用スロットに挿入し、同様に清掃します。

(6) 使用したワイプは廃棄します。

II. アナライザー本体のクリーニング:

(1) クリーニングを行う前に機器の電源を切ります。

(2) アルコール綿を使用して、アナライザー本体を綺麗になるまでを拭きます。

(3) 使用したアルコール綿は廃棄します。

III. 電源アダプター:

(1) アルコールを含まない洗剤を使用して布を浸してください。

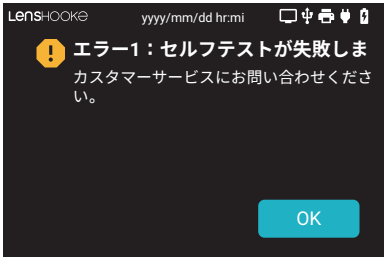
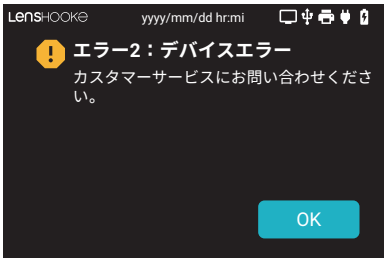
(2) 布を絞って、電源アダプターを丁寧に掃除します。

(3) きれいな水に浸した布で再度その部分を掃除します。

注意

- LensHooke® X1 PRO Semen Quality Analyzerのクリーニングには、LensHooke® Cleaning Wipeを使用します。
- LensHooke® X1 PRO Semen Quality Analyzerは、10,950回のクリーニングサイクルと10,950回の消毒サイクルの後、アナライザーの性能や外部材料に変化がないことを確認されています。このテストは、3年間毎日10回の洗浄と消毒のサイクルを行うことと同等であることを意味しています。

IX. エラーメッセージ

エラーメッセージ	対応策
	**エラー1:** セルフテストが失敗しました 起動時にエラーが発生した可能性があります。 代理店までご連絡ください。
	**エラー2:** デバイスエラー アナライザーに問題がある可能性があります。 テストカセットを取り外して「OK」を選択し、ホーム画面に戻り、機器の電源を一度落とします（5ページの「電源のon/off」を参照ください）。 このエラーが継続して表示される場合は代理店までお問い合わせください。
	エラー3: カメラエラー カメラに問題がある可能性があります。 テストカセットを取り外して「OK」を選択し、ホーム画面に戻ります。新しいテストカセットを挿入して、再度検査を行います。 このエラーが継続して表示される場合は代理店までお問い合わせください。 *必ず検査にはLensHooke® Semen Test Cassetteを使用していることを確認してください。
	エラー4: ソフトウェアエラー ソフトウェアに問題がある可能性があります。 テストカセットを取り外し、「OK」を選択し、ホーム画面に戻り、機器の電源を一度落とします（5ページの「電源のon/off」を参照ください）。

X. 仕様

製品名
LensHooke® X1 PRO Semen Quality Analyzer

コントロールパネル
3.5インチの抵抗膜方式タッチスクリーン

外部電源入力
AC 100-240V / 50~60 Hz; 出力 DC 5V / 2A

バッテリー
2500 mA (内蔵充電式リチウムポリマーバッテリー、DC3.7V / 2.5Ah)

内部ストレージ容量
データと画像を含む30検査分

検出時間
2~5 分 (検体の状態により異なります)

電源アダプター
入力: 100~240 Vac, 50~60 Hz,0.5 A
出力: 5 Vdc, 最大2 A

動作環境
温度 15°C~38°C (59°F~100°F)
湿度 <70%

保管環境
温度 15°C~38°C (59°F~100°F)
湿度 <70%

輸送環境
温度 -10°C~60°C (14°F~140°F)
湿度 <70%

測定範囲
pH 6.0~8.0 (各スケール範囲:0.2)
濃度 <0.1-300 (10^6/ml)
総運動性 <1-100%
形態 (標準形) <1-100%

XI. 参考

WHOラボマニュアル第5版 – ヒト精液検査と主義 で推奨されている精液所見

参照	WHO 5th 下限値	WHO 4th 下限値
精子濃度	15 x 10^6 (12-16)/ ml	≧ 20 x 10^6 / ml
運動率	40% (38-42%)	a + b ≧ 50% or a ≧ 25%
前進運動率	32% (31-34%)	
正常形態率	4% (3-4%)	≧ 15%

a：高速前進運動精子 (≧25μm/s)
b：低速前進運動精子

XII. ステートメント

Bonraybio Co.、LTDからの書面による許可なしに、この製品に関連するユーザーマニュアルのすべての関連コンテンツを、いかなる種類の検索システムでも複製、配布、複製、または保存することは許可されていません。Bonraybioは、事前の通知なしに、このマニュアルのハードウェアおよびソフトウェアの技術仕様の説明をいつでも変更するすべての権利を留保します。また内容の保証に最善を尽くします。間違いや不明な情報がある場合は、お近くの販売店にお問い合わせください。このマニュアルに関するご意見をお待ちしています。

XIII. 注意事項

1. 過電圧カテゴリ: レベル II
2. 汚染度: レベル 2
3. 高度: < 2000 メートル
4. 相対湿度 (RH%): < 70%
5. 屋内使用
6. イーサーネットケーブルプラグはIP21規格（防塵・防水機能）に準拠しており、外部からの異物の挿入等にも耐久性があります。
7. ケーブル等がもつれて窒息を引き起こす恐れがあるので、子供の手の届かないところで保管して下さい。
8. 小さなパーツを飲み込んでしまう恐れがあるので、子供の手の届かないところで保管して下さい。
9. 検査結果はWHOラボマニュアル – ヒト精液検査と主義に準拠しています。LensHooke® Semen Test Cassetteのユーザーマニュアルを参照してください。

注意

- LensHooke® X1 PRO Semen Quality Analyzer, LensHooke® Semen Test Cassette, C-KUP™ Liquefaction Test Cup, LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen), LensHooke® X QC Video (For Semen).

  In Vitro診断医療機器指令98/79 / ECに準拠した製品。(CE)
- 電磁両立性試験、エミッション、イミュニティ、およびIEC 61326-2-6に定められるの要求事項を満たしています。
- 製造元:
  Bonraybio 株式会社
  4F., No. 118, Gongye 9th Rd.,
  Dali Dist., Taichung City 41280,
  台湾 (R.O.C.)

XIV. 保証

製造元では 本機器(レンズフック X1 PRO 精子自動分析装置 LensHooke® X1 PRO Semen Quality Analyzer)において購入日から 1 年間の保証を設けています。保証期間内に起きました機器の不良については無償で対応させて頂きます。
本保証は製造元からの純正品のみの対応となります。また機器の改良や、誤った使用方法におきましての故障等はこの限りではありません。

メーカー : Bonraybio 株式会社
Address : 4F., No.118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280, 台湾(R.O.C.)
Tel : +886-4-2491-2385
ファックス : +886-4-2491-2885
メール : support@bonraybio.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

CE

LensHOOKe®

LensHOOKe®

Semen Quality Analyzer

Manuale d'uso

X1 PRO

Rev.29-0X10400 20210224X1E003IT

Leggere attentamente il manuale operatore al fine di un corretto utilizzo dello strumento. Questo manuale è disponibile anche sul sito **www.LENSHOOKE.com**.

Simboli

Simboli presenti nel Manuale Operatore

"AVVISO"

"ATTENZIONE"

"NUMERO DI PAGINA"

"NON RIUTILIZZARE"

"SCADENZA"

LOT **"LOTTO"**

SN **"NUMERO DI SERIE"**

"DATA DI PRODUZIONE"

"PRODUTTORE"

EC REP **"RAPPRESENTANTE AUTORIZZATO NELLA COMUNITA' EUROPEA"**

IVD **"USO DIAGNOSTICO IN VITRO"**

"TEMPERATURA DI CONSERVAZIONE"

"CONSULTARE LE ISTRUZIONI D'USO"

"SMALTIMENTO RIFIUTI"

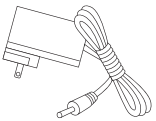
CE Marchio CE

"SEGUIRE LE ISTRUZIONI D'USO"

"L'USO PREVISTO DI UN PRODOTTO IVD SU PRESCRIZIONE"

La confezione include

- Semen Quality Analyzer
- Alimentatore AC (analizzatore)



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I. Introduzione

Il LensHooke® X1 PRO Semen Quality Analyzer è stato realizzato esclusivamente per uso diagnostico in vitro. Si consiglia la lettura del Manuale Operatore prima di utilizzare il dispositivo al fine di familiarizzare con lo strumento e con le istruzioni operative.

Per quesiti sul prodotto o per assistenza tecnica, non esitare a contattare TEMA RICERCA srl chiamando il servizio di assistenza (+ 39 051 6240700)
Orario della hotline di servizio ： Lun ~ Ven 09:00~ 17:30

II. Uso Previsto

Il LensHooke® X1 PRO Semen Quality Analyzer utilizzato con LensHooke® Semen Test Cassette è un dispositivo per l'analisi del liquido seminale umano in grado di fornire vaolri relativi a:

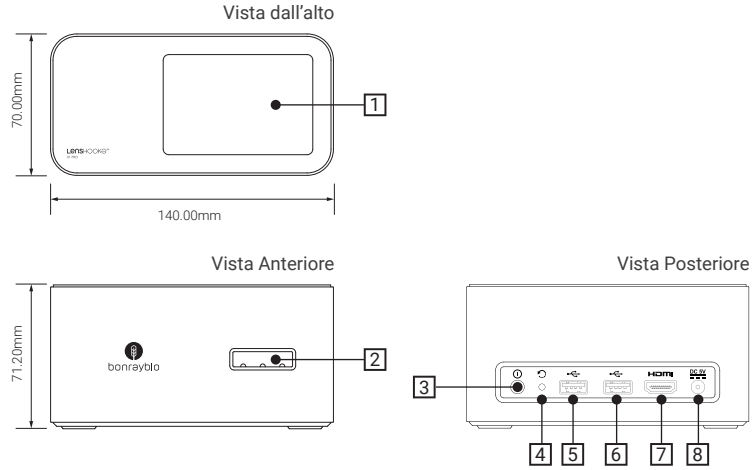
(1) Concentrazione degli spermatozoi (10^6 per ml)
(2) Motilità (PR+NP, %)
- Motilità progressiva (%)
- Motilità non-progressiva (%)
- Spermatozoi Immobili (%)
- Altri parametri del sistema CASA (MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, e BCF)

(3) Morfologia (forme normali, %)
(4) pH

Il LensHooke® X1 PRO Semen Quality Analyzer non fornisce una valutazione in merito alla fertilità del paziente ed è indicato esclusivamente per uso diagnostico in vitro. Per uso Professionale.

III. Descrizione del prodotto

LensHooke® X1 PRO Semen Quality Analyzer



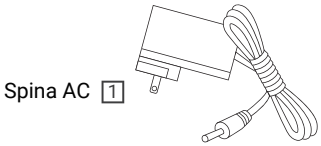
1 Touch Screen
2 Vano per la Cassetta
3 Tasto Accensione
4 Tasto Reset
5 Porta USB
6 Porta USB
7 Porta HDMI
8 Attacco per l'Alimentatore

NOTA

- **Porta USB :** High-speed USB 2.0
- **Tasto Reset :** Se l'analizzatore si blocca, premere il pulsante Reset con l'aiuto di uno spillo.
- **Porta HDMI :** L'analizzatore è provvisto di porta HDMI per permetterne la connessione ad un monitor e visualizzare le immagini e i dati.

Accessori

- **Alimentatore**



2 Spina dell'Alimentatore

Dongguan Shilong Fuhua Electronic Co., Ltd;
UES12LCP-050200SPA

Icone sullo schermo touch screen

1 **Icona per la connessione HDMI:** L'analizzatore può essere collegato al monitor tramite una porta HDMI.
2 **Icona per la connessione USB:** L'analizzatore può essere collegato ad una chiavetta USB tramite una porta USB.
3 **Icona per la connessione alla stampante:** L'analizzatore può essere collegato ad una stampante.
4 **Icona di alimentazione:** L'analizzatore può essere collegato alla corrente.
5 **Icona della batteria:** mostra la carica della batteria.

NOTA

- **Icona per la connessione USB:** se questa porta viene utilizzata per collegare altri dispositive come tastiera, mouse, dongle ecc...questa icona non apparirà sullo schermo.

Le seguenti icone permettono di accedere ad alcune funzioni

6 **Icona "Utilities" (Utilità), permette di accedere a:**
- Quality Controls (Controlli di qualità): Verificano la qualità dell'analizzatore/dispositivo.
- Backup All Records (Backup tutti i dati): Consente il backup di tutti i risultati.
- System Update (Sistema Update): Aggiorna il software dell'analizzatore/dispositivo.
- About (Di): Fornisce informazioni dettagliate dell'analizzatore/dispositivo.
- Delete All Records (Eliminare tutti i dati): Elimina tutti i dati.
- Insert LOGO(Inserisci LOGO): per inserire il logo nella parte superiore del report PDF.

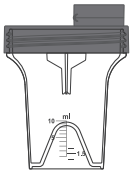
7 **Icona "Settings" (IMPOST.): permette di accedere a:**
- WHO Standard: Per selezionare la 4a o la 5a edizione della WHO.
- Date & Time(Data e Ora): Per impostare la data e l'ora.
- Network Connection(Connessione di): per selezionare la preferenza IP.
- Access Password(Accesso password): per ottenere o modificare la password e per accedere all'analizzatore.
- Brightness (Luminosità): Correggere la luminosità.
- Language(lingua): Per impostare la lingua.

8 **Icona "Recent Tests" (Test Recenti):** per vedere le utime analisi effettuate.
9 **Icona "New Test" (Nuovi Test):** Per iniziare una nuova analisi.

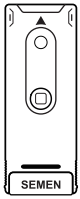
IV. Consumabili

I dispositivi consumabili per LensHooke® X1 PRO Semen Quality Analyzersono i seguenti:

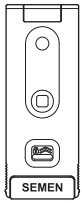
- **C-KUP™ Liquefaction Test Cup**



- **LensHooke® CS0 Semen Test Cassette**



- **LensHooke® CS1 Semen Test Cassette**



- **LensHooke® Cleaning Wipe**

- **LensHooke® X QC Beads (For Semen)**

- **LensHooke® X QC Reticle (For Semen)**

- **LensHooke® X QC Video (For Semen)**

Il risultato potrebbe essere impreciso se NON si utilizza LensHooke® Semen Test Cassette o i prodotti della serie LensHooke® X QC.

NOTA

- Le immagini dei prodotti sono solo dimostrative.Fare riferimento ai prodotti reali.
- C-KUP™ Liquefaction Test Cup è inteso per la raccolta del campione di liquido seminale.
- LensHooke® Semen Test Cassette è studiata per essere inserita nell'analizzatore per fare l'analisi sul campione.
- LensHooke® Cleaning Wipe è pensata per pulire il vano di inserimento della cassetta sull'analizzatore.
- LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) e LensHooke® X QC Video (For Semen) vengono utilizzati per il controllo di qualità dell'analizzatore.

V. Funzioni Principali

LensHooke® X1 PRO Semen Quality Analyzer

Accensione e spegnimento, on / off

1 Accensione:

Premere il pulsante di accensione per 2 secondi per accendere l'analizzatore (Fig.1). Quando si accende lo schermo (Fig. 2), l'analizzatore è pronto.

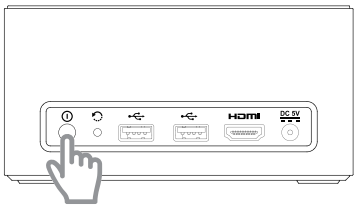


Fig.1

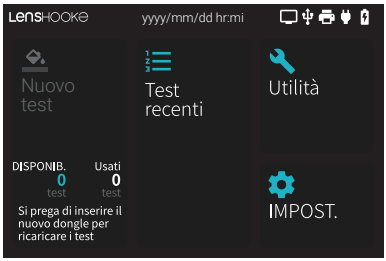


Fig.2

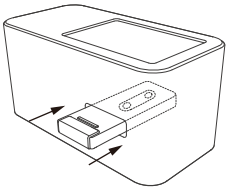
2 Spegnimento dell'analizzatore:

Tenere premuto il pulsante di accensione per 10 secondi per spegnere direttamente l'analizzatore, oppure è anche possibile premere il pulsante di accensione per 2 secondi fino a quando il touch screen mostra Spegnimento e selezionare l'icona per spegnerlo.

Introduzione ed Estrazione della cassetta test

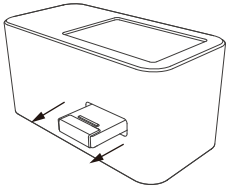
1 Inserire la cassetta del test:

Inserire la cassetta test nella fessura e spingerla fino in fondo.



2 Rimuovere la cassetta del test:

Dopo il test, estrarre la cassetta del test dallo slot.



Cambiare la batteria

1 Quando compare il messaggio **"Low Battery"** sullo schermo (Fig.3), significa che la batteria è quasi scarica. Usare immediatamente l'alimentatore per ricaricare la batteria. Il simbolo della **"Spina"** apparirà sullo schermo (come indicato dalla ⬇ nella Fig. 4) durante la fase di ricarica. Se il simbolo della **"Spina"** non dovesse comparire, assicurarsi che l'alimentatore sia collegato correttamente all'analizzatore e alla presa di corrente.

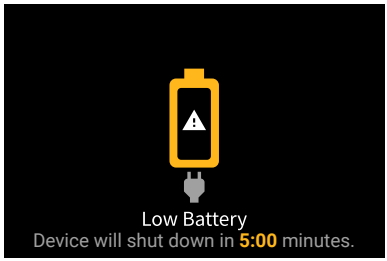


Fig.3

Fig.4

- L'analizzatore è dotato di una batteria ai polimeri di ioni di litio da 2500 mAh incorporata.
- La batteria non può essere rimossa o sostituita. Contattateci se dovessero verificarsi problemi con la batteria.

NOTA

- Per passare nella modalità di risparmio energetico premere velocemente il tasto di accensione. Per riattivare lo strumento premere di nuovo velocemente il tasto di accensione.
- Se il dispositivo non viene utilizzato per 10 minuti entrerà automaticamente in modalità di risparmio energetico.

  *** Modalità Risparmio Energetico:** Spegnere il display per ridurre il consumo della batteria
- Per aumentare la durata della batteria, caricare la batteria utilizzando l'alimentatore anche se lo strumento non viene utilizzato.
- Se lo strumento non viene utilizzato per più di 3 mesi ricaricarlo prima dell'uso
- Se si dovesse scaricare la batteria, la data e l'ora dell'analizzatore potrebbero essere ripristinate con quelle di fabbrica. Verificare e aggiornare la data e l'ora (come mostrato a Pagina 17).
- Se sullo schermo vengono visualizzati i messaggi di avviso "Surriscaldamento della batteria" o "Temperatura della batteria troppo bassa", l'analizzatore si spegnerà automaticamente entro 5 minuti come autoprotezione. Quando viene visualizzato il messaggio, spegnere l'analizzatore, quindi posizionare l'analizzatore in un ambiente operativo di 15 ° C ~ 38 ° C (59 ° F ~ 100 ° F), umidità <70% per più di 1 ora, quindi collegare l'adattatore di alimentazione all'analizzatore e accendere l'analizzatore per l'uso

Preparare l'analizzatore per il test

1. Posizionare l'analizzatore su una superficie piana.
2. Verificare che l'analizzatore si trovi in ambiente operativo idoneo.
3. Verificare lo stato della batteria. Se la batteria è scarica, collegare l'adattatore di alimentazione prima del test.

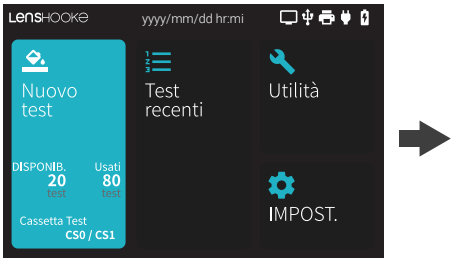
Preparazione del campione

1. Fare riferimento al manuale utente LensHooke® Semen Test Cassette per preparare il campione.

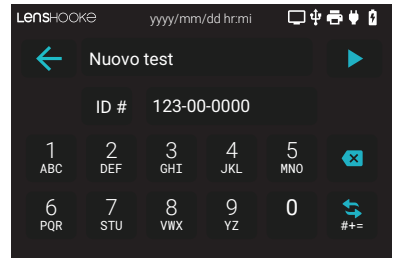
Esecuzione dell'Analisi

1 Nuovo Test

Passaggio 1. Selezionare icona **"Nuovo Test"**.

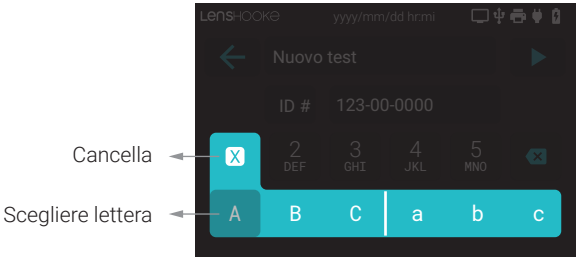


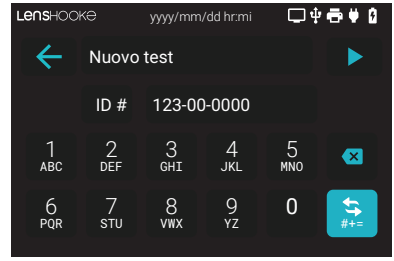
Passaggio 2. Inserire ID paziente e selezionare icona " ▶ " per andare al passaggio seguente.



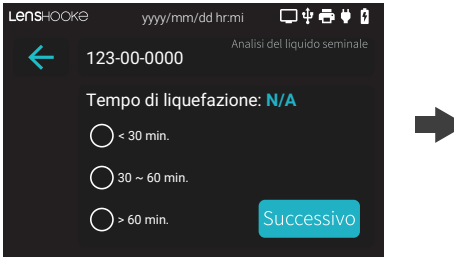
NOTA

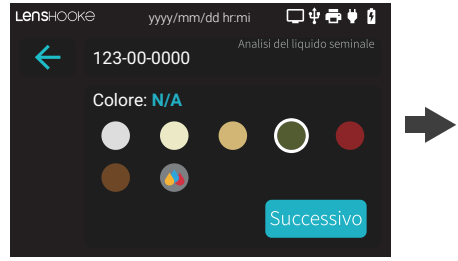
- NON UTILIZZARE più di 15 caratteri o simboli per l'ID# del paziente.
- Per inserire una lettera premere l'icona per 0.5-1 secondi e selezionare la lettera. Per inserire un simbolo cliccare l'icona ⇆ per cambiare tastiera.
- E' possibile anche usare un lettore ottico per scansionare il barcode del paziente ID#. (Pagina 25 per collegare il lettore ottico allo strumento.)
- Fare riferimento a pagina 22 di questo manuale utente per la ricarica dei test sullo strumento.

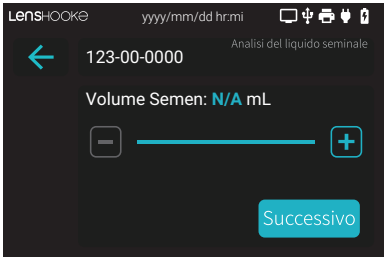


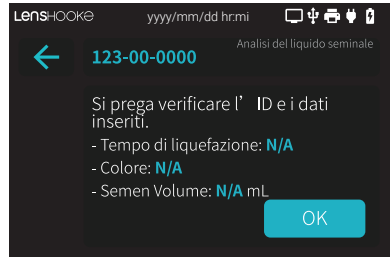


Passaggio 3. Selezionare il tempo di liquefazione, il colore dello sperma, il volume dello sperma, quindi selezionare **"Successivo"** per andare al passaggio successivo. Selezionare l'icona **"OK"** se le informazioni sono corrette.









NOTA

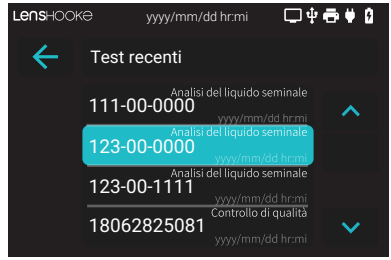
- Cliccare ⊟ e ⊞ per correggere il volume del campione.
- NON muovere la cassetta test o l'analizzatore durante il calcolo dei risultati.

Passaggio 4. Inserire la cassetta test (con il campione) nella fessura e spingerla fino in fondo.

Visualizzare i Risultati

1 Test Recenti (Recent Tests)

(1) Cliccare l'icona "Test Recenti" e selezionare l'ID del campione che si vuole visualizzare.



(2) Il risultato apparirà sullo schermo. Se si desidera tornare all'elenco dei record, selezionare l'icona "⟵" per tornare alla pagina precedente.

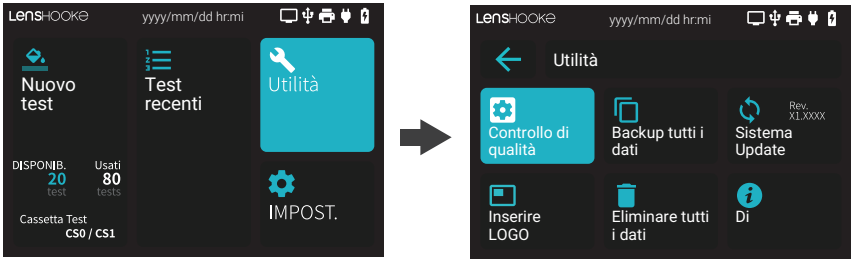
NOTA

- SOLO le icone Blu possono essere selezionate.
- È possibile collegare l'analizzatore alla LAN per stampare il risultato. (Fare riferimento a pagina 24 per collegare l'analizzatore alla LAN.)
- Se accanto al risultato della concentrazione viene visualizzato un simbolo " ❄ ", significa che il campione presenta un'aggregazione di spermatozoi, cristalli di sperma o bolle che potrebbero influire sul risultato. Si suggerisce di annotare il risultato o di ripetere il test o di chiedere assistenza professionale.
- Se accanto al risultato della motilità viene visualizzato il simbolo " ▨ ", significa che il dispositivo rileva che gli spermatozoi si muovono spingendo piuttosto che **"nuotando"** che possono influire sul risultato. Ti suggeriremo di annotare il risultato o di ripetere il test o di richiedere assistenza professionale.
- L'analizzatore non calcolerà i **"pinhead"**, poiché non sono considerati spermatozoi in quanto,non hanno la cromatina.
- Se si desidera utilizzare il nostro analizzatore per esaminare il paziente per il follow-up post vasectomia, utilizzare per conferma anche l'esame microscopico.
- Se non hai applicato il campione all'area del pH, il risultato del valore del pH mostrerà <6.0. Quindi, si prega di controllare l'area del pH della cassetta test, se il risultato mostra <6.0.

Utilità

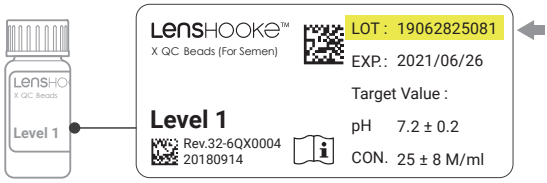
1 Controlli di qualità

(1) Select **"Utilità"** and then select the **"Controlli di qualità"** icon.

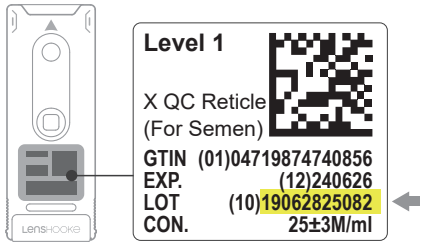


(2) Inserire il numero di LOTTO sull'etichetta di LensHooke® X QC Beads (For Semen) o LensHooke® X QC Reticle (For Semen) o LensHooke® X QC Video (For Semen). Confermare il numero di LOTTO e quindi selezionare " ▶ " per andare al passaggio successivo.

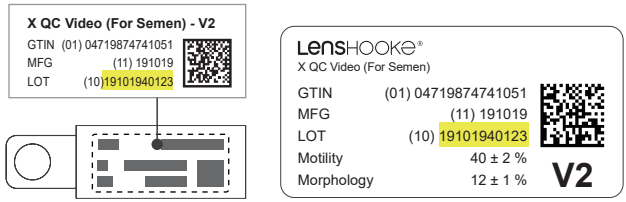
• LOT number of X QC Beads (For Semen)



• LOT number of X QC Reticle (For Semen)



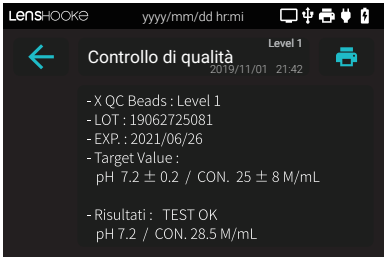
• LOT number of X QC Video (For Semen)



(3) Seguire le istruzioni di LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) o LensHooke® X QC Video (For Semen) per il funzionamento, quindi inserisci la cassetta nello **"slot di inserimento"** o inserisci il video USB LensHooke® X QC nella porta USB.

(5) Dopo 2-5 minuti, il risultato apparirà automaticamente sullo schermo.

• Risultati del X QC Beads



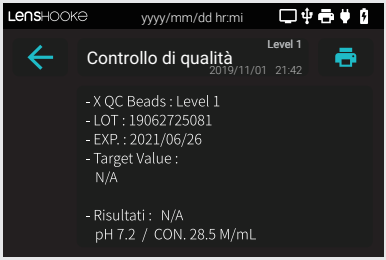
• Risultati del X QC Reticle

• Risultati del X QC Video

NOTA

- LensHooke® X QC Beads (For Semen) controlla il valore del pH e della concentrazione.
  LensHooke® X QC Reticle (For Semen) controlla SOLO il valore della concentrazione.
  LensHooke® X QC Video (For Semen) SOLO esamina motilità e morfologia.
- Se si immette il numero LOT di LensHooke® X QC Beads (For Semen) ma si inserisce la cassetta del LensHooke® X QC Reticle (For Semen), l'analizzatore mostrerà il messaggio di avviso come sotto.

- Se nella schermata dei risultati viene visualizzato N / A, significa che le sfere del LensHooke® X QC Beads (For Semen) o LensHooke® X QC Reticle (For Semen) sono scadute.
  Utilizzare un altro nuovo o contattare il servizio clienti.



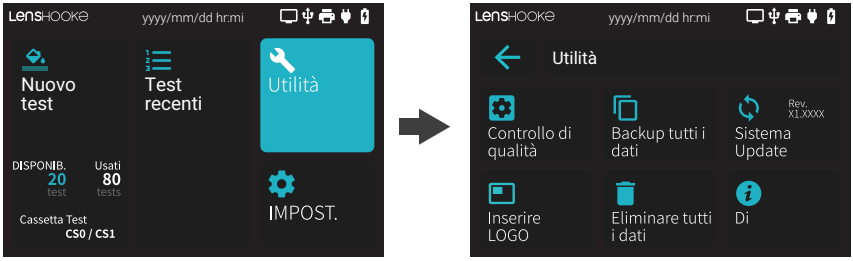
X QC Beads

X QC Reticle

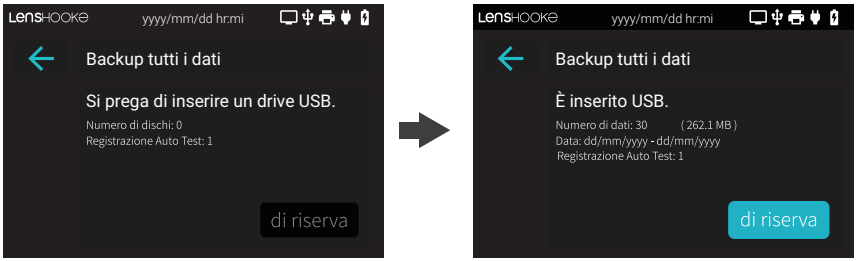
2 Backup tutti i dati

(1) Preparare una chiavetta USB. (Memoria: minimo 1GB)

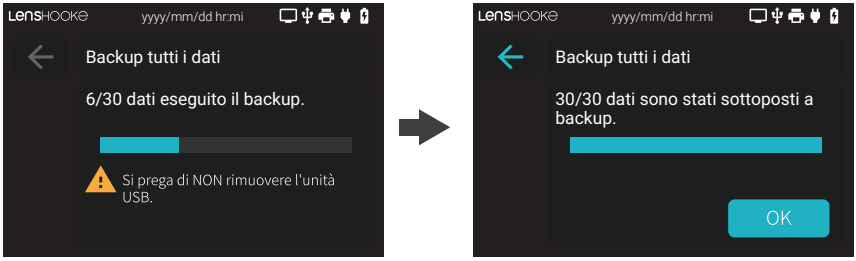
(2) Cliccare l'icona **"Utilità"** e cliccare l'icona **"Backup tutti i dati"**.



(3) Inserire la chiavetta USB. Quando l'icona **"Backup"** diventa blu, cliccarla per fare il backup tutti i dati.



(4) Quando i dati sono stati salvati sulla chiavetta USB, cliccare l'icona **"OK"** per tornare alla schermata principale.



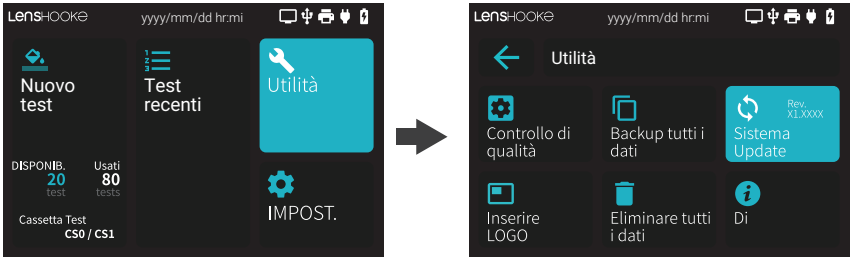
NOTA

- NON RIMUOVERE la chiavetta USB Drive durante il Backup.
- Il messaggio **"Insufficient Storage Available"** apparirà sullo schermo se la memoria dello strumento è piena. Fare il backup adi tutti i risultati prima di eliminarli per aumentare lo spazio sulla memoria.
- Se la memoria della chiavetta USB risultasse insufficiente, rimuovere la chiavetta USB e cancellare i file dal computer per aumentare lo spazio sulla memoria o utilizzare una nuova chiavetta USB.
- Dopo aver eseguito il backup dei record, si avranno contemporaneamente i file PDF, MP4 e CSV.

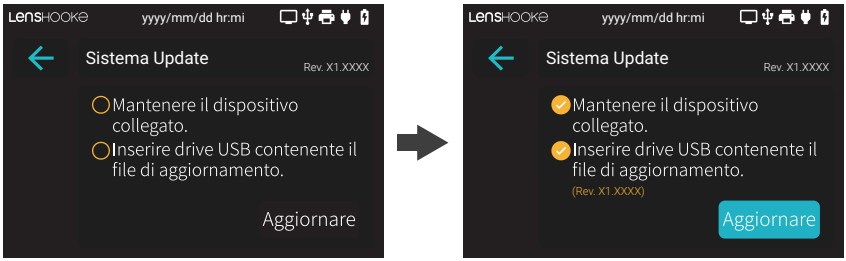
3 Sistema Update

(1) Preparare la chiavetta USB con l'aggiornamento del software. (Memoria della chiavetta USB: almeno 1GB) (Contattare il distributore locale per l'aggiornamento del software).

(2) Cliccare l'icona **"Utilità"** e cliccare l'icona **"Sistema Update"**.



(3) Collegare il dispositivo con l'alimentatore e collegare l'unità USB con il file di aggiornamento all'analizzatore. Seleziona l'icona Aggiorna per aggiornare il sistema.



(4) Selezionare l'icona Riavvia per riavviare l'analizzatore e completare l'aggiornamento del sistema. Il sistema configurerà gli aggiornamenti automaticamente e riavvierà l'analizzatore al termine dell'aggiornamento del sistema

NOTA

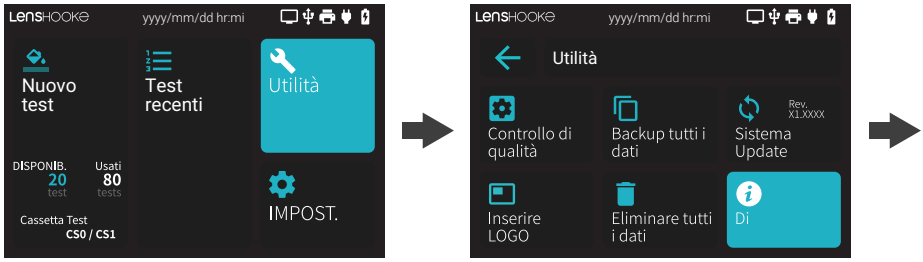
- Eseguire il backup di tutti i record prima dell'aggiornamento del sistema.
- NON spegnere o scollegare lo strumento durante la fase di aggiornamento. Assicurarsi di collegare l'alimentatore e inserire la chiavetta USB con il file di aggiornamento software quando si effettua l'aggiornamento del sistema.

NOTA

- Se compare il messaggio **“Update File is Corrupted”** significa che non è stato scaricato il file completo. Scaricare il file di aggiornamento del Sistema e procedere nuovamente all’aggiornamento.
- Se compare il messaggio **“Update Failed”** significa che la chiavetta USB è stata rimossa. Inserire nuovamente la chiavetta USB con il file di aggiornamento del sistema e ripetere la procedura.

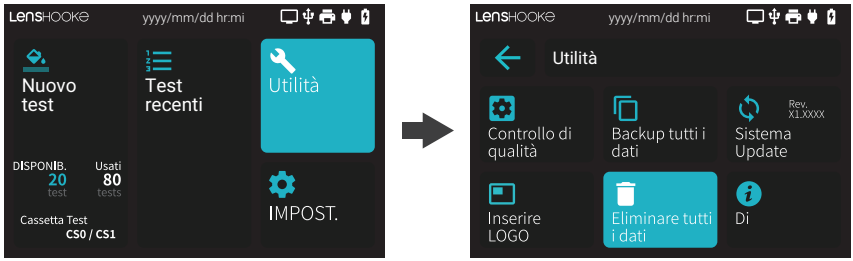
4 Icone sullo schermo

Cliccare l’icona **“Utilità”** e poi l’icona **“I”** per conoscere le informazioni dello strumento.

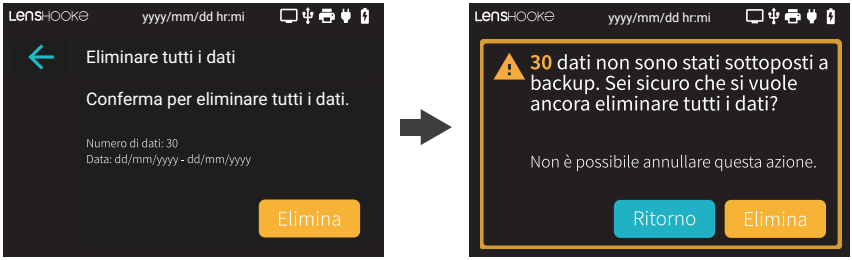


5 Eliminare tutti i dati

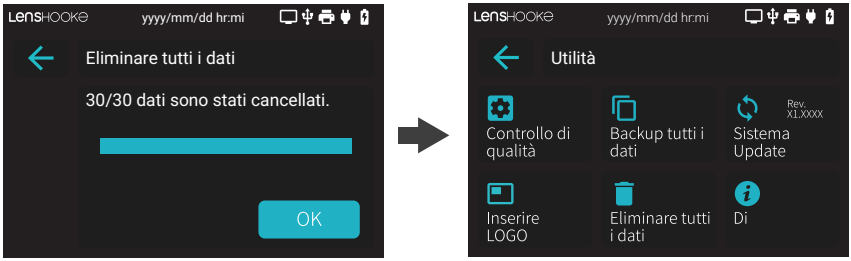
(1) Cliccare l’icona **“Utilità”** e successivamente l’icona **“Eliminare tutti i dati”**.



(2) Cliccare l'icona gialla **"Elimina"** per confermare e cancellare tutti i risultati.



(3) Cliccare l'icona **"OK"** per ritornare alla schermata iniziale.

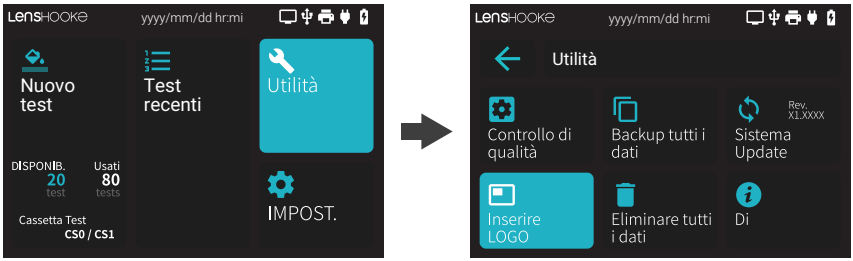


NOTA

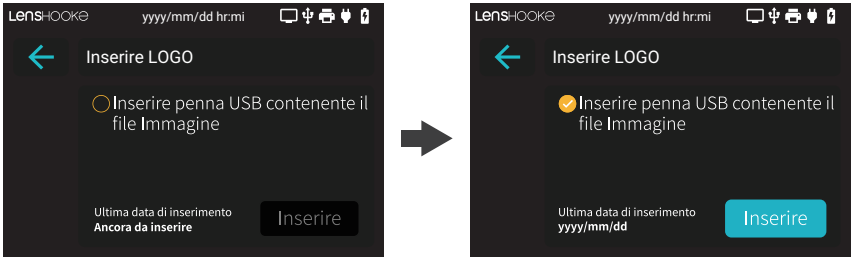
- I dati non possono essere recuperati dopo averli eliminati. Assicurarsi di volerli eliminare definitivamente prima di cliccare l'icona **"Delete"**.

6 Inserisci LOGO

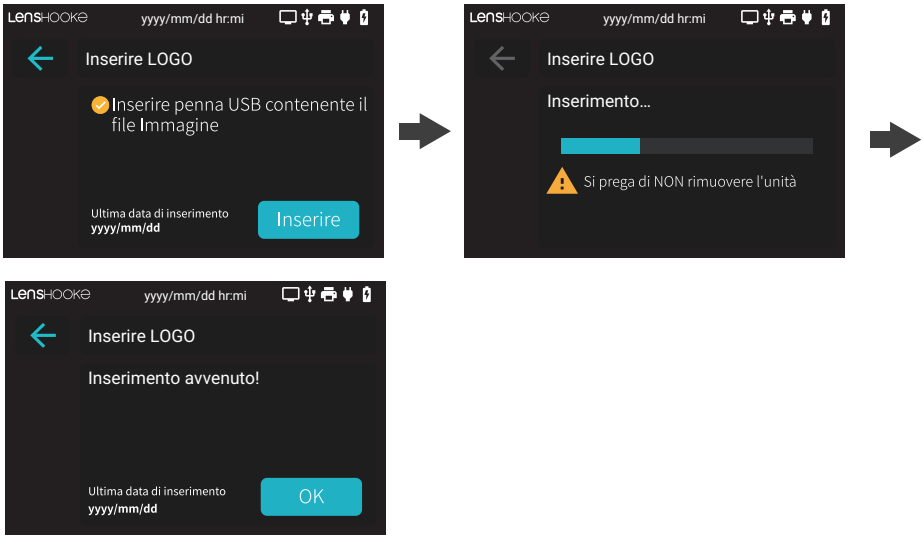
(1) Selezionare l'icona **"Utilità"** e quindi selezionare l'icona **"Inserisci LOGO".**



(2) Inserire una chiavetta USB.



(3) Seleziona l'icona **“Inserisci”** e attendi fino al messaggio **“Inserimento riuscito!”** che appare sullo schermo.



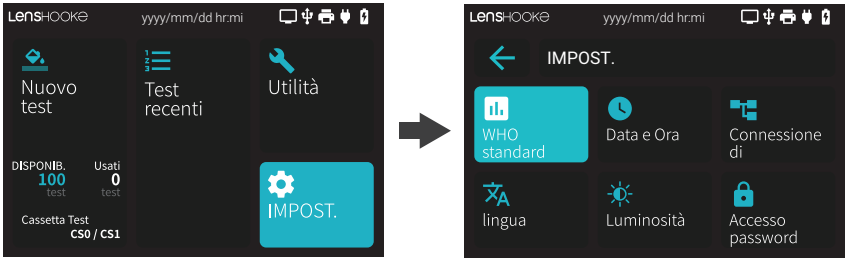
NOTA

- L'immagine LOGO deve essere in formato PNG da 2040x168 pixel e il file deve essere denominato **“lenshooke_X1_pdf_logo.png”**.
- Salvare il file direttamente sull'unità USB. Si prega di non salvarlo nella cartella.

IMPOSTAZIONI

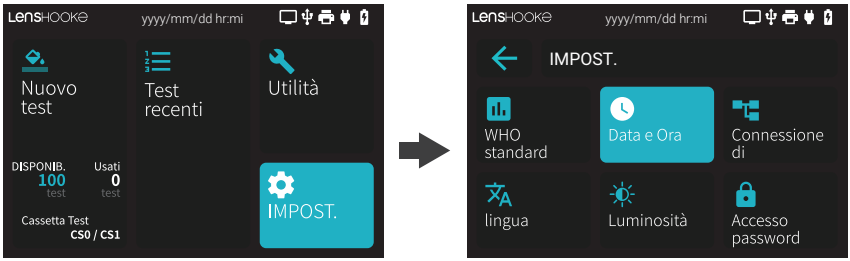
1 WHO Edition

(1) Cliccare l'icona **“IMPOST.”** e successivamente **“WHO Standard”**. Selezionare l'edizione prescelta e cliccare la **“** ← **”** per tornare alla pagina precedente.

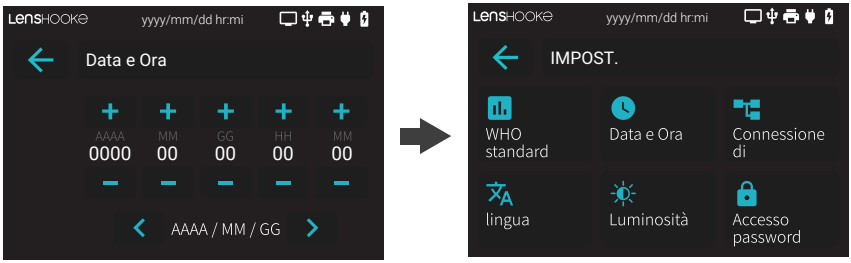


2 Data e Ora

(1) Cliccare l'icona **"IMPOST."** e successivamente **"Data e Ora"**.

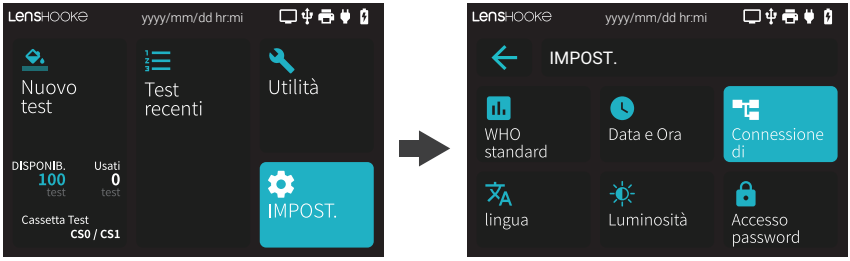


(2) Si può selezionare il formato GG/MM/AAAA, MM/GG/AAAA o AAAA/MM/GG cliccando sull' icona " < " o " > ", e impostando data e ora cliccando l'icona " + " o " − ". Dopo aver impostato Data e ora, cliccare " ← " per ritornare alla pagina.



3 Connessione di

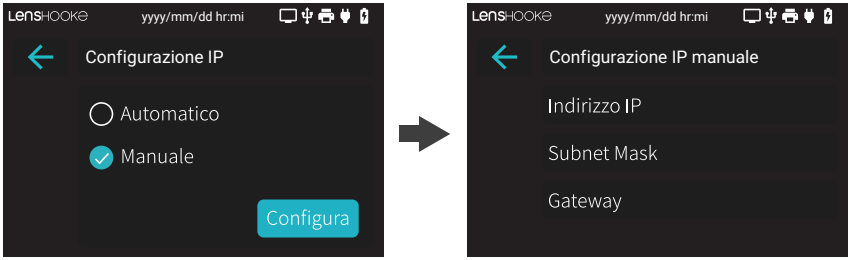
(1) Selezionare **"IMPOST."** e quindi selezionare l'icona **"Connessione di"**.



(2) Selezionare **"Configurazion IP"**.

(3) L'impostazione predefinita è **"Automatico"**. Quando scegli questa icona, il dispositivo utilizza l'indirizzo IP dinamico, che viene assegnato quando la rete è connessa e cambia nel tempo.

(4) L'impostazione predefinita è **"Manuale"**. Quando scegli questa icona, il dispositivo utilizza l'indirizzo IP dinamico, che viene assegnato quando la rete è connessa e cambia nel tempo.

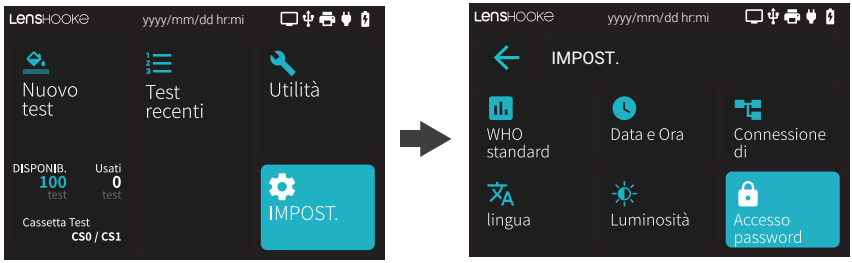


NOTA

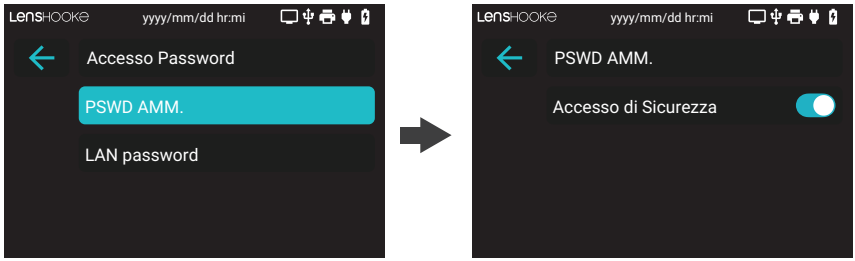
- Se non inserisci le informazioni complete per indirizzo IP, subnet mask e gateway, lo stato dell'IP di configurazione rimarrà su **"Automatico"**.

4 Accesso Password

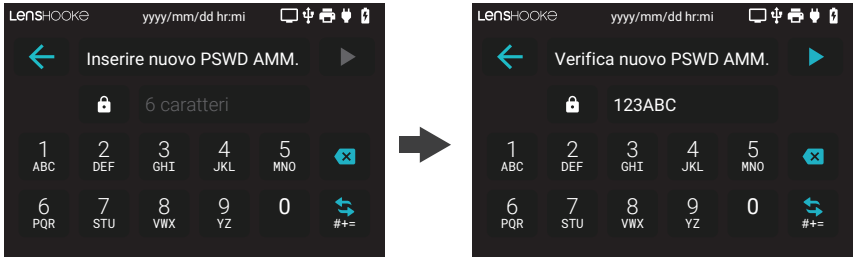
(1) Selezionare **"IMPOST."** e quindi selezionare l'icona **"Accesso password"**.



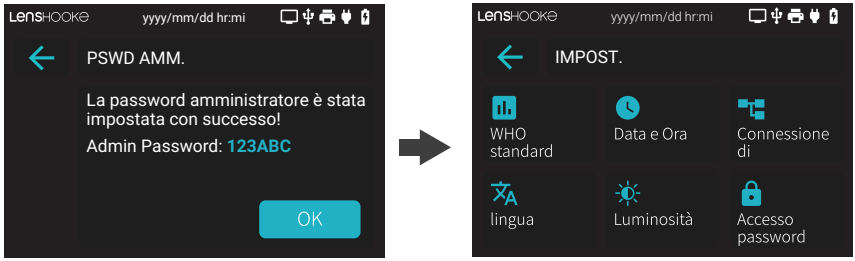
(2) Selezionare l'icona della password amministratore. Accendere di Admin Password per proteggere il tuo accesso.



(3) Immettere sei caratteri qualsiasi come nuova password amministratore, selezionare l'icona " ▶ " per passare alla fase successiva. Immettere nuovamente i sei caratteri per verificare la nuova password amministratore.



(4) Dopo aver verificato la nuova password amministratore, selezionare l'icona " ▶ " per andare al passaggio successivo. Seleziona OK per tornare alla pagina precedente.

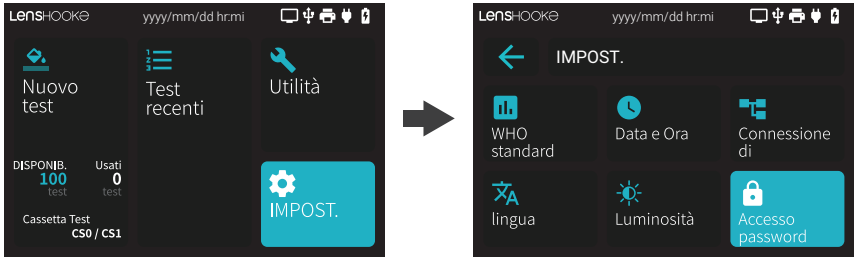


NOTA

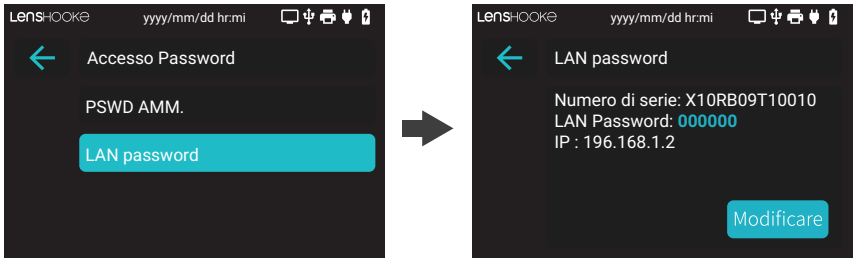
- La password predefinita per la password amministratore è **"000000"**.
- Una volta selezionate le icone " ◯ ", significa che il tuo accesso è protetto.
- Se si desidera accedere all'analizzatore, è necessario inserire la password amministratore per riattivare l'analizzatore dalla modalità di risparmio energetico.

5 Password LAN

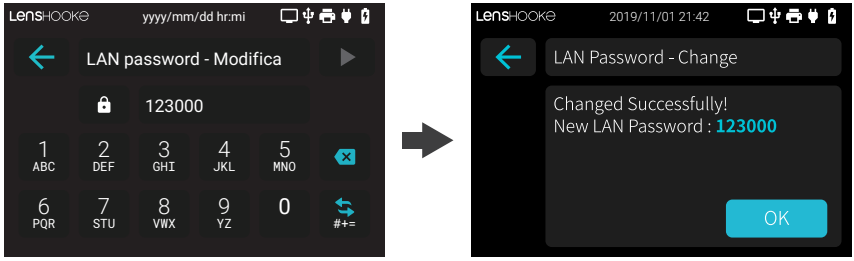
(1) Selezionare **“IMPOST.”** e quindi selezionare l'icona **“Accesso password”**.



(2) Selezionare l'icona della password LAN e la password apparirà sullo schermo. Se si desidera modificare questa password LAN, è possibile selezionare Modifica.



(3) Immettere un codice numerico a sei cifre per impostare la nuova password. Dopo aver inserito la nuova password, selezionare l'icona “ ▶ ” per andare al passaggio successivo. Selezionare l'icona **“OK”** per tornare alla pagina precedente.

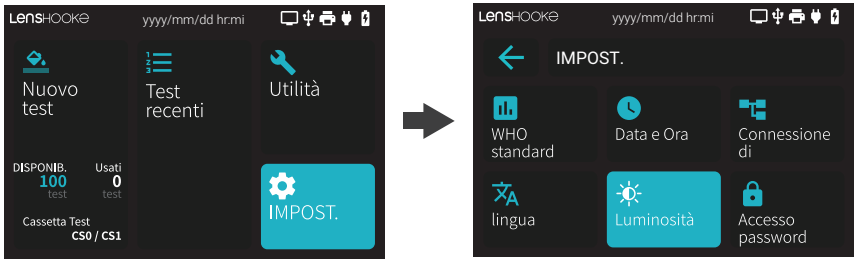


NOTA

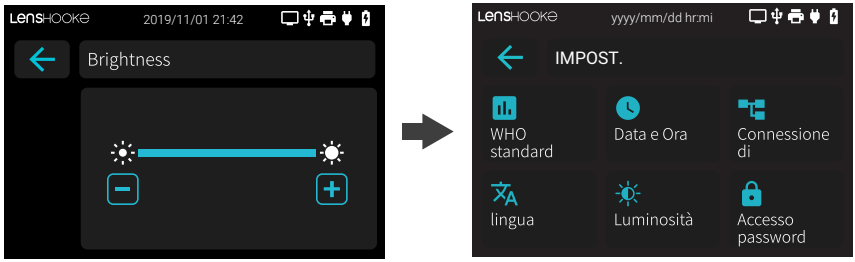
- La password predefinita per la password LAN è **“000000”**.
- Per accedere allo strumento per scaricare i risultati con altri dispositive è necessario inserire la password per la LAN.
- È necessario inserire un codice numerico di 6 cifre per permettere l’attivazione del tasto.
- Utilizzare l’adattatore USB to RJ45 Gigabit Ethernet per collefare lo strumento alla LAN (Local Area network) via cavo. (Fare riferimento a Pag.25 per ulteriori dettagli)

6 Luminosità

(1) Cliccare l'icona **"IMPOST."** e successivamente l'icona **"Luminosità"**.

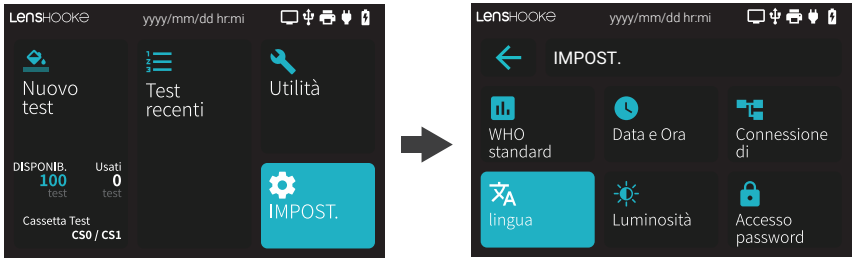


(2) Impostare la luminosità dello schermo cliccando le icone " + " o " − " , e poi cliccare l'icona " ← " per tornare alla pagina precedente.



7 Lingua

(1) Cliccare l'icona **"IMPOST."** e cliccare l'icona **"Lingua"**.

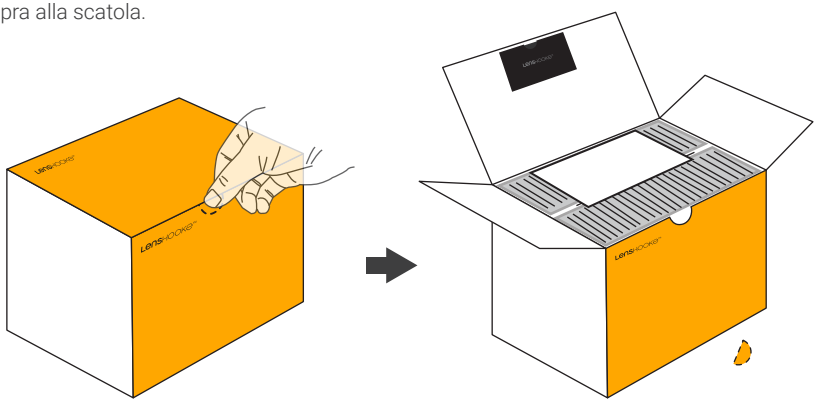


VI . Accessori

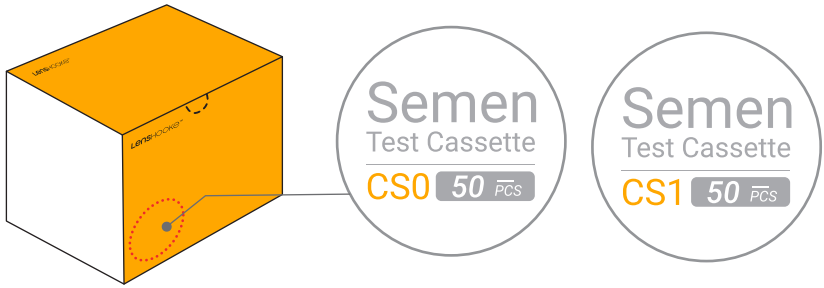
License Dongle

1 Per Ricaricare la disponibilità delle cassette

(1) All'apertura della scatola contenente le LensHooke® Test Cassette, la **"license dongle"** si troverà sopra alla scatola.

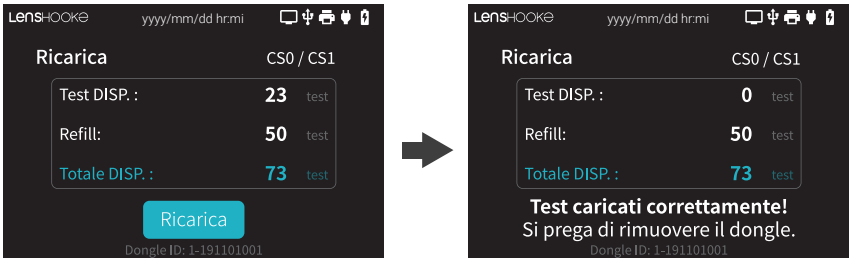


(2) Verificare che il tipo di cassetta test sia corretto prima di inserire il dongle per ricaricare la licenza.



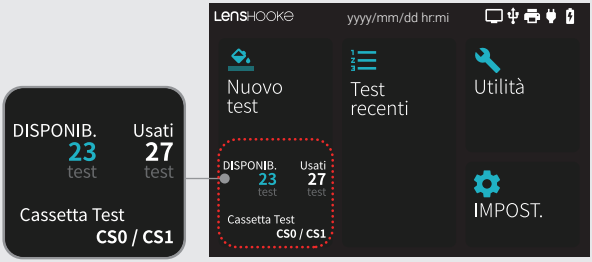
(3) Inserire il dongle di licenza nella porta USB dell'analizzatore.

(4) Selezionare l'icona **"Ricarica"** per ricaricare le licenze. Verificare che le informazioni sulla ricarica siano corrette e selezionare l'icona **"Ricarica"**. Una volta ricaricato correttamente, rimuovere il dongle.



NOTA

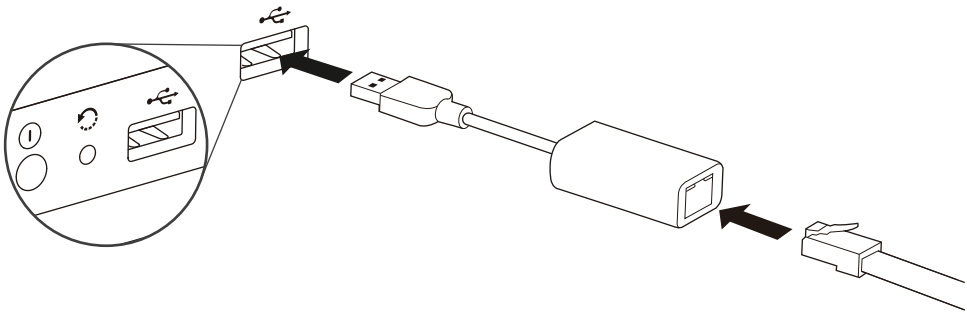
- Se la **"license dongle"** non viene fornita da BONRAYBIO Co., LTD., l'icona **"Ricarica"** non apparirà sullo schermo.
- Una volta utilizzata, la **"license dongle"** non può essere riutilizzata. Se inserita nuovamente apparirà un messaggio di errore.
- Inserire il dongle per ricaricare la licenza subito dopo aver aperto la scatola LensHooke® Semen Test Cassette.
- Quando si inserisce un nuovo **"license dongle"** per ricaricare la licenza, il calcolo**"Used"** (Test Utilizzati) si azzererà e il calcolo **"Available"** (Test Disponibili) si aggiornerà.



Adattatore USB to RJ45 Gigabit Ethernet

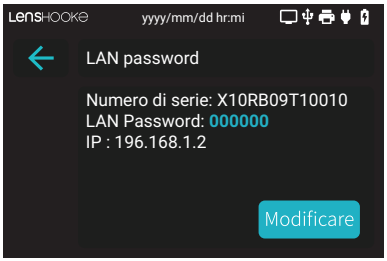
1 Analizzatore: Connettere alla LAN (Local Area Network)

(1) Utilizzare l'adattatore USB to RJ45 Gigabit Ethernet per collegare lo strumento alla LAN (Local Area network) via cavo.



2 Altri Dispositivi: Accesso allo Strumento

(1) Aprire il browser del computer/Laptop ed inserire l'indirizzo IP. (Queste informazioni possono essere verificate sullo strumento cliccando sull'icona **"Settings & LAN Password"**.)



(2) Accedere inserendo la Password per la LAN. (Queste informazioni possono essere verificate sullo strumento cliccando sull'icona **"Settings & LAN Password"**.)

(3) Si possono vedere in anteprima i file PDF e MP4.

(4) È possibile scaricare file PDF, MP4 e CSV.

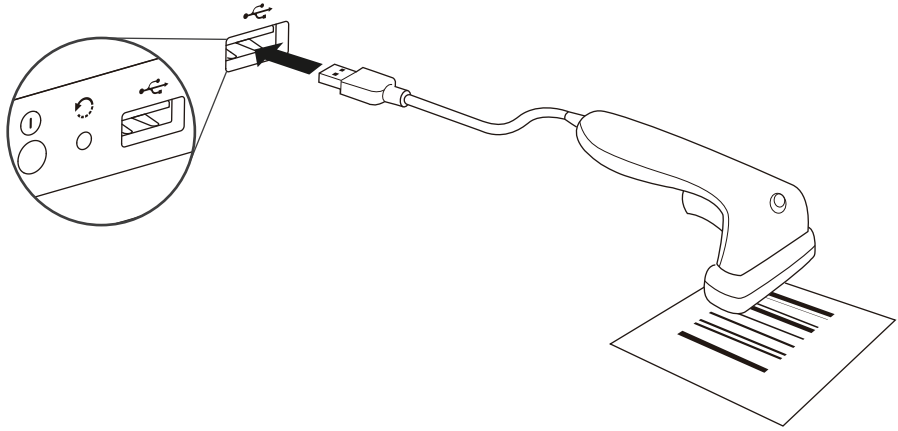
NOTA

- Se troppe persone accedono allo strumento contemporaneamente è possibile che ne vengano compromesse le performance.
- Utilizza uno dei seguenti browser per accedere alla pagina di accesso.
  - Firefox (Ver: 62 o superiore), Chrome (Ver: 69 o superiore), Microsoft Edge per Windows 10 e Safari ... ecc.
  (Fare riferimento a www.LensHooke.com per maggiori dettagli.)
- Supporta solo iPad, PC o laptop.
- Lo status dei dati sulla LAN è inteso solo per lo status analizzatore .

Lettore Barcode

1 Collegare un Lettore Barcode allo Strumento

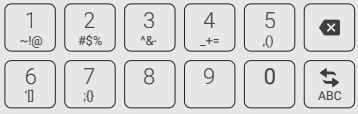
(1) Collegare il lettore barcode allo strumento tramite porta USB Port.



(2) Il lettore barcode può essere usato per scannerizzare l'ID# del campione del paziente o il LOTTO# del X QC Beads, X QC Reticle, e X QC Video per il test di controllo qualità.

NOTA

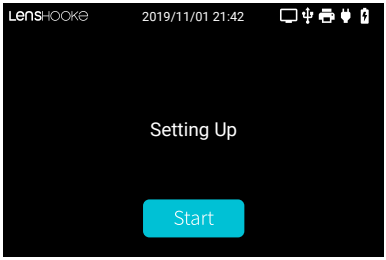
- L'analizzatore può connettersi SOLO allo scanner di codici a barre utilizzando la porta USB.
- L'analizzatore può leggere SOLO le seguenti lettere, numeri e simboli.



VII. Per Iniziare

Impostare lo strumento:

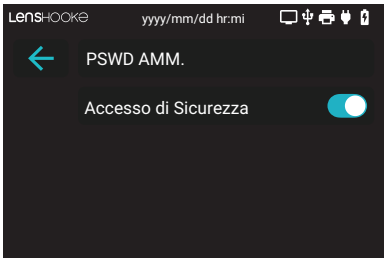
(1) Selezionare **“Start”** e quindi selezionare la lingua.



(2) Impostare la data e l'ora. Selezionare “ < ” o “ > ” per regolare il formato della data e utilizzare l'icona “ + ” o “ − ” per regolare i valori.

(3) Seleziona l'edizione dell'OMS. Seleziona “ ▶ ” per procedere alla selezione dell'edizione WHO.

(4) Accesso protetto. Se vuoi proteggere l'accesso all'analizzatore, fai scorrere l'icona per girare blu, quindi inserire sei caratteri qualsiasi come nuova password amministratore



Si prega di caricare la batteria dell'analizzatore per 3 ore prima di iniziare a utilizzarlo nel primo tempo.

VIII. Pulizia e Manutenzione

1 Suggerimenti per la pulizia

(1) Il vano di inserimento delle Test Cassette può essere pulito esclusivamente utilizzando **“LensHooke® Cleaning Wipe”.**

(2) NON utilizzare altro materiale per pulire il vano di inserimento delle Test Cassette.

(3) LensHooke® Cleaning Wipe è monouso. NON riutilizzare.

(4) Tenere LensHooke® X1 PRO Semen Quality Analyzer lontano da polvere, acqua o liquidi e ambienti estremi (che sono al di fuori dell'ambiente operativo o di conservazione indicato nelle specifiche.

(5) Pulire l’esterno dello strumento LensHooke® X1 PRO Semen Quality Analyzer tutti i giorni dopo averlo utilizzato.

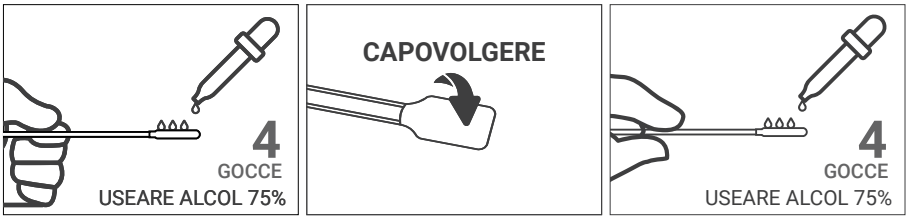
2 Passaggi per la Pulizia

I. Vano di inserimento delle Test Cassette:

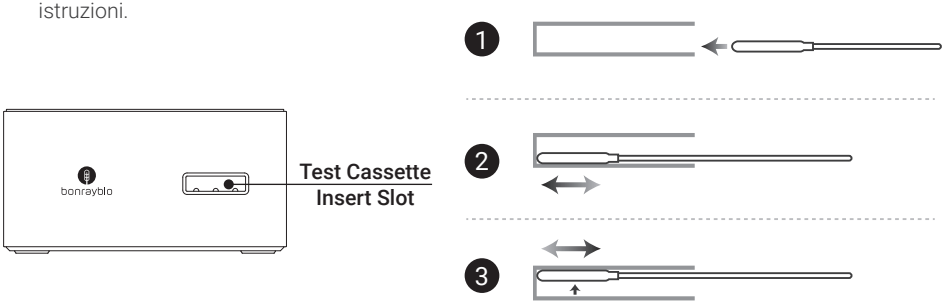
(1) Spegnere lo strumento prima di pulirlo.

(2) Preparare 2 LensHooke® Cleaning Wipe.

(3) Bagnare ogni lato dellel LensHooke® Cleaning Wipe con 4 gocce di alcol 75%.



(4) Inseririe le LensHooke® Cleaning Wipe nel vano di inserimento delle Test Cassette e seguire le istruzioni.



(5) Utilizzare una nuova LensHooke® Cleaning Wipe asciutta (senza alcol o altri liquidi) per pulire nuovamente il vano.

(6) Buttare le LensHooke® Cleaning Wipe utilizzate.

II. Corpo dell'analizzatore:

(1) Spegnere l'analizzatore prima della pulizia.

(2) Utilizzare un tampone imbevuto di alcol per pulire il corpo dell'analizzatore.

(3) Gettare via il tampone imbevuto di alcol usato.

III. Adattatore dell' alimentazione:

(1) Si prega di utilizzare sapone senza alcool.

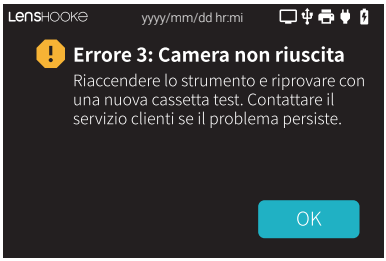
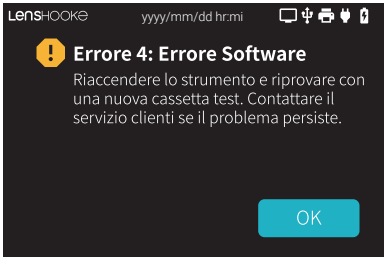
(2) Strizzare il panno e pulire delicatamente l'alimentatore.

(3) Pulire nuovamente l'area con un panno imbevuto di acqua pulita.

NOTA

- Utilizzare LensHooke® Cleaning Wipe per pulire la LensHooke® X1 PRO Semen Quality Analyzer.
- LensHooke® X1 PRO Semen Quality Analyzer è stato testato per assicurare che non vi siano alterazioni nelle performance o nei materiali dello strumento dopo 10,950 cicli di pulizia e 10,950 cicli di disinfezione. Questo test ha simulato 10 cicli di pulizia e disinfezione al giorno per la durata media di vita dello strumento (3 years).

IX. Messaggi di Errore

Messaggi di Errore	Soluzioni
	Errore 1: **"Self Test non riuscito"**. Potrebbe essersi verificato un errore nello start up. Contattare il servizio clienti.
	Errore 2: **"dispositivo guasto"**. Potrebbe esserci un errore nello strumento. Rimuovere la "Test cassette" e cliccare l'icona **"OK"** per ritornare alla pagina iniziale e spegnere lo strumento. (Fare riferimento a Pagina 5 **"Turn on/off"**). Se il messaggio dovesse ricomparire, contattare il servizio clienti.
	**Errore 3:** **"Camera non riuscita"**. Potrebbe essere un problema della lente. Rimuovere la **"Test cassette"** e cliccare l'icona **"OK"** per ritornare alla pagina iniziale. Inserire una nuova **"Test cassette"** e ripetere l'analisi. Se il messaggio dovesse ricomparire, contattare il servizio clienti. *Accertarsi che si stia utlizzando le LensHooke® Semen Test Cassette corrette.
	**Errore 4:** **"Errore Software"**. Potrebbe essere un problema di software. Rimuovere la **"Test cassette"** e cliccare l'icona **"OK"** per ritornare alla pagina iniziale e spegnere lo strumento. (Fare riferimento a Pagina 5 **"Turn on/off"**).

X. Informazioni sullo Strumento

Nome dello strumento
LensHooke® X1 PRO Semen Quality Analyzer

Pannello di Controllo
3.5-in touch screen

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

Batteria
2500 mA (batteria al litio ricaricabile incorporata, DC3.7V / 2.5Ah)

Memoria interna
30 analisi inclusi i dati e le immagini

Tempo di analisi
2~5 minuti (in base alla qualità del campione)

Adattatore
Input: 100~240 Vac, 50~60 Hz,0.5 A
Output: 5 Vdc, 2 A Max

Temperatura di Analisi
Temperatura 15°C~38°C (59°F~100°F)
Umidità <70%

Temperatura di Stoccaggio
Temperatura 15°C~38°C (59°F~100°F)
Umidità <70%

Temperatura di Trasporto
Temperatura -10°C~60°C (14°F~140°F)

Range di Misurazione
pH 6.0~8.0 (intervallo di scala:0.2)
Concentrazione <0.1-300 (10^6/ml)
Motilità Totale <1-100%
Morfologia (Forme normali) <1-100%

XI. Fonti

I Parametri di Riferimento sono stati estrapolati dal Manuale di Laboratorio WHO per l'Analisi e la Processazione del Liquido Seminale Umano.

Parametri	WHO 5th Low Reference	WHO 4th Low Reference
Concentrazione	15 x 10^6 (12-16)/ ml	≧ 20 x 10^6 / ml
Motilità	40% (38-42%)	a + b ≧ 50% or a ≧ 25%
PR (Motilità Progressiva)	32% (31-34%)	
Morfologia(Forme Normali)	4% (3-4%)	≧ 15%

a：Motilità Progressiva Rapida (≧25μm/s)
b：Motilità Progressiva Lenta

XII. Dichiarazione

Tutti i contenuti del manuale operatore relativi a questo prodotto non possono essere copiati, distribuiti, duplicati o conservati senza autorizzazione scritta da Bonraybio Co., LTD. Bonraybio si riserva il diritto di cambiare la descrizione delle caratteristiche hardware e software in qualsiasi momento e senza comunicazione preventiva. Se vi fossero errori o informazioni poco chiare, contattare il distributore locale. Ogni feedback su questo manuale sarà apprezzata.

XIII. Avvertenze e Precauzioni

1. Sovravoltaggio: Livello I II
2. Categoria inquinanti: Level 2
3. Operatività altitudine: < 2000 meters
4. Umidità Realtiva (RH%): < 70%
5. Utilizzare in locali chiusi idonei
6. IL codice IP IP21 è protetto dall'inserimento delle dita e non sarà danneggiato o non sarà sicuro durante una prova specifica in cui è esposto a gocciolamento verticale dell'acqua.
7. Evitare di lasciare I cavi a portata dei bambini,rischio strangolamento.
8. Evitare di lasciare le piccole parti a portata dei bambini,rischio soffocamento.
9. I risultati dei test ottenuti sono in accordo con WHO Laboratory Manual for the Examination and Processing of Human Semen. Si prega riferissi al manuale d'uso del LensHooke® Semen Test Cassette.

NOTA

- LensHooke® X1 PRO Semen Quality Analyzer, LensHooke® Semen Test Cassette, C-KUP™ Liquefaction Test Cup, LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen), e LensHooke® X QC Video (For Semen).
  Il prodotto è conforme alla Direttiva sui dispositivi medico-diagnostici in vitro 98/79 / CE.
- Conforme compatibilità elettromagnetica, l'emissione e l'immunità e i requisiti della norma IEC 61326-2-6 E

Produttore:
Bonraybio Co., LTD.
4F., No. 118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280,
Taiwan (R.O.C.)

XIV. Garanzia

Bonraybio offre 1 anno di garanzia dal momento dell'acquisto del LensHooke® X1 PRO Semen Quality Analyzer. Durante il period di garanzia lo strumento verrà riparato o sostituito senza costi aggiuntivi.

La garanzia è valida solo sullo stumento originale LensHooke® X1 PRO Semen Quality Analyzer prodotto da Bonraybio. La garanzia non sarà applicata se lo strumento è stato modificato o utilizzato in maniera impropria.

Produttore : Bonraybio Co., LTD.
Indirizzo : 4F., No.118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280, Taiwan(R.O.C.)
Tel : +886-4-2491-2385
Fax : +886-4-2491-2885
Email : support@bonraybio.com

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

CE

LensHOOKe®

LensHOOKe®

Semen Quality Analyzer

Manual do usuário

X1 PRO

Rev.29-0X10700 20210308X1E003PT

Por favor, leia atentamente este manual do usuário para garantir o uso adequado do produto. Este manual do usuário também está disponível em **www.LENSHOOKE.com**.

Símbolos

Os seguintes ícones podem aparecer no conteúdo deste manual do usuário.

Símbolo para **"AVISO"**

Símbolo para **"CUIDADO"**

Símbolo para **"NÚMERO DA PÁGINA"**

Símbolo para **"NÃO REUSAR"**

Símbolo para **"VALIDADE"**

Símbolo para **"CÓDIGO do LOTE"**

Símbolo para **"NÚMERO de SÉRIE"**

Símbolo para **"DATA DE FABRICAÇÃO"**

Símbolo para **"FABRICANTE"**

Símbolo para **"REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA"**

Símbolo para **"DISPOSITIVO DE DIAGNÓSTICO IN VITRO"**

Símbolo para **"LIMITE DE TEMPERATURA"**

Símbolo para **"INSTRUÇÕES CONSULTA PARA USO"**

Símbolo para **"RECICLAGEM DE RESÍDUOS WEEE"**

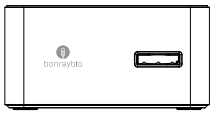
Marca CE

Símbolo para **"SIGA AS INSTRUÇÕES DE UTILIZAÇÃO"**

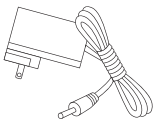
Símbolo para **"USO PRETENDIDO DE UM PRODUTO DE PRESCRIÇÃO IVD"**

A embalagem inclui

- **LensHooke® X1 PRO Semen Quality Analyzer**



- **Adaptador de energia (para analisador)**



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I. Introdução

LensHook® X1 PRO Semen Quality Analyzer é apenas para diagnóstico in vitro. O usuário deve ler este Manual do Usuário primeiro para se familiarizar com o dispositivo e seu procedimento de operação adequado antes de usar o analisador.

"LensHooke® Semen Test Cassette" é a descrição geral para "LensHooke® CS0 Semen Test Cassette" e "LensHooke® CS1 Semen Test Cassette.

Se você tiver alguma dúvida sobre o produto ou precisar de assistência, não hesite em entrar em contato com a Bonraybio ligando para a linha direta de atendimento (+ 886-4-2491-2385) ou contate o seu distribuidor local.

Horário da Linha de Serviço: seg ~ sex 08: 30 ~ 17: 30 (GMT + 8)

II. Uso pretendido

O LensHooke® X1 PRO Semen Quality Analyzer usado com o LensHooke® Semen Test Cassette um dispositivo óptico fácil de usar para análise de sêmen humano que fornece medições diretas e calculadas para:

(1) concentração de espermatozoides (10^6 por ml)

(2) Motilidade total (PR+NP, %)

- Motilidade progressiva (%)
- Motilidade não progressiva (%)
- Imotilidade (%)
- Outros parâmetros da avaliação do CASA (MSC, PMSC, VAP, VSL, VCL, LIN, STR, WOB, ALH, and BCF)

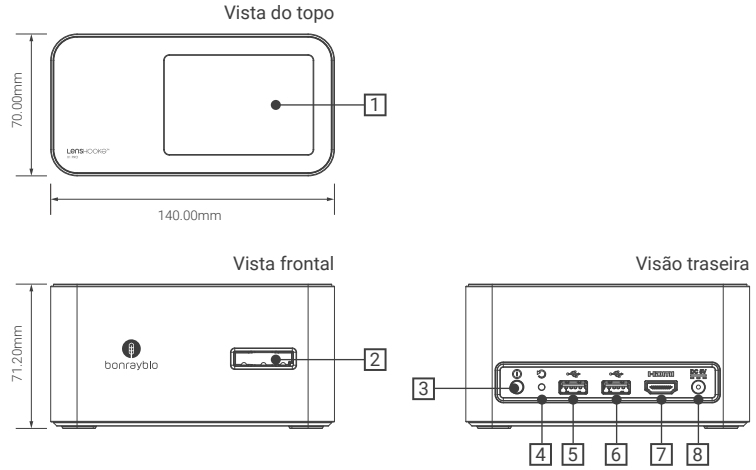
(3) morfologia espermática (formas normais, %)

(4) valor de pH

O LensHooke® X1 PRO Semen Quality Analyzer não fornece uma avaliação abrangente do estado de fertilidade do homem e destina-se apenas a diagnóstico in vitro. Para uso profissional.

III. Resumo do Produto

LensHooke® X1 PRO Semen Quality Analyzer



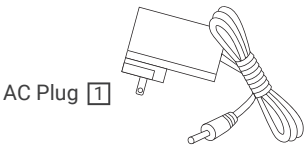
1 Tela sensível ao toque
2 Teste Slot de inserção de cassete
3 Botão de energia
4 Botão de Reset
5 Porta USB
6 Porta USB
7 HDMI
8 Porta do adaptador de energia

NOTA

- **Porta USB:** USB 2.0 de alta velocidade
- **Botão de reset:** Se o analisador falhar, por favor, use um pino para pressionar o botão de reset.
- **Porta HDMI:** O analisador permite a conexão de um cabo HDMI a um monitor de alta definição para rever as imagens e dados.

Accessórios

- **Adaptador de força**



2 Plugue adaptador de alimentação

Dongguan Shilong Fuhua Electronic Co., Ltd;
UES12LCP-050200SPA

Ícone da tela de toque

1 **Ícone de conexão HDMI:** este analisador está conectado ao monitor pelo HDMI.
2 **Ícone de conexão USB:** este analisador está conectado à unidade por um porta USB.
3 **Ícone de conexão da impressora térmica:** este analisador está conectado à impressora térmica portátil.
4 **Ícone de conexão do adaptador de energia:** é conectado ao adaptador de energia para carregar a bateria.
5 **Ícone da bateria:** Mostra a capacidade da bateria.

NOTA

- **Ícone de conexão USB:** Ícone de conexão USB: Se você inserir o outro dispositivo pela porta USB, como teclado, mouse, dongle etc, este ícone não aparece rá na tela.

Os ícones abaixo são funcionais

6 **Ícone de utilitários:** inclui as funções de:
- Controle de Qualidade: Para verificar a qualidade do analisador / dispositivo.
- Backup de todos os registros: para fazer backup dos dados de todos os resultados.
- Atualização do Sistema: Para atualizar o sistema do analisador / dispositivo.
- Sobre: Para obter as informações detalhadas do analisador / dispositivo.
- Excluir registros: Exclui os resultados.
- Inserir logotipo: Para inserir o logotipo na parte superior do relatório PDF.

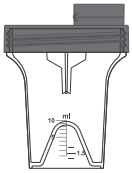
7 **Ícone de configurações:** Inclui as funções:
- Padrão da OMS: Para selecionar a edição da OMS de 4ª ou 5ª.
- Data e hora: para configurar a data e a hora.
- Conexão de rede: para selecionar a preferência de IP.
- Idioma: para selecionar a preferência de idioma.
- Senha da LAN: Senha de acesso: para obter ou alterar a senha de acesso ao analisador.
- Brilho: Para ajustar o brilho da tela.

8 **Ícone de testes recentes:** para rever os resultados dos testes anteriores.
9 **Novo ícone de teste:** para iniciar o teste.

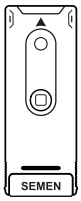
IV. Consumíveis

Os consumíveis para o analisador de qualidade do LensHooke® X1 PRO Semen Quality Analyzer são os seguintes:

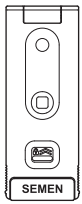
- **C-KUP™ Liquefaction Test Cup**



- **LensHooke® CS0 Semen Test Cassette**



- **LensHooke® CS1 Semen Test Cassette**



- **LensHooke® Cleaning Wipe**

- **LensHooke® X QC Beads (For Semen)**

- **LensHooke® X QC Reticle (For Semen)**

- **LensHooke® X QC Video (For Semen)**

⚠ **O resultado pode ser impreciso, se você NÃO usar o LensHooke® Semen Test Cassette ou os produtos da série LensHooke® X QC.**

NOTE

- As imagens do produto são apenas diagramas esquemáticos. Por favor, consulte os produtos reais.
- C-KUP™ Liquefaction Test Cup é para coleta de amostra de sêmen.
- LensHooke® Semen Test Cassette é usado para armazenar amostras de sêmen para análise.
- LensHooke® Cleaning Wipe é usad a para limpar o slot de inserção do cassete de teste.
- LensHooke® X QC Beads (For Semen) e LensHooke® X QC Reticle (For Semen) são usados para o controle de qualidade do analisador.
- LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) e LensHooke® X QC Video (For Semen) são utilizados para controle de qualidade do analisador.

V. Função Principal

LensHooke® X1 PRO Semen Quality Analyzer

Ligar / desligar

1 Ligue o analisador:

Pressione o botão por cerca de 2 segundos para ligar (como na Imagem 1).
Quando a tela acende (como na Imagem 2), o analisador está pronto para operar.

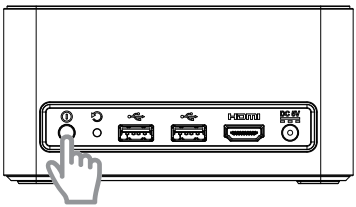


Image 1

Image 2

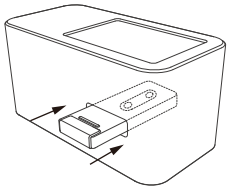
2 Desligue o analisador:

Mantenha pressionado o botão liga/desliga por 10 segundos para desligar diretamente o analisador, ou você também pode pressionar o botão liga/desliga por 2 segundos até que a tela de toque mostre **"Desligar"** e selecione o ícone para desligá-lo.

Inserir / Remover o Cassete de Teste

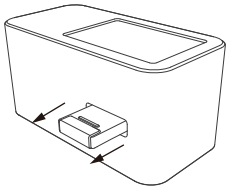
1 Insira o cassete de teste:

Insira o cassete no slot e empurre-o até o fim.



2 Remova o cassete de teste:

Após o teste, remova o cassete de teste na direção oposta da **"seta"**.



Carregando a bateria

1 Quando a mensagem **"Bateria Fraca"** aparecer na tela de toque (Imagem 3), significa que a carga da bateria está baixa. Use o adaptador de energia para carregar a bateria imediatamente. O símbolo **"plug"** aparecerá na tela de toque (como na imagem 4) durante o carregamento. Se o símbolo **"plug"** não aparecer na tela, verifique se o adaptador está conectado corretamente ao analisador e ao soquete.

Image 3

Image 4

- O analisador é equipado com baterias de polímero de íons de lítio incorporadas com capacidade de 2500 mA.
- A bateria não pode ser removida ou alterada. Se você tiver problema da bateria, entre em contato conosco.

NOTE

- Se você quiser entrar no modo de economia de energia, pressione o botão liga/desliga . Se você quiser acordar o analisador, por favor pressione o botão de energia novamente rapidamente.

  Se não houver operação por 10 minutos, o sistema entrará automaticamente no modo de economia de energia.

  *** Modo de economia de energia: desliga a tela de toque para reduzir o consumo de energia da bateria.**

- Para o propósito de prolongar a vida útil da bateria de polímero de íons de lítio incorporada, por favor, mantenha o adaptador conectado mesmo sem usar o analisador.
- Se o analisador não for operado durante 3 meses, por favor use o carregador de energia antes de usar.
- Se o analisador ficar sem bateria, o indicador de data e hora poderá ser redefinido para as configurações padrão. Verifique e configure a data e a hora corretamente.
- Se as mensagens de aviso **"Bateria superaquecida"** ou **"Temperatura da bateria estiver muito baixa"** aparecerem na tela, o analisador será desligado automaticamente em 5 minutos para se proteger. Quando vir a mensagem de aviso acima, desligue o analisador e, em seguida, coloque o analisador no ambiente de operação de 15°C a 38°C (59°F - 100°F), umidade <70% por mais de 1 hora, depois conecte o adaptador de energia ao analisador e ligue o analisador para uso.

Prepare o analisador de teste

1. Por favor, coloque o analisador em uma superfície plana, ex. mesa.
2. Verifique se o analisador está sob o status operacional normal.
3. Verifique o status da bateria. Se a bateria estiver fraca, conecte o adaptador de energia antes de testar.

Prepare a Amostra

1. Consulte o manual do usuário do LensHooke® Semen Test Cassette para preparar a amostra.

Teste a amostra

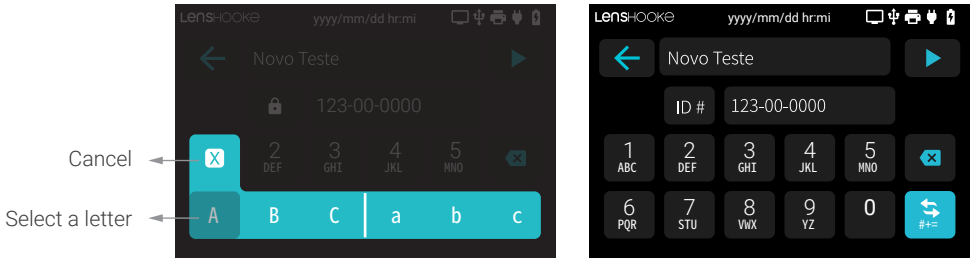
1 Novo teste

Passo 1. Clique no ícone **“Novo Teste”**.

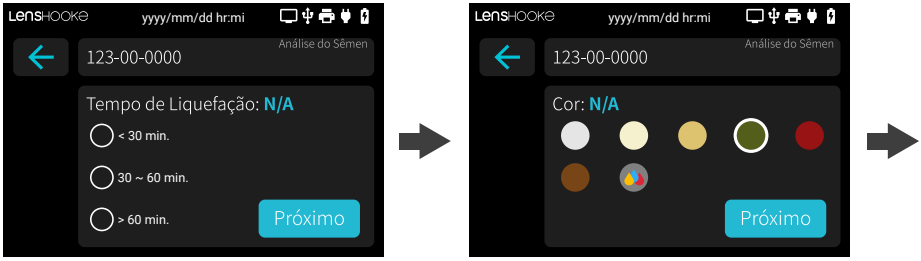
Passo 2. Por favor, digite o número de identificação e clique para ir para a próxima etapa.

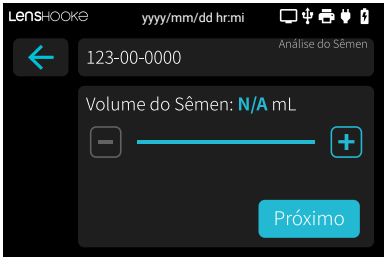
NOTE

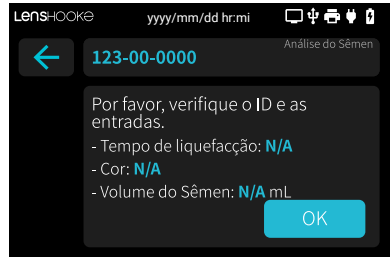
- NÃO use mais de 20 caracteres e símbolos para o número de ID do paciente.
- Se você quiser inserir um caractere, pressione o ícone por 0,5 a 1 segundo e selecione a letra. Se você quiser inserir um símbolo, clique no ícone “ ⇆ ” para alternar o teclado.
- Você também pode usar o scanner de código de barras para escanear o código de barras do número de identificação do paciente. identificação do paciente. (Consulte a página 27 para conectar o scanner de código de barras ao analisador.)
- Por favor consulte a Página 24 do manual para reabastecer.



Passo 3. Por favor selecione o Tempo de Liquefação, Coloração da amostra, Volume do ejaculado após liquefação e selecione **“Próximo”** para ir ao próximo passo. Selecione o ícone **“OK”** se as informações inseridas estiverem corretas.







NOTE

- Por favor clique ⊖ e ⊕ ajustar o volume de esperma.
- NÃO mova o cassete ou analisador durante o cálculo dos resultados.

Passo 4. Insira o cassete de teste (com amostra) na abertura do equipamento e empurre-o até o fim.

Revise o resultado do teste

1 Testes Recentes

(1) Clique no ícone **"Testes Recentes"** e, em seguida, clique no registro que você deseja revisar pelo ID do paciente.

(2) Os resultados irão aparecer na tela. Se não, selecione o ícone " ← " para retornar à página anterior.

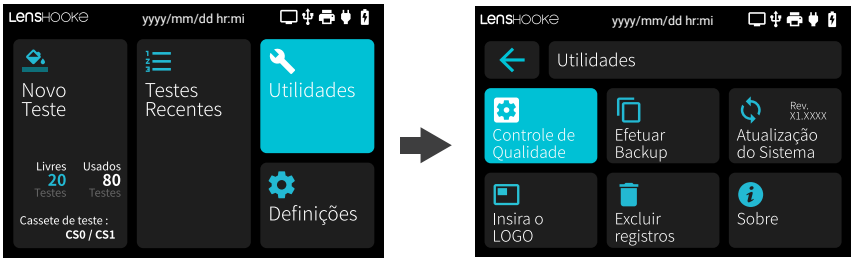
NOTE

- SOMENTE os ícones azuis podem ser clicados.
- Você pode conectar o analisador à LAN para imprimir o resultado. (Consulte a página 26 para conectar o analisador à LAN.)
- Se " ❄ " aparecer ao lado do resultado da concentração, Isso significa que a amostra tem agregação de espermatozoides, cristais de esperma ou bolhas que podem afetar o resultado. Sugerimos que você anote o resultado ou refaça o teste.
- Se o símbolo " ▨ " aparecer próximo ao resultado de motilidade, significa que o dispositivo detecta o movimento dos espermatozoides por impulso em vez de nadar, o que pode afetar o resultado. Sugerimos que você anote o resultado ou refaça o teste ou procure ajuda profissional.
- Se você quiser usar o analisador para paciente de vasectomia, por favor use o método de exame manual confirmar a leitura.
- Se você não aplicou a amostra na área de gotejamento do pH, o resultado do valor do pH mostrará <6,0. Portanto, verifique a área de gotejamento do pH do cassete de teste, se o resultado for <6,0.

Utilidades

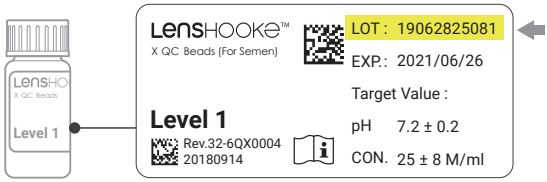
1 Controle de qualidade

(1) Clique no ícone de **"Utilidades"** e, em seguida, clique no ícone de **"Controle de qualidade"**.

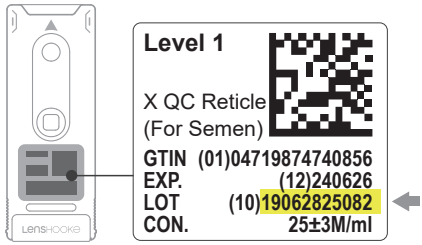


(2) Insira o número do LOTE no rótulo do LensHooke® X QC Beads (For Semen) ou LensHooke® X QC Reticle (For Semen) ou LensHooke® X QC Video (For Semen). Por favor confirme o número do LOTE e selecione " ▶ " para ir para a próxima etapa.

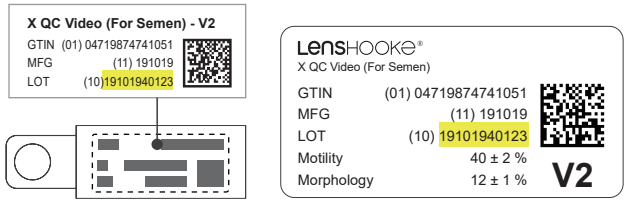
• Número de LOTE do X QC Beads



• Número de LOTE do X QC Reticle



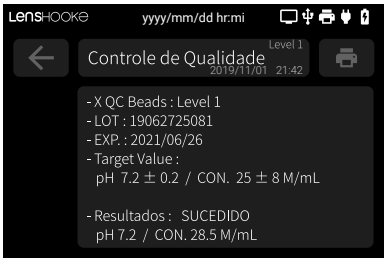
• Número de LOTE do X QC Video



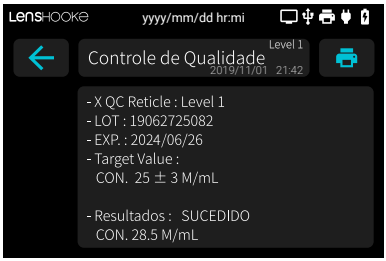
(3) Por favor siga as instruções do LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) ou LensHooke® X QC Video (For Semen) para operar e, em seguida, insira o cassete no **"slot de inserção"** ou insira o USB do LensHooke® X QC Video na porta USB.

(4) Depois de 2 a 5 minutos, o resultado aparecerá na tela automaticamente.

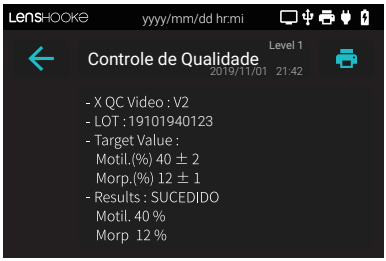
• Resultado do X QC Beads



• Resultado do X QC Reticle

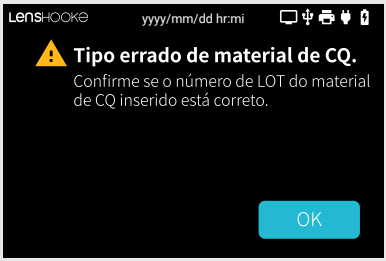


• Resultado do X QC Video

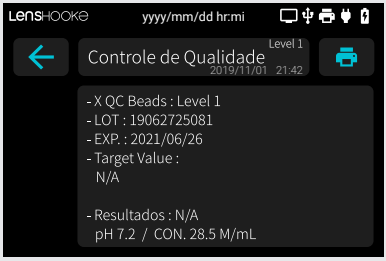


NOTE

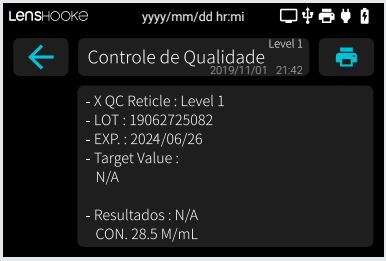
- LensHooke® X QC Beads (For Semen) examina o valor de pH e concentração.
  LensHooke® X QC Reticle (For Semen) SOMENTE examina a concentração.
  LensHooke® X QC Video (For Semen) SOMENTE examina motilidade e morfologia.
- Se você inserir o número de LOTE do LensHooke® X QC Beads (For Semen), mas inserir o cassete do LensHooke® X QC Reticle (For Semen), o analisador mostrará a mensagem abaixo para avisá-lo, e vice-versa.



- Se N/A aparecer na tela de resultados, isso significa que o LensHooke® X QC Beads (For Semen) ou o LensHooke® X QC Reticle (For Semen) estão vencidos. Utilize um novo ou entre em contato com o atendimento ao cliente.



X QC Beads

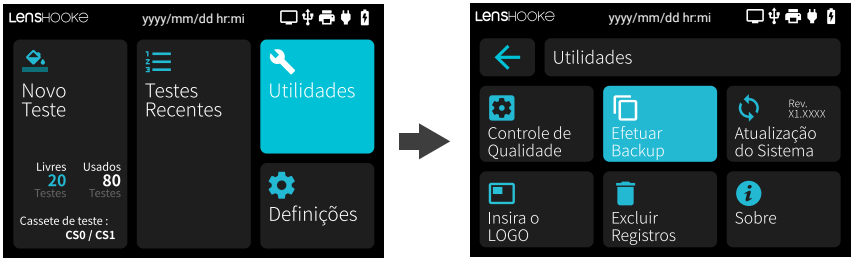


X QC Reticle

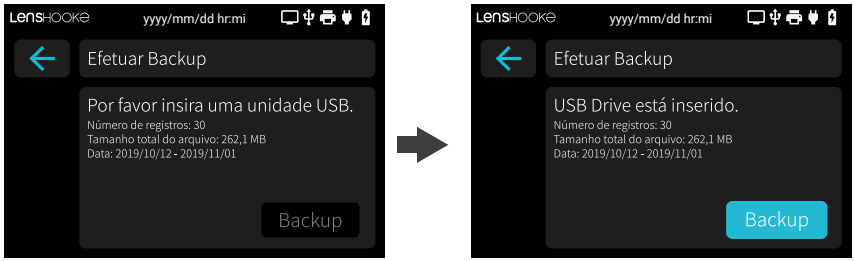
2 Backup de todos os registros

(1) Prepare uma unidade USB com antecedência. (Capacidade: 1GB ou mais)

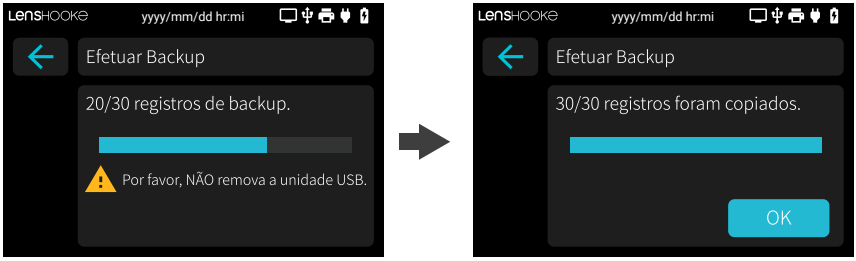
(2) Clique no ícone de **"Utilidades"** e, em seguida, clique no ícone de **"Efetuar Backup"**.



(3) Insira o drive USB. Quando o ícone de **"Backup"** ficar azul, clique nele para fazer backup dos registros.



(4) Quando os registros foram copiados para o seu drive USB com sucesso, clique no ícone **"OK"** para voltar para a página inicial.



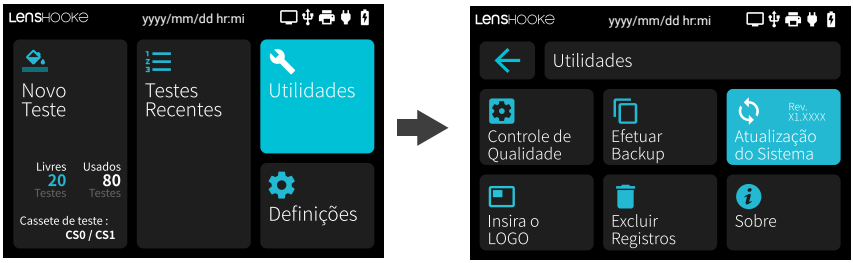
NOTE

- Não remova a unidade USB enquanto os registros ainda estiverem em backup.
- Se a capacidade de memória do analisador for insuficiente, a mensagem **"Armazenamento insuficiente disponível"** aparecerá na tela. Por favor, faça backup de todos os registros antes de excluir registros para liberar a capacidade.
- Se a capacidade de me mória da unidade USB for insuficiente, remova a unidade USB e exclua os arquivos pelo computador / laptop para liberar a capacidade ou use outra unidade USB.
- Após o backup dos registros, você obterá os arquivos PDF, MP4 e CSV ao mesmo tempo.

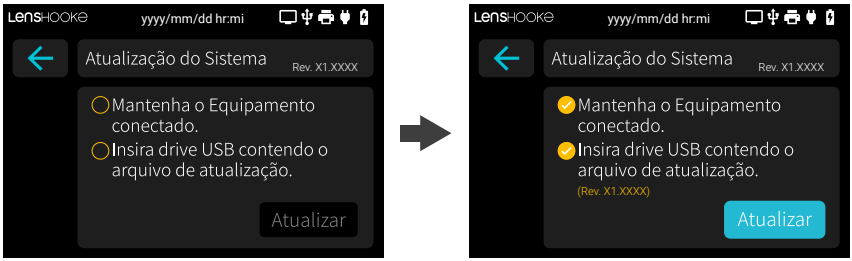
3 Atualização do Sistema

(1) Prepare a unidade USB com o software de atualização do sistema. (A capacidade do drive USB: 1GB ou mais) (Entre em contato com o seu distribuidor local para o software de atualização do sistema).

(2) Clique no ícone **"Utilidades"** e, em seguida, clique no ícone **"Atualização do sistema"**.



(3) Por favor, conecte o dispositivo ao adaptador de energia e conecte a unidade USB com o arquivo de atualização ao analisador. Selecione o ícone **"Atualizar"** para atualizar o sistema.



(4) Selecione o ícone **"Reiniciar"** para reiniciar o analisador e concluir a atualização do sistema. O sistema configurará as atualizações automaticamente e reiniciará o analisador quando a atualização do sistema for concluída.

NOTE

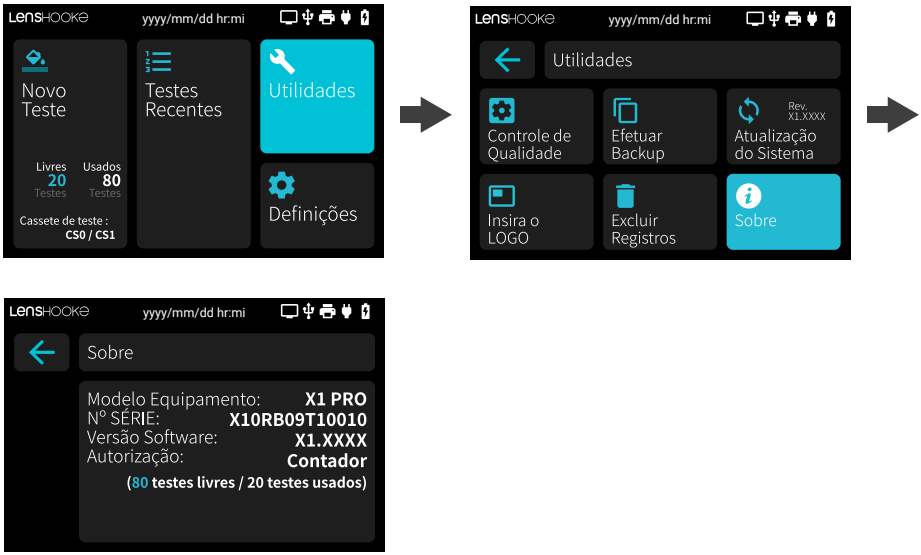
- Por favor, faça o backup de todos os registros antes de atualizar o sistema.
- NÃO desligue ou desconecte o dispositivo durante o processo de atualização. Certifique se de conectar o daptador de energia e insira a unidade USB com o arquivo de atualização do sistema ao atualizar o sistema.

NOTE

- Se a mensagem de aviso **“Atualizar arquivo estiver corrompido”** Se a mensagem de aviso **“Atualizar arquivo estiver corrompido"** for exibida na tela, isso significa que você não fez o download do arquivo completo. Faça o download do arquivo de atualização do sistema novamente para a unidade USB e refaça a atualização do sistema.
- Se a mensagem de aviso **“Falha na atualização”** Se a mensagem de aviso **"Falha na atualização”** aparecer na tela, o que significa que a unidade USB para atualização do sistema foi removida, insira a unidade USB com o arquivo de atualização do sistema novamente para refazer a atualização do sistema.

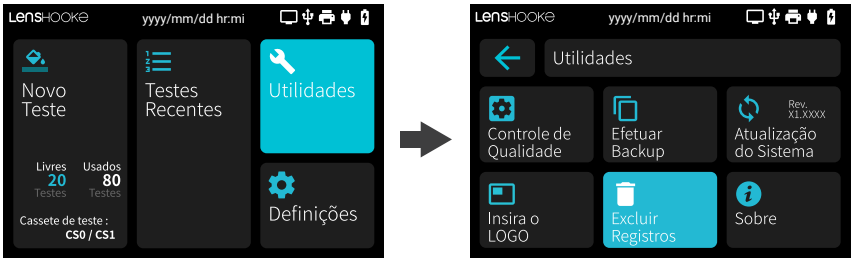
4 Sobre

Clique no ícone **“Utilidades”** e, em seguida, clique no ícone **“Sobre”** para saber sobre as informações do analisador.

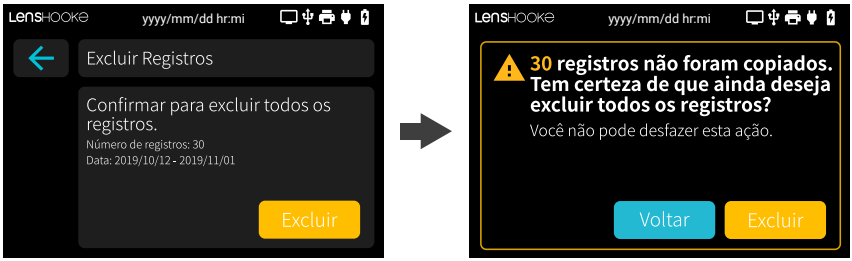


5 Excluir todos os registros

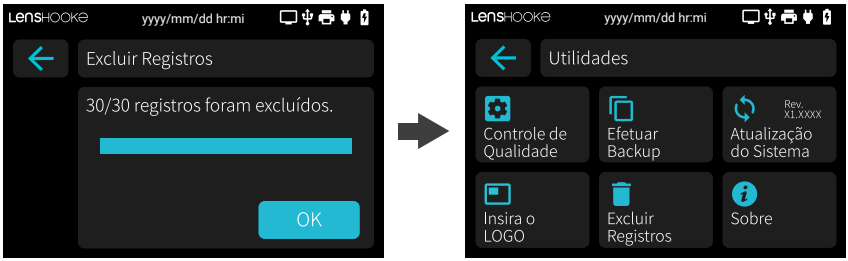
(1) Clique no ícone **“Utilidades”** e clique no ícone **“Excluir registros”**.



(2) Clique no ícone amarelo **"Excluir"** para confirmar e excluir todos os registros.



(3) Clique no ícone **"OK"** para retornar à página inicial.

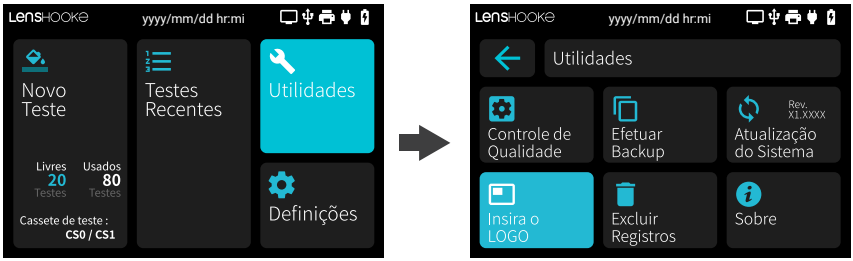


NOTE

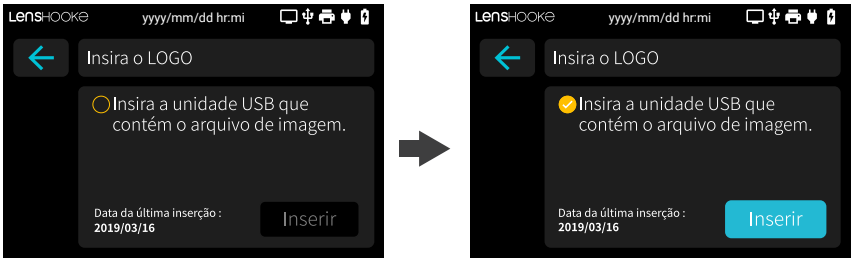
- Os registros não podem ser recuperados depois que você os excluir. Certifique se de que deseja excluí los permanentemente antes de clicar no ícone **"Excluir"**.

6 Insira o LOGO

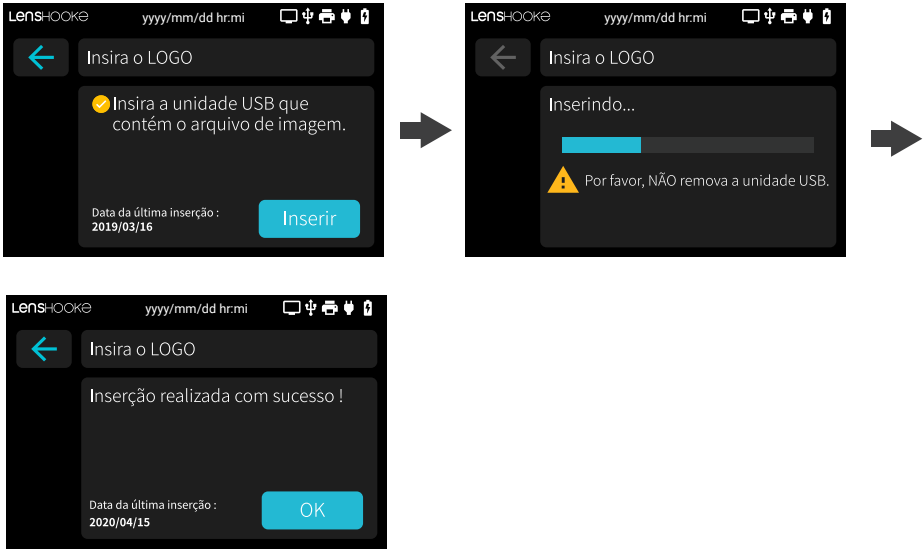
(1) Clique no ícone **"Utilidades"** e, em seguida, selecione o ícone **"Insira LOGO"**.



(2) Insira a unidade USB.



(3) Selecione o ícone **“Inserir”** e aguarde até a mensagem **“Inserir com sucesso!”** aparecer na tela.



NOTE

- A imagem do LOGO deve estar no formato PNG por 2040x168 pixels e o arquivo deve ser nomeado **“lenshooke_X1_pdf_logo.png”**.
- Apenas salve o arquivo na unidade USB diretamente. Por favor, não salve na pasta.

Definições

1 Edição OMS

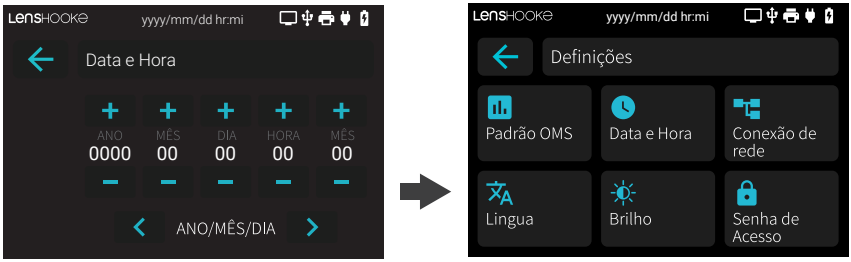
(1) Clique no ícone **“Definições”** e, em seguida, clique no ícone **“Padrão OMS”**.

2 Data e Hora

(1) Clique no ícone **“Definições”** Configurações **“Data e Hora”**.

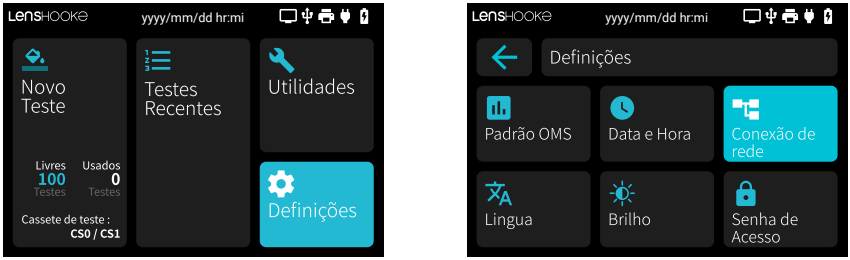
(2) Você pode selecionar o formato de data selecionando o ícone “ < ” ou “ > ”e ajustar data e hora clicando no ícone “ + ” or “ − ”.

Depois de definir a data e a hora, clique em “ ← ” para retornar à página anterior.

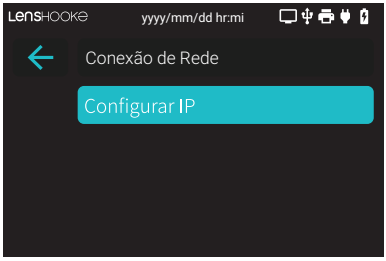


3 Conexão de Rede

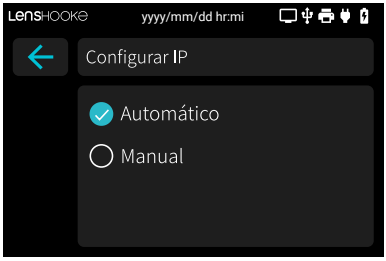
(1) Selecione **“Definições”** e depois selecione o ícone **“Conexão de rede”**.



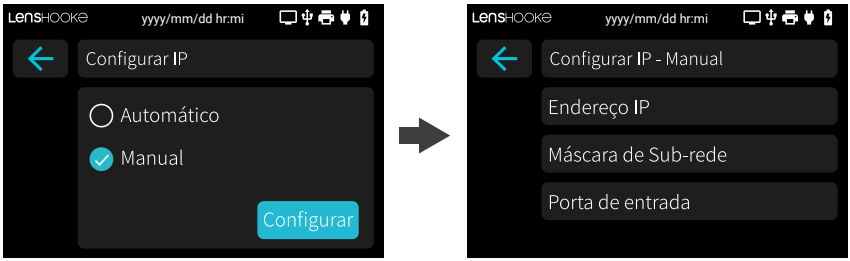
(2) Selecione **“Configurar IP”**.



(3) A configuração padrão é **"Automático"**. Quando você escolhe esse ícone, o dispositivo usa um endereço IP dinâmico, que é atribuído quando a rede está conectada e muda com o tempo.



(4) Se você deseja alterar para o endereço IP estático, selecione **"Manual"** e, em seguida, selecione **"Endereço IP"**, **"Máscara de sub-rede"**, **"Gateway"** e preencha as informações, respectivamente.



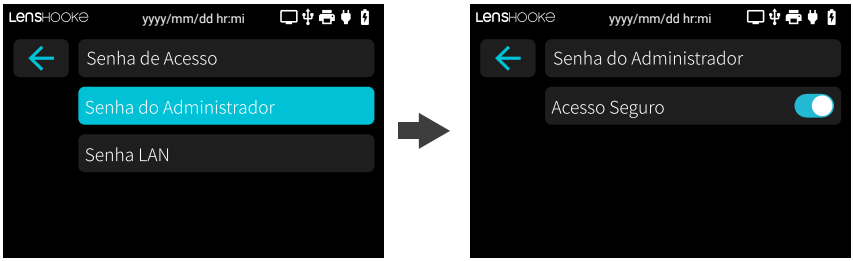
NOTE

- Se você não inserir as informações completas para endereço IP, máscara de sub-rede e gateway, o status de configuração do IP permanecerá em **"Automático"**.

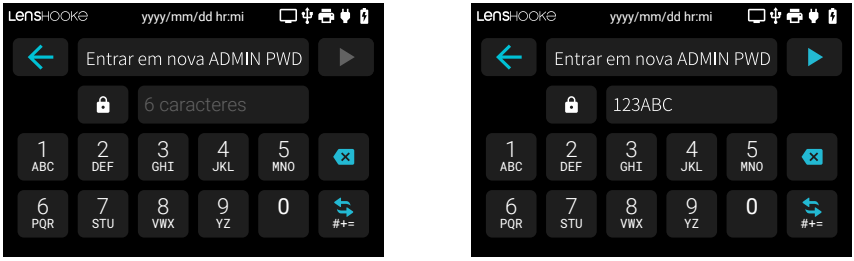
4 Senha de Acesso

(1) Clique no ícone **"Definições"** e depois clique no ícone **"Senha de Acesso"**.

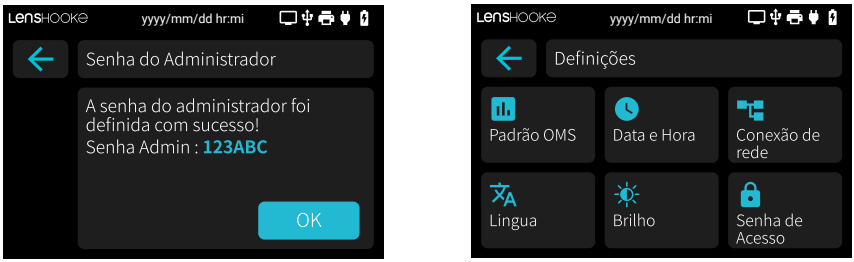
(2) Selecione o ícone **"Senha do Administrador"** senha aparecerá na tela. Ative a senha do administrador para proteger seu acesso.



(3) Coloque uma senha de 6 caracteres clique em " ▶ " para ir para a próxima etapa. Coloque a senha novamente para verificação.



(4) Após verificar a nova Senha de Administrador selecione a seta para ir para o próximo passo. Por favor selecione **"OK"** para ir para a próxima página.

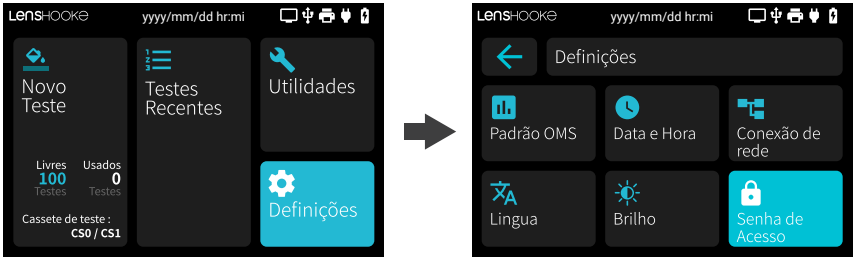


NOTE

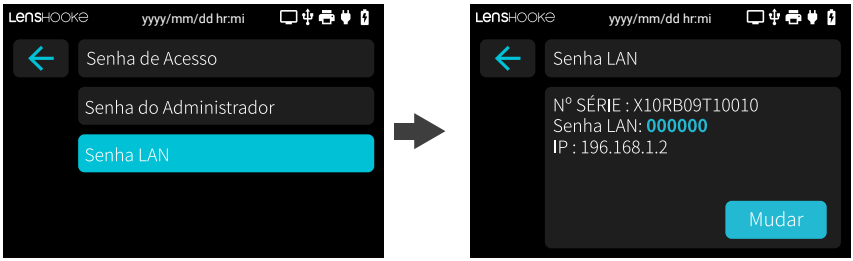
- A senha padrão do administrador é **"000000"**.
- Quando o ícone " ⬭ " for selecionado significa que seu acesso está protegido.
- Se você deseja acessar o analisador, é necessário inserir a Senha do administrador para ativar o analisador a partir do modo de economia de energia.

5 Senha LAN

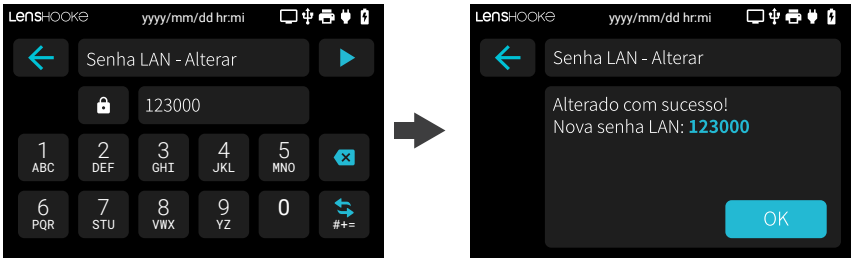
(1) Clique no ícone **"Definições"** e, em seguida, clique no ícone **"Senha de Acesso"**.



(2) Selecione **"Senha LAN"** e a senha aprecerá na tela. Se desejar trocar a senha selecione **"Mudar"**.



(3) Insira qualquer código numérico de seis dígitos para configurar a nova senha. Depois de inserir a nova senha, selecione a seta para ir para a próxima etapa. Selecione o ícone **"OK"** para retornar à página anterior.

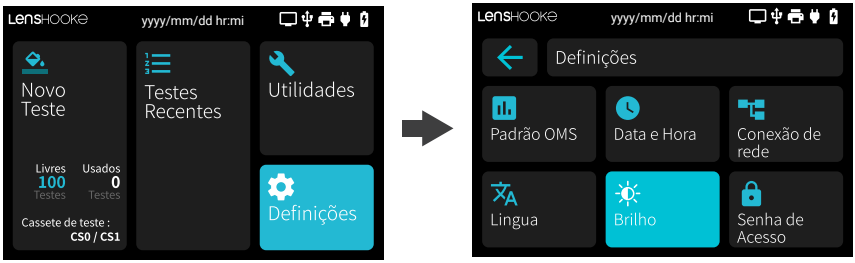


NOTE

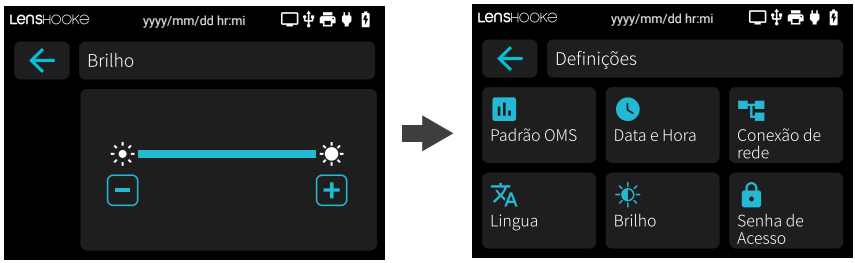
- A senha LAN padrão é **"000000"**.
- Se você deseja acessar o analisador para ler ou baixar os resultados por outros dispositivos, é necessário digitar a senha da LAN.
- Se você não inserir códigos numéricos comseis dígitos suficientes para configurar a nova senha, o " ▶ " ícone não ficará azul para permitir que você clique.
- Por favor, use USB para RJ45 Gigabit Ethernet Adapter para conectar o analisador à LAN (rede de área local) por cabo.

6 Configuração de brilho da tela

(1) Clique no ícone **“Definições”** e, em seguida, clique no ícone **“Brilho”**.



(2) Ajuste o brilho da tela clicando no ícone “ [+] ” ou “ [−] ” e, em seguida, clique no ícone “ [←] ” para retornar à página anterior.



7 Idioma

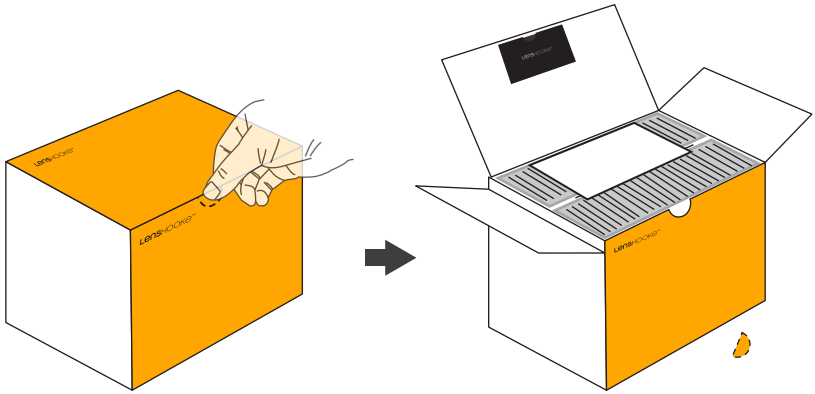
(1) Clique no ícone **“Definições”** e clique no ícone **“Língua”**.

VI . Acessórios

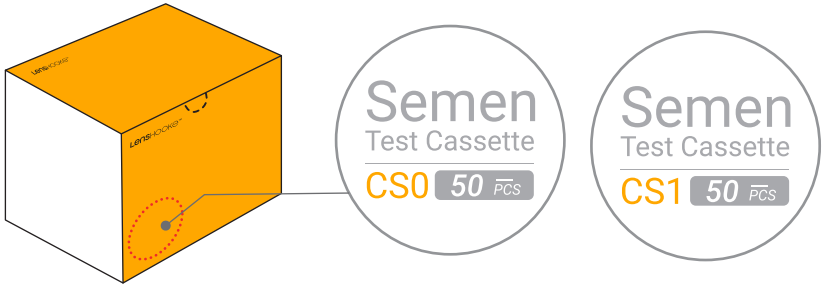
Dongle de licença

1 Para recarregar a licença

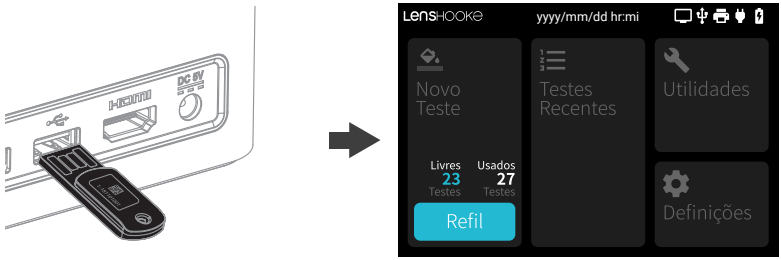
(1) Quando você abrir a caixa de LensHooke® CS0 Semen Test Cassette, você encontrará o dongle de licença na parte superior da caixa.



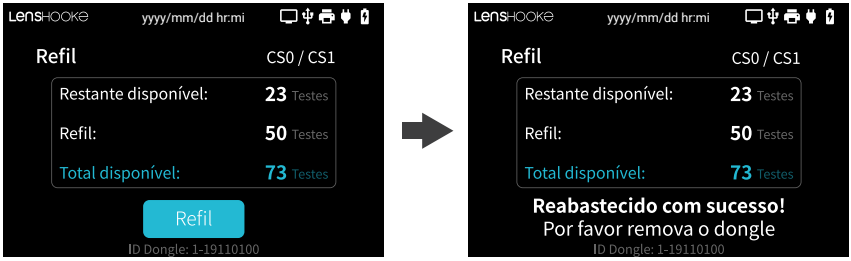
(2) Verifique se o tipo de cassete de teste está correto antes de inserir o dongle para recarregar a licença.



(3) Insira este dongle de licença na porta USB do analisador.

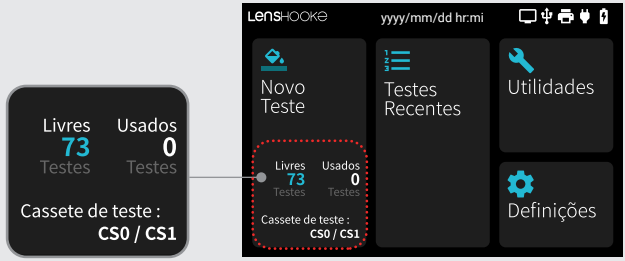


(4) Selecione o ícone **“Recarregar”** para recarregar as licenças. Verifique se as informações de recarga estão corretas e selecione o ícone **“Refil”**. Se você recarregar com êxito, remova o dongle da licença.



NOTE

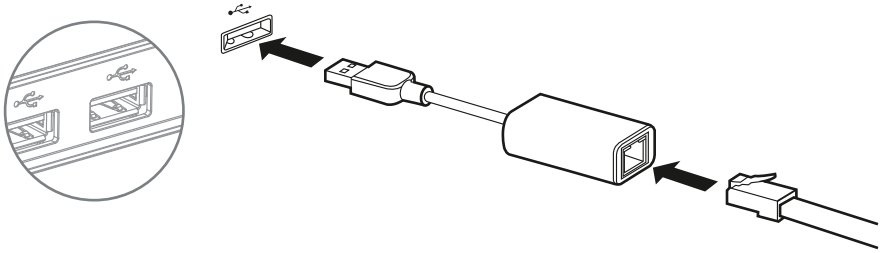
- Se o dongle da licença não for oferecido pela BONRAYBIO Co., LTD., O ícone **“Refil”** não aparecerá na tela.
- Uma vez que o dongle de licença tenha sido recarregado no analisador, ele não pode ser reabastecido novamente. Se você inserir este dongle novamente, a mensagem de erro do dongle aparecerá na tela.
- Por favor, insira o dongle para reabastecer a licença imediatamente quando v ocê desembalar a caixa do LensHooke® Semen Test Cassette
- Quando você insere um novo dongle para reabastecer a licença, o cálculo de **“Usados”** retornará a zero e o cálculo de **“Livres”** será adicionado pela licença do dongle ao restante disponível.



Adaptador Ethernet USB para RJ45 Gigabit

1 Analisador: Conecte à rede local (rede local)

(1) Por favor, use USB para RJ45 Adaptador Gigabit Ethernet para conectar o analisador à LAN (rede local) por cabo.



2 Outro dispositivo: acesso ao analisador

(1) Por favor, abra o navegador do seu computador / laptop e digite o IP. (Você pode verificar essas informações no analisador clicando no ícone Configurações & Senha da LAN.)

(2) Por favor entre com a senha da LAN. (Você pode verificar essas informações no analisador clicando no ícone Configurações & Senha da LAN.)

(3) Você pode visualizar arquivos PDF ou MP4.

(4) Você pode baixar arquivos PDF, MP4 e CSV.

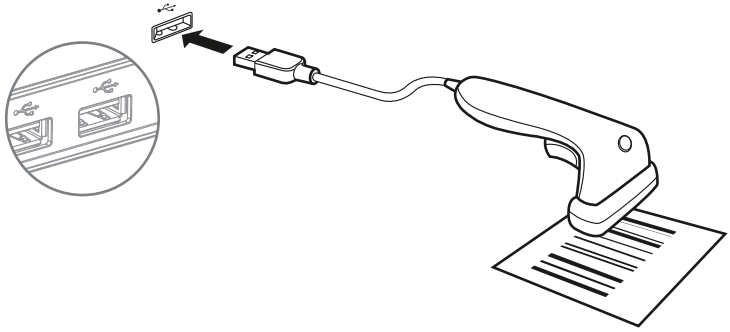
NOTE

- Se houver muitas pessoas acessando o mesmo analisador ao mesmo tempo, isso pode afetar o desempenho do analisador.
- Por favor, use um dos seguintes navegadores para acessar a página de login.
  -Firefox (versão: 62 ou mais), Chrome (versão: 69 ou mais), Microsoft Edge para Windows 10 e Safari ... etc.
- Suporta apenas iPad, PC ou laptop.
- É recomendável manter a energia conectada enquanto estiver conectado à LAN.

Barcode Scanner

1 Para conectar o Scanner de Código de Barras ao Analisador

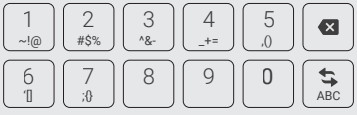
(1) Por favor, conecte o scanner de código de barras com o analisador por porta USB.



(2) O scanner de código de barras insere a identificação do paciente ou o LOTE do LensHooke® X QC Beads (For Semen) e LensHooke® X QC Reticle (For Semen) para o teste.

NOTE

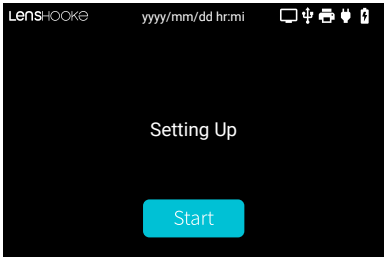
- O analisador só poder á se conectar com o scanner de código de barras por porta USB.
- O analisador só poderá ler as seguintes letras, números e símbolos.



VII. Iniciando

Configurar o analisador:

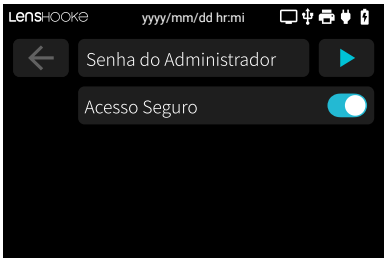
(1) Selecione **“Iniciar”** e depois selecione sua preferência de idioma.



(2) Configure a data e hora. Por favor, selecione “ [<] ” ou “ [>] ” para ajustar o formato da data e use o ícone “ [+] ” ou “ [−] ” para ajustar os valores.

(3) Selecione a edição da OMS. Selecione “ [▶] ” para prosseguir para a seleção da edição da OMS.

(4) Acesso seguro. Se você deseja proteger o acesso ao analisador, por favor deslize o ícone para deixá-lo azul e insira seis caracteres como sua nova senha de administrador.



Por favor, carregue a bateria do analisador por 3 horas antes de começar a usá-lo na primeira vez.

VIII. Limpeza e Manutenção

1 Suggestion for Cleaning Routine

(1) O slot de inserção do cassete de teste só pode ser limpo com a **“LensHooke® Cleaning Wipe”.**

(2) NÃO use outros materiais para limpar o slot de inserção do cassete de teste.

(3) LensHooke® Cleaning Wipe é descartável. NÃO reutilize.

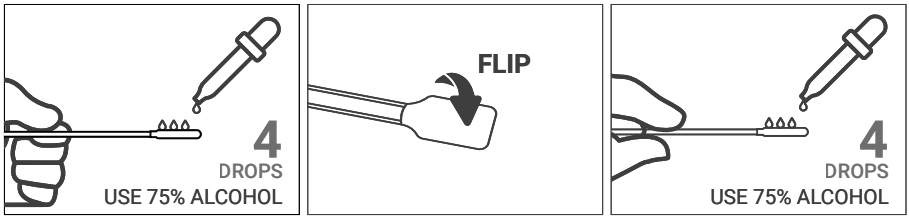
(4) Mantenha o LensHooke® X1 PRO Semen Quality Analyzer longe de poeira, água ou líquidos e ambiente extremo (que está além do ambiente de operação ou armazenamento indicado na especificação).

(5) Limpe o corpo do LensHooke® X1 PRO Semen Quality Analyzer todos os dias quando terminar os testes.

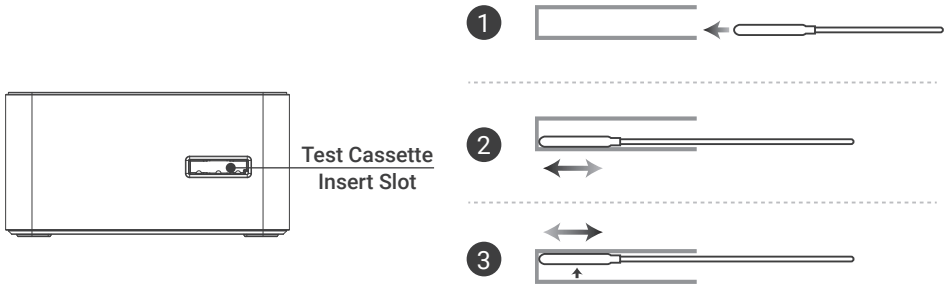
2 Etapas para limpeza

I. Encaixe da inserção do cassete de teste:.

(1) Desligue o analisador antes de limpar.
(2) Prepare 2 peças da LensHooke® Cleaning Wipe.
(3) Por favor, derrube 4 gotas de álcool a 75% em cada lado da LensHooke® Cleaning Wipe.



(4) Por favor, insira esta LensHooke® Cleaning Wipe no slot de inserção do cassete de teste e siga as instruções para limpar.



(5) Por favor, use outra LensHooke® Cleaning Wipe seco (sem álcool ou qualquer líquido) para limpar novamente o slot de inserção.
(6) Jogue fora a pá de limpeza usada.

(Para o mercado dos EUA, por favor, use **CaviWipes** para desinfetar o slot de inserção antes de começar a usar o LensHooke® cleaning wipe para limpar.)

II. Corpo do Analisador:

(1) Use o cotonete com álcool para limpar o corpo do analisador.
(2) Jogue fora o cotonete usado com álcool.
(3) Jogue fora o algodão com álcool usado.

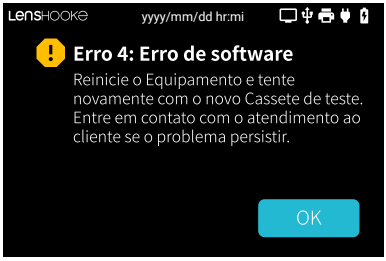
III. Adaptador de energia:

(1) Por favor, use o sabão sem álcool para molhar o pano.
(2) Torça o pano e limpe cuidadosamente o adaptador de energia.
(3) Limpe a área novamente com um pano embebido em água limpa.

NOTE

- Use a LensHooke® Cleaning Wipe para limpar o LensHooke® X1 PRO Semen Quality Analyzer.

IX. Mensagens de Erro

Mensagens de erro	Solução
	Erro 1: **O teste automático falhou. Pode ser uma falha de inicialização.** Por favor entre em contato com o serviço ao consumidor.
	Erro 2: **Dispositivo falhou. Pode ser um problema de analisador.** Por favor, remova o cassete de teste e clique no ícone **"OK"** para retornar à página inicial e desligue o analisador. (Consulte **"Ligar / Desligar"** na página 7 para o status de operação normal.) Se esta mensagem ainda aparecer, entre em contato com o nosso serviço de atendimento ao cliente.
	Erro 3: **Câmera falhou. Pode ser um problema de câmera.** Por favor, remova o cassete de teste e clique no ícone **"OK"** para retornar à página inicial. Por favor, insira outra nova cassete de teste para refazer a ação. Se esta mensagem ainda aparecer, entre em contato com o nosso serviço ao cliente. ***Certifique-se de estar usando o LensHooke® Semen Test Cassette correto.
	**Erro 4:** **Erro de Software. Pode ser um problema de software.** Por favor, remova o cassete de teste e clique no ícone **"OK"** para retornar à página inicial e desligue o analisador. (Consulte **"Ligar / Desligar"**na página 7 para o status de operação normal.)

X. Especificação do Analisador

Nome do Analisador
LensHooke® X1 PRO Semen Quality Analyzer

Painel de controle
Tela sensível ao toque de 3,5 polegadas

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

Durabilidade da bateria
2500 mA (bateria de polímero de lítio recarregável incorporada, DC3.7V / 2.5Ah)

Capacidade de armazenamento interno
30 registros, incluindo dados e imagens

Tempo de detecção
2~5 minutos (depende da condição da amostra)

Adaptador de energia:
Entrada: 100~240 Vac, 50~60 Hz,0.5 A
Saida: 5 Vdc, 2 A Max

Ambiente de operação
Temperatura 15°C~38°C (59°F~100°F)
Umidade <70%

Ambiente de armazenamento
Temperatura 15°C~38°C (59°F~100°F)
Umidade <70%

Ambiente de transporte
Temperatura -10°C~60°C (14°F~140°F)

Faixa de Medidas
pH 6.0~8.0 (cada escala de escala:0.2)
Concentração <0.1-300 (10^6/ml)
Motilidade Total<1-100%
Morfologia (formas normais) <1-100%

XI. Referência

Referência do Parâmetro do Manual de Laboratório da OMS para o Exame e Processamento de Sêmen Humano.

Referência	WHO 5th Referência (valores baixos)	WHO 4th Referência (valores baixos)
Concentração	15 x 10^6 (12-16)/ ml	≧ 20 x 10^6 / ml
Motilidade	40% (38-42%)	a + b ≧ 50% or a ≧ 25%
PR (motilidade progressiva)	32% (31-34%)	
Morfologia (Normal)	4% (3-4%)	≧ 15%

a：Motilidade Progressiva Rápida (≧25μm/s)
b：Motilidade Progressiva Lenta ou Lenta

XII. Declaração

Todo o conteúdo relevante do manual do usuário relacionado a este produto não pode ser reproduzido, distribuído, duplicado ou armazenado em qualquer sistema de recuperação sem permissão por escrito da Bonraybio Co., LTD. A Bonraybio se reserva todos os direitos para alterar a descrição das especificações técnicas do hardware e software neste manual a qualquer momento, sem aviso prévio. Vamos tentar o nosso melhor para garantir o conteúdo. Se houver algum erro ou informações pouco claras, entre em contato com seu distribuidor local. Agradecemos muito qualquer feedback para este manual.

XIII. Avisos e Precauções

1. Categoria de Sobretensão: Nível II
2. Grau de Poluição: Nível 2
3. Altitude: <2000 metros
4. Umidade relativa (% UR): <70%
5. Uso Interno
6. O código IP é IP21 está protegido contra a inserção de dedos e não será danificado ou tornar-se inseguro durante um teste especificado em que é exposto a água pingando verticalmente.
7. Evite o estrangulamento resultante do entrelaçamento do bebê ou da criança nos cabos de monitoramento.
8. Evite asfixia resultante de uma criança engolir uma pequena parte.
9. O resultado do teste é seguido pelo Manual de Laboratório da OMS para o Exame e Processamento de Sêmen Humano. Por favor, consulte o manual do usuário de LensHooke® Semen Test Cassette.

NOTE

- LensHooke® X1 PRO Semen Quality Analyzer, LensHooke® Semen Test Cassette, C-KUP™ Liquefaction Test Cup, LensHooke® X QC Beads (For Semen), LensHooke® X QC Reticle (For Semen) e LensHooke® X QC Video (For Semen).

  Produto de acordo com a Diretiva de Dispositivos Médicos de Diagnóstico In Vitro 98/79 / EC. (CE)
- Compatibilidade eletromagnética, emissão e imunidade, e os requisitos da IEC 61326-2-6 aplicam se.

Fabricante:
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XIV. Garantia

A Bonraybio oferece uma garantia de um ano a partir do dia em que você adquirir o LensHooke® X1 PRO Semen Quality Analyzer. Durante o período de garantia, iremos reparar ou substituir o analisador gratuitamente.

A garantia aplica-se apenas ao original LensHooke® X1 PRO Semen Quality Analyzer da Bonraybio. A garantia será anulada se o analisador for modificado ou usado indevidamente.

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