Semen Quality Analyzer

User Manual

X1 PRO
Please read this user manual carefully first to ensure proper use of the product. This user manual is also available at www.LENSHOOKE.com.

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

- Symbol for “NOTICE”
- Symbol for “CAUTION”
- Symbol for “PAGE NUMBER”
- Symbol for “DO NOT REUSE”
- Symbol for “USE BY”
- Symbol for “BATCH CODE”
- Symbol for “SERIAL NUMBER”
- Symbol for “DATE OF MANUFACTURE”
- Symbol for “MANUFACTURER”
- Symbol for “AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”
- Symbol for “IN VITRO DIAGNOSTIC DEVICE”
- Symbol for “TEMPERATURE LIMITATION”
- Symbol for “CONSULT INSTRUCTIONS FOR USE”
- Symbol for “WEEE WASTE RECYCLING”
- CE mark (with the assigned certification body’s number)
- Symbol for “FOLLOW INSTRUCTIONS FOR USE”

The package includes
- Semen Quality Analyzer
- Power Adaptor (for analyzer)
- User Manual
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I. Introduction

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

If you have any questions about the product or require any assistance, please feel free to contact Bonraybio by calling the Customer Service hotline (+886-4-2491-2385) or contact your local distributor.

II. Intended use

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

1. Sperm concentration (10^6 per ml)
2. Total motility (PR+NP, %)
   • Progressive motility (%)
   • Non-Progressive motility (%)
   • Immotility (%)
   • Other parameters from CASA assessment (ex: VSL, VAP, STR, ALH.... etc.)
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 Key |
| 4 | Reset Key |
| 5 | USB Port |
| 6 | USB Port |
| 7 | HDMI Port |
| 8 | Power Adaptor Port |

NOTE

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

Accessories

- **Power Adaptor**
  - AC Plug 1
  - Power Adaptor Plug 2
- **LensHooke™ Semen Test Cassette**

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

※Sold separately
The icons below are functionable

1. **HDMI connection icon**: This analyzer is connected to a monitor by an HDMI port.
2. **USB connection icon**: This analyzer is connected to USB storage by a USB port.
3. **Thermal Printer connection icon**: This analyzer is connected to a Thermal Printer.
4. **Power Adapter connection icon**: This analyzer is connected to a power adapter to charge the battery.
5. **Battery icon**: It shows the battery capacity.

6. **Utilities icon**: It includes the functions of:
   - Backup All Records to USB: To backup the data for all results
   - Quality Control: To check the quality of the analyzer/device
   - Delete All Records: To remove/delete all results
   - System Update: To update the system

7. **Settings icon**: It includes the functions:
   - WHO Standard: To select the WHO edition of 4th or 5th
   - Date & Time: To set up the date and time
   - Language: To select the language preference
   - Brightness: To adjust the brightness of the screen

8. **Recent tests icon**: To review the previous test results
9. **New test icon**: To start testing
IV. Consumables
The consumables for LensHooke™ X1 PRO is as below:

- C-KUP™ Liquefaction Test Cup
- LensHooke™ Semen Test Cassette
- LensHooke™ Cleaning Wipe

! IMPORTANT
The result will be Inaccurate, if you do not use a LensHooke™ Semen Test Cassette.

NOTE
- C-KUP™ Liquefaction Test Cup is for semen sample collection.
- LensHooke™ Semen Test Cassette is used to hold semen sample for analysis with the analyzer.
- LensHooke™ Cleaning Wipe is used to clean the test cassette insert slot.

V. Major Function
LensHooke™ X1 PRO Semen Quality Analyzer

Turn on / off

1 Turn the analyzer on:
Push the power key for around 2 seconds to turn on the analyzer (as Image 1).
When the touch screen lights up (as Image 2), the analyzer is ready to operate.

2 Turn the analyzer off:
Hold the power key for around 10 seconds until the touch screen shows Power off and tap the icon to turn off the analyzer.
Insert / Remove the Test Cassette

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

2 Remove the Test Cassette:
After the test, remove the test cassette in the opposite direction of the “arrow”.

Charging the battery

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

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

- **Power saving mode:**
  To turn off the screen, press the power button quickly. To wake up the analyzer, press the power button again quickly.
  If there is no operation for 10 minutes, the system will automatically turn off the touch screen to reduce battery power consumption.
- For the purpose to extend the build-in Lithium-ion polymer battery’s life time, please keep charging the battery by using the adaptor even you don’t use the analyzer.
- If the analyzer is not operated over 3 months, please use the power charger before using.
- The date and time of the analyzer might be back to the default setting, if it ran out of battery. Please check and set up the date & time properly (refer to Page 12).

**Backup, Quality Control, Delete All Records and System Update functions**

1 **Backup the records**
   (1) Prepare a USB stick in advance.
   (2) Click the icon of **“Utilities”** and then click the icon of **“Backup All Records to USB”**.

   ![Backup screen 1](image1)
   ![Backup screen 2](image2)

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

   ![Backup screen 3](image3)
   ![Backup screen 4](image4)

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

   ![Backup screen 5](image5)
   ![Backup screen 6](image6)
2 Quality Control

(1) Click the icon "Utilities" and then click the icon "Quality Control".

(2) Prepare a semen test cassette.

   **Step 1.** Take out a new semen test cassette from the package.

   **NOTE**
   - DO NOT use expired test cassettes for testing.

   **Step 2.** Insert this new test cassette (without sample) into the “Insert Slot” until you hear the “Click” sound.
Step 3. Click the icon “Test” to begin testing.

If the result is "FAIL".

Please use another new test cassette (without sample) to redo the Quality Control again.

Please move out the previous test cassette before you insert this new one.

The system will disable the “New Test” function if the QC Test has failed 3 times.

NOTE

• Please redo the Quality Control again, if the result is "FAIL"
• Please use another new test cassette (without sample) to redo the Quality Control again. Please move out the previous test cassette before you insert this new one.
• The system will disable the “New Test” function if the QC Test has failed 3 times.
3 Delete the records

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

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

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

NOTE

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

(1) Prepare the USB stick with system update software. (Please contact with your local distributor for the system update software).

(2) Click the icon “Utilities” then click the icon “System Update”, and then insert the “USB stick with system update software”.

(3) Click the icon “Restart” to restart the analyzer.

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

Warning: Do not turn off your device during the update process.
**NOTE**

- Make sure to plug in the power adaptor when updating the system. DO NOT remove the plug during the update process.
- If you have not plugged in the power adaptor, the screen will show the message (as below) to remind you after you insert the “USB stick with system update software”. When you plug in the power adaptor, the icon of “Update” will turn BLUE to proceed to the next step.

---

**WHO Edition, Date & Time, Language & Brightness Setting Function.**

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

   ![WHO Edition Setting Diagram](image)

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

   ![Edition Selection Diagram](image)
2 Date & Time Setting

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

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

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

3 Language Setting

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

(2) Select your language preference and then click the icon of “<” to return to the previous page.
4 Screen Brightness Setting

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

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

Recent Test Function

1 Recent Tests

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

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

Prepare the Test Analyzer

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

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

Testing

1. Semen sample collection
   Refer to the C-KUP™ Liquefaction Test Cup user manual for details.

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

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

2. Check the color, volume, and liquefaction status for the semen sample.
   Step 1. Put the C-KUP™ Liquefaction Test Cup (with the semen) on the desk and wait 30 minutes for liquefaction.
   Step 2. Check the semen sample color and volume (using the scale of the C-KUP™ Liquefaction Test Cup).
   Step 3. Turn the C-KUP™ Liquefaction Test Cup upside down 8~10 times gently to mix the sample and check the liquefaction's status from the patented V-STICK.
Semen analysis should begin with a simple inspection soon after liquefaction, preferably at 30 minutes, but no longer than 1 hour after ejaculation, to prevent dehydration or changes in temperature from affecting semen quality, please refer to "WHO laboratory manual for the Examination and processing of human semen" for more detail.

If the sample has not liquefied, please wait an additional 30 minutes and check the liquefaction status again. If it still has not liquefied, DO NOT use the sample to do the test. (It will affect the test result.) According to the treatment for "Delayed liquefaction", please refer to "WHO laboratory manual for the Examination and processing of human semen" for more detail.

If the sample has liquefied, please use this sample to do the test immediately. Please remix the sample again to ensure all the sample has been mixed perfectly before the testing. Improperly mixed samples may lead to inaccurate results.

Follow the standard medical waste procedure to dispose of the remaining sample and used cassette and cup. Wear gloves or personal protection equipment at all times when disposing of the sample and used cassette and cup.

3 Open the cassette and drop the sample

**Step 1.** Remove one semen test cassette from the package.

**Step 2.** Open a test cassette cover by using your thumb. After that please place the opened test cassette on a flat and stable surface.

**Step 3.** Open the drip cover of the C-KUP™ Liquefaction Test Cup.

Please open the cover from △ area.

**NOTE**

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

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

**Completed liquefaction:** the sample drop is in small discrete drops. (Please refer to the images at right hand side for the difference.)
Step 4. Squeeze the body of the cup to release a drop of the sample on the 1st drip area of the cassette to test the pH value.

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

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

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

**NOTE**
- Insert the cassette into the analyzer within 30 seconds after adding the sample.

4 The test cassette is now ready for testing.  
Step 1. Click the icon “New Test”.

**NOTE**
- DO NOT use over 15 characters and symbols for the patient ID#.
- If you want to enter a character, please press the icon for 0.5 to 1 second and select the letter. If you want to enter a symbol, please click the icon " " to switch the keyboard.
Step 3. Please click the Liquefaction Time, Semen Colour, Semen Volume and click “Next” to go to the next step.

Step 4. Insert the cassette (with sample) into the “Insert Slot” until you hear the “Click” sound.

Step 5. After 2~5 minutes, the results will appear on the screen automatically.

NOTE
- The next step is semen test cassette guide. Please click "Skip" if you are familiar with the semen test cassette operation.
VII. Analyzer Cleaning and Maintenance

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

2 Steps for Cleaning
I. Test Cassette Insert Slot:
(1) Turn off the analyzer before cleaning.
(2) Prepare 2 pcs of LensHooke™ Cleaning Wipe.
(3) Please drop 4 drops of the 75% alcohol for each 2 sides of a LensHooke™ cleaning wipe.
(4) Please insert this LensHooke™ Cleaning Wipe into the test cassette insert slot, and follow the instruction to clean.
(5) Please use another new dry LensHooke™ Cleaning Wipe (without alcohol or any liquid) to clean the insert slot again.

(6) Throw away the used cleaning wipe.

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

II. Analyzer Body:

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

(2) Throw away the used alcohol swab.

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

**NOTE**

- Use LensHooke™ cleaning wipe to clean the LensHooke™ X1 PRO Semen Quality Analyzer.

Cleaning and Disinfection Procedure (For USA, CANADA)

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

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

**To clean the analyzer:**

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

**To disinfect the analyzer:**

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

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

(4) Allow to air dry.

**NOTE**

- Your LensHooke™ X1 PRO Semen Quality Analyzer 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).
VIII. Error Messages

Error Messages

<table>
<thead>
<tr>
<th>Error 1:</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self test Failed</td>
<td>Self test failed. It might be a start up failure. Please contact our customer service.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 2:</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Failed</td>
<td>Device failed. It might be an analyzer problem. Please remove the test cassette and click the icon &quot;OK&quot; to return to home page then turn the analyzer off. (Refer to &quot;Turn on/off&quot; on Page 4 for normal operation status.) Please turn the analyzer on and insert another new test cassette redo the action. If this message still appears, contact our customer service.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 3:</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera Failed</td>
<td>Camera failed. It might be a camera problem. Please remove the test cassette and click the icon &quot;OK&quot; 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 4:</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Move Failed</td>
<td>Move failed. You might have moved the analyzer or test cassette during the test. Please remove the test cassette and click the icon &quot;OK&quot; to return to home page. Ensure the analyzer is on a flat and stable surface and insert another new test cassette redo the action. If this message still appears, contact our customer service.</td>
</tr>
</tbody>
</table>
Error Messages

Error 5:
Connector failed. It means the capacity of the USB stick is not sufficient. Please move out this USB stick and delete the files by computer/laptop to release the capacity or use another USB stick.

Click the icon “OK” to return to the home page, and redo the action. If the message still appears, contact our customer service.

Error 6:
Low Space.
The memory capacity may not be sufficient.

Click the icon “OK” to return to the home page, and remove any excess records. (Refer to Page 9) If the message still appears, contact our customer service.

*Make sure that you have already backed up the records before you remove them.

Error 7:
Software error. You may not have downloaded the system update files completely.

Download the system update files again. Click the icon “OK” to return to the home page to redo the system update action. (Refer to Page 10)

Error 8:
Environmental Error. The analyzer may detect that it is in an unsuitable environment.

Ensure the analyzer is on a flat and stable surface and wait for 10 minutes.
Remove the test cassette and insert another new test cassette redo the action.
IX. Analyzer Specification

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

Internal storage capacity
30 records including data and images

Detection time
2~5 minutes (depends on the sample condition)

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

Operation environment
Temperature 15°~38°C (59°~100°F)
Humidity <70%

Storage environment
Temperature 15°~38°C (59°~100°F)
Humidity <70%

Transportation environment
Temperature -10°~60°C (14°~140°F)

X. 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.

XI. Warnings and Precautions

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

**NOTE**

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

**Manufacture:**
Bonraybio Co., LTD.
4F., No. 118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280,
Taiwan (R.O.C.)
Product complied with In Vitro Diagnostic Medical Device Directive 98/79/EC. (CE)

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

**XII. 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.

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