Semen Quality Analyzer

User Manual

X1 PRO
Symbols

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

Symbol for “NOTICE”

Symbol for “CAUTION”

Symbol for “PAGE NUMBER”

Symbol for “DO NOT REUSE”

Symbol for “USE BY”

Symbol for “BATCH CODE”

Symbol for “SERIAL NUMBER”

Symbol for “DATE OF MANUFACTURE”

Symbol for “MANUFACTURER”

Symbol for “AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”

Symbol for “IN VITRO DIAGNOSTIC DEVICE”

Symbol for “TEMPERATURE LIMITATION”

Symbol for “CONSULT INSTRUCTIONS FOR USE”

Symbol for “WEEE WASTE RECYCLING”

CE mark

Symbol for “FOLLOW INSTRUCTIONS FOR USE”

The package includes

- LensHooke™ X1 PRO 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 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.

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 measurements for:

(1) **Sperm concentration** (10⁶ 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**
  
  AC Plug [1]  
  2. Power Adaptor Plug

- **LensHooke™ Semen Test Cassette**

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

*Sold separately*
**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.

7 **Settings icon:** Functions include:
- WHO Standard: To select WHO edition of 4th or 5th.
- Date & Time: To set up the Date and Time.
- Language: To select the language preference.
- LAN Password: To get or change the LAN Password to access the analyzer/device through network.
- Brightness: To adjust the brightness of the screen.

8 **Recent Tests icon:** To review the previous test results.

9 **New Test icon:** To start testing.
IV. Consumables
The consumables for LensHooke™ X1 PRO Semen Quality Analyzer are as below:

- C-KUP™ Liquefaction Test Cup
- LensHooke™ Semen Test Cassette
- LensHooke™ Cleaning Wipe
- LensHooke™ X QC Beads (For Semen)

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

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

V. Major Function

LensHooke™X1 PRO Semen Quality Analyzer

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

2 Remove the Test Cassette:
After the test, remove the test cassette in the by the image as below.

- Make sure that 1st and 2nd windows are all into the analyzer
- Make sure to hear a “Click” sound after 2 windows are all into the analyzer.

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.

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

* Power Saving Mode: Turns off the touch screen to reduce battery consumption.

1. Refer to the C-KUP™ Liquefaction Test Cup user manual for details.
2. Refer to the LensHooke™ Semen Test Cassette user manual for details, but also following the Semen sample collection indication on the screen.

Test the Sample

1 New Test

Step 1. Select the “New Test” icon.

Step 2. Please input the patient ID number and select the “go to next” 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 0.5 to 1 seconds and select the letter. If you want to input a symbol, please select the "aley" icon to switch the keyboard.
- You can also use a barcode scanner to scan the bar or OR code of patient ID#. (Please refer to page 24 to connect the barcode scanner to the analyzer.)
- Please refer to Page 20 in this user manual for refill, if it is the first time you use.

Step 3. Please select the Liquefaction Time, Semen Colour, Semen Volume after semen sample is completely liquefied, and then select “Next” to go to the next step. Select the “OK” icon if the information you inputed is correct.

NOTE

- Refer to the LensHook™ Semen Test Cassette user manual for details, and following the indication on the screen to do New Test. If you are familiar with the LensHooke™ Semen Test Cassette operation, please select “Skip” to do the next step.
- Please select - and + to adjust the semen volume.
**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.

![Image](image1.png)

(2) The record will appear on the screen. If you want to print out this record, please connect the printer cable into the analyzer, and select the “Print” icon. If not, select the “Close” icon to return to the previous page.

![Image](image2.png)

**NOTE**

- ONLY the icon that turn white can be selected.
- If you want to print the result by Thermal Receipt Printer, please contact your distributor to order one.
- You can also connect the analyzer to the LAN to print the result. (Please refer to page 22 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.
- 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.

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>111-00-0000</td>
<td>2019/3/16 4:23 PM</td>
</tr>
<tr>
<td>123-00-0000</td>
<td>2019/3/15 5:12 PM</td>
</tr>
<tr>
<td>123-00-1111</td>
<td>2019/3/15 1:02 PM</td>
</tr>
<tr>
<td>18062825081</td>
<td>2019/3/16 10:59 AM</td>
</tr>
</tbody>
</table>

![Image](image3.png)

**Warning:** Please DO NOT move the cassette or analyzer.
The “Quality Control”, “Backup All Records”, “System Update”, “About” and “Delete All Records” functions.

1 Quality Control

(1) Select “Utilities” and then select the “Quality Control” icon.

(2) Please input the LOT number on the label of the X QC Beads, and select “ ” to go to the next step. Please confirm the LOT number, and if it matches, please select the “Proceed” icon to go to the next step.

(3) Please check the X QC Beads information of the screen. If this information matches the label on the X QC Beads, select “OK” to go to the next step.
(4) Open a new test cassette and place it on a flat surface. Invert the bottle for 8-10 times until there is no white precipitate at the bottom. Please do it gently to avoid the bubbles.

Upside Down 8~10 times

NOTE
- Please refer to the LensHook™ Semen Test Cassette user manual for the operation is related with test cassette.
- Please open a new test cassette and place it on a flat surface when applying the X QC Beads.
- The test cassette is single-use only. DO NOT reuse it.
- DO NOT touch the window and drip area of the test cassette.
- Insert the cassette into analyzer within 30 seconds of applying X QC Beads.

(5) Open the screw cap of bottle.

(6) Please place a new dropper into the bottle of X QC Beads and repeat pipetting for 3-5 times, and then squeeze the dropper to apply a drop of the X QC Beads on the drip area of the test cassette.

(7) Close test cassette tightly until you hear a “Click” sound, and then insert the cassette (with X QC Beads) into the “Insert Slot” until you hear a “Click” sound to start the test. After 2-5 minutes the result will appear on the screen automatically.

NOTE
- Please refer to the LensHook™ Semen Test Cassette user manual for the operation is related with test cassette.
- Please open a new test cassette and place it on a flat surface when applying the X QC Beads.
- The test cassette is single-use only. DO NOT reuse it.
- DO NOT touch the window and drip area of the test cassette.
- Insert the cassette into analyzer within 30 seconds of applying X QC Beads.
(8) Please check the test result with the information of the label.

Once you have opened the LensHooke™ X QC Beads (For Semen), please keep it in the refrigerator at 2-8 °C (36-46 °F) (DO NOT freeze). Please write down the discard date on the label to remind you of expiry date. DO NOT use after expired. (Shelf-life: 2 years, Opened vial: 90 days)

If you want to redo the Quality Control test, please make sure to use a new dropper, a new test cassette and new drop of X QC Beads.

Please make sure to mix the LensHooke™ X QC Beads (For Semen) every time when you want to get a drop of the beads.

Please gently mix the LensHooke™ X QC Beads (For Semen) well. If there are too much bubbles inside the bottle, please place it on a flat surface and wait for 10 minutes until the bubbles disappear. Afterwards, please gentle mix LensHooke™ X QC Beads (For Semen) well again.

DO NOT use if LensHooke™ Semen Test Cassette or LensHooke™ X QC Beads (For Semen) have expired. If they have expired, please use a new one to do the Quality Control test.

Please screw down the cap of LensHooke™ X QC Beads bottle tightly, immediately after use. If the LensHooke X QC Beads is spilled out, the concentration will be changed. DO NOT use it.

Please make sure to screw up the cap down tightly, because the beads might be stick onto the bottle tread if there is a gap between the bottle neck and cap.

Please compare the test result with the target value (on the label). The test result of real sample might be incorrect if the Quality Control result is outside the range of the target value.

Please keep children away from the LensHooke™ Semen Test Cassette and LensHooke™ X QC Beads (For Semen). Please consult a doctor if swallowed.

If external QC materials for multiple levels are required, please contact our customer service for more information.
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 backup.
- 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.
- When you 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.

![Image of Delete All Records screen]

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

![Image of OK screen]

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


1 WHO Edition
   (1) Select “Settings” and then select the “WHO Standard” icon.

![Image of Settings screen with WHO Standard selected]
(2) Select the preference edition and select “←” to return to the previous page.

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

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

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.

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”.
- Only the icons that turn blue can be selected.
- 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 22 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.

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 insert this license dongle into the USB Port of the analyzer.

(3) 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 check if the number of test cassettes and number of refilled dongle licenses match when you receive the product.
- Please insert the dongle to refill the license immediately after unpacking the box of the LensHooke™ Semen Test Cassette.
- Please go to the Home page to refill the license.
- 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 LAN (Local Area Network)
(1) Please use USB to RJ45 Gigabit Ethernet Adaptor to connect 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, 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 browsers to access the login page.
  - FireFox, Chrome, Microsoft Edge for Windows 10...etc. (Please refer to www.LensHooke.com for more details.)
• It is suggested to keep the power plugged in while connected to the LAN. Only support iPad and computer.
VII. Getting Started

Setup the analyzer:

1. Select “Start” and then select the Language preference icon. After that, please select the “" icon to set up the Date & Time.

2. Select the " " or " " icon to adjust the date format, and use the " " or " " icon to adjust the values.
   After selecting the WHO edition, select “ “ to proceed to the WHO edition selection.
   After you select the edition of WHO, please select the “ “ icon once more to complete the settings. The message of “Setting Completed” will show on the screen.

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

1 To connect the Barcode Scanner to the Analyzer
   (1) Please connect the barcode scanner to the analyzer using the USB Port.

(2) The barcode scanner to input the patient’s ID or the LOT of X QC Beads 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.
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.
(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.

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
• Use LensHooke™ Cleaning Wipe to clean the LensHooke™ X1 PRO Semen Quality Analyzer.

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 Messages

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 4 for normal operation status.)
If this message still appears, contact our customer service.

Error 3:
Camera failed. It might be a camera problem.

Please remove the test cassette and 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 4 for normal operation status.)
X. Analyzer Specification

Analyzer name
LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic)

Control panel
3.5-in resistive touch screen

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

Battery durability
2500 mA (embedded rechargeable 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

<table>
<thead>
<tr>
<th>Reference</th>
<th>WHO 5th Low Reference</th>
<th>WHO 4th Low Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>15 x 10^6 (12-16)/ ml</td>
<td>≧ 20 x 10^6 / ml</td>
</tr>
<tr>
<td>Total Motility</td>
<td>40% (38-42%)</td>
<td>a + b ≧ 50% or a ≧ 25%</td>
</tr>
<tr>
<td>PR (Progressive Motility)</td>
<td>32% (31-34%)</td>
<td></td>
</tr>
<tr>
<td>Morphology (Normal)</td>
<td>4% (3-4%)</td>
<td>≧ 15%</td>
</tr>
</tbody>
</table>

a : Rapid Progressive Motility (≧25μm/s)
b : Slow or Sluggish Progressive Motility
XII. Statement

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

XIII. Warnings and Precautions

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

NOTE

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

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

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

Bonraybio offers a one-year warranty from the day you purchase the LensHooke™ X1 PRO Semen Quality Analyzer. 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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