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 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”

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 Bonray-bio 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

**Top View**

1. Touch Screen
2. Test Cassette Insert Slot
3. Power Button
4. Reset Button

**Front View**

5. USB Port
6. USB Port
7. HDMI Port
8. Power Adaptor Port

**Rear View**

**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.

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.
   - Access Password: To get or change the password to access into the analyzer.
   - 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® CS0 Semen Test Cassette**
- **LensHooke® CS1 Semen Test Cassette**

- **LensHooke® Cleaning Wipe**
- **LensHooke® X QC Beads (For Semen)**
- **LensHooke® X QC Reticle (For Semen)**

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

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) and LensHooke® X QC Reticle (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.
Analyzer is equipped with a built-in 2500 mAh Lithium-ion polymer battery.

- The battery cannot 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.

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**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#. (Please 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.
Recent Tests
(1) Select the “Recent Tests” icon and then select the record you want to review by patient’s ID.

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.
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). Please confirm the LOT number and then select “下一步” to go to the next step.

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.
- 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.
(3) Please confirm the LOT number and check the information of the screen. If it matches the label on the LensHooke® X QC Beads (For Semen) or LensHooke® X QC Reticle (For Semen), select “OK” to go to the next step.

- Information of LensHooke® X QC Beads (For Semen)

- Information of LensHooke® X QC Reticle (For Semen)

(4) Please follow up the instructions of LensHooke® X QC Beads (For Semen) or LensHooke® X QC Reticle (For Semen) to operate and then insert the cassette into the “Insert Slot”.
(5) After 2-5 minutes, the result will appear on the screen automatically.

- Result of LensHooke® X QC Beads (For Semen)  
- Result of LensHooke® X QC Reticle (For Semen)

NOTE

- LensHooke® X QC Beads (For Semen) exam pH value and concentration.  
  LensHooke® X QC Reticle (For Semen) ONLY exam concentration.

- 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.
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”.

(4) Insert the USB Drive.
(5) 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 uses dynamic IP address, which is assigned when the network is connected and changes over time.

![Configure IP screen](image)

(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.

![Configure IP - Manual screen](image)

### 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 Language
(1) Select “Settings” and then select the “Language” icon, and select your language preference.
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.
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 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/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 browsers 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 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) and LensHooke® X QC Reticle (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

<table>
<thead>
<tr>
<th>Error 1: Self Test Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera failed. It might be a camera problem.</td>
</tr>
<tr>
<td>Please remove the test cassette and select the “OK” icon to return to home page.</td>
</tr>
<tr>
<td>Please insert another new test cassette redo the action.</td>
</tr>
<tr>
<td>If this message still appears, contact our customer service.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 2: Device Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device failed. It might be an analyzer problem.</td>
</tr>
<tr>
<td>Please remove the test cassette and select the “OK” icon to return to home page then turn the analyzer off.</td>
</tr>
<tr>
<td>(Refer to “Turn on/off” on Page 5 for normal operation status.)</td>
</tr>
<tr>
<td>If this message still appears, contact our customer service.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 3: Camera Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera failed. It might be a camera problem.</td>
</tr>
<tr>
<td>Please remove the test cassette and select the “OK” icon to return to home page.</td>
</tr>
<tr>
<td>Please insert another new test cassette redo the action.</td>
</tr>
<tr>
<td>If this message still appears, contact our customer service.</td>
</tr>
<tr>
<td>*Make sure you’re using correct LensHooke® Semen Test Cassette.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Error 4: Software Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Error. It might be a software problem.</td>
</tr>
<tr>
<td>Please remove the test cassette and select the “OK” to return icon to home page then turn the analyzer off.</td>
</tr>
<tr>
<td>(Refer to “Turn on/off” on Page 5 for normal operation status.)</td>
</tr>
</tbody>
</table>
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


<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. 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), and LensHooke® X QC Reticle (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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