

SEMEN QUALITY ANALYZER

**LensHooke X1 PRO SEMEN QUALITY ANALYZER**

User's Manual

Confidential

To help you correctly use this analyzer, make sure to carefully read this User's Manual and keep it well in good custody so that users of this product can refer to it at any time.

## Icons and common practice

To help you get the required information, this manual uses the following icons and common practices:



This icon denotes Caution, reminding you to read this information before using this analyzer.



This icon denotes Warning. To avoid any possible injury, first read all warnings before using this Bonraybio's product.



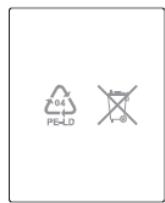
This icon refers to other page numbers for reference in this manual.

The items, selected items, and information shown on the screen of this analyzer are expressed in **bold** type.

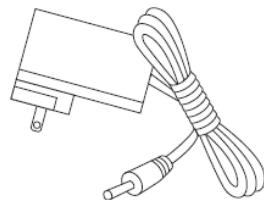
## Contents in the package

Make sure that the package of your analyzer contains all of the following items.

- Dust-proof bag: It prevents dust and protects your product.
- Adapter: The transmission line for power
- User's Manual/Warranty Card: Describes direction for use
- Thermal printer (optional): It prints the analytical report via the USB connection.



Dust-proof bag



Adapter

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## Foreword

Welcome to use LensHooke X1 PRO Semen Quality Analyzer .

This product is for *in vitro* diagnostic use only.

Before using, make sure to carefully read the Original User's Manual and follow all instructions when in use.

This LensHooke X1 PRO Semen Quality Analyzer can only be used with the LensHooke Semen Test Cassette exclusively for this analyzer. Using other analysis pieces may lead to inaccurate measuring results.

This LensHooke X1 PRO Semen Quality Analyzer is professionally made by Bonraybio Corporation and is sold via its authorized distributors. If you have any question or comment on our product, please feel free to call our Customer Service at XXXX-XXXX-XXXX or contact your local distributor. We will endeavor to provide our assistance to solve your problems.

## Intended use

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

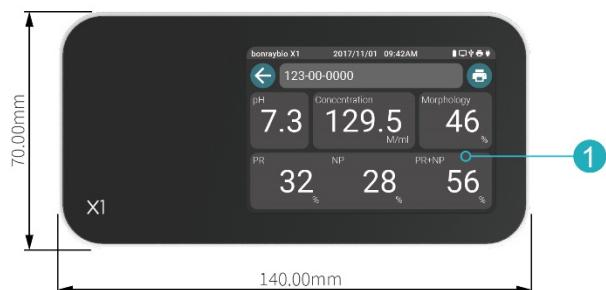
- Total sperm concentration
- Total motility and progressive motility
- % normal morphology
- pH value

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.

## Introduction

### LensHooke X1 PRO Semen Quality Analyzer

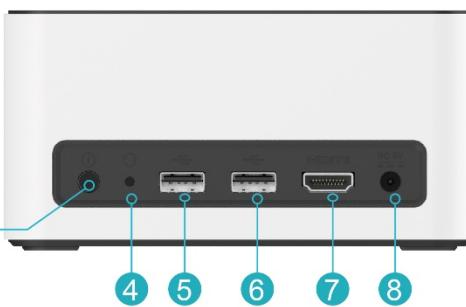
Top View



Front View

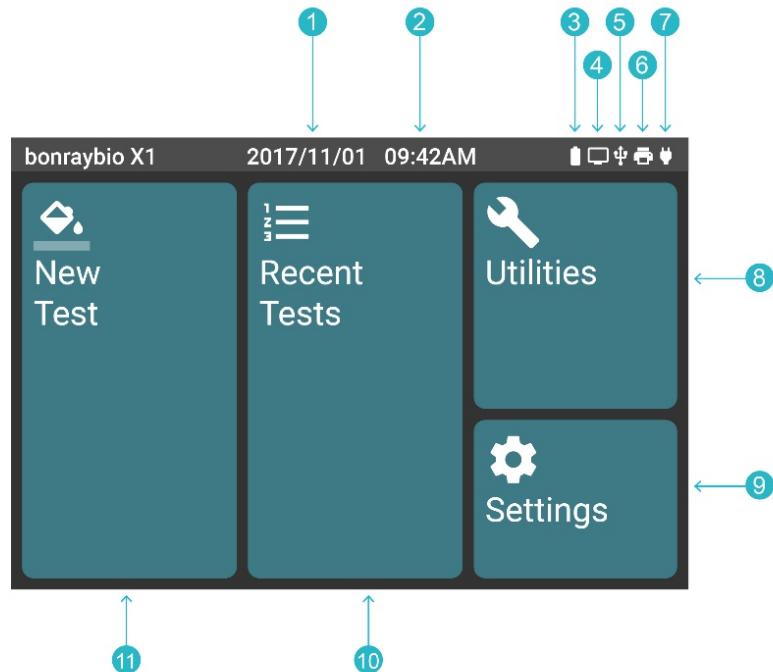


Rear View



- (1) 3.5-in touch screen: It provides operations for this analyzer, the analytical result and function setting.
- (2) Test Cassette inserting slot: A click sound will be heard when the test cassette is inserted in position.
- (3) Power ON/OFF button: To turn on or turn off this analyzer.
- (4) RESET button: To reset/redo the setting.
- (5) High-speed USB 2.0: To connect an external storage device or an external thermal printer.
- (6) High-speed USB 2.0: To connect an external storage device or an external thermal printer.
- (7) HDMI: To connect to a high definition multi-media interface.
- (8) Power adapter: To connect to a power connection.

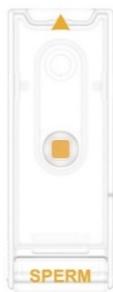
## Touch screen operation



- (1) **Date** icon: Date and format adjustment. Refer to Settings (p.18).
- (2) **Time** icon: Time and format adjustment. Refer to Settings (p.18).
- (3) **Multi-media** connection icon: When this icon illuminates, it means the multi-media has been connected.
- (4) **USB** connection icon: When this icon illuminates, it means the USB storage device has been connected.
- (5) **Thermal printer** connection icon: When this icon illuminates, it means the thermal printer has been connected.
- (6) **Adapter connection** icon: When this icon illuminates, it means the adapter has been connected.
- (7) **Power level** icon: It shows the % of power level.
- (8) **Utilities**: Backup, printing, removing all analytical results and the QC analysis tool. Refer to Utilities for detailed operational functions (p.21).
- (9) **Settings**: To set functions such as the date & time format, date, time, language and the analysis standard. Refer to Settings for detailed operational functions (p.18).
- (10) **Recent tests**: To search for historical analytical result records. Refer to the Analytical Result Record Inquiry for detailed operational functions (P.15).
- (11) **New Test**: Establish a new analytical record. Refer to Semen analysis for detailed operational functions (p.10).



C-KUP Sample Collection Cup



LensHooke Semen Test Cassette



LensHooke QC liquid    LensHooke cleaner



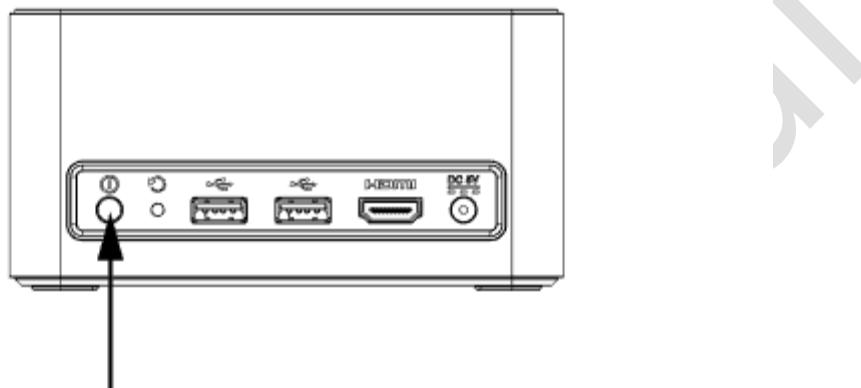
LensHooke Cleaning set

- **C-KUP Sample Collection Cup:** A container for collecting the sample
- **LensHooke Semen Test Cassette:** The test cassette is to detect the semen pH value, sperm concentration, motility and morphology.
- **LensHooke QC liquid:** To be used with the LensHooke Semen Test Cassette for QC analysis.
- **LensHooke Cleaning set:** It is used to clean the test cassette inserting slot.

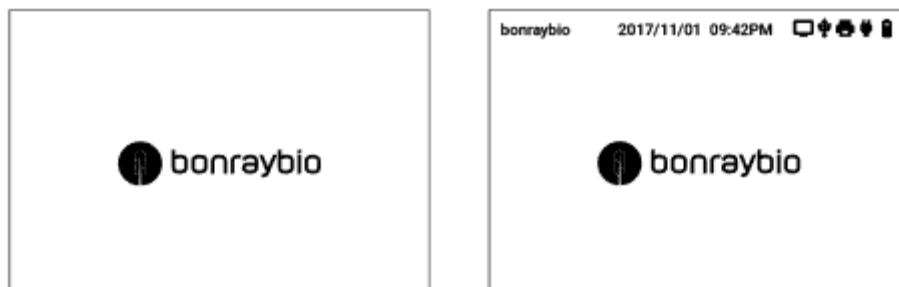
## Prior preparation

### Prior preparation before entering the main screen of the touch screen of the analyzer.

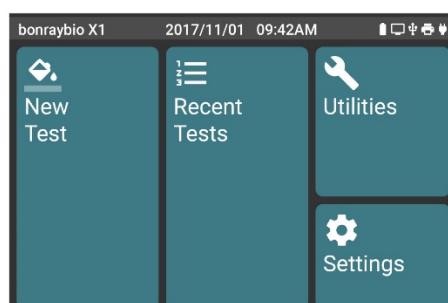
- Step 1. Place the analyzer on a flat and stable surface, e.g. the table top.
- Step 2. Connect one end of the adapter to the analyzer and the other end to the socket.
- Step 3. Press the power button at the back of the analyzer for 2 seconds. Now, the screen will display the Bonraybio icon (the starting screen) and start self-testing. When the upper status bar displays the Bonraybio icon, date & time and other icons, it means self-testing for power on has been completed.



Power on



- Step 4. When starting for the first time or after the battery has been replaced, first set the date and time.  
Date and time setting: Refer to [Settings\\_ Date & Time Settings \(p.18\)](#).
- Step 5. When the touch screen of the analyzer displays the main screen as shown on the following figure, it means power on of the analyzer has finished.



**Caution**

A lithium polymer battery has been embedded in the analyzer. A fully charged battery can provide 3 hours of continuous analysis.

After startup, ensure that the adapter has been plugged in and also check whether the upper status bar on the touch screen has shown the adapter icon. If this icon does not appear on the touch screen, check whether the adapter and the AC socket are correctly connected. If this icon still does not appear on the screen after examination, contact Customer Service.

**Shut down**

Press and hold the main button for 10 seconds. The LensHooke X1 PRO Semen Quality Analyzer will go to the shut-down procedure and the touch screen will display Shut Down. After the shut-down procedure is finished, the screen will turn off.

**Power saving mode**

When there is no operation for 10 minutes, the system will automatically turn the screen into the backlight mode to save battery power consumption.

**Wake-up method**

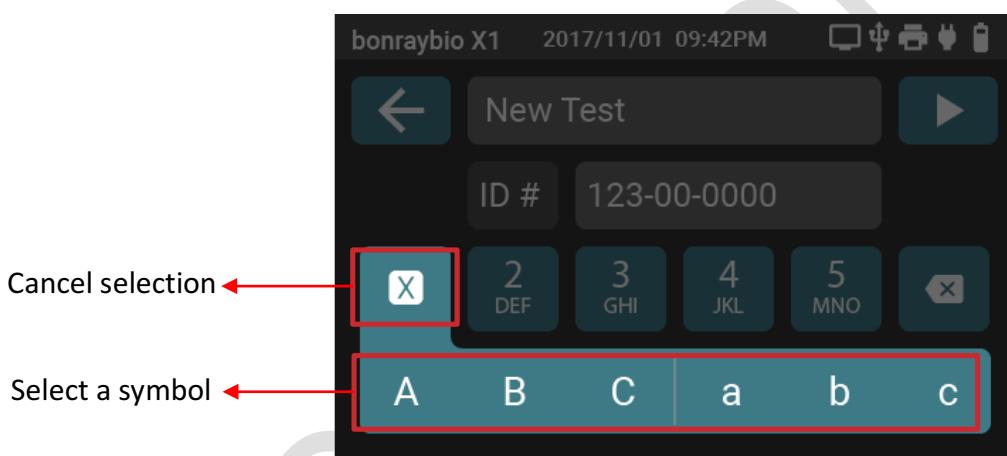
Press the power button or touch the screen of the analyzer to restart the system display.

## How to input the data

- Description of functions of the screen keyboard
  - Press and hold the button of  (0.5-1.0 sec); letters in capital or small type and symbols can be changed.



- Press and hold the  button (0.5~1.0 sec); you can then select A, B, C, a, b, and c. Select a symbol/Cancel selection



## It is used with the thermal printer (optional)

- Step 1. Connect the thermal printer by using the USB to the back side of the analyzer.
- Step 2. Connect one end of the adapter to the thermal printer and the other end to the socket.
- Step 3. Open the cartridge cover of the thermal printer to install the thermal printing paper.
- Step 4. Close the cartridge cover of the thermal printer.
- Step 5. Press the power button of the thermal printer to turn on the thermal printer. The thermal printer icon will appear in the upper status bar on the touch screen of the analyzer.

### Caution

- If the thermal printer icon does not appear on the upper side of the touch screen of the analyzer, check the adapter connection and USB connection.
- If the thermal printer icon still does not appear on the upper side of the touch screen after examination, contact Customer Service.

### Safety notice

1. To prevent damage to your analyzer or injury to you or others, before using this analyzer, thoroughly read the following safety notice and keep good custody of this safety guide so that users of this product can refer to at any time.  
Please follow each of the following precautions; or, it may cause damage to the product.



This icon denotes Warning. To prevent from any possible injury, first carefully read all warnings before using it.

2. This LensHooke X1 PRO Semen Quality Analyzer can only be used with the LensHooke Semen Test Cassette exclusively for this analyzer. Using other test cassette may lead to inaccurate measuring results.
3. Keep this LensHooke X1 PRO Semen Quality Analyzer away from dust, water or any other liquid. If this LensHooke X1 PRO Semen Quality Analyzer is not used, place it in the dust-proof bag. If the analyzer drops to the ground or has been damaged, first conduct the QC analysis before semen analysis. Refer to Utilities Instructions in Utilities(p.21)
4. Each time this LensHooke X1 PRO Semen Quality Analyzer completes use, remove the source of infection and clean it by following the instructions in the user's manual. Refer to Maintenance and Care (p.26)
5. To analyze another patient, change your gloves.
6. This LensHooke X1 PRO Semen Quality Analyzer has an embedded rechargeable lithium polymer battery. Users cannot replace the battery by themselves. If the battery cannot be recharged or it has been damaged, contact the original Customer Service or distributors for replacement.
7. When starting for the first time or after the battery has been replaced, first set the date and time. Refer to Setting Instructions in Settings (p.18).

### Example of the sample size

The recommended size of the sample is X.XX~X.XX $\mu$ L. If the sample size is less than X.XX $\mu$ L, it may cause inaccurate analytical results. Please use a new analysis piece to reanalyze it.

### Interfering substance

#### Touch screen

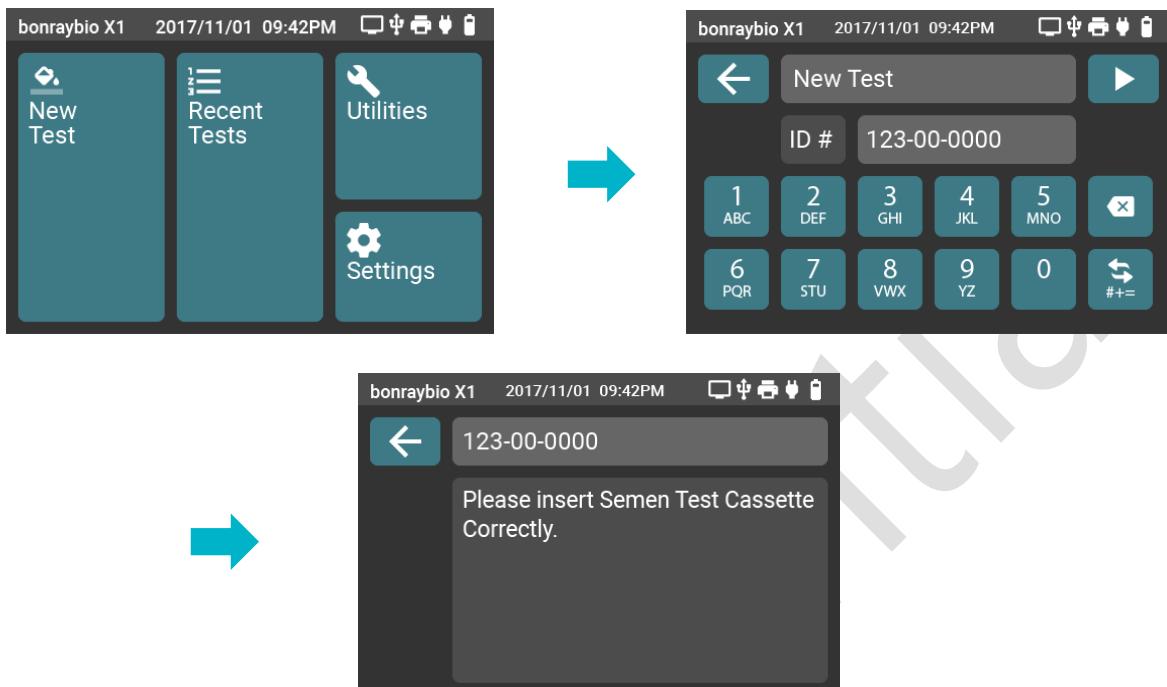
The touch screen is designed to be operated by using your finger. The PDA touch pen can also be used to substitute for your finger. Other than that, do not use any other pen or pointed object to touch the screen. Otherwise, it may cause damage to the touch screen.

#### Infection

The user shall use and clean the instrument by following the management guidelines of the user's institution and discard the used Sample Collection Cups and LensHooke Semen Test Cassette according to the relevant regulations to prevent any possibility of cross-infection.

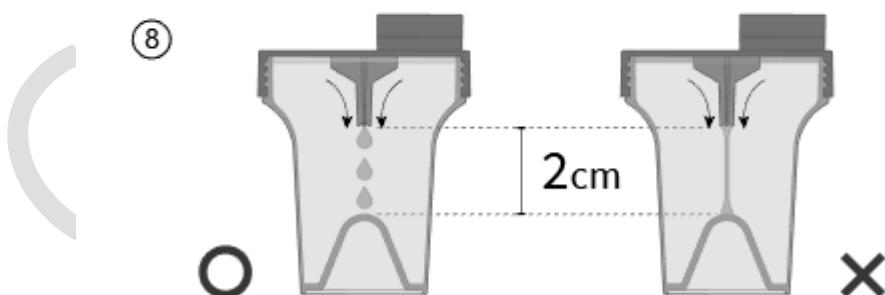
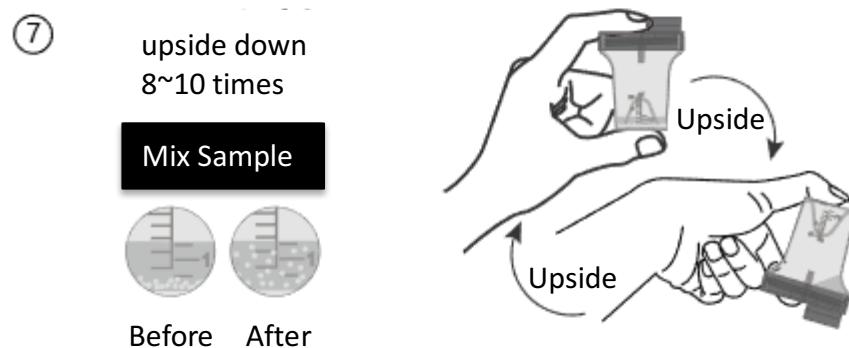
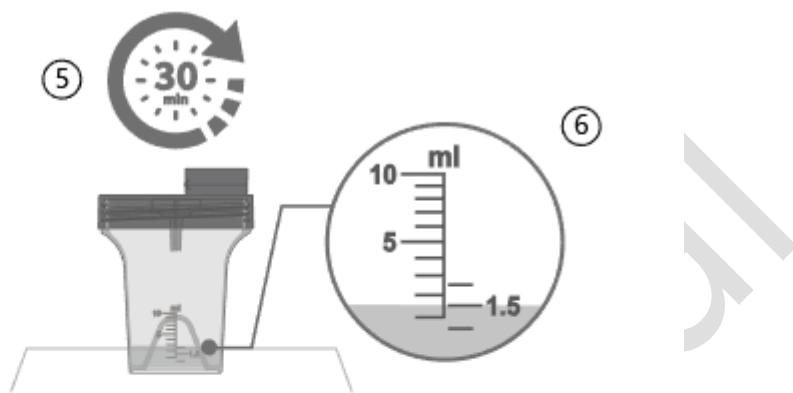
## Semen analysis

- Step 1. The touch screen of the analyzer will display the main screen. Click on **New Test**.
- Step 2. According to the screen display of the analyzer, enter the [ID] (Medical record number).
- Step 3. Click on  and complete the input.



- Step 4. Leave the sample in the C-KUP Sample Collection Cup. (Refer to the C-KUP Sample Collection Cup (not sterilized) user manual.)
- Step 5. Settle down for 30 minutes and wait for the semen to become liquefied.
- Step 6. Confirm the semen color and volume (confirm the scale on the C-KUP Sample Collection Cup).
- Step 7. Turn the C-KUP Sample Collection Cup upside down 8~10 times and make sure the sample has been shaken evenly.

Step 8. Turn the C-KUP Sample Collection Cup to observe whether the semen has been fully liquefied. If the sample becomes water drop-like when the patented V-STICK liquefaction stick drips into the sample, it means liquefaction has been completed. If there are non-continuous small drops dripping from the patented V-STICK liquefaction stick, it is normal semen. Otherwise, the droplets will form a thin thread over 2cm.



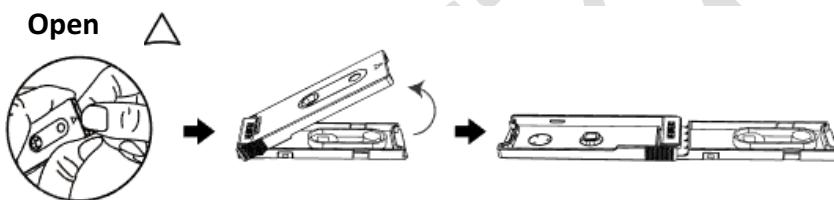
**Caution**

- After the sample is collected, put it at least for 30 minutes and complete analysis within one hour to ensure reliability of the analytical data.
- If there is no water drop-like dripping, it means liquefaction has not been completed or the sample cannot be liquefied. If the sample is found unable to be liquefied, wait for another 30 minutes and observe again whether it has become liquefied. If it is still not liquefied, do not conduct analysis with this sample, which may affect the sperm's analytical result.
- As soon as the semen is observed being liquefied, immediately drip the sample to start analyzing. If the sample has settled down for a while, it must be evenly shaken again before it is dripped for analysis, which can avoid the sample being unevenly mixed, affecting the sperm's analytical result.
- For a sample containing hazardous biological substances, it shall be collected and disposed of following the specification and steps of the usage location. While handling the sample containing biological hazardous substances, wear gloves or other types of personal protection equipment.

Step 9. Open the LensHooke Semen Test Cassette package and take out one new and non-expired LensHooke Semen Test Cassette.

Step 10. According to the arrow on the LensHooke Semen Test Cassette, open the LensHooke Semen Test Cassette to the maximum and place it on a flat and stable table top.

Step 11. Take one C-KUP Sample Collection Cup and remove the tip cover.



**Caution**

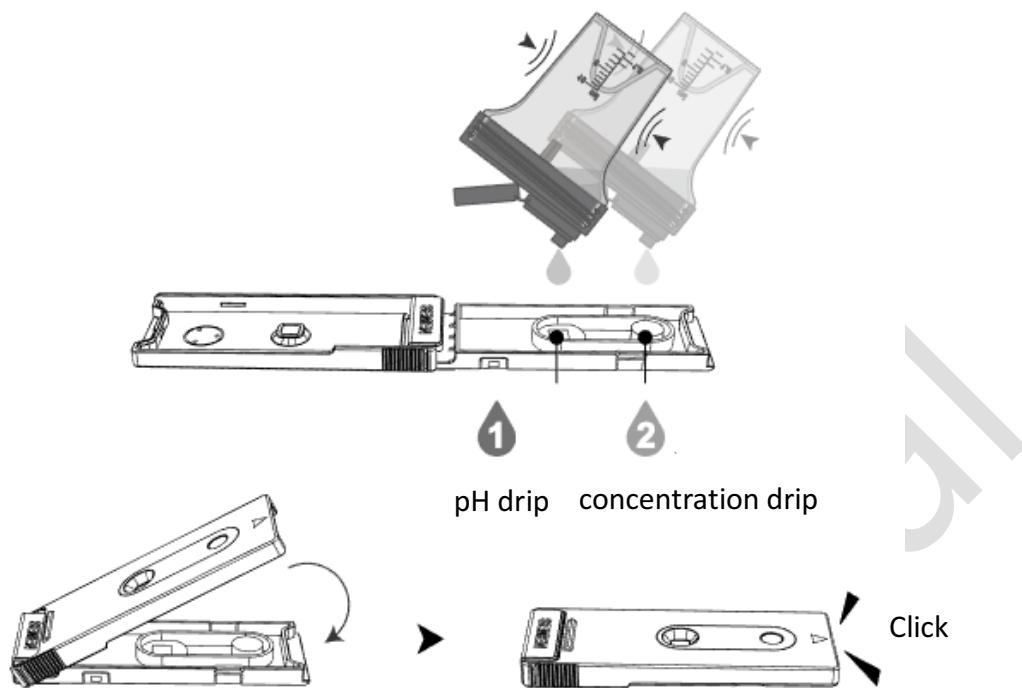
- Do not use the LensHooke Semen Test Cassette if it has exceeded the expiry date as shown on the package.
- Do not place the opened LensHooke Semen Test Cassette on an unstable table top.

Step 12. Squeeze the Cup to drip the first sample drop to the pH window on the LensHooke Semen Test Cassette.

Step 13. Squeeze the Cup to drip the second sample drop to the concentration window on the LensHooke Semen Test Cassette.

Step 14. Re-place the tip cover on the C-KUP Sample Collection Cup dripping mouth and ensure it is firmly in place.

Step 15. Close the LensHooke Semen Test Cassette until a [Click] sound is heard, meaning that the LensHooke Semen Test Cassette is fully closed.



**Caution**

- Make sure that there is a sufficient amount of sample in the Sample Collection Cup (at least X.XXml). If a sufficient amount of sample is unable to be collected, it may cause inaccuracy to the analytical result.
- After the sample is dripped to the LensHooke Semen Test Cassette, insert it in the slot of the Semen Quality Analyzer within 30 seconds for analysis.

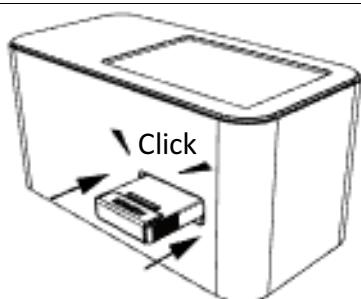
Step 16. Insert the LensHooke Semen Test Cassette whereon the sample has just been dripped into the slot of the analyzer.

Step17. Insert it all the way in until a [Click] sound is heard, meaning the LensHooke Semen Test Cassette has been correctly inserted.

Step 18. The analyzer will start to analyze the sperm. Wait for 2~5 minutes depending on the sample condition.

**Caution**

- While the analyzer is in operation, do not remove or move the LensHooke Semen Test Cassette.



Step 19. The upper side of the analyzer screen will display the sperm analytical results – pH value, concentration, Progressive motility (PR/%), Non Progressive motility (NP/%), total motility (PR+NP/%) and the sperm morphology (%).

(According to the Setting\_ WHO Standard (p.26), it will produce a different analysis standard name. This example is the 5th WHO standard).

Step 20. When the analyzer emits two [Beep] sounds, it means that the screen has displayed the complete sperm analytical results.

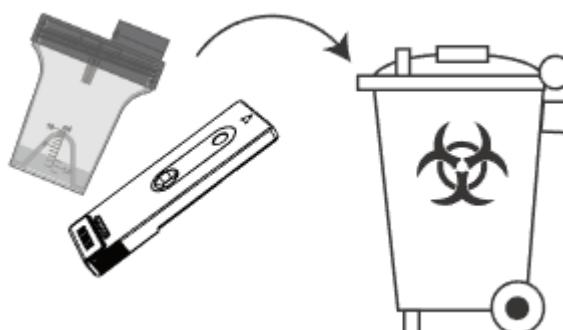


**Caution**

- The analyzer can be connected to the high definition multi-media interface via HDMI. From the connected interface, you can observe the illustrations of the relevant dynamic concentration, motility, and the abnormal sperm morphology.
- If the sperm concentration analytical value increases with the “\*” icon, it means that sperm in the sample is clustered, crystallized, or has other foreign substances that may affect the analytical result.

Step 21. Click on [ ← ] shown on the touch screen of the analyzer to go back to the main screen.

Step 22. Remove the LensHooke Semen Test Cassette and the C-KUP Sample Collection Cup. Throw them with the gloves in the trash can for medical wastes.

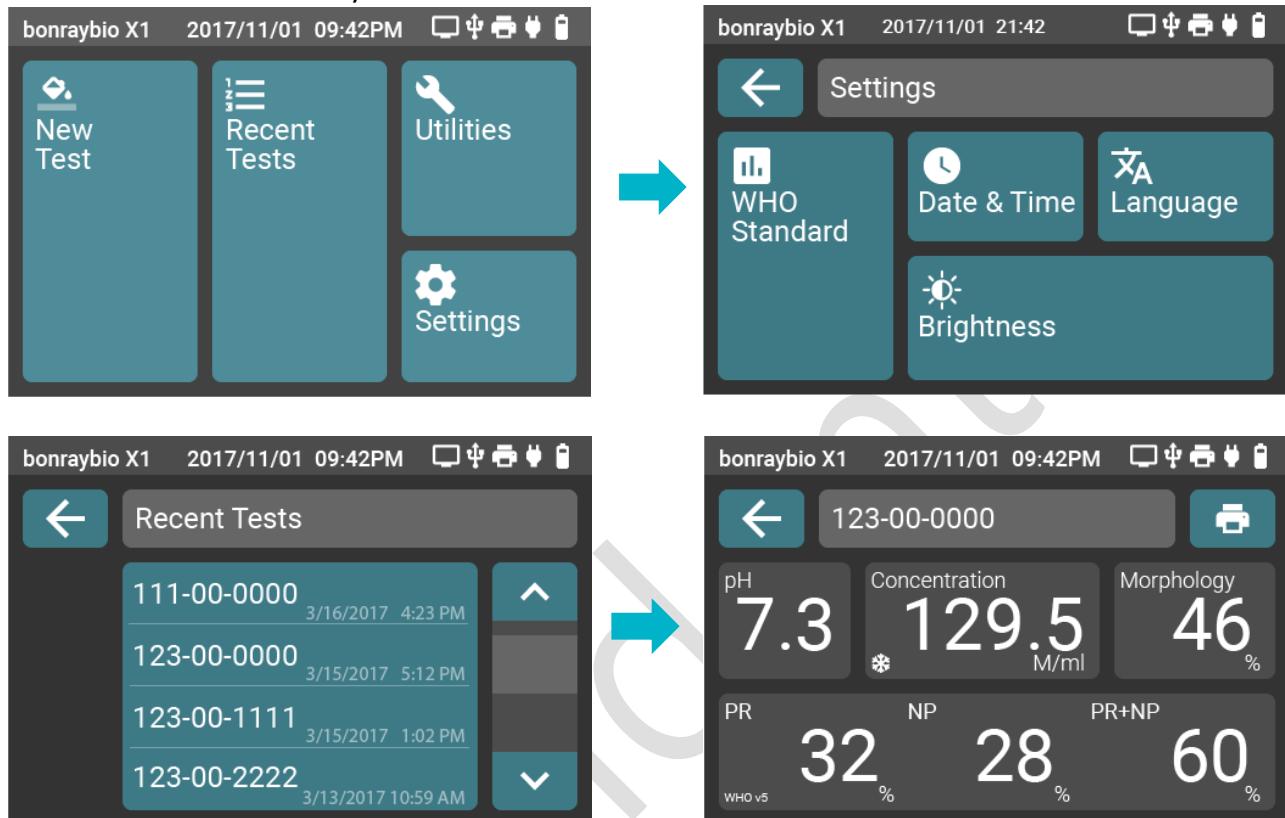


**Caution**

To prevent cross-contamination of LensHooke Semen Test Cassette, the C-KUP Sample Collection Cup can be used for only one time. Discard it after being used and do not use it again.

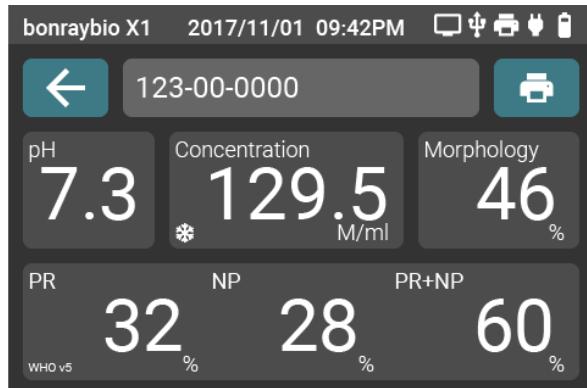
## Inquiry of the analytical result record

- Step 1. On the main screen of the touch screen of the analyzer, click on the Recent Tests.
- Step 2. The historical analytical result records are shown on the touch screen of the analyzer. Click on button on the right side of the touch screen to select upward or downward.
- Step 3. The historical analytical result records are shown on the touch screen of the analyzer, click on the analytical record to be viewed on the touch screen.



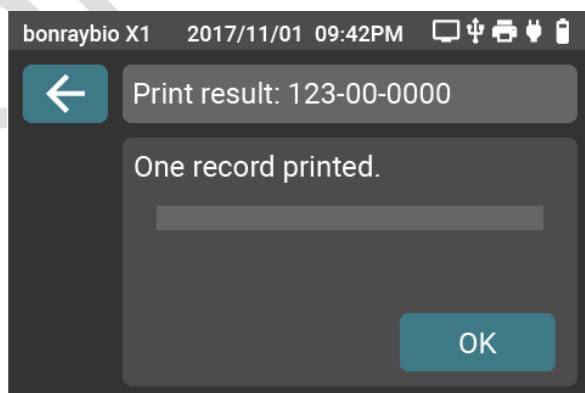
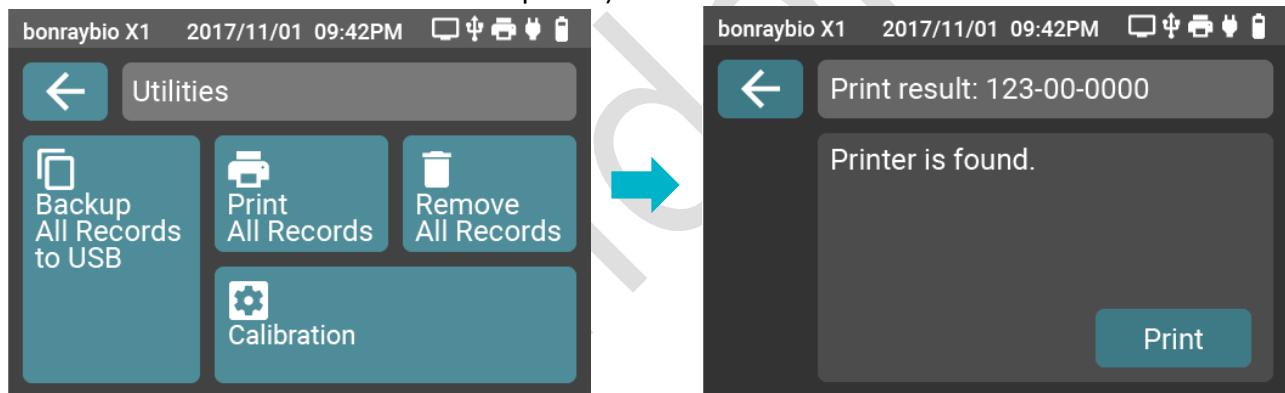
Step 4. This analytical result record will be displayed on the touch screen of the analyzer. (According to Setting> WHO Standard (p. 26), it produces a different analysis standard name. This example is the 5th WHO Standard).

Step 5. Click on the icon shown on the touch screen of the analyzer [ ← ] to go back to the main screen.



### Printing the analytical result data (an optional thermal printer is required)

- Step 1. The touch screen of the analyzer displays the entire sperm's analytical results. Refer to **Semen analysis** (p.16) or **Inquiry of the analytical result record** (p.21).
- Step 2. The thermal printer icon will appear on the upper right side of the touch screen of the **thermal printer**. Click on Print All Records shown on the touch screen to go to **Print** setting. (A thermal printer connected with the USB is required.)
- Step 3. The touch screen of the analyzer displays that the thermal printer is ready. Click on Print shown on the touch screen. (A thermal printer connected with the USB is required.)
- Step 4. The touch screen of the analyzer displays that the printer is printing. (A thermal printer connected with the USB is required.)



- Step 5. The touch screen of the analyzer displays that printing has been completed. Click on **OK** shown on the touch screen and **go back** to the main screen. (A thermal printer connected with the USB is required.)

**Caution**

While the touch screen of the analyzer displays that the printer is printing, do not move or remove relevant connections to the thermal printer.

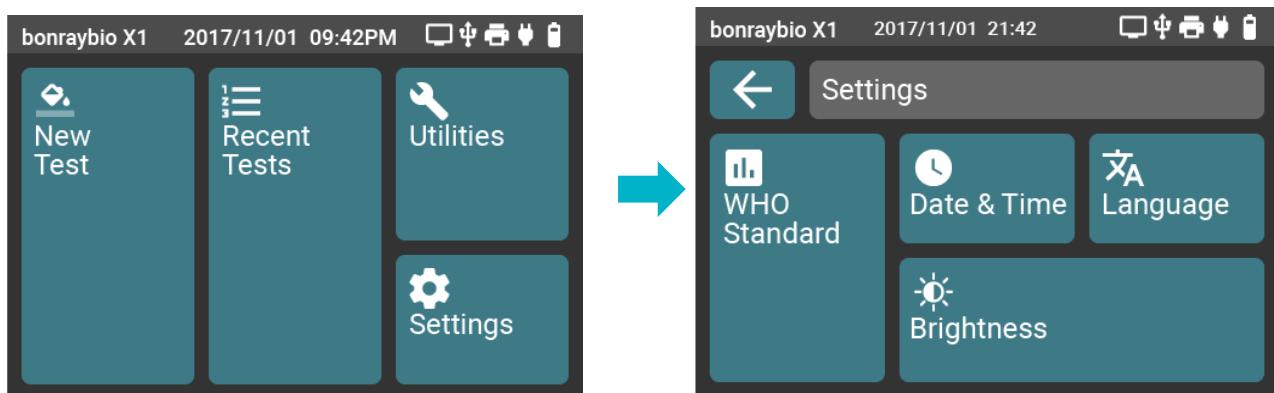
Confidential

## Description of detailed functions

### Settings

#### How to enter Settings

Step 1. The touch screen of the analyzer displays the main screen. Click on **Setting**.



#### Description of interfaces of operational functions

**Date & time:** To adjust date and time, select YYYY/MM/DD or DD/MM/YYYY.

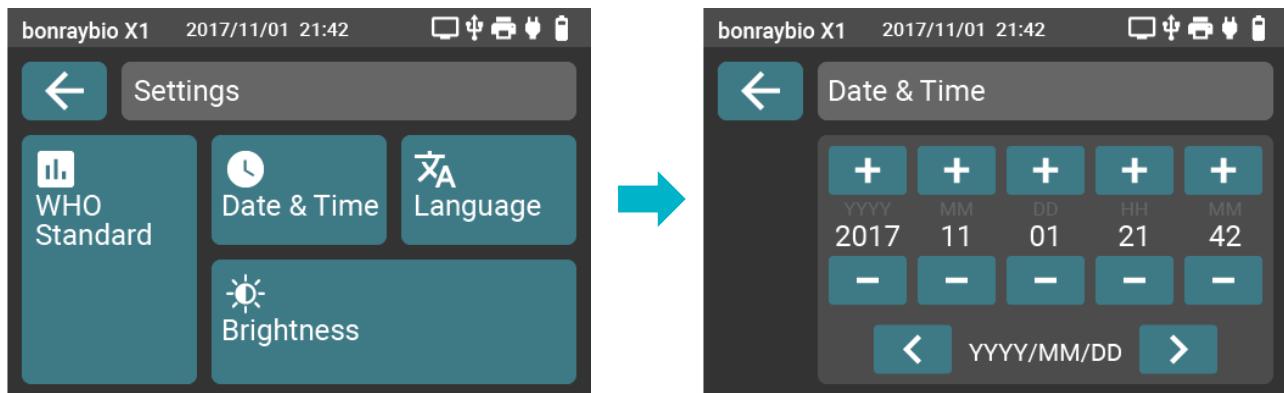
**Language:** To select or adjust a language

**WHO standard:** WHO 4th/ WHO 5th

**Brightness:** To adjust brightness of LCD.

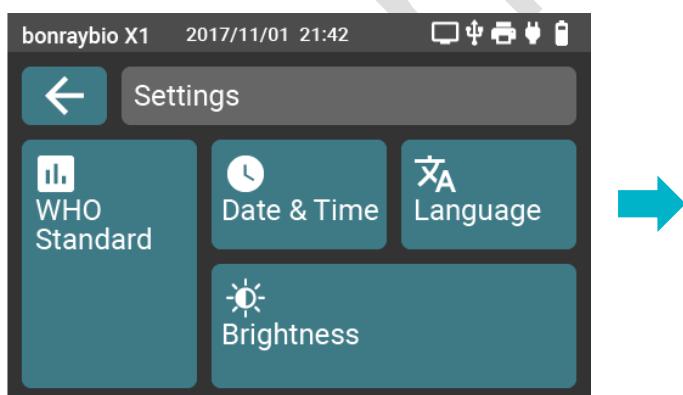
## Settings \_ Date & Time

- Step 1. The touch screen of the analyzer displays the **Setting** screen. Click on the **Date & Time** setting displayed on the touch screen.
- Step 2. The touch screen of the analyzer displays the **Date & Time** screen. Click on the +, and – buttons to set the A.D year, month, date and time.
- Step 3. Click on the icon displayed on the touch screen of the analyzer ← to go back to the **Setting** screen on the touch screen.



## Settings\_ Language

- Step 1. The touch screen of the analyzer displays the **Setting** screen. Click on the **Language** displayed on the touch screen.
- Step 2. The touch screen of the analyzer displays the **Language** screen. Click on the ^, and ^ buttons on the right side of the touch screen to set the language.
- Step 3. The touch screen of the analyzer displays the **Language** screen. Confirm the selected language.
- Step 4. Click on the icon displayed on the touch screen of [ ← ] the analyzer to go back to the **Setting** screen on the touch screen.





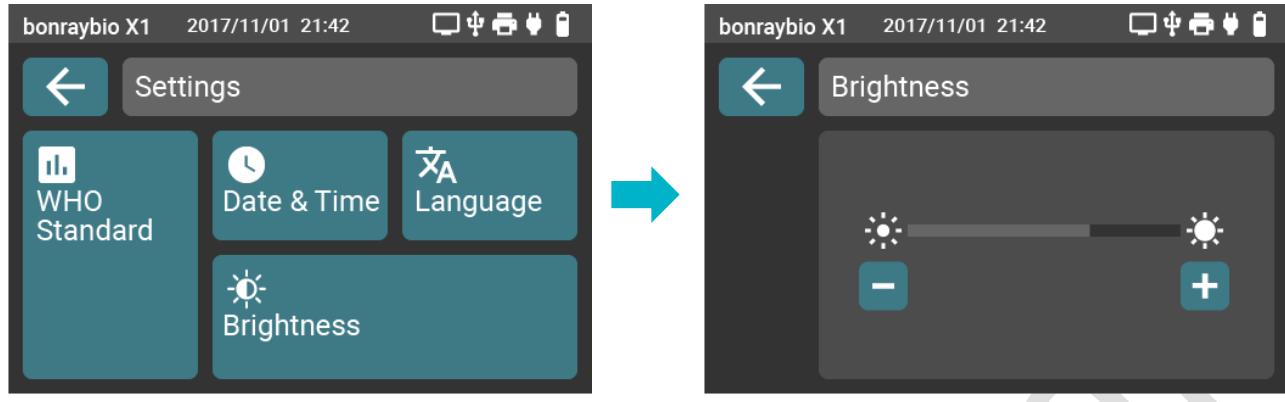
### Settings \_ WHO Standard

- Step 1. The touch screen of the analyzer displays the **Setting** screen. Click on the **WHO Standard** displayed on the touch screen.
- Step 2. The touch screen of the analyzer displays the **WHO Standard** screen. Click on Analysis Standard Setting to be selected for setting on the touch screen. (If the Fourth Edition/1999 is clicked, the analysis screen will display relevant analytical values of WHO 4th whereas if the Fifth Edition/2010 is clicked, the analysis screen will display relevant analytical values of WHO 5th.)
- Step 3. Click on the icon displayed on the touch screen of [ ← ] the analyzer to go back to the **Setting** screen on the touch screen.



### Settings \_ Brightness

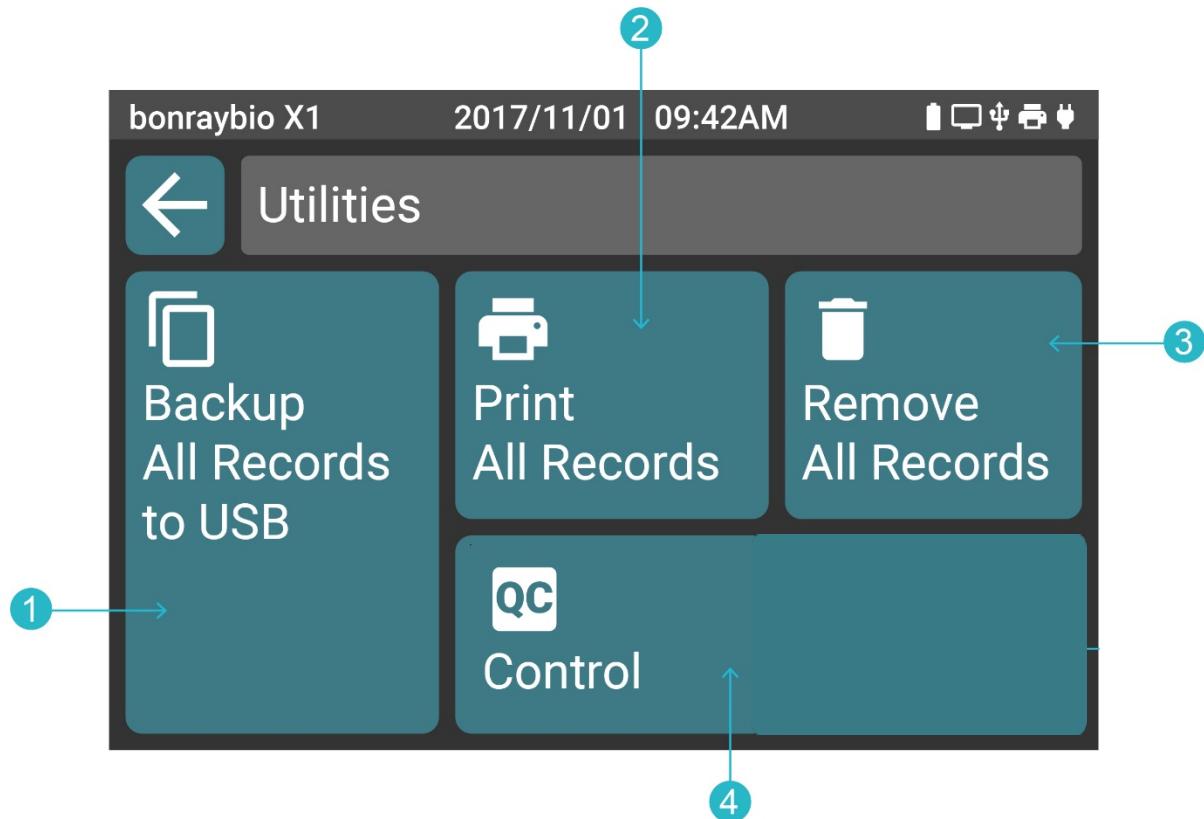
- Step 1. The touch screen of the analyzer displays the **Setting** screen. Click on **Brightness** displayed on the touch screen.
- Step 2. The touch screen of the analyzer displays the **Brightness** screen. Click on the touch screen to select +- for setting.
- Step 3. Click on the icon displayed on the touch screen of [ ← ] the analyzer to go back to the **Setting** screen on the touch screen.



## Utilities

### How to enter Utilities

Step 1. The touch screen of the analyzer displays the main screen of the touch screen. Click on **Utilities**



### Description of interfaces of operational functions

**Backup All Records to USB:** All analytical records are to be backed up to USB.

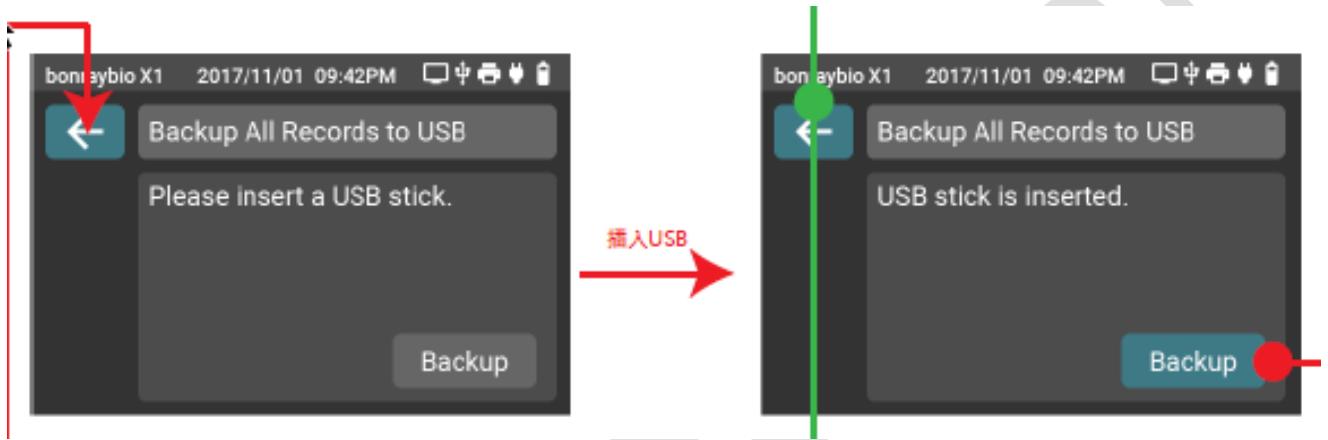
**Print All Records:** Analytical records can be printed out.

**Remove All Records:** Remove all analytical records

**Control:** QC analysis

## Utilities \_ Backup All Records to USB

- Step 1. Ensure that the USB backup device has been connected to the analyzer.
- Step 2. The touch screen of the analyzer displays the **Utilities** screen. Click on Backup displayed on the **touch screen**.
- Step 3. The touch screen of the analyzer displays the Backup screen of all analytical result records. Click on the **Backup** icon displayed on the touch screen to back up all analytical result records to the USB backup device. Click on the icon displayed on the touch screen of the analyzer [ ← ] to go back to the **Utilities** screen.
- Step 4. The touch screen of the analyzer displays the status screen of all analytical result records that have been backed up.



### Caution

- When the touch screen of the analyzer displays that all analytical result records are being backed up, do not move or remove the relevant connections to the USB backup device.

- Step 1. The touch screen of the analyzer displays the screen that all analytical result records have been completed backing up. Click on the icon displayed on the touch screen of the [ ← ] analyzer to go back to the **Utilities** screen on the touch screen.
- Step 2. Remove the USB backup device from the analyzer.

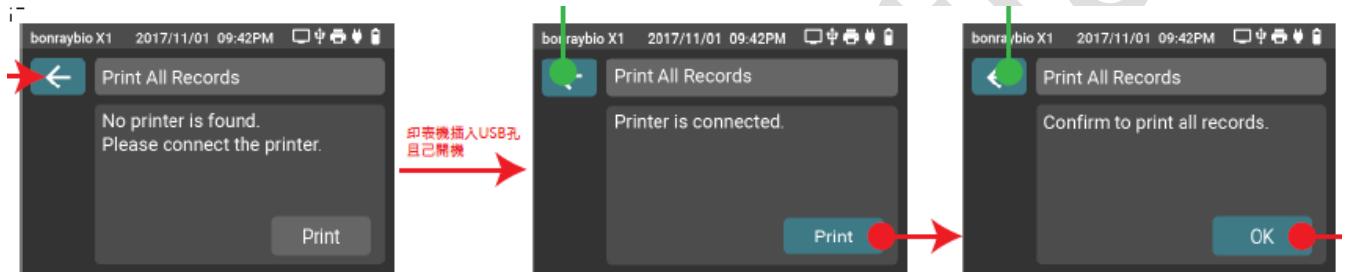
## Utilities\_ Print All Records (Thermal printer: Optional)

Step 1. Ensure that the USB connecting line has been connected to the analyzer and the thermal printer.

Step 2. Ensure that the thermal printer has been turned on and the paper cartridge in the thermal printer has paper in it.

Step 3. The touch screen of the analyzer displays the **Utilities** screen. Click on **Print** displayed on the touch screen.

Step 4. The touch screen of the analyzer displays the screen of all analytical result records to be printed. Click on the **Print** icon displayed on the touch screen to start printing all analytical result records. Click on the icon displayed on the touch screen of [ ← ] the analyzer to go back to the **Utilities** screen of the touch screen.



Step 6. The touch screen of the analyzer displays the status screen of all printed analytical result records.

### Caution

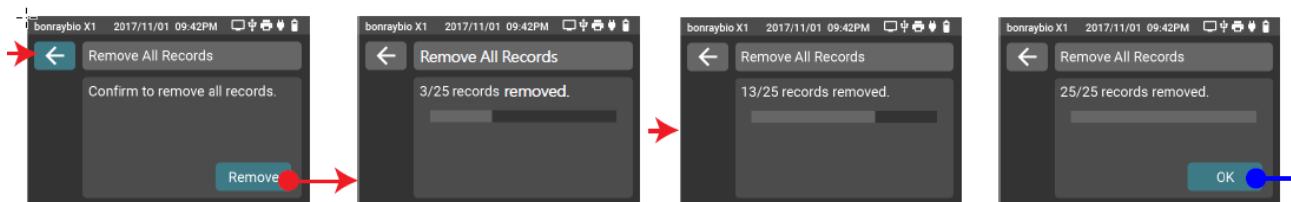
When the touch screen of the analyzer displays the status of the number of printed records, do not move or remove the relevant connections to the thermal printer.

Step 7. The touch screen of the analyzer displays the screen indicating that all analytical result records have completed printing. Click on the **OK** icon displayed on the touch screen of the analyzer to go back to the **Utilities** screen of the touch screen.

## Utilities\_ Remove All Records

Step 1. The touch screen of the analyzer displays the **Utilities** screen. Click on **Remove** displayed on the touch screen.

Step 2. The touch screen of the analyzer displays the screen that all analytical result records to be removed. Click on the **Remove** icon and start to remove all analytical result records. Click on the icon ← displayed on the touch screen of the analyzer to go back to the **Utilities** screen of the touch screen.



### Caution

The touch screen of the instrument displays the status of all analytical result records being removed, which means removed analytical result records will not be able to be recovered. Before removal is performed, make sure that the analytical result records have been saved correctly.

Step 2. The touch screen of the analyzer displays the screen indicating that all analytical result records have completed removal. Click on the **OK** icon displayed on the touch screen of the analyzer to go back to the **Utilities** screen of the touch screen.

## Utilities \_ Control

- Step 1. Open the LensHooke Semen Test Cassette package and take out one new LensHooke Semen Test Cassette.
- Step 2. According to the arrow on the LensHooke Semen Test Cassette, open the LensHooke Semen Test Cassette.
- Step 3. Open up the LensHooke Semen Test Cassette.
- Step 4. Take the QC liquid and shake it evenly. Screw up the QC liquid cap.

### Caution

- When the LensHooke Semen Test Cassette and the QC liquid have exceeded their expiry date shown on the package, do not use them.
- Do not place the LensHooke Semen Test Cassette that has been opened on an unstable table top.

- Step 5. Squeeze the bottle and drip the first drop of sample into the LensHooke Control Test Cassette – the pH drip.
- Step 6. Squeeze the bottle to drip the second drop of sample into the LensHooke Control Test Cassette – the concentration drip.
- Step 7. Take the QC liquid cap and truly screw up to tighten the upper cap.
- Step 8. From the test cassette inserting slot of the analyzer, insert the LensHooke Control Test Cassette with the QC liquid just being dripped and the cap tightened until a “Click” sound is heard, meaning that the LensHooke Control Test Cassette has been fully closed.

### Caution

- Having dripped the QC liquid, insert the LensHooke Control Test Cassette from the slot within 30 seconds for analysis.

- Step 9. The touch screen of the analyzer displays the **Utilities** screen. Click on QC.
- Step 10. The analyzer starts to conduct QC analysis, wait for the analysis for at least 2 minutes.

### Caution

- While the instrument is performing analysis, do not remove or move the LensHooke Control Test Cassette.

- Step 11. The touch screen of the analyzer displays the screen of the QC analysis result. Click on the icon displayed on the touch screen of the [  ] analyzer to go back to the **Utilities** screen on the touch screen.

## Maintenance and care

### Recommended routine precautions

- Under normal usage, the LensHooke X1 PRO Semen Quality Analyzer shall conduct QC analysis at least per one month.
- Clean the test cassette inserting slot at least once per week by using the cleaning set.
- The LensHooke X1 PRO Semen Quality Analyzer has no parts that users may need to repair or replace. For maintenance safety checks or repair, please contact the authorized vendor or Customer Service.

### Recommended routine precautions

Step 1. Shut down the analyzer in order not to cause any incorrect action to be taken.

Step 2. Take the cleaning set for cleaning the test cassette inserting slot.

Step 3. Open the package and drip a few drops of cleaning fluid onto the cleaning swab.

### Caution

For the test cassette inserting slot, use the cleaning set proprietary to Bonraybio to avoid improper cleaning and care actions, which may affects the overall analytical results.

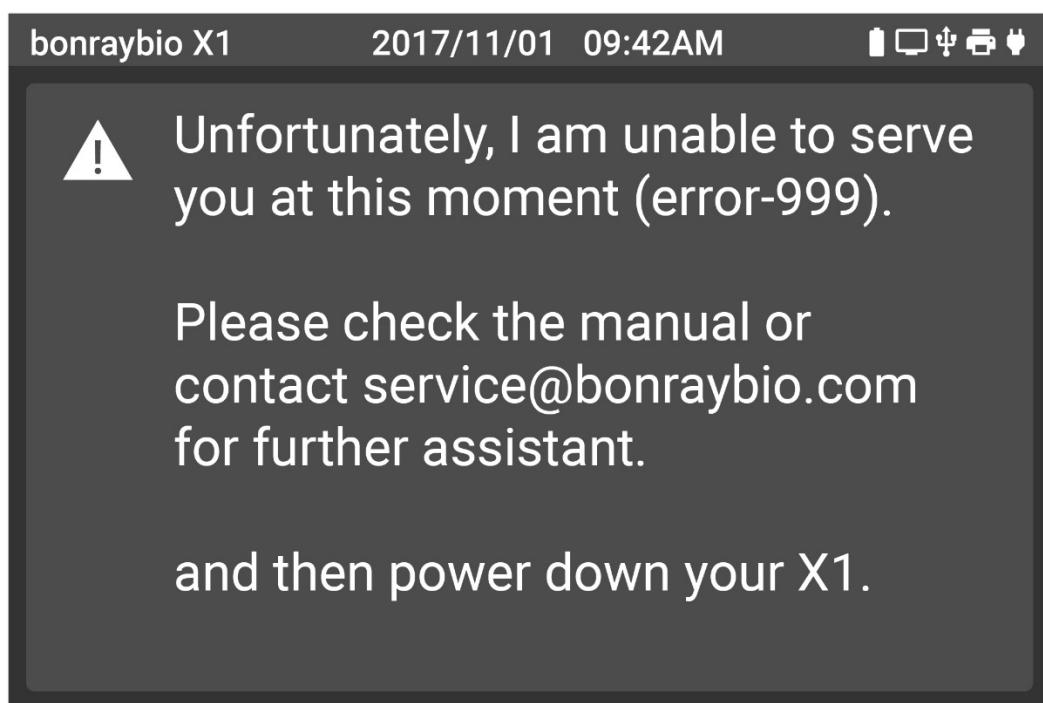
Step 4. Clean along the analysis inserting slot with the cleaning swab dipped with cleaning fluid.

Step 5. Discard the used cleaning swabs.

Step 6. To wipe the entire analyzer, use lens tissues dipped with alcohol to wipe the exterior.

Step 7. Discard used lens tissues.

## Error messages



### Description of error messages

#### Error 1 Self test Failed

Re-start the analyzer. If restarting cannot solve this problem, contact the Customer Service.

#### Error 2 Sample Failed

Re-place the LensHooke Semen Test Cassette and check whether the sample or the QC liquid has been dripped.

#### Error 3 Control Failed

Re-Control step - if re-Control cannot solve this problem, contact the Customer Service.

#### Error 4 Transmit Failed

Ensure that the USB has been connected and also ensure that HDMI has been corrected.

#### Error 5 Out of Range

Re-test

#### Error 6 Low Battery

Battery power is low. Please recharge the battery. Or contact the Customer Service to replace the battery.

#### Error message \_Error 1 Self Test Failed

- Step 1. The touch screen of the analyzer displays Error 1 error message.
- Step 2. Press and hold the power button at the back of the analyzer to shut down the analyzer.
- Step 3. Clean the analysis inserting slot of the analyzer. Refer to ( XX) Care and cleaning method.
- Step 4. Ensure that the analyzer is placed on a flat and stable surface or the table top.
- Step 5. Ensure that the environment and humidity are within the specifications of the analyzer. If not, please move to a proper environment and wait for 10 minutes.
- Step 6. Ensure that there is no other electromagnetic interference around the analyzer.
- Step 7. Press and hold the power button at the back of the analyzer to shut down the analyzer.
- Step 8. Ensure that Error 1 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

#### Error message \_Error 2 Sample Failed

- Step 1. The touch screen of the analyzer displays Error 2 error message.
- Step 2. Remove the LensHooke Semen Test Cassette from the test cassette inserting slot of the analyzer.
- Step 3. Take a new LensHooke Semen Test Cassette again. Drip the sample or QC liquid for re-analysis.
- Step 4. Ensure that Error 2 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

#### Error message \_Error 3 Control failed

- Step 1. The touch screen of the analyzer displays Error 3 error message.
- Step 2. Remove the Control piece from the test cassette inserting slot of the analyzer.
- Step 3. Take a new Control piece again.
- Step 4. Ensure that Error 3 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

#### Error message \_Error 4 Transmit Failed

- Step 1. The touch screen of the analyzer displays Error 4 error message.
- Step 2. Ensure that the USB connection device; or the HDMI connection device or the device of the connected thermal printer (Optional) is truly connected to the analyzer.
- Step 3. Ensure that Error 4 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

#### Error message \_ Error 5 Out of Range

- Step 1. The touch screen of the analyzer displays Error 5 error message.
- Step 2. Remove the LensHooke Semen Test Cassette from the test cassette inserting slot of the analyzer.
- Step 3. Thoroughly shake the C-KUP Sample Collection Cup /QC liquid.
- Step 4. Take a new semen analysis piece. Drip the sample or QC liquid onto the LensHooke Semen Test Cassette to analyze again.
- Step 5. Ensure that the Error 5 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

#### Error message \_ Error 6 Low Battery

- Step 1. The touch screen of the analyzer displays Error 6 error message.
- Step 2. Connect the adapter of the analyzer.
- Step 3. Ensure that Error 6 error message displayed on the touch screen of the analyzer has been removed. If not, please contact your distributor or the Customer Service.

## Specification

### Product specification

Product name

LensHooke X1 PRO Semen Quality Analyzer

Control panel

3.5-in resistive touch screen

Resolution of the screen panel

320 (H) x 480(V) color dotted matrix

External power input

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

Internal battery durability

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

Internal storage capacity

30 analytical results and images

Detection time

2~5 minutes depending on the sample condition.

Transmission interface

USB 2.0 / HDMI

Usage environment

15-38 deg. (Celsius); 59-100 deg. (Fahrenheit), humidity <70%

Storage environment

15-38 deg. (Celsius); 59-100 deg. (Fahrenheit), humidity <70%

Transport environment

15-38 deg. (Celsius); 59-100 deg. (Fahrenheit) , humidity <70%

power adaptor: Input: 100-240 Vac, 50-60 Hz, 0.5 A

Output: 5 Vdc, 2 A Max

## **Disclaimer**

All relevant contents in the manual related to this product must not be reproduced, distributed, duplicated or stored in any retrieval system or translated into other languages without prior permission in writing from Bonraybio.

Bonraybio reserves the right to change the technical specification of the hardware and software described in this manual at any time without prior notice.

We have made our best efforts to ensure accuracy and completeness of the information described in this manual. If you find any error or missing, please inform your local Bonraybio representative. For this, we express our deepest appreciation.

## **Limitations**

If the sample not liquefied or liquefaction do not complete, which may affect the sperm's analytical result.

Inaccurate test results may be obtained at high altitude more than about 2000 meters above sea level.

Overvoltage Category II

Pollution Degree 2

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

USB Port can be connected to the rated 5Vdc, 0.5A.

Indoor use

## **Parts of Critical Component**

Semen Quality Analyzer, Sample Collection Cup and Test Cassette

Manufacturer: Bonraybio Co., LTD.

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

( CE0197 )

## **Warranty**

Bonraybio Corporation offers you two-year warranty for maintenance from the day you purchase the Semen Quality Analyzer – Medical Edition. During the warranty period, we will perform repair and replacement of the analyzer free of charge.

This warranty only applies to the original LensHooke X1 PRO Semen Quality Analyzer made by Bonraybio Corporation. We will not be liable for the warranty if the product has been sabotaged, modified, damaged or used improperly.

## FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1. FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

2. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

3. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment has very low levels of RF energy that it deemed to comply without maximum permissive exposure evaluation (MPE). But it is desirable that it should be installed and operated keeping the radiator at least 20cm or more away from person's body.

4.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NCC 聲語

注意！

依據 低功率電波輻射性電機管理辦法

第十二條

經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條

低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電通信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。



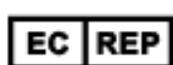
In vitro diagnostic



Do not use repetitively.



Manufacturer



European authorized  
representative



CE mark (with the assigned certification  
body's number)



Store at the room temperature between 4 C ~ 38 C (39 F ~ 86 F)



Bonraybio

4F., No.118, Gongye 9th Rd., Dali Dist.,  
Taichung City 412, Taiwan  
[www.bonraybio.com](http://www.bonraybio.com)  
Tel: +886-4-2491-2385  
Fax: +886-4-2491-2885  
Mail: [service@bonraybio.com](mailto:service@bonraybio.com)



EC REP

Klaus Ellensohn  
Torkelweg 17,  
6833 Klaus,  
Austria

Confidential



[www.bonraybio.com](http://www.bonraybio.com)

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