

PEBBLE qcLAMP Platform

A point-of-care diagnostic device for nucleic acids detection in clinical samples using real-time quantitative colorimetric loop-mediated isothermal amplification (qcLAMP).

For *in vitro* diagnostics use.
For professional use only.

PPL-01-INSTRUCTIONS FOR USE | v2.0 | DATE OF
ISSUE | 14.05.2024




BIOPIX DNA TECHNOLOGY S.A.
Science and Technology Park of Crete
N. Plastira 100, Vassilika Vouton
GR-700 13, Heraklion, Greece

REF 000057

 www.biopix-t.com

 info@biopix-t.com

 (+30) 281 0391986



BIOPIX-T

This Instructions for Use (IFU complies with the requirements of EN ISO 18113-3:2019, IEC 61326-2-6:2020 and IEC 61010-2-101:2018).

The labels used and described into the next sections comply with the requirements of EN ISO 15223-1:2016.

Module and Software Identification

This product is accompanied by:

PEBBLE qcLAMP Platform firmware.

(01) 5210166000041 (11) 28.06.2021 (8012) 1.0.0

PEBBLE qcLAMP Platform mobile application

(01) 5210166000058 (11) 22.02.2024 (8012) 1.0.3

PEBBLE qcLAMP Platform cloud system

(01) 5210166000065 (11) 28.06.2021 (8012) 1.0.0

Warranty and Responsibility

All products of BIOPIX DNA TECHNOLOGY S.A. are tested under rigorous quality management processes. BIOPIX DNA TECHNOLOGY S.A. guarantees to ensure the quality of the product during the warranty period. If there are any issues related to the quality of the product, please contact BIOPIX DNA TECHNOLOGY S.A.

BIOPIX DNA TECHNOLOGY S.A. warrants that the PEBBLE qcLAMP Platform will conform to its specifications and performance for a period of 12 months after its shipment date from the Seller. Non-complying with the warnings and precautions, as well as the product instructions, during the usage of the PEBBLE qcLAMP Platform, will result in the loss of warranty.

The warranty does not cover issues that result from: a) Servicing, fixing, or replacing the product, not authorized by BIOPIX DNA TECHNOLOGY S.A., b) External causes such as accident, abuse, misuse or problems with electrical power and c) missing or altered service tags or serial numbers.

This product complies with the requirements of the European IVD Directive 98/79/EC.

Quality Control System

All aspects of the quality management system, product creation, quality assurance, and supplier qualifications are certified under ISO 13485:2016.

Inquiries and customer service (A/S)

For any further information of inquiries for the product please send us an e-mail (info@biopix-t.com).

TABLE OF CONTENTS

1. INTENDED USE	5
2. PRODUCT DESCRIPTION	5
3. COMPONENTS AND PACKAGING SPECIFICATIONS	6
3.1 List of components	6
3.2 List of compartments	6
4. STORAGE AND HANDLING REQUIREMENTS	7
5. ADDITIONAL MATERIALS AND EQUIPMENT REQUIRED BUT NOT INCLUDED	8
A. Detection Kits	8
B. Equipment	8
C. Consumables	8
6. WARNINGS AND PRECAUTIONS	8
7. INSTRUMENT INSTALLATION	9
8. TEST PROCEDURE.....	14
9. BIOPIX-T CLOUD SYSTEM.....	31
10. RESULTS INTERPRETATION	33
11. CLEANING INSTRUCTIONS	35
12. LIMITATIONS OF USE.....	35
13. TROUBLESHOOTING	35
14. MAINTENANCE	37
14.1 PEBBLE qcLAMP Platform	37
14.2 PEBBLE Platform Application	38
15. DISPOSAL INFORMATION OF THE DEVICE	38
16. SAFETY AND DISCLOSURE OF RESIDUAL RISKS	38
17. REFERENCES.....	38
18. SYMBOLS EXPLAINED	38
19. TECHNICAL SUPPORT	41
20. ABBREVIATIONS USED	41
DOCUMENT HISTORY CHANGE.....	41

1. INTENDED USE

The PEBBLE qcLAMP Platform is a point-of-care diagnostic system for providing specimen examination results for various pathogens that attack the human body, and this is accomplished by using the appropriate sample. . The device can be used for decentralized testing (doctor’s office, ambulance, hotel, limited resource areas etc.).

The PEBBLE qcLAMP Platform is intended to be used only with test kits produced by BIOPIX DNA TECHNOLOGY S.A.

The PEBBLE qcLAMP Platform is intended to be used by professionals only. It is not intended to be used by individuals for self-testing.

2. PRODUCT DESCRIPTION

The PEBBLE qcLAMP Platform is a small-size and lightweight diagnostic device that allows the **molecular rapid** detection of infectious diseases (such as COVID-19 and Influenza type A) at the point-of-care or need. The system performs a real-time quantitative colorimetric loop-mediated isothermal amplification (qcLAMP) by using a novel method for heating the testing vials and reading the result.

During the process run, the color-change of the reagent within the vials is monitored via a digital camera. The camera collects images at predefined time intervals (10 sec), analyzes the red, green, and blue (RGB) pixel values and interprets the analysis into a graph. The graph shows the signal of the color-change (which is expressed as color index units) versus time.

The device connects via Bluetooth to a smart device (mobile phone or tablet) and operates through an Android application, named “PEBBLE Platform”. The application records the data sent from the PEBBLE qcLAMP Platform in real-time and the user has the ability to save the data through the application.

Physical Characteristics

The physical characteristics of PEBBLE qcLAMP Platform are 18.1 cm (length) x 10.7 cm (width) x 5.2 cm (height) and it weighs less than 300 gr, which makes it portable and ideal for use at the point-of-care or need.

3. COMPONENTS AND PACKAGING SPECIFICATIONS

3.1 List of components

1. 1 x PEBBLE qcLAMP Platform device (including the latest PEBBLE firmware)
2. 1 x AC/DC power supply unit
3. 1 x power plug (EU, US, or UK plug)

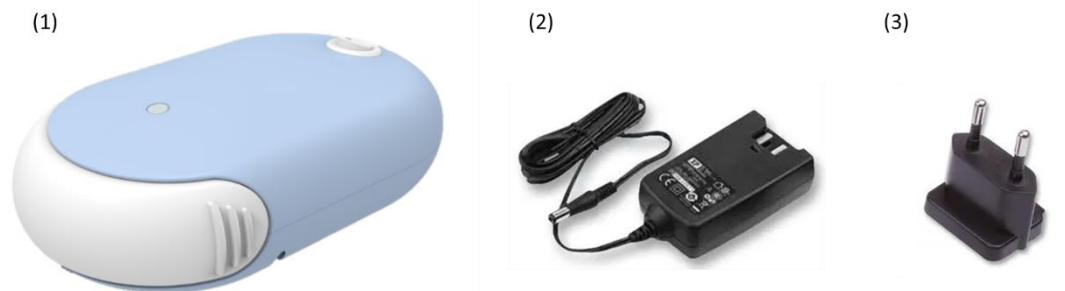
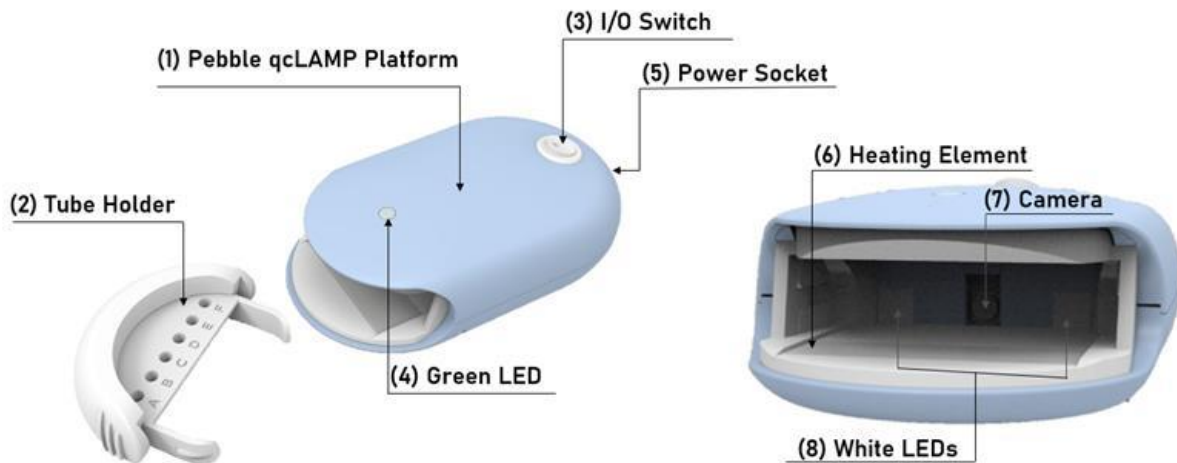


Figure 3.1: Physical components within the package of the PEBBLE qcLAMP Platform.

The PEBBLE Platform Android application is located at the Google Store. Access to BIOPIX-T's cloud system is achieved through the application, after registering the device to the user's account.

3.2 List of compartments

Label	Description	Use
1	PEBBLE qcLAMP Platform device	Main body of the device
2	Tube Holder	Removable part that accepts the vials
3	I/O Switch	Main power switch
4	Green LED Light	Switched on when system is running a test
5	Power Socket	Plugs to the power-supply, with a 5 V DC
6	Heating Element	Heats the vials
7	Camera	Records the pixels of the color-change in the vials
8	White LED Lights	Illuminates the chamber



4. STORAGE AND HANDLING REQUIREMENTS

Keep dry. Do not expose to water.

Operate at room temperature (suggested temperature range: 26°C -30 °C and humidity range at 30% to 75%). Do not refrigerate or freeze.

For long storage, please keep the system within its package at room temperature The acceptable range of temperature for storage is at -25 °C up to 70 °C and humidity permissible storage limits at 0% up to 93%.

During operation, keep the device away from air currents.

Environmental limitation for product’s stability.	
Operational temperature range	Functional: 20°C - 30°C Optimal *suggested range: 26°C-30°C
Storing temperature range	-25°C up to 70°C Suggested: Room Temperature
Transportation temperature range	-25°C up to 70°C
Operational humidity range	Functional up to 93% Suggested range 30%-75%
Storage humidity range	Up to 93%
Transportation humidity range	Up to 93%

***CAUTION:** In case of low room temperature (<20 °C) during the first run, it is suggested to pre-run a test without reagents until it’s finished and then wait for approximately 10 minutes to start the process as it is described in the following instructions.

5. ADDITIONAL MATERIALS AND EQUIPMENT REQUIRED BUT NOT INCLUDED

A. Detection Kits

Detection kits produced by BIOPIX DNA TECHNOLOGY S.A.

B. Equipment

- Android based smart device (mobile phone or tablet) with android version **v5.1 up to v14.0** (or the latest in the market). It is recommended to have a minimum of 4Gb RAM.

C. Consumables

- Multiply-Pro PCR single tube, 0.2 mL from SARSTEDT Cat. No. 72.737.002 (DNA-free, DNase-/RNase-free, PCR Inhibitor-free) or any other equivalent PCR single tube, 0.2 mL with the following specifications:

Specifications: safe lock, high-profile mini-PCR tubes.

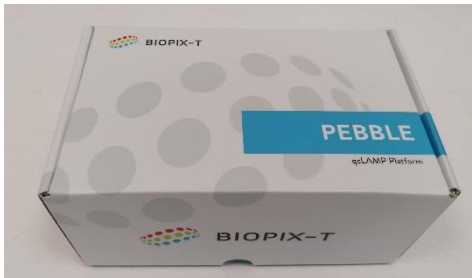

Dimensions: Height with lid: 21.6mm-21.7mm, outer diameter (OD): 5.9mm-6.1mm.

6. WARNINGS AND PRECAUTIONS


- For *in vitro* diagnostic (IVD) use.
- For professional use only.
- It is not intended to be used by individuals for self-testing.
- State guidelines on biosafety should be followed in all circumstances.
- Use DNase and RNase free disposable consumables.
- Testing should be performed in an appropriately equipped facility by trained personnel.
- Use the device in a non-contaminated and nuclease-free area. Non-complying with this, might result in false outcomes.
- Do not use this instrument near sources of strong electromagnetic radiation, as these may interfere with the proper operation of the PEBBLE qcLAMP Platform. It is advised that the electromagnetic environment should be evaluated prior to operation of the device.
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- Keep clean the reaction chamber. In case of contamination, contact BIOPIX DNA Technology S.A. help desk via e-mail (info@biopix-t.com).
- The device is neither water-resistant nor waterproof.
- Always place the device on a flat surface.
- Use only compatible kits, consumables and equipment that meets the specifications provided by BIOPIX-T.
- Make sure you have a strong Bluetooth connection to avoid unexpected termination of the device's operation.
- Ensure you have a strong and secure internet connection, to avoid connection loss with the cloud service.

- Handle with care. If not, parts could detach, dislocate, or deform. In such case, please contact BIOPIX DNA Technology S.A. technical support (see section 13.2).
- Do not disassemble the PEBBLE qcLAMP device as it might result to performance issues.
- Do not touch or move neither the camera nor camera lens. Sensitivity can be significantly reduced.
- After analysis qcLAMP reaction tubes must not be opened to avoid contamination with DNA amplicons, which could result in false positive results.
- Dispose the used tubes as medical waste.
- Non-compliance with these warnings and precautions may result in permanent malfunction of the system or/ and false diagnosis.
- Between runs, it is suggested to leave approximately a 10 min time-space (from the end of one analysis to the start of the next). During this time, keep the tube holder out of the chamber of PEBBLE qcLAMP Platform.


7. INSTRUMENT INSTALLATION

7.1 ACTIONS UPON DELIVERY		
STEP	DESCRIPTION	IMAGE
7.1.1	Check package. If it is damaged do not open and contact BIOPIX-T technical support.	
7.1.2	Unbox the components. Take out PEBBLE qcLAMP Platform, power supply body and power plug. Check the items. If they are damaged do not use the system prior to contacting BIOPIX-T.	

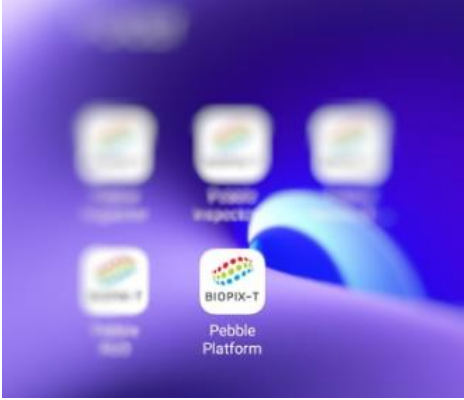
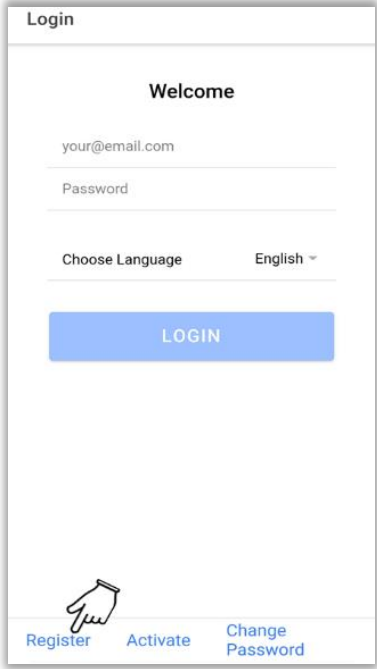


<p>7.1.3</p>	<p>Assemble power supply.</p> <p>Insert power plug in designated position on the power supply body, push and secure in place.</p>	
---------------------	---	---

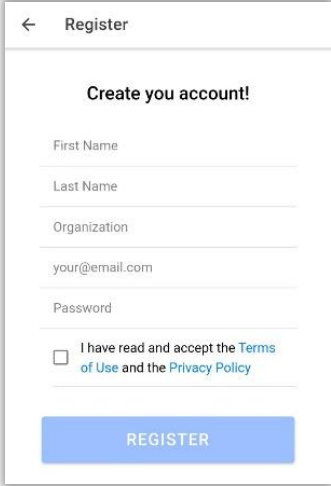
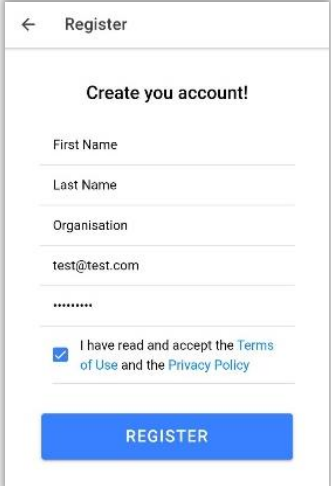
7.2 INSTALLATION OF APPLICATION AND REGISTRATION

<p>7.2.1</p>	<p>Open Google Play Store on the device. Search for the PEBBLE Platform application powered by BIOPIX-T, download and install it.</p>	
---------------------	---	--

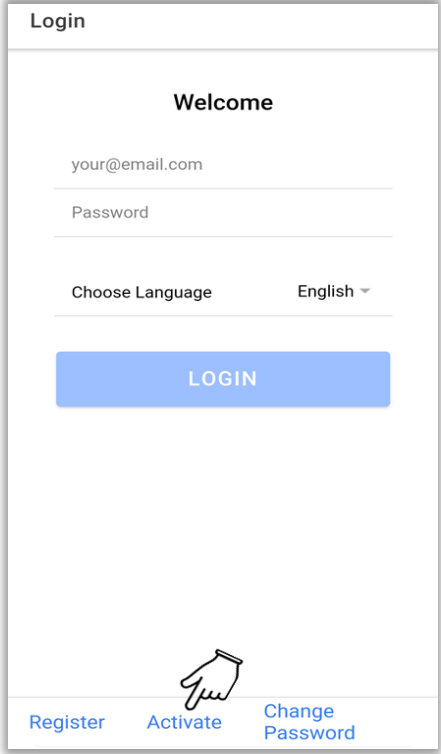
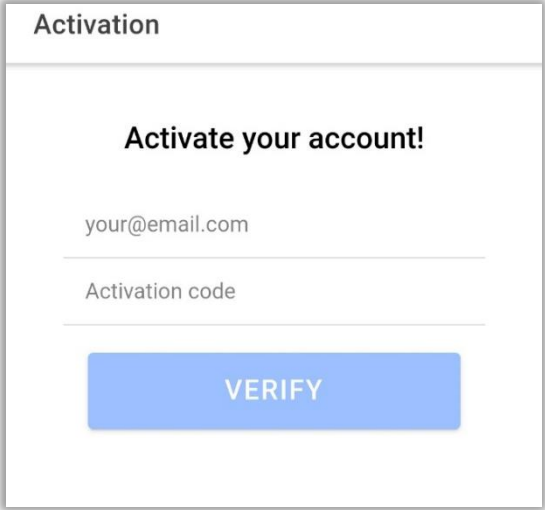


<p>7.2.2</p>	<p>Open application</p>	
<p>7.2.3</p>	<p>Choose language . To change language, click on “Choose Language”.</p>	
<p>7.2.4</p>	<p>Click on Register button</p>	



<p>7.2.5</p>	<p>Fill in the fields with the requested info. In order to be able to register, user has to accept the terms of use and privacy policy of BIOPIX DNA TECHNOLOGY S.A.</p>	 <p>The screenshot shows a mobile application interface for registration. At the top, there is a back arrow and the title 'Register'. Below this is the heading 'Create you account!'. The form contains several input fields: 'First Name', 'Last Name', 'Organization', an email field with the placeholder 'your@email.com', and a 'Password' field. At the bottom of the form, there is a checkbox that is currently unchecked, followed by the text 'I have read and accept the Terms of Use and the Privacy Policy'. A blue 'REGISTER' button is positioned at the very bottom of the form.</p>
<p>7.2.6</p>	<p>Click on the REGISTER button. A verification code will be sent to your registered e-mail account.</p>	 <p>This screenshot is identical to the one above, showing the same registration form. The only difference is that the checkbox for 'I have read and accept the Terms of Use and the Privacy Policy' is now checked with a blue checkmark.</p>



<p>7.2.7</p>	<p>To verify and activate your account, click on the Activate button.</p>	
<p>7.2.8</p>	<p>Fill in your email assigned to the account and the received activation code.</p>	



<p>7.2.9</p>	<p>Click on VERIFY</p>	
<p>7.2.10</p>	<p>After verifying your account, fill-in your e-mail and password and click LOGIN.</p>	
	<p>Contact information of BIOPIX DNA Technology S.A. are located in section 19 Technical Support.</p>	

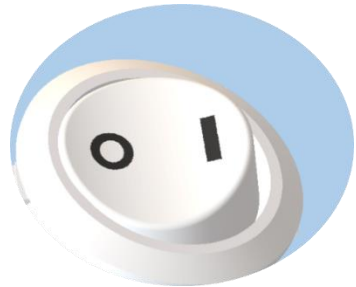
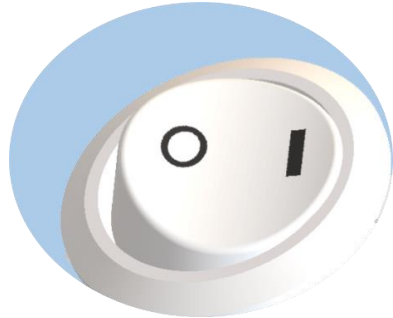
8. TEST PROCEDURE

Please read carefully the Instructions for Use for both the kit and the PEBBLE qcLAMP Platform before usage.

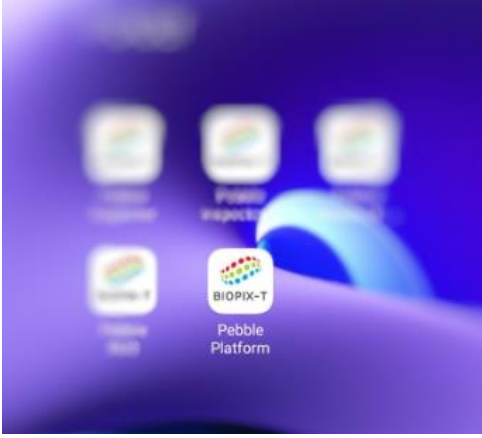
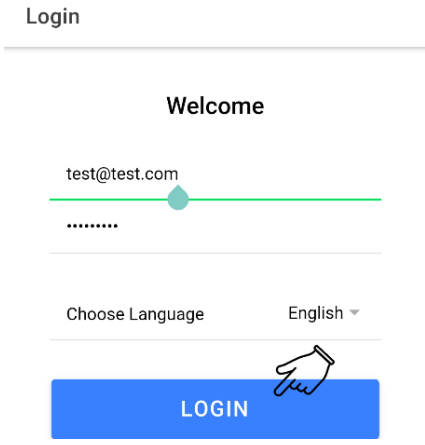

Ensure that your PEBBLE qcLAMP Platform will be operating in environmental conditions as described in section 4. STORAGE AND HANDLING REQUIEREMENTS, and is not exposed directly to air currents.

Make sure you have a strong and secure internet connection during testing.

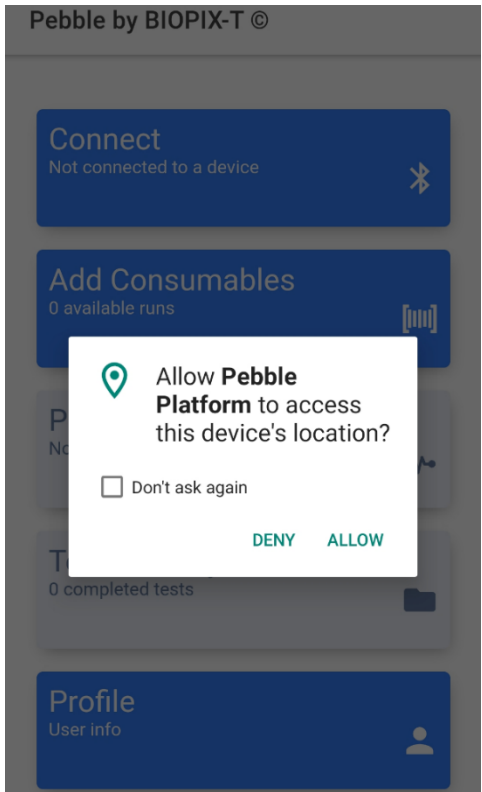
Clickable buttons are depicted as either bright Blue or bright Red. When buttons are disabled, their colors are either grey, light blue, or light red.

8.1 POWERING ON PEBBLE qcLAMP Platform		
STEP	DESCRIPTION	IMAGE
8.1.1	<p>Ensure that the device is switched off before plugging the power supply.</p> <p>When O is pressed, the device is OFF. When I is pressed, the device is ON.</p>	
8.1.2	<p>Turn on the device.</p> <p>You need to wait approximately two to three minutes (2-3 min) for the system to boot, in order to be detected via Bluetooth.</p> <p>If it is the first time that you turn on the system, you will have to wait for 5-6min.</p>	

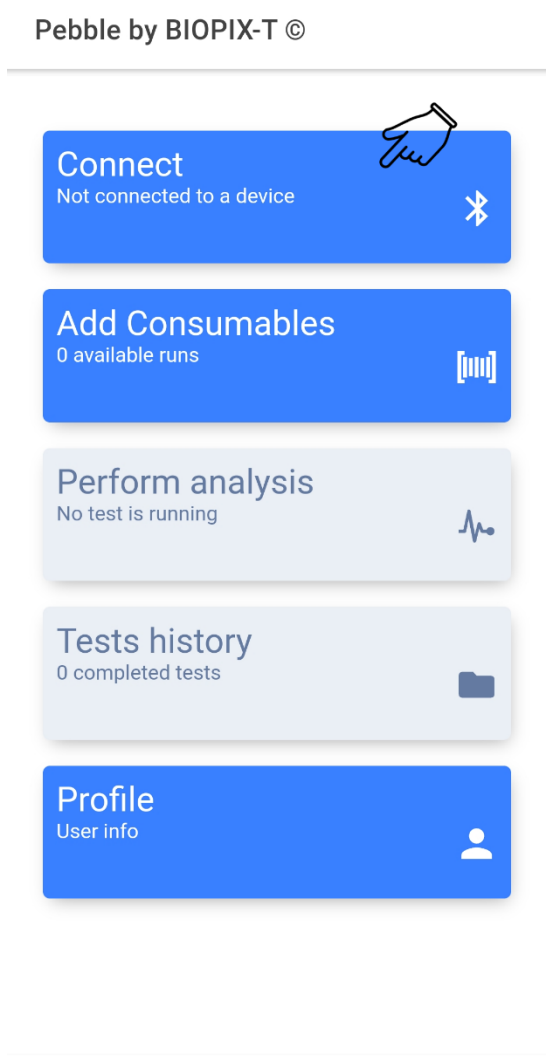
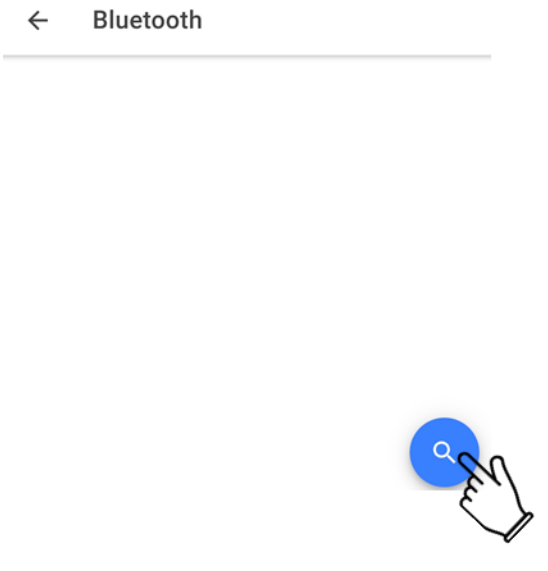


<p>8.1.3</p>	<p>Open PEBBLE Platform application on your smart device.</p>	
<p>8.1.4</p>	<p>Once the application is active, user must login by inserting the registered e-mail and password and press LOGIN.</p>	
<div style="background-color: red; width: 100%; height: 100%;"></div>	<p>Make sure that you have enabled the Bluetooth and the internet option on your smart device.</p>	

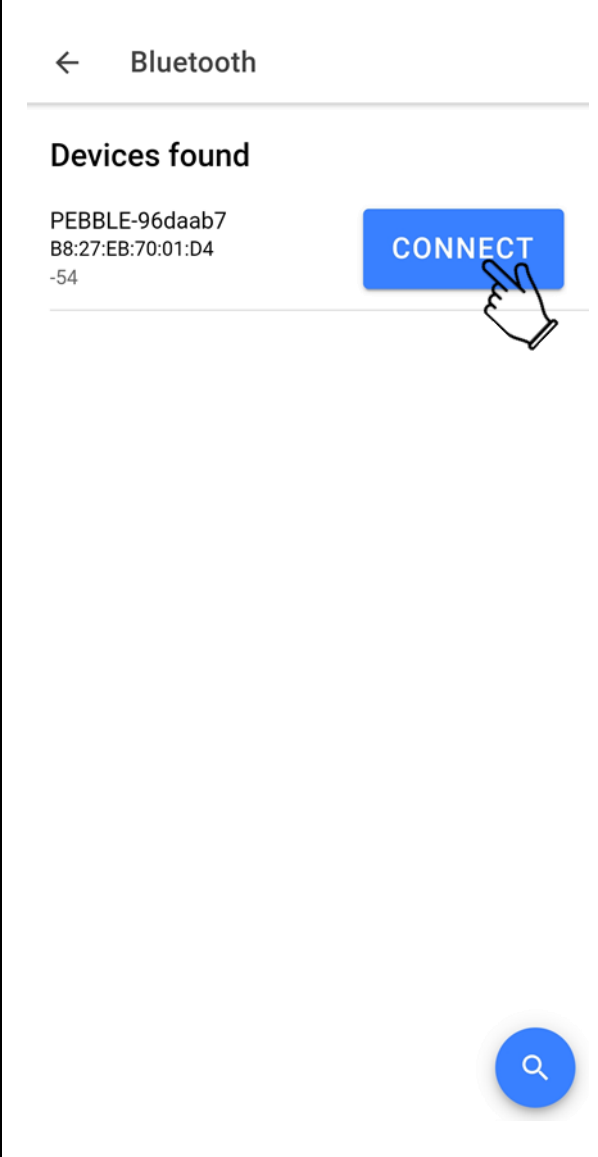


<p>8.1.5</p>	<p>After login, you will be redirected to the home menu.</p> <p>A message will appear which will inform you regarding the reason why Pebble Platform application has to access the device's location data. At this point, you have to accept the reason by pressing the 'ACCEPT' button.</p> <p>Your smart-device will ask to allow Pebble Platform application to access device's location via a popup window. To use the application, location permissions must be allowed.</p>	<p>This app needs location data even when the app is closed or not in use, to enable Bluetooth connectivity with the corresponding device while collecting them helps us better understand the spread of the infectious diseases we are trying to combat.</p> <p>ACCEPT REJECT</p> <hr/> 
---------------------	---	--




<p>8.1.6</p>	<p>Click on option Connect.</p>	<p>Pebble by BIOPIX-T ©</p> 
<p>8.1.7</p>	<p>Available devices will show up automatically. You can also search for devices by clicking on the blue search button on the bottom right corner of the screen.</p>	<p>← Bluetooth</p> 





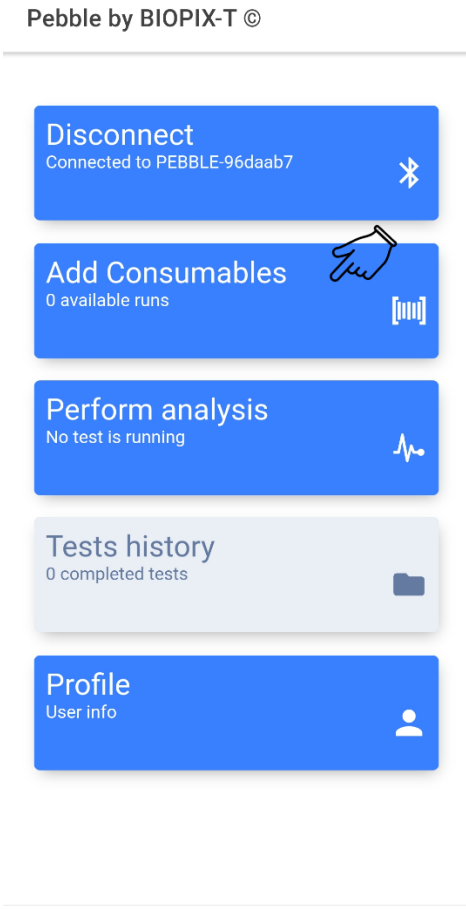
<p>8.1.8</p>	<p>Once device is found, click on the CONNECT button in order to pair your smart-device with the available device.</p> <p>Otherwise, scan again.</p>	 <p>The screenshot shows a mobile application interface for Bluetooth connections. At the top, there is a back arrow and the title "Bluetooth". Below this is a section titled "Devices found". A single device is listed with the name "PEBBLE-96daab7", the MAC address "B8:27:EB:70:01:D4", and a signal strength indicator "-54". To the right of the device name is a blue button labeled "CONNECT". A hand icon is shown pointing at the "CONNECT" button. At the bottom right of the screen, there is a blue circular button with a magnifying glass icon, representing a search or scan function.</p>
---------------------	---	--



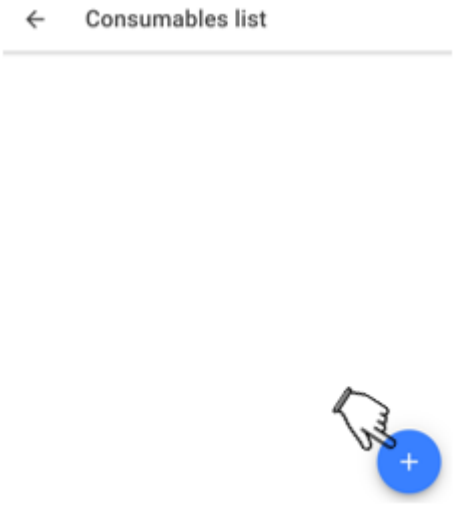
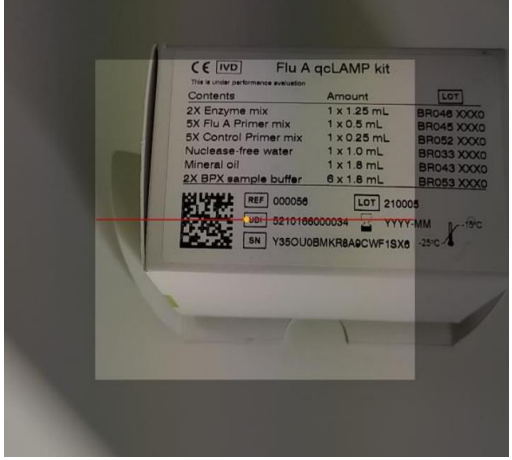
<p>8.1.9</p>	<p>after the connection you will be automatically redirected to the diagnostic interface of the app. If diagnostics are successfully completed, you will be redirected in the next screen.</p>	<p>Diagnostics</p> <hr/>  <p>Everything was fine. You will be redirected in 3 seconds.</p>
<p style="background-color: red; color: red;"> </p>	<p>If hardware diagnostics fail, please contact BIOPIX-T (see section 19 Technical Support).</p> <p>For example, if the temperature sensor is disconnected you will see a message. Same for camera, led light and hardware controls.</p>	<p>← Diagnostics</p> <hr/> <p>Temperature sensor seems disconnected.</p>




<p>8.1.10</p>	<p>After completing the hardware diagnostics check, you will need to assign your PEBBLE device by simply scanning the data matrix code (QR code).</p>	<p>Diagnostics</p> <hr/> <p>Device is not assigned yet. Using the button below, please scan the code of the device to continue.</p> 
	<p>The QR code is found either on the bottom of the device or on the side of the PEBBLE qcLAMP Platform packaging. The assign verification takes place only during the first connection of the system with a smart device.</p> <p>During any following connection, a pop-up message will appear to confirm the successful connection right after the diagnostics without demanding a new assign verification.</p>	

8.2 ADD CONSUMABLES		
STEP	DESCRIPTION	IMAGE
8.2.1	To load consumables, click on the Add Consumables button.	




<p>8.2.2</p>	<p>A pop-up window will appear to scan your data matrix code (it is located on the back side of the KIT package).</p> <p>Your smart device will ask to allow Pebble Platform application to take pictures and record video via a pop-up window.</p> <p>To use the application, permissions must be allowed.</p>																						
<p>8.2.3</p>	<p>Hold your smart device until the scan is successful.</p> <p>For any following use of the same kit, the above steps will not be part of the procedure, only in case of new purchased kit.</p>	 <table border="1" data-bbox="1047 882 1372 1018"> <thead> <tr> <th>Contents</th> <th>Amount</th> <th>LOT</th> </tr> </thead> <tbody> <tr> <td>2X Enzyme mix</td> <td>1 x 1.25 mL</td> <td>BR046 XXXX</td> </tr> <tr> <td>5X Flu A Primer mix</td> <td>1 x 0.5 mL</td> <td>BR045 XXXX</td> </tr> <tr> <td>5X Control Primer mix</td> <td>1 x 0.25 mL</td> <td>BR052 XXXX</td> </tr> <tr> <td>Nuclease-free water</td> <td>1 x 1.0 mL</td> <td>BR033 XXXX</td> </tr> <tr> <td>Mineral oil</td> <td>1 x 1.8 mL</td> <td>BR043 XXXX</td> </tr> <tr> <td>2X BPX sample buffer</td> <td>6 x 1.8 mL</td> <td>BR053 XXXX</td> </tr> </tbody> </table>	Contents	Amount	LOT	2X Enzyme mix	1 x 1.25 mL	BR046 XXXX	5X Flu A Primer mix	1 x 0.5 mL	BR045 XXXX	5X Control Primer mix	1 x 0.25 mL	BR052 XXXX	Nuclease-free water	1 x 1.0 mL	BR033 XXXX	Mineral oil	1 x 1.8 mL	BR043 XXXX	2X BPX sample buffer	6 x 1.8 mL	BR053 XXXX
Contents	Amount	LOT																					
2X Enzyme mix	1 x 1.25 mL	BR046 XXXX																					
5X Flu A Primer mix	1 x 0.5 mL	BR045 XXXX																					
5X Control Primer mix	1 x 0.25 mL	BR052 XXXX																					
Nuclease-free water	1 x 1.0 mL	BR033 XXXX																					
Mineral oil	1 x 1.8 mL	BR043 XXXX																					
2X BPX sample buffer	6 x 1.8 mL	BR053 XXXX																					

8.3 PREPARE YOUR SAMPLES		
STEPS	DESCRIPTION	IMAGE
	<p>For this step, please refer to the respectively Instruction for Use (IFU) of the respective kit.</p> <p>You can find the Instructions for Use of all BIOPIX-T's products at the company's website (www.biopix-t.com).</p>	


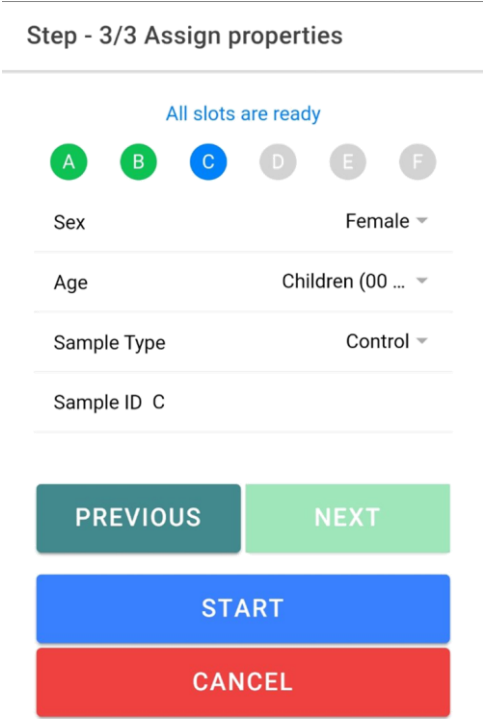
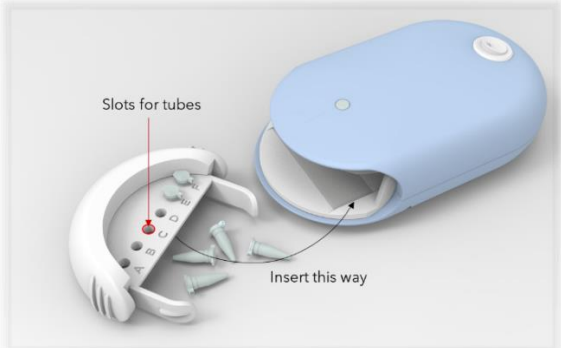


8.4 PERFORM ANALYSIS AND START TESTING		
STEP	DESCRIPTION	IMAGE
8.4.1	Click on Perform analysis button.	
8.4.2	<p>Set the Number of samples. Set number of samples (ranging from minimum 1 to maximum 6) and click ok.</p> <p>When selecting the number of samples, you should include your control sample (if applicable).</p>	





<p>8.4.3</p>	<p>Then, select the name of the consumable that you will use for the run.</p> <p>You may have more than one options, based on the purchased kits.</p> <p>The number of available runs is shown on this screen.</p>	<p>Step - 2/3</p> <hr/> <p>Select consumable</p> <p>Name </p> <p>4817 available runs ID: Z7XW90PGHS8YJ3F11ECM</p> <hr/> <p>NEXT</p> <p>CANCEL</p>
<p>8.4.4</p>	<p>Enter the required information for each sample you will use.</p> <p>Based on the number of samples you have chosen (including any control samples) the equivalent number of slots will be available.</p> <p>Blue background color indicates the current slot that is filled with data.</p> <p>Green border color indicates that the slot has no data yet and needs to be filled with data.</p> <p>Grey background indicates that the current slot is unavailable.</p>	<p>Step - 3/3 Assign properties</p> <hr/> <p>A B C D E F</p> <p>Sex <input type="text"/></p> <hr/> <p>Age <input type="text"/></p> <hr/> <p>Sample Type <input type="text"/></p> <hr/> <p>Sample ID Write here <input type="text"/></p> <hr/> <p>PREVIOUS NEXT</p> <p>START</p> <p>CANCEL</p>



	<p>Please note down the information of each sample for your own use, since data is erased from the screen after the end of the test. To get access to previous data information please refer to section 9. BIOPIX-T CLOUD SYSTEM.</p> <p>Please make sure that personally identifiable information (e.g. passport number, social security number, name, etc.) should not be used in the Sample ID field.</p>	
<p>8.4.5</p>	<p>Once you assign the information of all the samples, the slots are activated by changing color to green.</p> <p>ATTENTION! DO NOT PRESS YET THE START BUTTON.</p>	
<p>8.4.6</p>	<p>When your samples are prepared, push them in the tube holder slots starting from A to F. Make sure to place them in the correct order.</p> <p>Make sure that tubes are pushed all the way in. Insert the tube holder in the PEBBLE qCLAMP Platform.</p>	



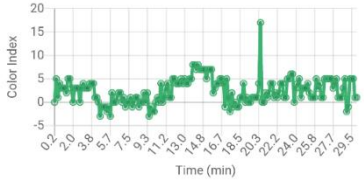
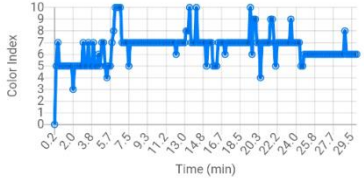

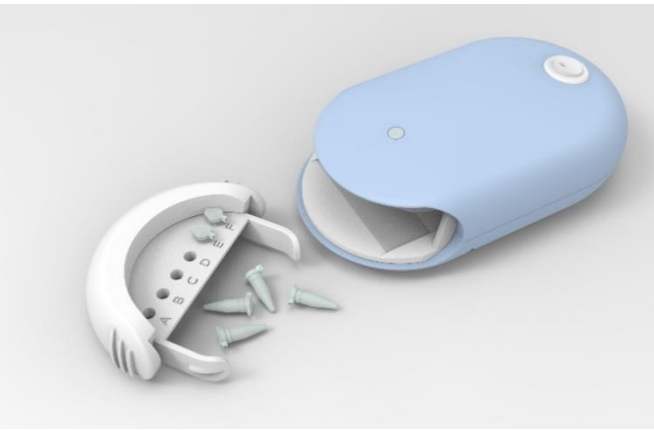

	<p>There are guiding paths to make sure the tube holder is in place, into the device</p>	
<p>8.4.7</p>	<p>Once you have inserted the tube holder inside the main body of PEBBLE qcLAMP device, click the START button.</p>	<p>Step - 3/3 Assign properties</p> <hr/> <p style="text-align: center;">All slots are ready</p> <p style="text-align: center;"> A B C D E F </p> <p>Sex Female ▾</p> <hr/> <p>Age Children (00 ... ▾</p> <hr/> <p>Sample Type Control ▾</p> <hr/> <p>Sample ID C</p> <hr/> <p style="text-align: center;"> PREVIOUS NEXT </p> <p style="text-align: center;"> START </p> <p style="text-align: center;"> CANCEL </p> 
<p>8.4.8</p>	<p>A green LED light on top of the PEBBLE device should light up to indicate that the test run started.</p>	




<p>8.4.9</p>	<p>The data curves are displayed in real time on the smart device (color index units as a function of time).</p>	<p>Test monitoring</p> <p>STOP LOGS</p> <p>Slot: A Sample ID: A Sample Type: Covid-19</p> <p>Slot: B Sample ID: slot B Sample Type: Control</p> <p>Slot: C Sample ID: C Sample Type: Covid-19</p>
	<p>For data readout and decision making please refer to section 10. RESULT INTERPRETATION.</p>	

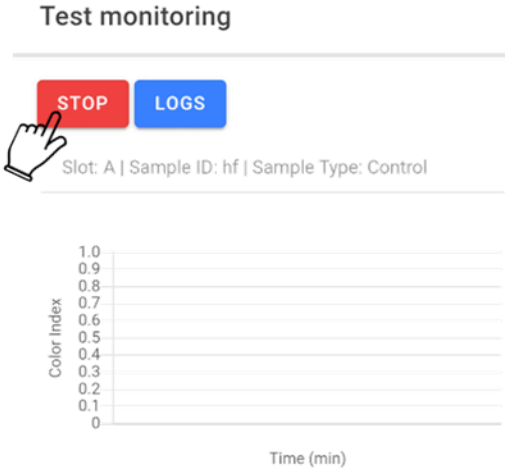
8.5 END OF TEST		
STEP	DESCRIPTION	IMAGE



<p>8.5.1</p>	<p>When the top green LED turns off, the test is completed. User can choose to EXIT from the test monitoring screen.</p>	<p>Test monitoring</p> <p>EXIT LOGS</p> <p>Slot: A Sample ID: A Sample Type: Covid-19</p>  <p>Slot: B Sample ID: slot B Sample Type: Control</p>  <p>Slot: C Sample ID: C Sample Type: Covid-19</p> 
<p>8.5.2</p>	<p>You can now safely remove the tube holder part and the vials from the tube holder.</p>	
	<p>Please be careful when removing the tube holder from the main body of PEBBLE.</p> <p>CAUTION! DO NOT OPEN the tubes after the analysis as there is a high risk of contaminating the area, including the device.</p>	



	<p>In case of an incident, please contact BIOPIX-T. For tech support information refer to section 19 Technical Support.</p>	
	<p>Do not touch the heating element since it reaches high temperatures and could resort to burn injury.</p>	

8.6 STOP TEST		
STEP	DESCRIPTION	IMAGE
<p>8.6.1</p>	<p>To stop the test prior to the completion of the process, click on the STOP button on the top of the test monitoring screen.</p>	



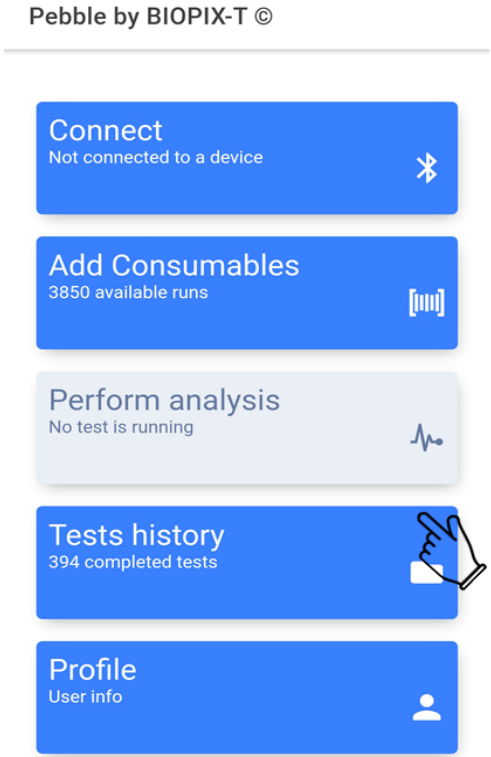
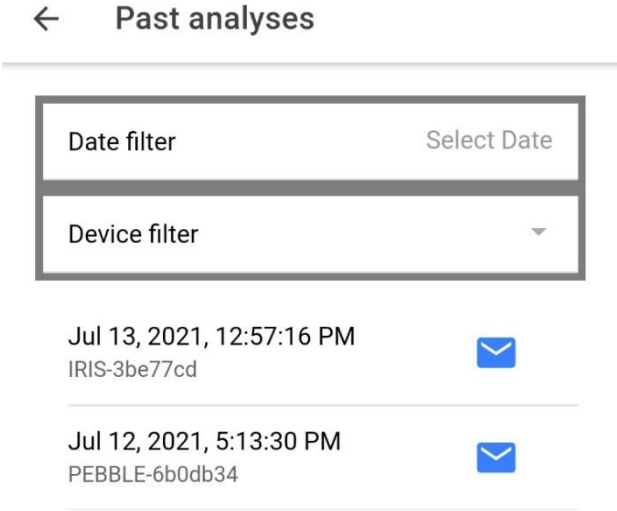
<p>8.6.2</p>	<p>A pop-up message will appear. Click on CONFIRM and you will be automatically redirected to the home menu.</p> <p>Any recorded data up to the stop time will be available through the application.</p> <p>For accessing old data, please refer to section 9. BIOPIX-T CLOUD SYSTEM.</p>	
---------------------	---	--

9. BIOPIX-T CLOUD SYSTEM


BIOPIX-T provides PEBBLE users the ability to access past records. Data from previous tests are stored in the Test History within the application which can be recalled at any time.

9.1 USE OF CLOUD SYSTEM		
STEP	DESCRIPTION	IMAGE



<p>9.1</p>	<p>To access your data, click on the Tests History tab in home menu.</p>	
<p>9.2</p>	<p>You can filter and select by date or/and by device of your choice (in case you have more than one PEBBLE qcLAMP Platform).</p>	



	<p>Please make sure that the data are visible only by the authorized user.</p>	
--	--	--

10. RESULTS INTERPRETATION

- Color change is expressed as color index units on the Y-axis of a real-time curve that is displayed on the screen of a smart device. Up to six (6) curves can be displayed simultaneously.
- The duration of a test is 30 min. Evaluation of the results should be performed by the end-user.

POSITIVE TEST RESULTS

The specific time-point at which a change in the slope of the real-time curve occurs (color index units increase) corresponds to the “time-to-positive” result (red solid line). This is the point at which the two dotted red lines cross each other. When a sample is positive for any target, the slope of the curve **WILL CHANGE** as shown in the following image (Figure 1).

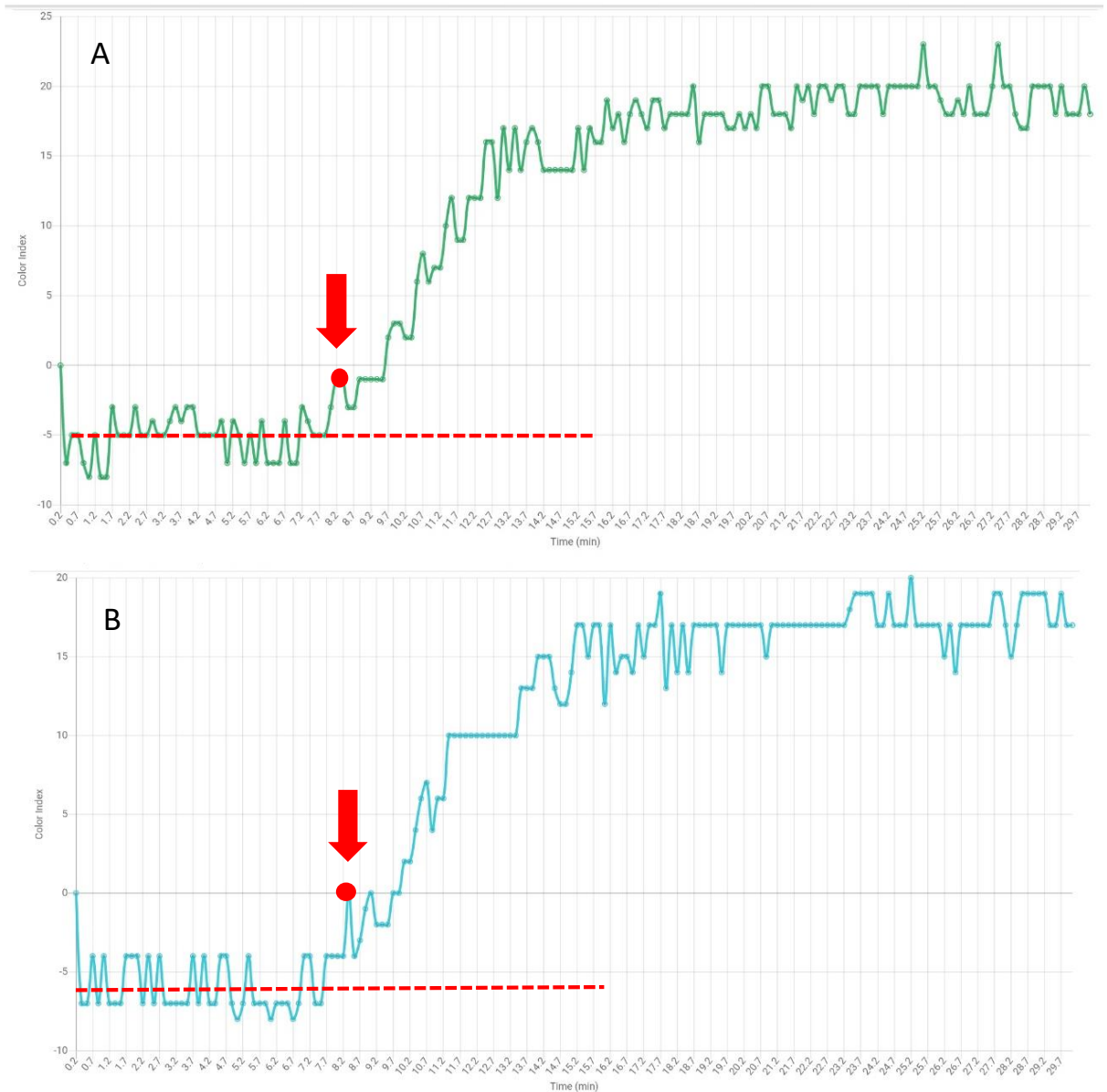


Figure 1: Time-to-positive interpretation results when a sample is positive (samples A,B).

NEGATIVE TEST RESULTS

A negative result is indicated by a flat curve (color index units do not increase to positive values) maintained throughout the monitoring period. When a sample is negative for any target the slope of the curve **WILL NOT CHANGE** (see Figure 2).

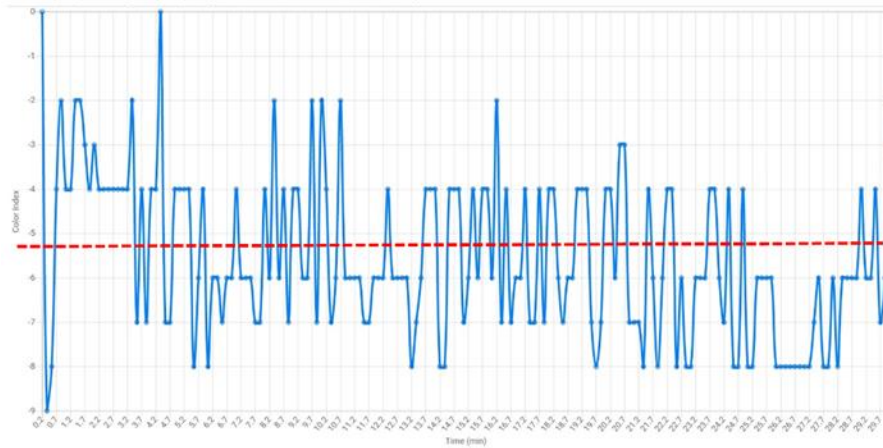


Figure 2: Time-to-positive interpretation results when sample is negative.

11. CLEANING INSTRUCTIONS

- In case of contamination, use gentle surface decontaminants such as 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite) or equivalent to disinfect reaction chamber and tube holder of the system.
- Please be careful while cleaning. Do not touch the camera or camera lens.
- Ensure the tube holder is dry before loading onto the device.
- Do not use ethanol at the outer parts of the device, as it may cause the loss of color's intensity.

12. LIMITATIONS OF USE

- PEBBLE qcLAMP Platform should be used by professionals only.
- PEBBLE qcLAMP Platform has been validated for use with diagnostic kits of BIOPIX DNA TECHNOLOGY S.A.
- For reliable results, it is essential to adhere to this IFU, as well as to the IFU related to the kits. Changes may result to incorrect results. BIOPIX-T does not have any responsibility for data produced from users that deviate from instructions for use of the product.
- Results must be evaluated by a trained health care professional, in the context of medical history, clinical samples and other diagnostic tests, in order to make a medical diagnosis.
- A false negative test result may occur if the viral load level in a sample is below the limit of detection of the test or if the sample was improperly collected, handled, or transported.
- PEBBLE qcLAMP Platform must be used only under environmental specifications as described in section 4. STORAGE AND HANDLING REQUIREMENTS).

13. TROUBLESHOOTING

MOST COMMON CAUSES OF FALSE RESULTS		
RESULT	POTENTIAL REASON	SOLUTION
False Positive	Contamination of workspace area	Decontaminate with 10% bleach
	Opening of reaction tubes after the analysis	Decontaminate with 10% bleach
	Deviation from handbook protocol	Consult the instructions for use of the IVD kit
	Incorrect heating temperature.	Contact BIOPIX-T
	Improper handling of samples and/or positive controls	Refer to the instructions for use of the IVD kit
False Negative	Samples with viral load lower or close to the limit of detection	Refer to the instructions for use of the IVD kit
	Incorrect heating temperature	Contact BIOPIX-T
	Deviation from handbook protocol	Consult the instructions for use of the IVD kit
	Improper collection, handling, and/or storage of samples (including improper extraction process)	Confirm that all the handling procedures have been done correctly or repeat the sample collection procedure.
	Tubes are not properly placed inside the tube holder.	Make sure that the tubes are firmly placed in the tube holder
	The presence of inhibitors or interfering substances	Refer to the instructions for use of the kit

PEBBLE qcLAMP Platform device		
FAILURE MODE	POTENTIAL CAUSE	SOLUTION
Green LED does not light up when you start the test	Malfunction of green LED	No action needs to be taken. The system remains functional.
	Malfunction of electronics	Contact BIOPIX-T
White LEDs inside the device do not light up	The run button is not pressed	Press the start button again
	Malfunction of electronics	Contact BIOPIX-T
Device does not power up	The device is not plugged	Plug the device
	Malfunction of electronics	Contact BIOPIX-T
	Device plugged in with wrong power supply	Plug in only the power supply that comes along with the Pebble device.



Power Outage	Device shuts down if it is not connected to a UPS.	Any data points of the experiment are saved to your cloud account up to the point where device lost the power input.
Plastic parts are deformed/distressed or damaged	User misuse or dropping device.	Do not use the device. Contact BIOPIX-T
Heating element does not work	Malfunction of electronics	Contact BIOPIX-T
Over heating	Temperature sensor is detached	Contact BIOPIX-T
Loss of sensitivity	Camera lens has relocated, or the focus is off.	Contact BIOPIX-T
Noisy data	Illumination of the chamber is not constant	Contact BIOPIX-T

APPLICATION AND CLOUD SYSTEM		
FAILURE MODE	POTENTIAL CAUSE	SOLUTION
Inability to install application	Incompatible Android version.	Use a device with a compatible version of Android.
Inability to login to user's account	Lack of internet access	Connect to an available network
Inability to connect to the device	User's smart device lacks location (GPS) and Bluetooth modules.	Use a device with enabled options of Bluetooth and location (GPS).
	Smart device and Pebble are out of Bluetooth range.	Try to keep both devices within the same room.
Loss of credential	The user does not remember his/her username/password and is unable to login to the account.	Contact BIOPIX-T

- For technical support refer to section 19 TECHNICAL SUPPORT.

14. MAINTENANCE

14.1 PEBBLE qcLAMP Platform

PEBBLE qcLAMP device does not have an applicable maintenance process.

14.2 PEBBLE Platform Application

- PEBBLE Platform Application updates will be delivered through the Google's Play Store.
- After each release, the users are informed about the changes that have been made to the system via a pop-up message once the application is activated.

15. DISPOSAL INFORMATION OF THE DEVICE

- All plastic parts are 100% recyclable.
- Packaging box is 100% recyclable.
- PEBBLE qcLAMP Platform should be disposed as an electrical device according to all local, state, country, and federal regulations.
- For disposal of the tubes and consumables, refer to disposal information in the Instructions for Use of each kit you are using.

16. SAFETY AND DISCLOSURE OF RESIDUAL RISKS

The Risk Management Process for BIOPIX-T complies with the ISO 14971:2019. Therefore, the Pebble qcLAMP Platform does not carry any residual risks.

All the identified risks have been accepted by the BIOPIX-T by mitigation control measures.











Furthermore, Pebble qcLAMP Platform has successfully passed all the safety tests and complies with the requirements IEC 61010-2-101:2018 and IEC 61326-2-6:2012.

17. REFERENCES












- [1] G. Papadakis et al., "Real-time colorimetric LAMP methodology for quantitative nucleic acids detection at the point-of-care," no. 89, pp. 1–20, 2020, doi: 10.1101/2020.07.22.215251.
- [2] World Health Organization (WHO), "Coronavirus disease 2019 (2019-nCoV) Situation Report – 11," WHO Bull., no. January 31, pp. 1–7, 2020.
- [3] COV19 qcLAMP kit, Instructions for Use, BIOPIX-T
- [4] Flu A qcLAMP kit, Instructions for Use, BIOPIX-T



18. SYMBOLS EXPLAINED



Symbol	Title/Meaning/Referent	Function/description
	Website	To identify the website of the manufacturer.
@	E-mail	To identify the e-mail of the manufacturer.
	Phone number	To identify the phone number of the manufacturer.
	Manufacturer	To identify the manufacturer of a product.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	European Conformity	To identify the approval of the National Competent Authority
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Waste Electrical and Electronic Equipment	To indicate that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	Do not use if package is damaged	To indicate that the device must not be used if the package holding the device is damaged.
	<i>In vitro</i> diagnostic	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device.



	Unique Device Identifier	Indicates a carrier containing Unique Device Identifier information.
	Keep away from rain/moisture	To indicate that the transport package and stored device shall be kept dry and away from rain and water.
	Temperature limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
	Humidity limitation	To indicate the acceptable upper and lower limits of relative humidity for handling, transport and storage.
	Read operator's electronic manual	To indicate that the operator's electronic manual or card should be read before continuing the operation.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.
	Wireless Communications	To identify the control that enables or activates wireless communications. To indicate the operational status of the wireless communications function.
	Use by date	To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
	Click here	To guide the user where to click on the application.
	Not for self-testing	To indicate that the device (applies to rapid tests only) is not intended for self-testing.
	For near patient testing	To indicate that the device is only to be used in a near patient setting by a health professional.

	Caution, Hot surface	To indicate that the marked item can be hot and should not be touched without taking care.
	Color Indicator	To indicate the color of the PEBBLE qcLAMP device.

19. TECHNICAL SUPPORT

For technical support, please contact BIOPIX-T at:

Address: BIOPIX DNA TECHNOLOGY S.A. , Science and Technology Park of Crete, N. Plastira 100, Vasilika Vouton, GR-700 13, Heraklion, Greece.

Phone: (+30) 281 0391985

E-mail: info@biopix-t.com

20. ABBREVIATIONS USED

- BIOPIX-T: BIOPIX DNA TECHNOLOGY S.A
- CAT# : Catalogue Number
- DNA: Deoxyribonucleic acid
- EU: European Union
- IFU: Instructions for Use
- LAMP: Loop-mediated isothermal amplification
- LED: Light Emitting Diode
- OD: Outer Dimension
- PCR: Polymerase Chain Reaction
- qcLAMP: quantitative colorimetric Loop-mediated isothermal amplification
- RNA: Ribonucleic acid
- UI: User Interface
- UK: United Kingdom
- US: United States
- UPS: Uninterruptible Power Supply

DOCUMENT HISTORY CHANGE

REVISION NUMBER	DATE	DESCRIPTION CHANGE
1.0	19-Jul-2021	<ul style="list-style-type: none"> • First Issue
1.1	10-Aug-2021	<ul style="list-style-type: none"> • Added in 6. Warnings and Precautions the 10 min time gap between two runs.



		<ul style="list-style-type: none">• Updated Screenshots 7.2.6, 7.2.7, 8.4.7, 8.4.8, 8.4.9, 8.4.11, 8.4.12• Added section 20. Document History Change
1.2	16-Dec-2021	<ul style="list-style-type: none">• Added step 8.1.6 related to permissions requested by the tablet or phone.• Corrected typo related to storage temperature range
2.0	14/05/2024	<ul style="list-style-type: none">• “Storage and handling requirements” include the new ranges of temperature and humidity.• Updated Screenshots 7.2.4• Minor changes on some words have been done to section 7.2.• Minor changes on some words have been done to section 8.1, 8.2, 8.4.• Section “Results interpretation” is updated.• Typos correction on Section “Troubleshooting”.• Section “Maintenance” is updated.• BIOPIX DNA TECHNOLOGY P.C. is changed to BIOPIX DNA TECHNOLOGY S.A.