



pixl™ Real-Time PCR Platform Instructions for Use Manual

Revision 01-1.81

The instruction manual must be properly placed in the product box during shipment.

The user is required to keep this manual in a safe place so that it can be consulted when needed.

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Warranty

BioGX warrants the pixl™ Real-Time PCR Platform you are using has been fully tested and performs as described in the manual. The instructions and safety warnings given in this instruction manual must be followed to use the instrument, otherwise the warranty does not apply.

Software description

The software is a necessary tool for the operation of the instrument. For improving its performance and reliability, the manufacturer has the right to modify its functions or design, etc., in advance or subsequently without informing the clients, and the manufacturer has all the intellectual property rights of the modified version.

Responsibility statement

BioGX is not responsible for direct or indirect incidental damages arising from non-compliance with the operating instructions or incorrect use of the pixl™ Real-Time PCR Platform. Only BioGX technicians may inspect or provide parts for the instrument in question, and we are not responsible for direct or indirect collateral damage resulting from the user's disassembly and replacement of parts. The responsibility of BioGX is limited to the repair of the machine and the replacement of the parts, but not for the results of the experiments.

Intellectual property statement

The manufacturer owns the copyright for this manual and other proprietary information provided. The information in this instruction manual may only be used for installation, training, and service. Any copying, reproduction, or translation of this information, in whole or in part, into other languages, or other processes not mentioned herein, without the prior written consent of the manufacturer, is prohibited. The manufacturer holds the copyright to the software mentioned in this instruction manual and has the right to grant the customer the right to use the software.

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1. Important Notes

The following safety measures must be observed during all phases of operation, maintenance, and servicing of this instrument. Failure to observe these measures or the warnings and precautions indicated in this manual will likely undermine the safety standards for which the instrument was designed and manufactured and the intended scope of use of the instrument.

Intended Use

The pixl™ Real-Time PCR Platform is an in vitro diagnostic device intended to perform fluorescence-based PCR to provide detection of nucleic acid sequences in various specimens derived from human, animals, or environmental samples. The pixl™ Real-Time PCR Platform is intended to be used by trained professionals in combination with in vitro diagnostic assays. The following safety measures must be observed during all phases of operation, maintenance, and servicing of this instrument. Failure to observe these measures or the warnings and precautions indicated in this manual will likely undermine the safety standards for which the instrument was designed and manufactured and the intended scope of use of the instrument.

Assumptions

This manual assumes that end users possess the following:

- Molecular biology knowledge necessary for nucleic acid sample preparation/analysis.
- Reagent manufacturer documentation for appropriate use of assay(s).
- Knowledge of Microsoft® Windows® 10 operating system (if applicable).
- Knowledge necessary for computer data storage and computer file transfers.

Instrument grounding

To ensure the personal safety of the operator, please use the power adapter provided by the manufacturer, which has a 10A three-prong grounding plug at the input end. When using the adapter, please use a grounding socket that matches the plug to ensure that the input power line of the instrument is reliably grounded.

Use of power supply

Before the instrument adapter is connected to the power cord, it must be ensured that the AC power supply voltage (100 to 240 VAC) and frequency (50/60Hz) are consistent with those required by the instrument adapter. When making the power cord connection, make sure that the instrument power switch is off. Do not touch the power switch and power cord with wet hands. Do not disconnect the power cord when the instrument is not powered. Keep power cord away from hot surfaces. Do not clean the instrument when it is not disconnected. Please turn off the power when the instrument is no longer in use.

Power cord

The instrument should normally use the power cord supplied with it. If the power cord is broken, it must be replaced without repair. When replacing the power cord, it must be replaced with the same type of power cord of the same specifications. When this instrument is in use, do not place anything on the power cord, and do not place the power cord in a place where people move around.

Connect the power cord and ensure that the plug is secured into the socket. Disconnect power cord at the adapter connection point.

Placement of the Instrument

- 1) The instrument should not be placed in a location where it is difficult to disconnect the power supply.
- 2) The instrument uses semiconductor cooling and fan-assisted heat dissipation, so when placing the instrument, ensure that there is no obstacle within 15 cm around the instrument, and when multiple instruments are used at the same time, the distance between each instrument should be not less than 30 cm.
- 3) The instrument should be placed in a location with the following parameters: low humidity, dust-free, no running water, well ventilated, no corrosive gases, no magnetic field interference, away from direct sunlight or strong light sources. Place the instrument on a horizontal and stable surface.
- 4) High ambient temperature will affect the testing performance of the instrument or cause malfunction. Do not use this instrument in the place of direct sunlight and strong light source to avoid affecting the fluorescence detection of the instrument, and it should be far away from heating, stove, and all other heat sources.
- 5) Turn off the power when the instrument is not in use. When the instrument is not used for an extended period, unplug and store to prevent dust accumulation.

Precautions






- 1) During the test operation, protect instrument electronic exposure to liquids.
- 2) The consumables and reagents used in the test should be disposed of according to the relevant standards and should not be discarded or dumped at will.
- 3) If there are hazardous substances in the test, related training must be conducted before using them.
- 4) After use, the hazardous substances should be handled and stored properly in strict accordance with the relevant regulations.
- 5) The test personnel who operate the instrument need to be trained and have relevant qualifications.
- 6) When handling toxic, corrosive, or infectious substances, safety goggles and gloves must be worn.
- 7) To avoid burns, do not touch the metal module when the instrument is running or immediately after the operation.
- 8) Do not open the instrument during operation, doing so will cause abnormal experimental results.

After-sales service

- 1) After receiving the instrument, please confirm the warranty card. Contact the BioGX or authorized distributor if you have any questions.
- 2) After unpacking the instrument, please keep the packing box and packing materials should the instrument require after-sales service.
- 3) The instrument must be disinfected before shipping for after-sales service.











Packaging, storage, and transportation marking

Table 1.1. Package, storage and transportation identification.

| Symbol | Title | Description | Position |
|---|------------------|--|-----------------------|
|  | Fragile | This symbol is used to indicate that the product is a precision instrument and should be handled carefully and gently. | On the packing carton |
|  | This Way Up | This symbol is used to indicate the instrument orientation must be kept upward during handling, storage and use, and must not be placed sideways or upside down to avoid damage to the instrument. | On the packing carton |
|  | Keep Dry | This symbol is used to indicate that the instrument must not be stored in a humid environment or in a place where it can be splashed with liquid. | On the packing carton |
|  | Stacking Height | This symbol is used to indicate that a maximum of 5 boxes can be safely vertically stacked. | On the packing carton |
|  | Handle With Care | This symbol is used to indicate that the instrument should be handled, stored, and used with care to avoid any impact on the performance of the instrument. | On the packing carton |

Instrument Identification Information

Table 1.2. Instrument identification information.

| Symbol | Description | The location on the instrument where the symbol will appear |
|---|--|---|
|  | Caution, Hot surface | On the equipment |
|  | Date of Manufacture | On the equipment nameplate |
|  | CE marking | On the equipment nameplate |
|  | Caution | On the equipment nameplate |
|  | In vitro diagnostic medical instrument | On the equipment nameplate |
|  | Waste stream disposal status | On the equipment nameplate |
|  | Catalog number | On the equipment nameplate |
|  | Serial number | On the equipment nameplate |
|  | Consult instructions for use | On the equipment nameplate |
|  | FCC marking | On the equipment nameplate |

2. Product overview

The pixl™ Real-Time PCR Platform is a portable, high performance real-time quantitative PCR system with an optional large 10-inch touch screen for integrated operation. The pixl™ Real-Time PCR Platform is equipped with a multi-channel fluorescence optical system powered by an ultra-low-light CMOS bio-imaging sensor. The pixl™ Real-Time PCR Platform is optimally suited for applications where portability, minimal space, and fast time-to-result is required. The applications of the pixl™ Real-Time PCR Platform include: point-of-care molecular diagnostics test (POCT), food safety and environment testing, agriculture, veterinary and research laboratories where bench space is limited.



Figure 2.1. pixl™ Real-Time PCR Platform.

Features

- Compact and rugged design. No internal moving parts, and no need for calibration.
- Multi-wavelengths up to 4-channels fluorescence sensing capability¹.
- Cross platform software for Android® OS, with cloud-ready connectivity.
- Low power requirement. External supply with ~90W active peak power for both 4 well and 8 well devices. External supply with ~140W active peak power for 16 well devices.
- Battery-backup option for outdoor use and power loss protection.
- Efficient and fast: with ultra-fast temperature rise and fall system and unique fluorescence collection chip technology, fast detection can be achieved without specific consumables.
- Touch operation: available 10-inch LCD touch screen, integrated touch operation, no external computer, simple and convenient.
- Lightweight and portable: compact and portable body (247 x 188 x133 mm for 16 well devices), light weight (2.6 kg for 16 well devices), easy to move, strong environmental adaptability.
- Stable and reliable: the whole machine has no moving parts, and the structure is sturdy and durable without regular calibration even after a long time of use.
- Intelligent management: optional 4G module allows remote management or cloud management of experimental data as needed.
- Multiple options: Support 2 or 4 fluorescence channels (more channels can be customized), suitable for most of current dyes, no cross interference between channels, no need for regular calibration maintenance.
- Stable light source: independent LED light source for each fluorescence channel, stable and non-decaying LED light source, no need for regular replacement.
- High sensitivity chip: the unique "Ultra-Low-Light CMOS Image Sensor (CIS) Chips", millisecond-level extremely fast shooting, stable and reliable data.

¹ Support Intercalating dyes, hydrolysis probes and FRET probes

Key parameters

Table 2.1. Instrument key features and specifications.

| | |
|--|---|
| Capacity (# of wells) | pixl.4: 4 wells pixl.8: 8 wells pixl.16: 16 wells |
| Channels (# of Fluorophores per well) | 1. FAM/SYBR Green 2. JOE/HEX/VIC/TET 3. ROX/Texas Red 4. CY5/LIZ/Cy5.5) |
| Multiplex capability | Up to 4 targets per well |
| Minimum detection threshold | 4 copies |
| Dynamic range | >1.0E9 |
| Signal Interface | USB 2.0, Bluetooth® 2.0 |
| Excitation source | High endurance LED |
| Detector | Ultra-low-light CMOS Bio-imaging chip |
| Thermal system | Solid-state, Peltier-based |
| Tube/plate formats | 0.2 mL, 4 or 8-tube strip |
| Reaction volume | 10 µL – 60 µL |
| Excitation Range: | 460 nm – 670 nm |
| Emission Range | 510 nm – 720 nm |
| DNA probes supported: | DNA binding dyes, hydrolysis probes and hybridization probes. |
| Temperature Uniformity | <= ±0.25°C |
| Temperature control resolution | <= ±0.1 °C |
| Temperature Ramp Rate | 6°C/s heating; 4°C/s cooling |
| Detection accuracy | Ct value Cv <= 3% |
| Size | pixl.4: 198 mm (L) x 134 mm (W) x 98 mm (H) pixl.8: 147 mm (L) x 182 mm (W) x 99 mm (H) pixl.16: 247 mm (L) x 188 mm (W) x 133 mm (H) |
| Weight | pixl.4: 1.2 kg pixl.8: 1.45 kg pixl.16: 2.6 kg |
| Power supply (Adapter provided that accepts 110 V/240 V AC) | pixl.4 and pixl.8: DC 10 V, 90 W pixl.16: DC 15 V, 9.6 A, 144 W |

Applications

- Point-of-care molecular diagnostics²
- Food safety test
- Environmental microbial-threat monitoring
- Agriculture DNA testing
- Forensic testing
- Research and educational lab use
- Drug quality assurance testing

Instrument external dimensions

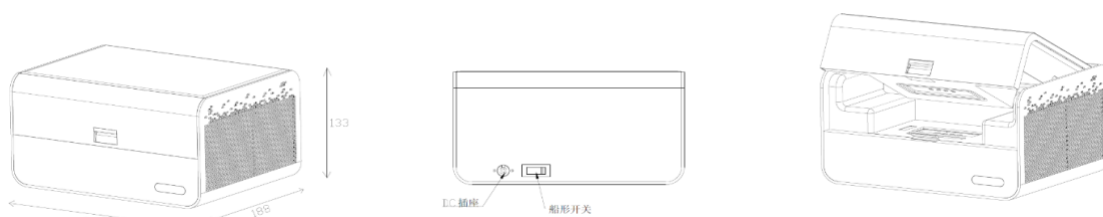


Figure 2.2. pixl™ Real-Time PCR Platform product dimension.

Instrument models

Table 2.2 Instrument models.

| Model (Cat. No.) | Channel | Sample throughput |
|------------------------------------|------------|-------------------|
| FQ1044 or pixl.4 (650-004-PXL) | 4 channels | 4 wells |
| MQ1084 or pixl.8 (650-008-PXL) | 4 channels | 8 wells |
| MQ4164 or pixl.16 (650-016-PXL) | 4 channels | 16 wells |

² Clinical clearance required.

3. Hardware set-up guide

This chapter describes the use and storage conditions of the pixl™ Real-Time PCR Platform, its structural components, unpacking from shipping box, installation/uninstallation of the software, and preparation for power-up.

Environmental conditions

- 1) Transportation and storage conditions of the instrument
 - a. Environmental temperature : -5°C to 40°C
 - b. Relative humidity : ≤75%
- 2) Working conditions requirements
 - a. Environmental temperature : 15°C to 35°C
 - b. Environmental humidity : 35% to 75%
 - c. Input voltage : DC 15 V 9.6 A

Instrument packing list

After opening the box, please check the contents of the box according to the packing list. If the items are found to be damaged or missing, please contact the BioGX immediately.

Table 3.1 Packing list within each pixl™ Real-Time PCR Platform.

| Accessory | Quantity |
|------------------------------|----------|
| pixl™ Real-Time PCR Platform | 1 |
| Power Adapter | 1 |
| Power Cable | 1 |
| USB Cable | 1 |
| USB Drive | 1 |
| Product QA Certification | 1 |
| Factory Inspection Report | 1 |
| Warranty Card | 1 |
| Certificate of Conformity | 1 |

Instrument unpacking procedure

- 1) The outer packaging of the product is a cardboard box, filled with shock-absorbing foam inside. After unpacking, first check whether the items you receive are missing or damaged.
- 2) If the outer packaging of the product is obviously damaged during transportation, please do not use it and contact BioGX.
- 3) Check the completeness of the provided accessories against the packing list (Table 3.1).
- 4) If the instrument or accessories have been damaged or lost in transit, please inform the shipping company and authorized distributor or BioGX.

Instrument Power Requirements

The instrument is powered through an external AC/DC power adapter. The power adapter accepts AC input ranging 110 V to 240 V and produces DC output of 15 V³.

The DC power input connector port is located at the back of the instrument. Once the power is provided, the green power indicator light will turn on.

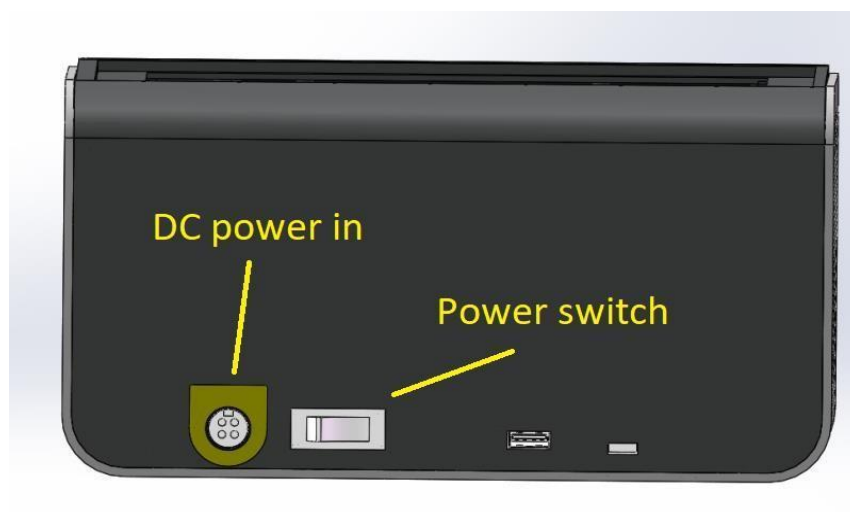


Figure 3.1. Rear image of pixl™ Real-Time PCR Platform identifying ports and power switch.

³ 10.5 V for pixl.4 and pix.8 models

Light indicator states

There are two LED indicator lights. The green light is used to indicate power supply. The green LED indicator is illuminated as long as the instrument is powered.

Power cord connection

- 1) Adapter connection: the adapter supplied with the instrument should be used to connect the adapter to the instrument.
- 2) Power cord connection: use the power cord provided with the instrument. When connecting, the instrument power switch should be in the "off" state, and then turn on the instrument switch after connecting.

Instrument Use

- 1) Insert the DC connector into the power jack of the instrument until it clicks, indicating it is properly connected (Figures 3.2.1 – 3.2.3)
- 2) Turn on the instrument power switch (power switch) and the instrument power indicator illuminates (green).
- 3) Open the flap of the instrument and put the collected sample tubes into the sample table position shown in the figure.
- 4) Close the flap, run the test, the instrument starts normally and then the operation indicator lights on (blue).

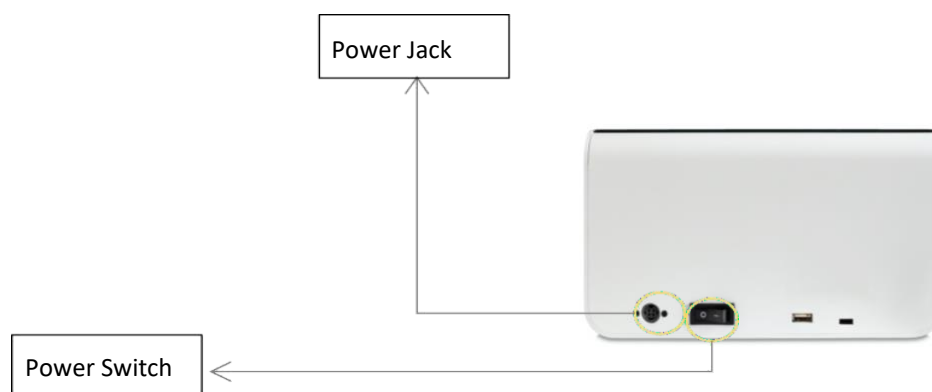


Figure 3.2.1 Rear image of the pixl™ Real-Time PCR Platform power jack and power switch locations.

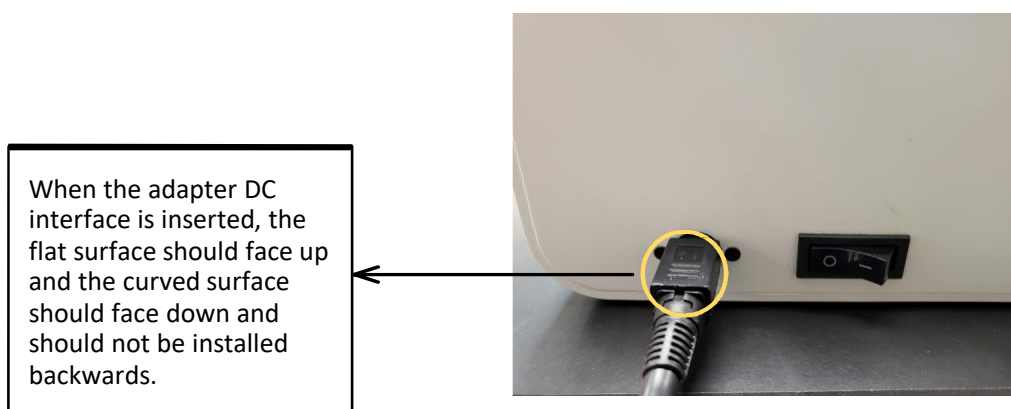


Figure 3.2.2. Rear image of the pixl™ Real-Time PCR Platform with power cord adapter connected.

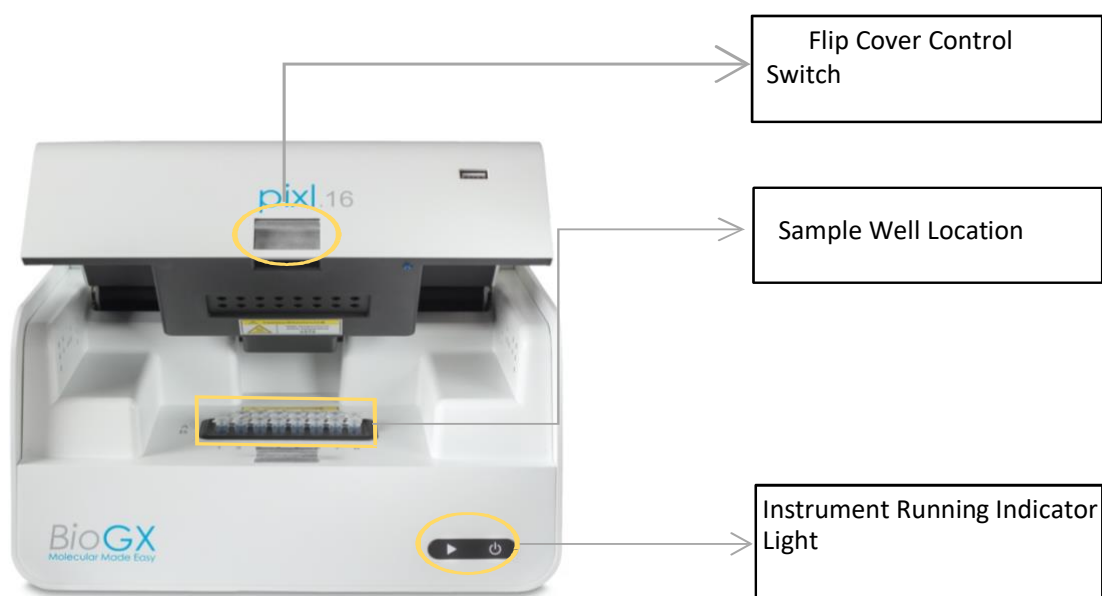


Figure 3.2.3 Front image of pixl™ Real-Time PCR Platform with lid open.

pixl™ Real-Time PCR Platform tube/plasticware requirement

The pixl™ Real-Time PCR Platform requires the use of full transparent PCR tubes with flat optical caps (Figure 3.3 and 3.4).



Figure 3.3. pixl™ Real-Time PCR Platform compatible 8-tube PCR strip.

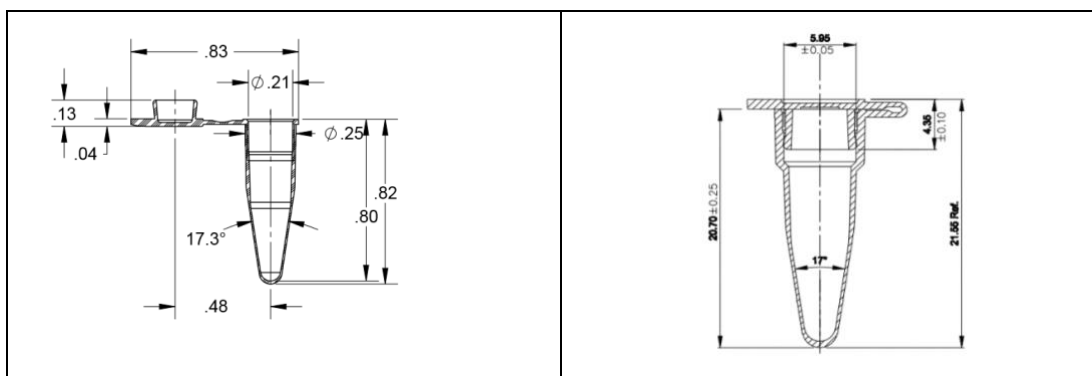


Figure 3.4. pixl™ Real-Time PCR Platform compatible PCR tube dimensions in English (left) and Metric (right) units.

List of PCR tubes compatible with pixl™ Real-Time PCR Platform

UltraFlux® i PCR Tubes with Caps. SSIBio Part Number: 3247-00

(<https://www.ssibio.com/search-results/?display=search&newSearch=true&keywords=3247-00>)

EasyStrip™ Plus Tube Strip with Attached Ultra Clear Caps. Thermo Fisher Part Number: AB2005

(<https://www.thermofisher.com/order/catalog/product/AB2005>)

Axygen® 0.2 mL Polypropylene PCR Tube Strips and attached Flat Cap Strips, 8 Tubes/Strip, 8 Flat Caps/Strip, Clear. Corning Product Number: PCR-0208-AF-C

(<https://ecatalog.corning.com/life-sciences/b2b/US/en/Genomics-%26-Molecular-Biology/PCR-Consumables/PCR-Tubes-and-Strip-Tubes/Axygen%C2%AE-PCR-Strip-Tubes/p/PCR-0208-AF-C>)

4. Software Operation Guide (Android Software)

pixl™ Real-Time PCR Platform software can be used to set up experiments, run experiments, and collect, analyze and manage experimental data. The software contains three main functional modules, namely "Test", "Data" and "Setup".

- 1) "Test" module: It mainly includes creating new experiments, setting experimental parameters, importing experimental templates and running experiments.
- 2) "Data" module: mainly contains experimental data analysis, upload, import data, export data, export PDF, standard curve.
- 3) "Setup" module: mainly contains upload configuration, user management, user switching, WLAN, Bluetooth, language, virtual keyboard, date and time, display, application information, version update, software version check, instrument number.

Launch software

- 1) After the instrument is turned on, it automatically enters the main interface of the software - Test.

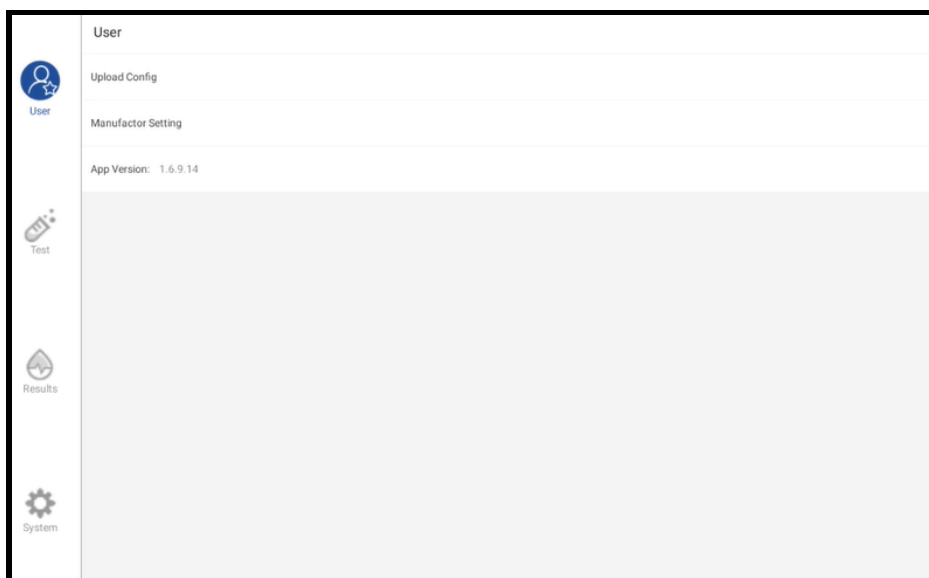


Figure 4.1. pixl™ Real-Time PCR Platform software interface page.

Experimental settings

- 1) In the Test interface, click **"New Experiment"** (Figure 4.2) the right panel is the Experiment Information parameter that allows for editing Experiment Name, Sample Name (well position) and Channel Selection (fluorophore selection). Click "Next" to proceed to **Cycling Parameters**.

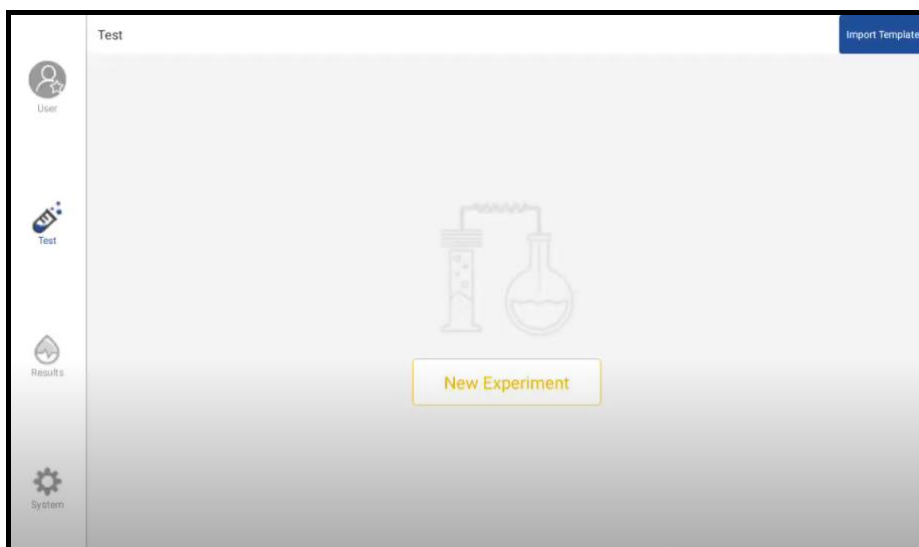


Figure 4.2 pixl™ Real-Time PCR Platform New Experiment interface.

- 2) Cycling Program Interface (Figure 4.3) allows for thermocycling parameters to be programmed (parameters such as reaction temperature, reaction time, number of cycles, photo stage, etc.).



Figure 4.3. pixl™ Real-Time PCR Platform Cycling Program interface.

- 3) Click the "Save Template" icon in the upper right corner to save the current template (Figure 4.4).

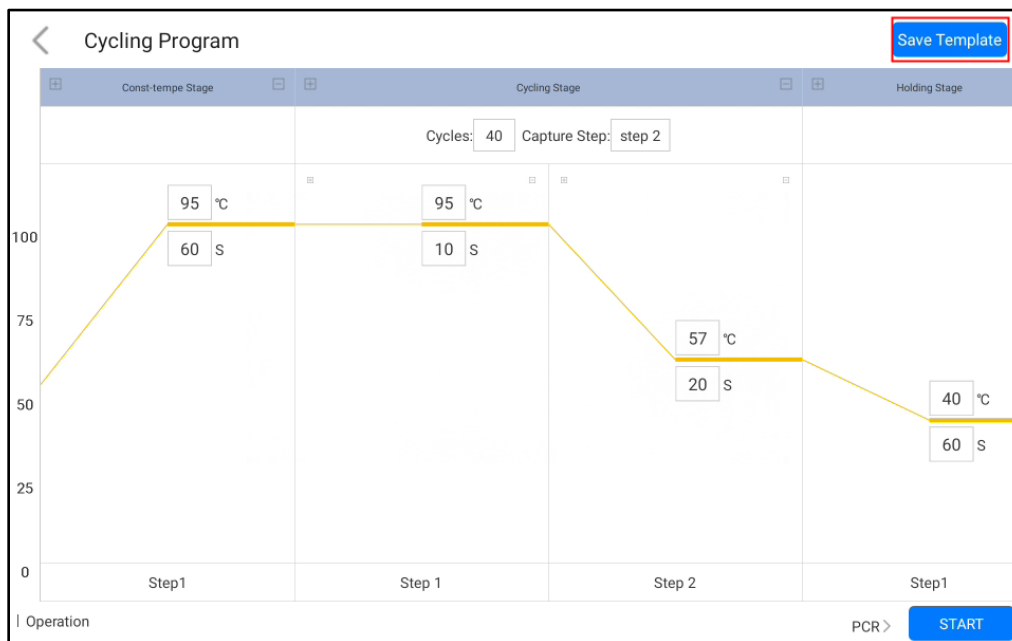
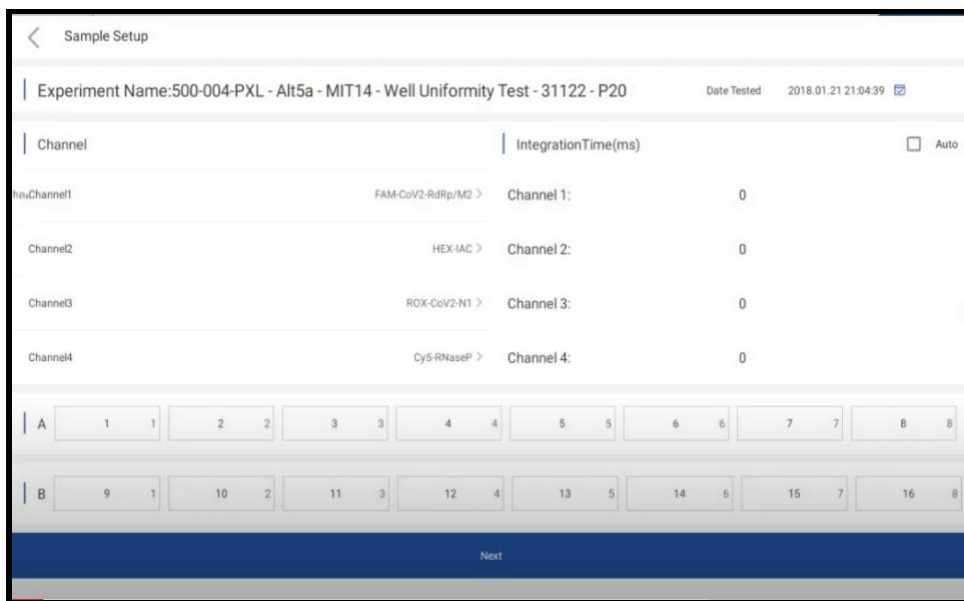


Figure 4.4. Saving thermocycling program by pressing “Save Template” button.

Saved Test Parameters

- 1) The saved templates will appear in the "Test" interface for selection. Click the second option "Import Template" to import other experiment templates.



The screenshot shows the "Sample Setup" interface. At the top, there is a back arrow and the title "Sample Setup". Below this, the "Experiment Name" is "500-004-PXL - Alt5a - MIT14 - Well Uniformity Test - 31122 - P20" and the "Date Tested" is "2018.01.21 21:04:39".

Below the experiment name, there is a table with columns "Channel" and "IntegrationTime(ms)". The table has four rows:

| Channel | IntegrationTime(ms) |
|----------|---------------------|
| Channel1 | 0 |
| Channel2 | 0 |
| Channel3 | 0 |
| Channel4 | 0 |

Below the table, there is a section for "Sample Setup" with a grid of wells. The grid has two rows, A and B, and eight columns. The wells are numbered 1 through 16. The values in the wells are:

| Row | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|-----|---|----|----|----|----|----|----|----|
| A | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| B | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |

At the bottom of the grid, there is a "Next" button.

Figure 4.5. View saved Test template.

Run the experiment

After the experiment settings are completed, click the "Start" button to start the experiment and enter the "Running" interface. Click "Force to stop" at the top right corner to stop the experiment.

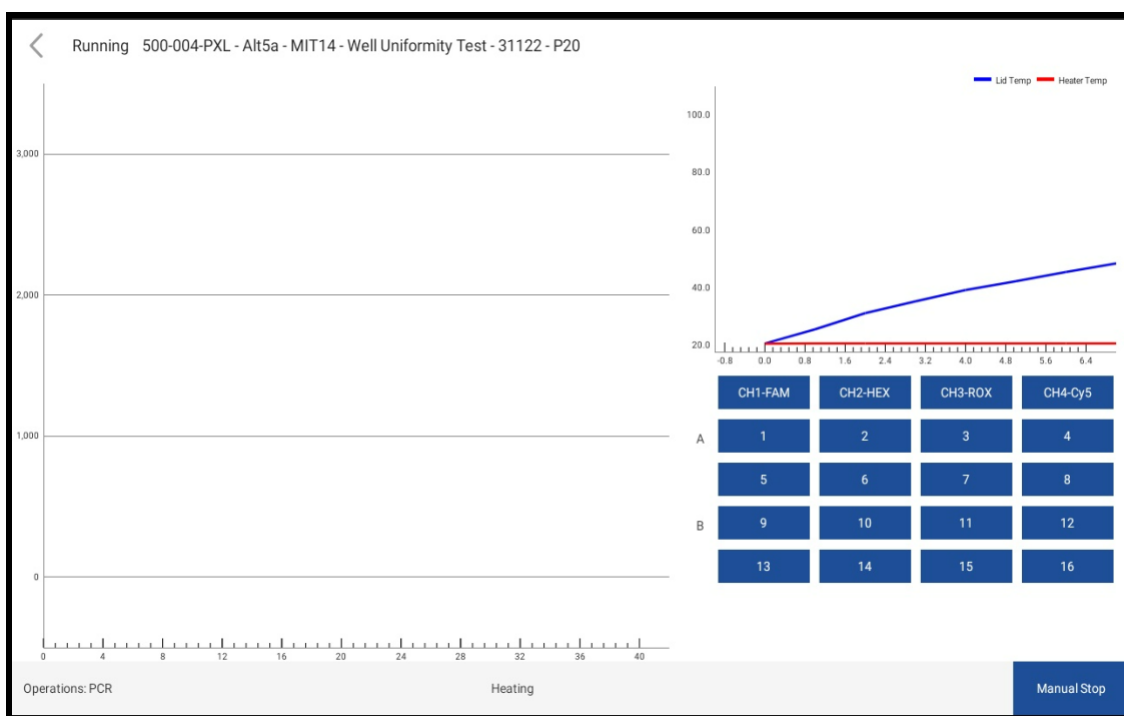


Figure 4.6. pixl™ Real-Time PCR Platform software demonstrating beginning of PCR run.

Experimental analysis

1. Click the "Result" Tab on the main page to enter the Result Analysis (Figure 4.7). Click on any one of the experimental result files to view completed PCR Results (Figure 4.8).

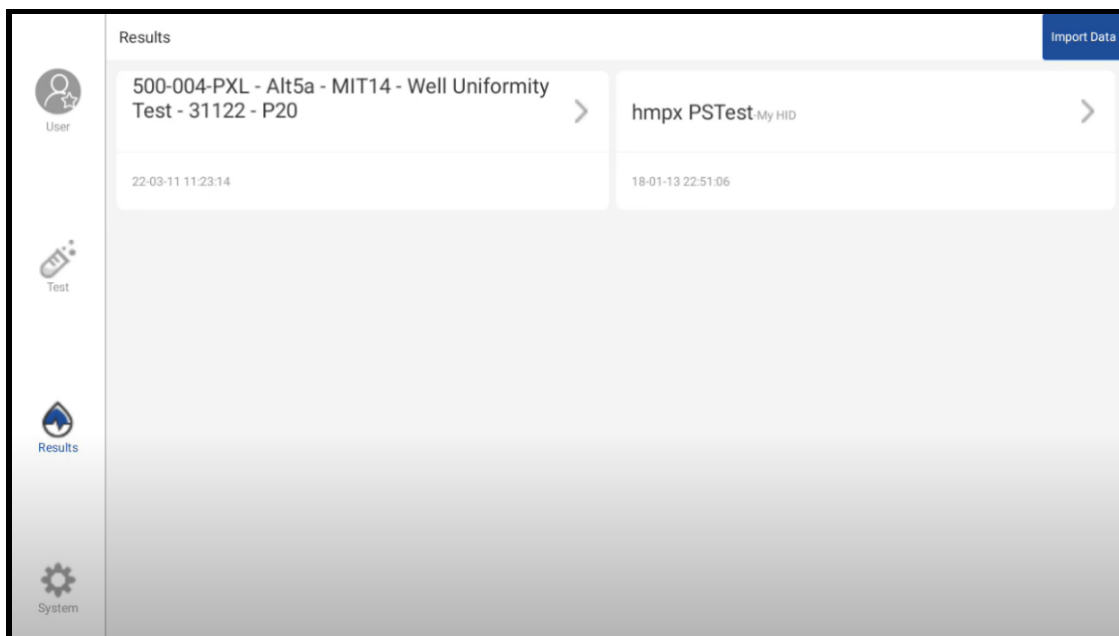


Figure 4.7. pixl™ Real-Time PCR Platform Result analysis interface.

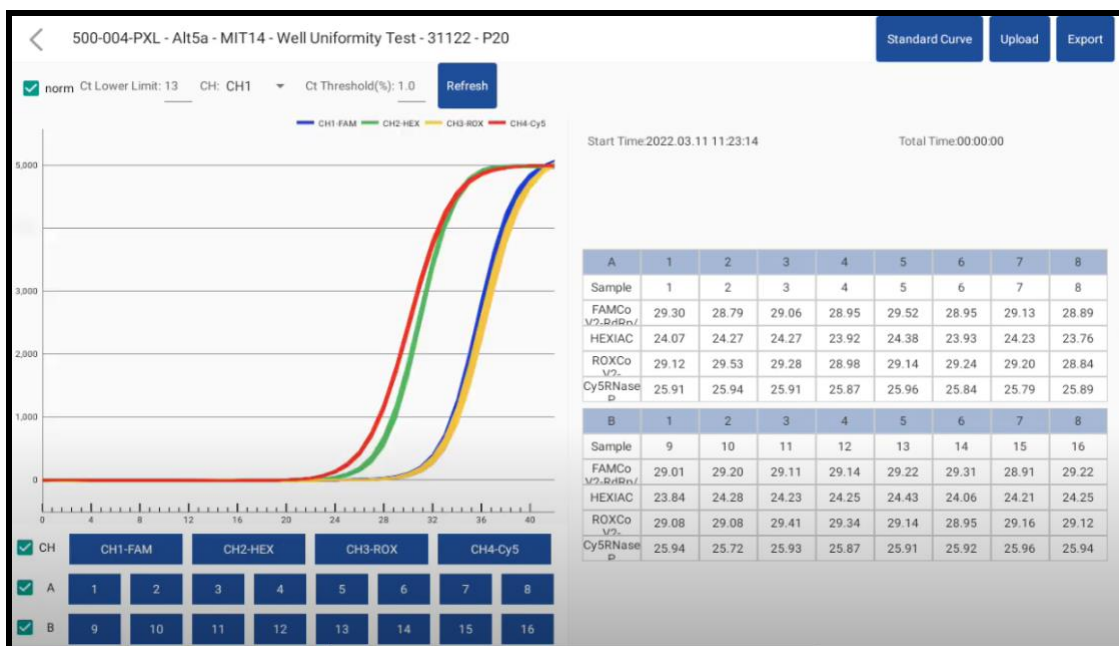


Figure 4.8. pixl™ Real-Time PCR Platform Result thermocycling amplification curves presentation.

2. Experimental analysis (click the Advanced Setting button)
 - a. Adjust the baseline Ct lower limit.
 - b. Adjust Ct threshold percentage (Figure 4.9): default is 10%.
 - c. Normalize: normalize the amplification curve without affecting the results (Figure 4.10).
 - d. Click on the channel and well buttons in the data table on the right to select the wells and channels for data analysis. (Gray button means not selected; Figure 4.10)

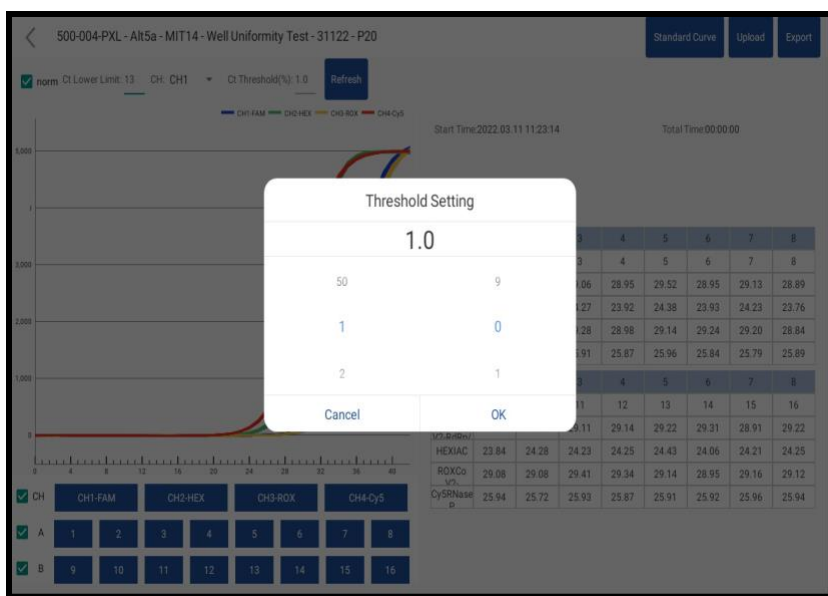


Figure 4.9. pixl™ Real-Time PCR Platform Experimental analysis Advanced setting interface.



Figure 4.10. pixl™ Real-Time PCR Platform Data filtering interface

3. Calculating standard curves

- Click the Standard Curve button in the data interface to enter the standard curve interface (Figure 4.11).
- Manually input the standard concentration, calculate the standard curve, and save (Figure 4.11 and Figure 4.12).
- Then select Unknown Points, click Find Unknown, and select Use Saved Standard Curve to calculate the concentration of the unknown sample based on the Ct value (Figure 4.13).

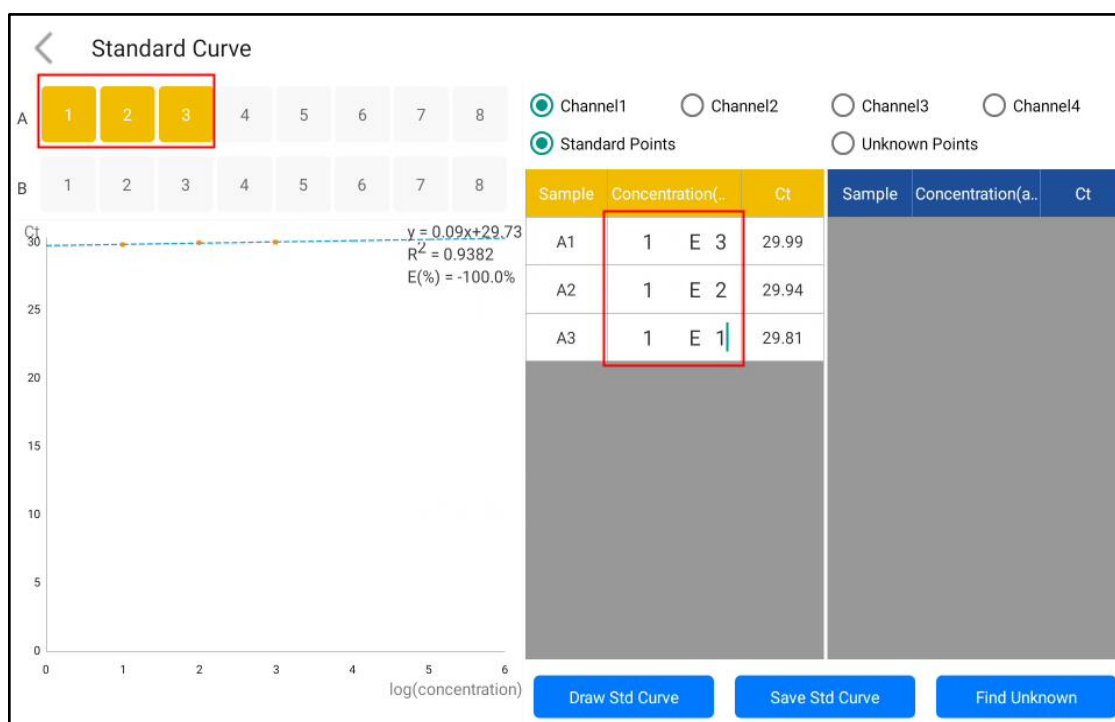


Figure 4.11. pixl™ Real-Time PCR Platform Standard curve interface.

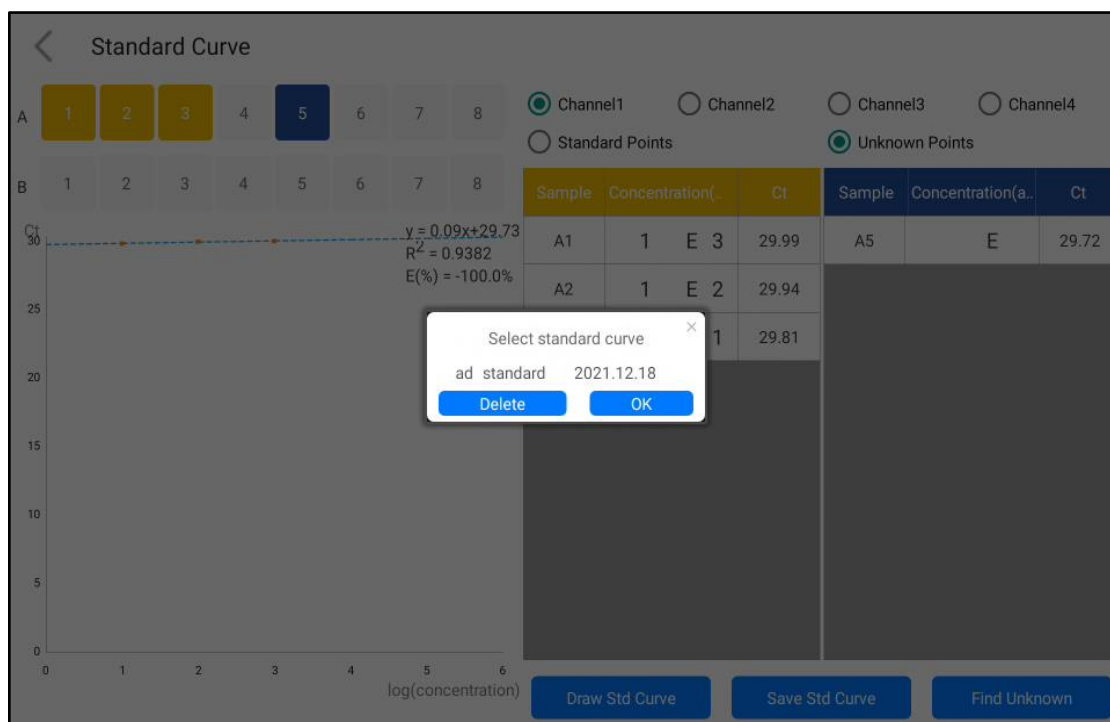


Figure 4.12. pixl™ Real-Time PCR Platform Selecting the standard curve used for calculation.

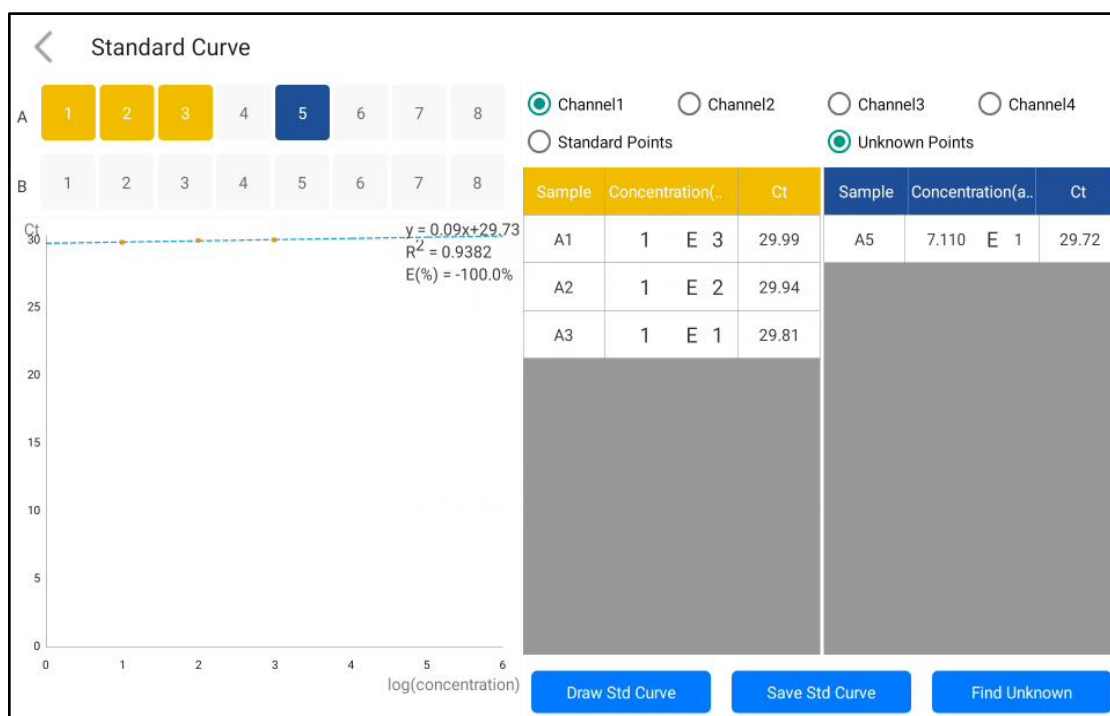


Figure 4.13. Calculating unknown concentration of unknown samples.

Data export

- 1) Click the "Report" button in the experiment analysis interface to enter the PDF preview interface of the experiment report (Figures 4.14 and 4.15).

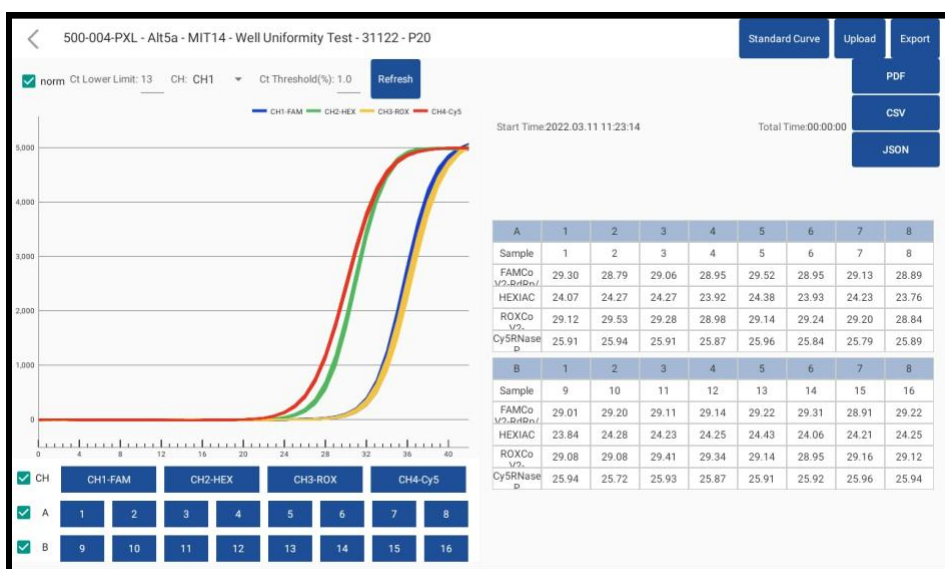


Figure 4.14. pixl™ Real-Time PCR Platform Data export interface.

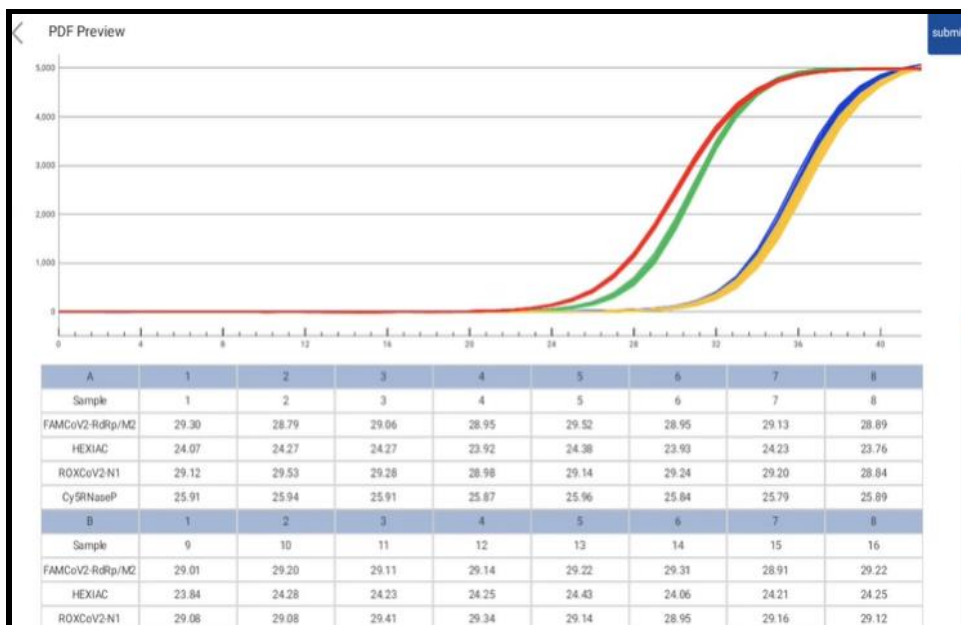


Figure 4.15. pixl™ Real-Time PCR Platform Data export PDF preview page.

- 2) At present, pixl™ Real-Time PCR Platform supports data export to a USB flash drive. After inserting the USB flash drive, click the export button, select PDF and “Export Success” will be indicated in center of screen (Figure 4.16).

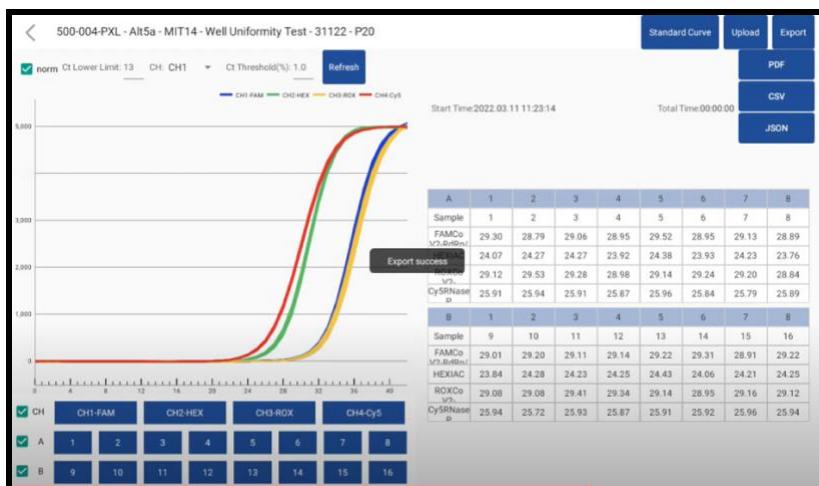


Figure 4.16. pixl™ Real-Time PCR Platform Data export PDF indicating “Export success”.

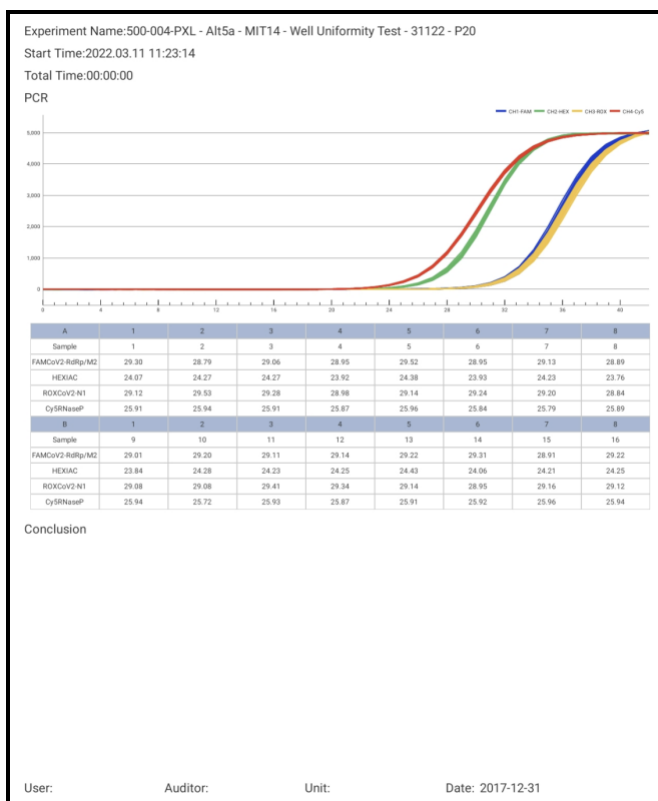


Figure 4.17. Preview of exported PDF file.

5. Instrument Maintenance

Instrument cleaning




Regular cleaning

For everyday cleaning, unplug all external power sources, devices, and cables. Use a clean damp lint-free cloth to wipe the external surface of your instrument and dry with lint-free cloth. Avoid abrasive cloths, towels, paper towels, and similar items that might cause damage and avoid getting moisture into any openings.


Well cleaning

Spills entering reactions wells may cause fluorescence background, cross talk etc. The reaction wells can be cleaned with lint-free wipes or swabs. Moreover, to remove potential contaminants, it is recommended to use 10% bleach solution to clean contaminated areas. The cleaning solution can be left on the surface for 10-15 minutes before being rinsed with deionized water.


Additional recommendations about cleaning

- (1) Instrument surface cleaning: the surface of the instrument should be wiped regularly with a soft cloth with 75% alcohol, and the instrument should be wiped dry after cleaning.
- (2) Reaction well cleaning:
 - a.  The power must be turned off and the power cord unplugged before cleaning the instrument.
 - b.  Do not pour liquids into the reaction module or inside the instrument.
 - c.  Do not use corrosive solvents or organic solvents to scrub the instrument.
 - d. Dust or impurities in the reaction wells can affect PCR amplification and fluorescence detection, thus, regular cleaning is recommended.
 - e. To prevent dust from entering the reaction wells, the flip-up cover must be closed when the instrument is not in use.
 - f. If any reagent enters the sample well, it should be wiped clean with a dust-free soft cloth with anhydrous ethanol.

Instrument protection

- (1) Do not switch the instrument on and off frequently.
- (2) Only use the adapter provided with the instrument.
- (3)  Do not expose instrument to temperatures that exceed operating temperature

range of -5°C to 40°C .

- (4)  Disassembling the instrument voids instrument warranty. Only BioGX personnel are authorized to disassemble the instrument.

Waste disposal

- (1) After each experiment run, a high concentration of amplification products is generated in each PCR tube. All tubes containing amplified DNA should be disposed of as soon as possible according to local and relevant regulations. Be sure to avoid contaminating the laboratory and instrument.
- (2) To prevent laboratory contamination, do not open the cover of the test tube after the PCR run is completed and is removed from the instrument.

Overheat protection

- (1) When the instrument temperature control module exceeds the set threshold (120°C), the device will automatically stop heating and will force all run parameters to stop.
If an overheating failure is observed, stop using the instrument and promptly contact BioGX or authorized distributor for maintenance to be scheduled.

Operation requirements

- (1) During the use of the instrument, the operator may be in contact with harmful substances or infectious substances. All operators should have relevant training and qualifications. See Chemical Hazard Warning section below.
- (2) The operator should operate the instrument in strict accordance with all relevant regulations.

Preventative maintenance requirements

- (1) Once a year, the following preventative maintenance steps are conducted to confirm proper performance:
 - a. Clean the instrument as described earlier.
 - b. Perform visual inspection of the instrument to ensure there is no mechanical damage. This check should include checking for loose fittings, checking for loose or missing screws. There should be no rattling sound when the instrument is picked up and gently shaken by hand. The plastic surface should be free of any visible cracks or deep cuts.
 - c. Perform a standard assay utilizing all optical channels to check instrument performance. The assay should have positive and negative controls for all

optical channels and the result should match validated performance characteristics.

- d. If the instrument is used for quantitative nucleic acid analysis, the user should test the performance of the instrument running standard curve analysis. The linearity of the test should match what is expected of the assay used.

Chemical Hazard Warning

Chemical Hazard

Before handling any chemicals, refer to the Material Safety Data Sheet (SDS) provided by the manufacturer, and observe all relevant precautions. All chemicals in the instrument, are potentially hazardous. Always track the chemicals used in the instrument before changing reagents or instrument components. Wear appropriate eyewear, protective clothing, and gloves when working with the instrument.

Chemical Storage Hazard

To avoid risk of breaking or shattering, never collect or store waste in glass containers. Waste bottles should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position. Wear appropriate eyewear, clothing, and gloves when handling reagent and waste bottles.

Chemical manufacturers Material Safety Data Sheets (SDSs) enclosed with shipments of hazardous chemicals to new customers should be filed for easy reference by all laboratory staff. Consult the SDS safety information needed to store, handle, transport, and dispose of the chemicals safely.

Chemical Safety

- Review Material Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials.
- Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Do not leave chemical containers open. Use only with adequate ventilation. If recommended by the manufacturer, utilize a fume hood for safe use of volatile chemicals.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended on the SDS.

- Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal.

Chemical Waste Safety Guidelines

- Review the Material Safety Data Sheets (SDSs) provided by the manufacturers of the chemicals before you store, handle, or dispose of chemical waste.
- Laboratory staff should clearly identify primary and secondary waste containers. Primary waste containers are utilized for storage of routine waste storage. Secondary waste containers are clearly identified for failure of primary containers, spills or leaks. Both containers must be compatible with the chemical waste that is being generated. Both containers must meet federal, state, and local requirements for chemical waste storage.
- Wear appropriate personal protective equipment when handling chemicals (ie, safety glasses, gloves, and protective clothing).
- Do not leave chemical containers open. Use only with adequate ventilation. If recommended by the manufacturer, utilize a fume hood for safe storage of volatile chemical waste.

6. Troubleshooting guide

Issue with connecting the power

Please note that the power connector at the back of the instrument has an orientation. Make sure that the connector is properly aligned with this orientation. Do not force insertion of the connector. Instead make sure the connector and receptacle are properly aligned.

Also make sure the AC cable is connected to a power source and ensure the power switch is at “on” position when using the instrument.

There is a blue indicator light on the AC/DC adapter. It will light up when the AC cord is receiving power from the AC source.

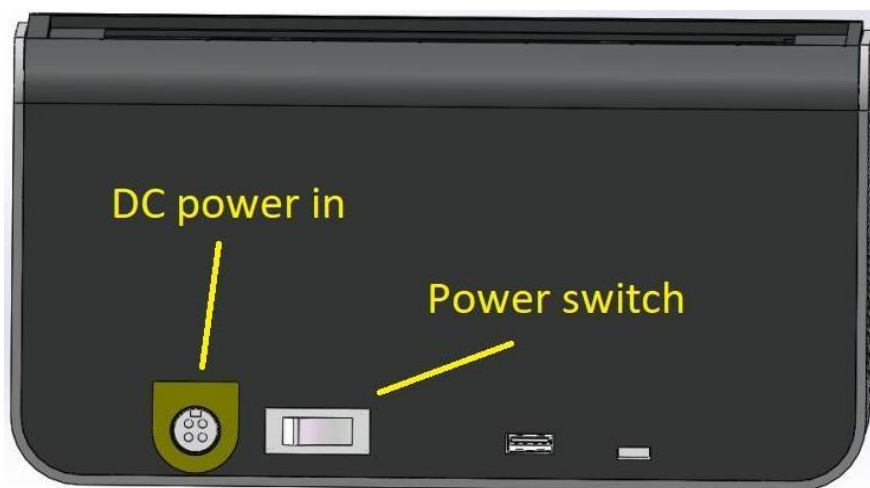


Figure 6.1. Rear image of pixl™ Real-Time PCR Platform.

The test tube does not fit or the lid does not close with PCR tubes loaded

Please make sure to follow the directions from section [pixl™ Real-Time PCR Platform tube/plasticware requirement](#) to select the proper test tube.

Touchscreen blank on power up

If the touchscreen panel is blank on power up, there are several steps to diagnose this event. Note: the following troubleshooting steps are only applicable to pixl™ instruments equipped with a touchscreen interface:

1. Make sure the instrument is indeed powered on. See section “Issue with connecting the power” to debug the power problem.
2. The screen may have been inadvertently locked up through user settings input. Completely power down the system – switch off the instrument, unplug power input, plug power input, and power on the system again.
3. If the steps above are not effective, contact BioGX support to report possible hardware issues.

Temperature Profile Abnormal

During the experiment run, the user can visually judge if the temperatures of the lid and reaction wells rise as expected. If for any reason the lid or the well temperatures do not increase, and decrease as expected, diagnose power problem, and confirm power cord connection are secured.

Additional troubleshooting guide

Table 6.1. Trouble-shooting guide

| No. | Failure Phenomenon | Cause Analysis | Processing |
|-----|---|--|---|
| 1 | The screen shows a black screen | Screen motherboard damage | Must replace the screen motherboard, please contact with the supplier or manufacturer |
| | | If the screen lock function is incorrectly operated, the screen enters the black screen standby mode | Close the lock screen, and enter the test interface directly after the startup |
| | | Screen damage | Need to replace the screen, please contact BioGX or authorized distributor. |
| | Software prompts "Abnormal auxiliary heating" | Auxiliary temperature self-test abnormal | Please restart the instrument first to confirm, if issue still cannot be solved please contact BioGX or authorized distributor. |
| | Abnormal heat-up curve of hot cover | Power supply problems | Verify that the power is plugged in properly |
| | | Hot cover assembly problems | Please restart the instrument first to confirm, if issue still cannot be solved please contact BioGX or authorized distributor. |
| 2 | Unable to turn on | Power supply problems | Verify that the power is plugged in properly |
| | | Switch or power cable damage | Please restart the instrument first to confirm, if issue still cannot be solved please contact BioGX or authorized distributor. |
| 3 | USB flash drive export failed | The USB flash drive is not in good contact | Reinsert the USB flash drive for confirmation |
| | | | If the problem persists, contact BioGX or authorized distributor. |
| 4 | No experimental data after instrument operation | Incorrect setting of experimental parameters | Verify that the thermal cycling parameters and sample parameters are set correctly, and set the fluorescent markers |
| 5 | Test time and report time are not synchronized | Time synchronization without network connection | The default time is used when the device is not connected to the network. Please connect to the network for immediate time update |
| 6 | Software prompts "Please close the hot cover" | Instrument flip cover is not closed in place | Re-close the flap to ensure it is closed properly |

Revision History

| Revision | Date | Description of Change |
|----------|-----------|-----------------------|
| 01-1.81 | 03MAR2023 | Initial Release |