

FranklinTM Real-Time PCR Thermocycler

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Franklin™ Thermocycler

The Biomeme Franklin™ transforms your smartphone into a thermocycler for real-time PCR or isothermal analysis with sample-to-result in 30-60 minutes, depending on the test protocol. Our mobile thermocycler enables multiplex real-time detection of up to 27 targets from 1 sample or test 9 samples for up to 3 targets each. Just under 3 lbs, hand-held, and battery-operated for maximum portability enabling a full day's work out in the field on a single charge. Franklin™ comes in 3 different variations depending on the color channel detection you require (see *Technical Specifications* for details).

Technical Specifications

SPECIFICATION	VALUE
Sample Capacity	9 Wells
Reaction Volume per Well	20μL
Total Channels	3
Franklin™ one9 Fluorophore*	FAM / SYBR (Green)
Franklin™ two9 Fluorophores*	FAM / SYBR (Green), ATTO647N (Red)
Franklin™ three9 Fluorophores	FAM / SYBR (Green), TexasRedX (Amber), ATTO647N (Red)
System Control & Data Transfer	Wireless (BLE)
Integrated Barcode Scanner	Yes
Max Samples per Run	9
Max PCR Targets per Run	27
Weight	1.20 kg / 2.65 lb

Operating Ambient Temperature	4 - 40°C / 39 - 104°F
Operating Humidity Limit	0 - 99%
Operating Altitude Limit	3,048 m / 10,000 ft
Wall Power (VAC)	100 - 240V
Voltage	19V
Full Load Current	3.3A
Internal Battery	5 hrs
Quantitative	Yes
IP Rating	IP30
Indoor/Outdoor?	Indoor or Outdoor in a Covered Area
Pollution Degree	2
Degree of Ingress Protection	Keep 5 cm Clearance Around the Thermocycler for Proper Performance

Note: The Franklin^{\top} one9 is limited to the FAM/SYBR (Green) channel and the two9 is limited to the FAM/SYBR (Green) and ATTO647N (Red) channels only. You can <u>upgrade your thermocycler(s)</u> at any time without returning your device.

Thermocycler Button Layout

There are a total of 4 buttons located on the top of your Franklin™ thermocylcer:



LED Status Indicators

Vertical LED on the front of your thermocycler.

Franklin™ has 5 LEDs on the front of the unit. The LEDs are used to convey various states of the thermocycler as outlined in the table below.

COLOR	INTERPRETATION
WHITE	5 solid indicates your thermocycler is on 5 blinking indicates Bluetooth (BLE) is pairing
GREEN	2 solid indicates remaining battery is between 21 and 40% 3 solid indicates remaining battery is between 41 and 60% 4 solid indicates remaining battery is between 61 and 80% 5 solid indicates remaining battery is between 81 and 100% 1 blinking indicates charging
YELLOW	1 solid indicates run start to 9% complete 2 solid indicates run is between 10 and 31% complete 3 solid indicates run is between 32 and 53% complete 4 solid indicates run is between 54 and 75% complete 5 solid indicates run is between 76 and 99% complete
RED	1 solid indicates remaining battery is between 0 and 20% 5 blinking indicates thermocycler lid is open or an error Note: If the battery is in the red, you shouldn't start your run until you plug your thermocycler into power.
BLUE	5 blinking indicates your test is complete and data is ready to be synced to your smartphone

Turning Your Thermocycler On and Off

To power on your thermocycler, press and hold the power button $\ensuremath{\mathfrak{O}}$ (located on the top of the unit) for roughly half a second. The status LED on the front of your thermocycler will illuminate white to indicate it has successfully turned on. To turn the unit off, press and hold the power button for 1.5 seconds and the status LED will turn off upon release of the button. The unit will also turn itself off after 15 minutes of inactivity.

Charging & Checking Battery Status



Note: To preserve your smartphone's battery life, disconnect from the thermocycler when it's not in use.

If your battery is running low, simply plug the AC power adapter into an outlet and insert the power connector into the back of your thermocycler. The LED on the back of the thermocycler will illuminate blue. If you're unable to turn your thermocycler off using the power button on top, you may press the reset button to force it off (all test data on the unit will be lost). Lastly, when the battery button is held, the LED on the front of your thermocycler indicates the battery charge status as follows:

ι	ED STATUS	BATTERY PERCENTAGE
5 solid	GREEN	81 - 100%
4 solid	GREEN	61 - 80%
3 solid	GREEN	41 - 60%
2 solid	GREEN	21 - 40%
1 solid	RED	0 - 20%

A single green LED will blink while charging. If your battery charge is between 0 and 20%, the bottom most LED will blink green while charging. If your battery charge is greater than 20%, the top most LED will blink green while charging. For proper battery maintenance and performance, please fully charge the thermocycler battery at least once every six months. The thermocycler should not be left without charging for extended periods of time. If your device has not been charged in more than six months and you cannot get the thermocycler to turn back on, please contact support@biomeme.com

Enabling & Disabling Bluetooth (BLE *)

Bluetooth can be turned on or off at any time by pressing and holding the Bluetooth button on the top of your thermocycler for roughly half a second. By default, Bluetooth is disabled. A blue LED will light up next to the BLE button indicating it is enabled.

Once enabled, tap <u>Connect via BLE</u> when prompted in the smartphone app. If working with multiple Franklin™ thermocyclers, select the appropriate unit and tap <u>Confirm</u>. The LED on the front of your thermocycler will flash white indicating it's connected.

Recovering & Reattaching Test Data

What Is Recovery?

Pressing the Recovery ${\bf C}$ button on the top of your thermocycler will safely restore the unit to the same state as the previously completed or failed run such that your smartphone can collect the result data.

Note: This feature is not intended to restart an interrupted test, but only to recover partial or whole test data. Once a new test is started, any previous data will be erased. For security reasons, the same smartphone that was used to initiate the test must be used to download the test results.

What Is Reattaching?

The connection may be lost between your smartphone and your thermocycler for a number of reasons (i.e. phone battery died, mobile app crashed, etc.). If this happens, you can easily reattach your smartphone to the thermocycler.

To do so, relaunch the Biomeme mobile app and on the app home screen tap the Reattach Test button. From there, select your test from the list of incomplete runs. After selecting your test, please wait roughly 30 seconds before your run data begins to populate. Other common scenarios are listed below.

Be sure to connect to the thermocycler via Bluetooth so the app can automatically transfer data off the unit once available.

Common Scenarios

Did you start your run and return to your thermocycler later in the day only to realize it's now off? Maybe your app crashed or your phone died and your wondering how to retrieve your test results? Below are some common scenarios and the steps to take to get your results.

"My thermocycler is on, my test is currently running or has completed, and my Biomeme Go app is still open."

- 1. Press the <u>Bluetooth</u> button on top of the thermocycler twice in order to cycle the pairing OFF then ON again.
- 2. Press <u>Scan</u> in the Biomeme Go app.
- 3. Select your thermocycler.
- 4. Tap Confirm in the app.

Note: If your test is currently running, the LED on the front of your thermocycler will be blinking amber. If your test has been completed, the LED will be blinking blue.

"My thermocycler is on, my test is currently running or has completed, and my Biomeme Go app has closed."

- 1. Relaunch the Biomeme Go app by selecting the icon on your smartphone's home screen.
- 2. Press the <u>Bluetooth</u> button on top of the thermocycler twice in order to cycle the pairing OFF then ON again.
- 3. From the app's home screen, tap Incomplete Runs.
- 4. Select your test from the list of incomplete runs.
- 5. Press the <u>Scan</u> button in the app and select your thermocycler.

- 6. Tap Connect via BLE.
- 7. Tap the <u>Reattach Test</u> button.
- 8. Please wait while your run data is transferred.

"My thermocycler is off and my Biomeme Go app is open."

- 1. Press the <u>Power</u> button on top of your Franklin[™] thermocycler to turn it back on. If your thermocycler doesn't turn back on, make sure it's connected to a power source as your battery may have died.
- 2. Press the <u>Recovery</u> button on top of your thermocycler.
- 3. The thermocycler will quickly blink blue, white, red, then green indicating it has successfully recovered the previously completed or failed run.
- 4. Press the <u>Bluetooth</u> button on top of your thermocycler.
- 5. Press <u>Scan</u> in the Biomeme Go app.
- 6. Select your thermocycler.
- 7. Please wait while your run data is transferred.

"My Biomeme Go app is returning a WRONG THERMOCYCLER error."

Turn off Bluetooth by pressing the <u>Bluetooth</u> button on top of your thermocycler.

Press the <u>Recovery</u> button on top of your thermocycler.

The thermocycler will quickly blink blue, white, red, then green indicating it has successfully recovered the previously completed or failed run.

Press the <u>Bluetooth</u> button on top of your thermocycler to enable Bluetooth again.

Press Scan in the Biomeme Go app.

Select your thermocycler and tap <u>Confirm</u>.

Please wait while your run data is transferred.

"My thermocycler is off and my Biomeme Go app is closed."

Press the <u>Power</u> button on top of your Franklin[™] thermocycler to turn it back on. If your thermocycler doesn't turn back on, make sure it's connected to a power source as your battery may have died.

Press the <u>Recovery</u> button on top of your thermocycler.

The thermocycler will quickly blink blue, white, red, then green indicating it has successfully recovered the previously completed or failed run.

Press the <u>Bluetooth</u> button on top of your thermocycler.

Relaunch the Biomeme Go app by selecting the icon on your smartphone's home screen.

From the app's home screen, tap Incomplete Runs.

Select your test from the list of incomplete runs.

Press the <u>Scan</u> button in the app and select your thermocycler.

Tap Connect via BLE.

Tap the <u>Reattach Test</u> button.

Please wait while your run data is transferred.

If you're still having problems recovering and/or reattaching your test data, please contact support@biomeme.com.

Transferring Data



Wireless (Bluetooth)

On your computer, make sure your Bluetooth is set to <u>Receive a File</u>. This will prepare your computer to accept the data transfer from your smartphone.

- In the mobile app, navigate through <u>View Results</u> and select a test.
- Once on the test result screen, tap <u>Send</u> in the top right corner.
- A menu will slide in with sharing options. Select <u>Bluetooth</u> and transition to the <u>Choose Bluetooth Device</u> screen.

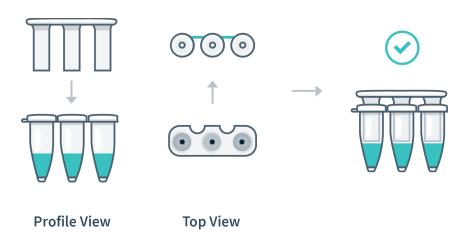
Note: Instructions could vary depending on your computer and/or smartphone Operating System. If you require further assistance, please contact support@biomeme.com.

Note: Cutting and pasting OR deleting the .xlsx files will permanently delete them off the smartphone. If you want them to remain, make sure to only copy and paste.

Loading Sample into Go-Strips

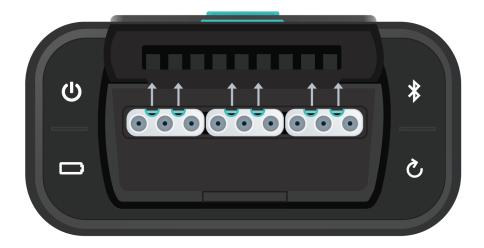
Attention: Contents of the Go-Strip may shift during transport. When starting to work with your test, make sure the cake of the lyophilized reagent rests at the bottom of the Go-Strip wells. Tap the bottom of the sealed Go-Strip gently but firmly against a solid surface before removing the foil seal and adding your sample.

- Tear open the foil pouch to retrieve your Go-Strip, but do not discard the foil pouch as you'll need to scan the QR code.
- Remove the foil seal from your Go-Strip, and transfer 20µL of purified sample into each well of your Go-Strip.
- Once all wells of your Go-Strip are filled, place a void filling cap into the strip.
- Align the Go-Strip and void filling cap so that the strip connections are visible through the cap cutouts as shown in the illustration below.



Placing into Franklin™ Thermocycler

- Open the lid of your thermocycler by pressing the latch on top of the unit.
- Place your Go-Strip, with the void filling cap inserted, into a 3-well slot. Don't worry if the void filling cap feels slightly loose. When the lid of the thermocycler is closed, it will secure the caps into place, sealing the PCR reaction.
- It's important to make sure your Go-Strip is oriented correctly when placing it into your thermocycler. Make sure the strip connections that are visible through the void filling cap cutouts are facing the back of your thermocycler as shown in the illustration below, then close the lid.



• Navigate to the Biomeme Go mobile application on your smartphone to begin your testing protocol. For further instructional information, please contact support@biomeme.com.

Note: Transport your Franklin™ thermocycler in its carrying case. Additionally, moving your thermocycler while thermocycling could result in errors. We highly recommend not moving or opening the device while thermocycling to avoid losing your PCR run. After your run has completed, be careful when removing your Go-Strips and void filling caps to avoid liquid splatter.

Maintenance & Cleaning

The Biomeme Franklin™ thermocycler is maintenance-free and has no serviceable parts. In the case of thermocycler failure or damage, please contact support@biomeme.com.

The outside of the Franklin™ thermocycler can be cleaned using 70% ethanol solution which must be sprayed on a cloth rather than directly on the Franklin thermocycler. Lysol wipes or Micro-Chem Plus wet paper towels are acceptable as well. Do not spray or pour solution directly onto the thermocycler when cleaning.

- Do not disassemble the thermocycler for cleaning
- Do not immerse in water or cleaning solutions
- Do not clean with soap or other solutions
- Avoid cleaning the heating wells (silver)

If you do need to clean your heating wells because it's impacting performance, please contact support@biomeme.com for specific instructions.

Safety Notice

The instrument can pose electrical hazards to the operator if used inappropriately and hence it is important to understand, familiarize and implement the safety notices given below to ensure safety of the operator.

The instrument and its equipment should be operated, maintained, stored and as directed in this document. Failure to comply may impair the protection provided by the instrument and its ancillary equipment.

General Safety Warnings



Do not modify the instrument hardware. The system is not user serviceable by the user in any circumstances.



Do not place the instrument near liquid filled containers or areas where the instrument and its equipment may be subjected to dripping or splashing liquids.



Do not use the instrument in extreme heat, humidity, dust and vibration conditions Electrical Safety Notice.



CAUTION - Heating wells may be hot. Care must be taken when inserting or removing cuvettes.

Electrical Safety Warnings



Unplug AC power cord from the wall outlet in case of an emergency.

SYMBOL	DESCRIPTION
	Caution, possibility of electric shock
	Caution, hot surface
į	Caution
Ť	Keep Dry
	No Waste This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

Declaration of Conformity

This declaration of conformity is issued for:

Product: Biomeme Franklin™ qPCR Thermocycler

Model Number: Franklin™

The object of this declaration is in conformity with European Union directives 2014/35/EU, 2014/30/EU and 2011/65/EU.

The following harmonized standards were applied:

Safety:	IEC 61010-1:2010, AMD1:2016
	IEC 61010-2-010:2014
	IEC 61010-2-081:2015
	IEC 62133-2:2017
EMC:	IEC 62479:2010
	IEC 61326-1:2013
	ETSI EN 301 489-1 V2.1.1
	ETSI EN 301 489-17 V3.1.1
Hazardous Substances:	EN 50581:2012

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Troubleshooting

Why is my Bluetooth not connecting?

If you are having trouble connecting, ensure that you enabled Bluetooth on both your smartphone and thermocycler.

Why is my thermocycler not showing up in the connection list?

Ensure that Bluetooth is turned on. The LED next to the button should be illuminating blue. If your thermocycler is still not showing, try scanning multiple times to allow for discovery.

My Bluetooth connection was lost during a test run...

If you lose Bluetooth connection, the smartphone app will notify you that the connection has been lost. It will prompt you to reconnect to the thermocycler if you are able to. Upon reconnecting, the test data will update on the smartphone after a short delay (1-2 seconds).

What happens if my test stops prematurely?

If your test fails, the smartphone will notify you of the error returned from the thermocycler. Your last run will be saved in the Biomeme mobile app up to the point of failure, but the data will not be processed resulting in no Cq values, baseline, or graph of smooth data. The raw data and information about your run is still exportable through the xlsx spreadsheet, however.

My thermocycler turned off during a test run...

If your thermocycler turns off during a test, then the thermocycler battery may be dead and the unit should be plugged into power. Your connection to the

smartphone will also be lost. If this happens, we recommend you to stop the run in the smartphone mobile app. See Recovering & Reattaching Test Data for more details.

I have a low battery warning at test start...

You are able to start a test, but ensure that you are plugged into a charger before the thermocycler runs out of power.

My app closed during a test run...

If the smartphone app closes during a test, you can sync to the test by reopening the app and pressing the incomplete runs option. This will display the previous incomplete run. See Recovering & Reattaching Test Data for more details.

I reconnected to the wrong thermocycler...

If you accidentally reconnect to the wrong thermocycler, the app will notify you that you are connected to the wrong thermocycler and not fetch any data from the current run.

How do I stop a test?

While the test is running, you have the ability to press the stop run button. Doing so will prompt the mobile app to ask you to confirm that you would like to stop the test in progress. Upon stopping, your run will be saved to the current point, and available in the test results section of the mobile app.

The thermocycler failed to start test...

If your run fails to start, the app will return to the home screen and have you restart the setup of your test. Restart the thermocycler then reconnect the smartphone. If starting still fails after many retries, please contact support@biomeme.com.

The USB failed to send the protocol...

Make sure your thermocycler is on. If on and still failing, power cycle your thermocycler and go through the setup again.

How do I upgrade my one9 and/or two9 thermocycler to add additional color channel detection?

Adding additional color detection channels to your thermocycler is easy and does not require you to return your unit or purchase any new parts. All you'll need is the MAC address for the thermocycler(s) requiring an upgrade which can be found on the label on the bottom of your unit(s).

Start by navigating to the settings menu in the Biomeme mobile app and tap upgrade. From there, you'll be redirected to our mobile-friendly online store where you can purchase additional color channels such as ATTO647N (Red) and TexasRedX (Amber). Once your order is received, a Biomeme representative will follow up regarding your MAC address(es) and use this to provide you with a unique 16-character unlock code (per unit) to be entered using the Biomeme mobile app. Please note, your smartphone must be connected to the thermocycler via Bluetooth or serial in order to complete the upgrade.

What should I do if I receive a heater error message?

Retry running your test, but if the error persists please contact support@biomeme.com.

What should I do if my test is complete, but I can't reattach my smartphone to get my results?

Steps to try, in order:

- Turn off Bluetooth on your smartphone. Then, turn Bluetooth back on and attempt to reconnect to the thermocycler.
- Close the Biomeme mobile app completely then re-open it and attempt to access Incomplete Runs from the app home screen to recover your test results.

Disclaimer

For Research Use Only. Not for use in human or veterinary diagnostics. The performance characteristics of this product have not been established.

Biomeme products may not be transferred to third parties, resold, modified for resale or used to manufacture commercial products or to provide a service to third parties without written approval of Biomeme, Inc.

Biomeme warrants every thermocycler to be free of defects in material and workmanship for one year from the date of shipment to buyer. All warranties are subject to our <u>Terms and Conditions and Privacy Policy</u> (https://biomeme.com/privacy-policy-and-terms-of-use/).

Biomeme, Inc. 1015 Chestnut Street, Suite 1401 Philadelphia, PA, USA 19107 <u>support@biomeme.com</u> <u>Patent Protected</u> (https://biomeme.com/patents/)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device contains: FCC ID: XPYNINAB1 IC: 8595A-NINAB1

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

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

This device may not cause interference.

This device must accept any interference, including interference that may cause undesired operation of the device.