

Franklin™ Real-Time PCR Thermocycler (EUA)

For IVD Use ONLY. For Emergency Use Authorization ONLY.

This product has not been FDA cleared or approved; the product has been authorized by FDA for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

This product has been authorized only for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Franklin™ Thermocycler

The **Biomeme Franklin™** transforms your smartphone into a thermocycler for real-time PCR analysis with results in under an hour. 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.

Technical Specifications

SPECIFICATION	VALUE
Sample Capacity	9 Wells
Reaction Volume per Well	20µL
Total Channels	3
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

Thermocycler Button Layout






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




LED Status Indicators

Vertical LED on the front of your thermocycler.

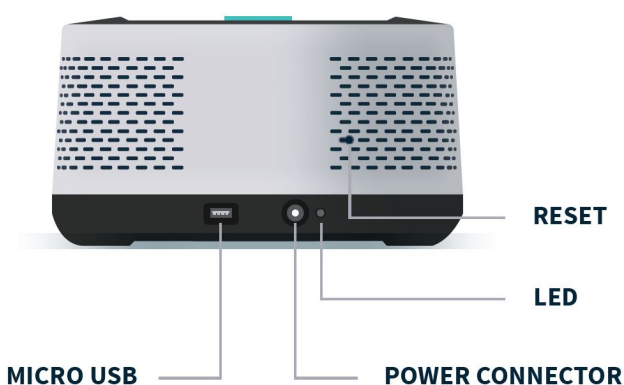
Franklin™ has 5 LEDs on the front of the unit. The LEDs are used to convey various states of the thermocycler as outlined in the table below.

COLOR	INTERPRETATION
 <p>WHITE</p>	<p>5 solid indicates your thermocycler is on 5 blinking indicates Bluetooth (BLE) is pairing</p>
 <p>GREEN</p>	<p>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</p>
 <p>YELLOW</p>	<p>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</p>
 <p>RED</p>	<p>1 solid indicates remaining battery is between 0 and 20% 5 blinking indicates thermocycler lid is open or an error</p> <p><i>Note: If the battery is in the red, you shouldn't start your run until you plug your thermocycler into power.</i></p>
 <p>BLUE</p>	<p>5 blinking indicates your test is complete and data is ready to be synced to your smartphone</p>


Turning Your Thermocycler On and Off






To power on your thermocycler, press and hold the power button  (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:

LED STATUS		BATTERY PERCENTAGE
5 solid		81 - 100%
4 solid		61 - 80%
3 solid		41 - 60%
2 solid		21 - 40%
1 solid		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 Connect via BLE when prompted in the smartphone app. If working with multiple Franklin™ thermocyclers, select the appropriate unit and tap Confirm. The LED on the front of your thermocycler will flash white indicating it's connected.

Recovering & Reattaching Test Data

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 you're wondering how to retrieve your test results? Below are some common scenarios and the steps to take to get your results. You can find these same protocols with their connected How-To videos on our Help Desk:

<https://help.biomeme.com/reattach-recover-guide>

Scenario Reference Table		Biomeme Go App	
		Open	Closed
Franklin Thermocycler	On	A	B
	Off	C	D

Note: DO NOT push Stop Run in the app. This will lose any run data that has not successfully synced from the device to the app. For security reasons the same smartphone that was used to initiate the test must be used to download the test results.

“My test has been running for a while but the number of cycles isn’t decreasing on the app. What should I do?”

This means that the Bluetooth connection between the device and the app has been interrupted. **DO NOT press Stop Run**. Instead you just need to reset the Bluetooth connection. Follow the steps in Scenario **A** below.

“My run has completed and I’ve pressed a bunch of buttons. I’m feeling flustered, confused, and frustrated; what should I do?”



1. Turn off the thermocycler and close the Biomeme Go app.
2. Follow the steps described in Scenario **D** below.

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

“My Biomeme Go app is returning a WRONG THERMOCYCLER error.”

1. Turn off the thermocycler and close the Biomeme Go app.
2. Follow the steps described in Scenario **D** below.



A: Thermocycler ON / App OPEN

1. Press the Bluetooth  button on top of the thermocycler to turn OFF the Bluetooth.
2. Press the Bluetooth  button on the top of the thermocycler to turn the Bluetooth back on.
3. Within the Biomeme Go app, you should see a pop-up screen that reads: **“Connect via BLE”**. If so, press Scan in the Biomeme Go app. If not, power OFF the thermocycler, CLOSE the app, and to Scenario **D** below.
4. Select your thermocycler.



5. 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.

B: Thermocycler ON / App CLOSED

1. Relaunch the Biomeme Go app by selecting the icon on your smartphone's home screen.
2. Press the Bluetooth  button on top of the thermocycler to turn OFF the Bluetooth connection.
3. Press the Bluetooth  button on the top of the thermocycler to turn the Bluetooth connection back ON.
4. From the app's home screen, tap Incomplete Runs.
5. Select your test from the list of incomplete runs.
6. Press the Scan button in the app and select your thermocycler.
7. Tap Connect via BLE.
8. Tap the Reattach Test button.
9. Please wait while your run data is transferred.




C: Thermocycler OFF / App OPEN

1. Press the Power  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 Recovery  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 Bluetooth  button on top of your thermocycler.
5. Press Scan in the Biomeme Go app.
6. Select your thermocycler.
7. Please wait while your run data is transferred.

*Note: This assumes your test was completed **before the thermocycler powered off**. It is usually not possible to reattach and recover the run data if the thermocycler shut off during the run. Please always ensure your device has at least 20% battery power before starting your run.*

D: Thermocycler OFF / App CLOSED

1. Press the Power  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 Recovery  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 Bluetooth  button on top of your thermocycler.
5. Relaunch the Biomeme Go app by selecting the icon on your smartphone's home screen.
6. From the app's home screen, tap Incomplete Runs.
7. Select your test from the list of incomplete runs.
8. Press the Scan button in the app and select your thermocycler.
9. Tap Connect via BLE.
10. Tap the Reattach Test button and wait until your run data is transferred.

Note: This assumes your test was completed **before the thermocycler powered off**. It is usually not possible to reattach and recover the run data if the thermocycler shut off during the run. Please always ensure your device has at least 20% battery power before starting your run.

Transferring Data



Wireless (Bluetooth)

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

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

1. Open the contents of a Biomeme SARS-CoV-2 Go-Strips pouch. Do not immediately discard the Go-Strips pouch as you'll need to scan the QR code in a later step.
2. Start with a single Go-Strip and remove the foil covering.
3. Attach a pipette tip to a 20 μ L fixed volume pipette or prepare your own 20 μ L pipette.

Note: The strip connections between the tubes of your Go-Strip will face the back of the thermocycler once inserted. When resuspending your reactions and transferring your extracted RNA into the different reaction wells, replicate this orientation to ensure accurate result interpretation (e.g. transfer sample 1 into the far left reaction well of your first Go-Strip, sample 2 into the middle reaction well of your first Go-Strip, and sample 3 into the far right reaction well of your first Go-Strip).

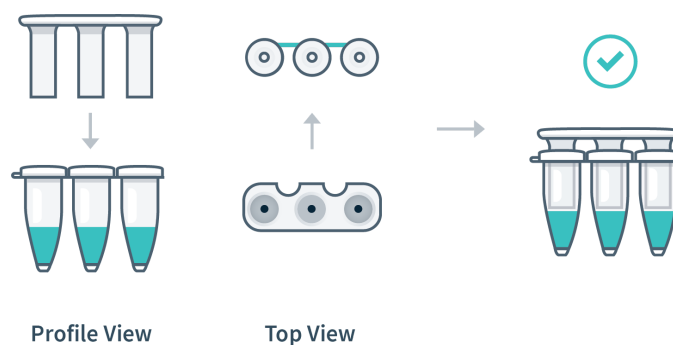
4. Additionally, when mixing your samples try to avoid introducing bubbles.



Note: If bubbles have been introduced, remove them from the lower portion of the PCR tubes by gently tapping the Go-Strips against your work surface before capping. Bubbles may remain at the top of the tube, but bubbles at the bottom are not acceptable.

5. Unscrew the cap of your first purified sample in the 2mL tube and transfer 20 μ L of the extracted RNA into the **first** reaction well of your Go-Strip. Pipette up and down 3-5 times to mix your PCR reaction.

- Discard your pipette tip and repeat the process of transferring your samples only for the remaining 2 reaction wells. Once all wells of a single Go-Strip are filled, make sure to place a void filling cap into the Go-Strip to minimize any risk of contamination. 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:

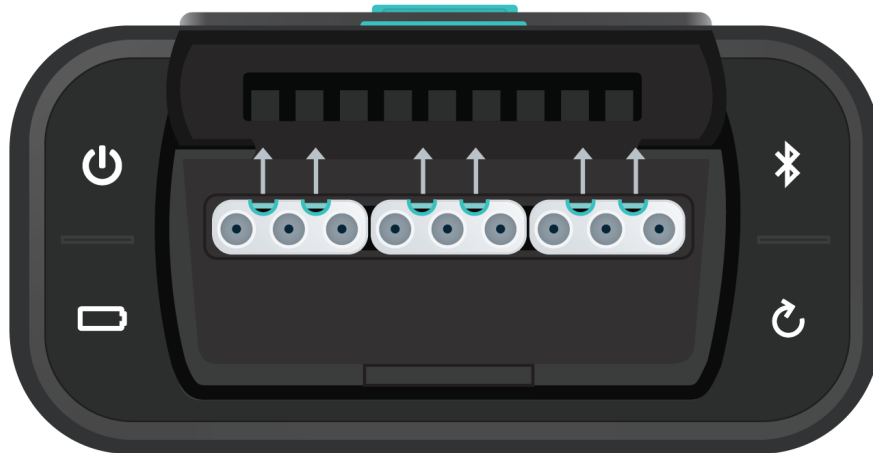


- The void filling caps may feel slightly loose, this is normal. The thermocycler lid will secure the caps into place when closed, sealing each PCR reaction. **DO NOT** attempt to push the cap down.

Note: If utilizing a No Template Control (NTC) and/or external Positive Control (PC), add in a similar manner to other samples. It is recommended that the NTC be added first (Well 1) and the PC last (Well 9) after the addition of samples.

Placing Go-Strips into Franklin™ Thermocycler

1. Open the lid of your thermocycler by pressing the latch on top of the unit.
2. Place your Go-Strips, with the void filling caps inserted, into each 3-well slot. Once again, make sure the strip connections are visible through the void filling cap cutouts and are facing the back of the thermocycler as shown in the illustration below.



3. Close the thermocycler lid securely and navigate to the Biomeme Go mobile application on your smartphone to begin your testing protocol. For further instructional information, please contact support@biomeme.com.

PCR Layout Example (for one full Franklin™ run) Without External Controls

Go-Strip	Go-Strip 1 (left)			Go-Strip 2 (middle)			Go-Strip 3 (right)		
Well	1	2	3	4	5	6	7	8	9
Samples	S1	S2	S3	S4	S5	S6	S7	S8	S9

PCR Layout Example (for one full Franklin™ run) With External Controls

Go-Strip	Go-Strip 1 (left)			Go-Strip 2 (middle)			Go-Strip 3 (right)		
Well	1	2	3	4	5	6	7	8	9
Samples & Controls	NTC	S2	S3	S4	S5	S6	S7	S8	PC

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 and PCR amplicon contamination.

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 a 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.

4. Do not disassemble the thermocycler for cleaning
5. Do not immerse in water or cleaning solutions
6. Do not clean with soap or other solutions
7. 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.







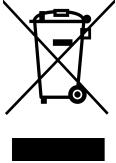
CAUTION - Heating wells may be hot. Care must be taken when inserting or removing cuvettes.

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

	Caution
	Keep Dry
	No Waste <i>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.</i>

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.

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.

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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 [Terms and Conditions and Privacy Policy](https://biomeme.com/privacy-policy-and-terms-of-use/) (<https://biomeme.com/privacy-policy-and-terms-of-use/>).

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[Patent Protected](https://biomeme.com/patents/)
(<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: XPNINAB1

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.