



Automated Thermal Block Product Instructions

Product No. MCH2023



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Instrument Overview

The Automated Thermal Block is a Peltier-driven heating and cooling device pre-programmed to perform the lysis steps of the BAX® System protocols. It has been designed as a solid-state device with minimal moving parts to help ensure quality performance over time. The temperature of the plate is sensed by a platinum resistance temperature device mounted under the plate. The computer in the unit compares the plate temperature with the target temperature and instructs the module to heat or chill the plate as required.



The block automatically provides the sequential heating and cooling conditions for lysis protocols, eliminating the need to transfer samples between separate heating and cooling blocks. Once the lysis program is complete, the block holds the samples at 4 °C until they are removed.

This model has been optimized for use with the cluster tubes and metal tube holder supplied with the BAX System. Other tubes and holders are not recommended.

Supplied Components

The purchase of the thermal block includes the following components:

- 1. Thermal block unit
- 2. Metal tube holders (2)
- 3. Power supply and cord
- 4. User documentation

Specifications and Requirements

Item	Specification
Dimensions (with lid)	6.5" W x 8.75" D x 8" H (16.5 x 22.25 x 20.3 cm)
Weight	Approximately 8 lbs. (3.6 kg)
Power usage	12 volts, 8.4 amps
Power requirements	90 to 265 volts AC, 50/60Hz
Thermal range	–10 to 110 °C (14 to 230 °F)
Thermal uniformity	±1 °C as measured at the block surface
Thermal accuracy	±1 °C as measured at the block surface
Sample throughput	1 – 96 samples per cycle
Room environment	Temperature between 18 and 32 °C (65 and 89 °F)



Safety Symbols and Precautions

Safety Symbols

Symbol	Description
Â	Indicates that you should consult the manual for further information and proceed with appropriate caution.
	Indicates the presence of a hot surface or other high-temperature hazard. Proceed with appropriate caution.
<u>A</u>	Indicates the presence of an electrical shock hazard. Proceed with appropriate caution.

General Safety Information

Safety Topic	Information
Extreme Temperatures	The thermal block can reach 110 $^\circ$ C (230 $^\circ$ F), which can burn the skin if touched.
	To prevent injury, remember the following:
<u>\m\</u>	Always use extreme caution around the block.
	Never leave the block accessible to others when it is hot.
	• Do not touch the plate surface unless you are sure it has cooled.
	Always keep the lid in place when the block is not in use.
Power Requirements	Always use the supplied AC power cord when connecting the heating block to a power source. Use the normal care and precaution that one would use with any electrical appliance.

Connecting the Thermal Block

The Automated Thermal Block is pre-programmed to perform the sequential heating and cooling steps needed for BAX System assays. No calibration or software installation is required when the thermal block is used as specified.

Follow these steps to connect the thermal block:

- 1. Place the thermal block unit on a level, dry laboratory workbench. Allow at least 4 inches (10 cm) on all sides of the unit for ventilation.
- 2. Insert one end of the provided power cord into the power supply and plug the other end of the power cord into a 3-wire outlet.

Note: Ensure the outlet is properly grounded and runs at the appropriate voltage (see specifications on the previous page).

3. Insert the power supply jack into the power input port on the back panel of the thermal block.





4. Seat the metal tube holder over the metal plate surface on the top of the thermal block unit.



Front Panel Display

The front panel of the Automated Thermal Block contains the following items:

- 1. LCD display—shows the program menu, program selection, settings and instructions.
- 2. **SCROLL button**—changes the selected menu item in the LCD display. An audible beep sounds when the button is pressed.
- 3. **Blue ACTION NEEDED LED**—indicates that the user must perform an action before the program can continue. This notification is accompanied by an audible alarm.
- 4. **SELECT/CONTINUE button**—sets the menu item in the LCD display as the selected program and is also used to confirm required actions. An audible beep sounds when the button is pressed.
- 5. **Green POWER LED**—indicates that the thermal block is turned on.





Program Menu

The Automated Thermal Block is pre-programmed with four lysis protocols:

1. Gram positive—use with gram-positive bacteria, including Staphylococcus and Listeria

Note: For *Listeria* 24E assays, use the "24E" program. For real-time *Listeria* assays, use the "RT Listeria" program.

- 2. <u>Gram negative</u>—use with gram-negative bacteria, including *Salmonella*, *E. coli*, *Campylobacter*, *Vibrio* and *Cronobacter*
- 3. <u>24E</u>—use with *Listeria* 24E assays:

BAX System PCR Assay for Genus Listeria 24E	KIT2003
BAX System PCR Assay for L. monocytogenes 24E	KIT2002

4. <u>RT *Listeria*</u>—use with real-time *Listeria* assays:

BAX System Real-Time PCR Assay for Genus Listeria	KIT2019
BAX System Real-Time PCR Assay for L. monocytogenes	KIT2005

Turn the Thermal Block On and Off





Run the Gram-Positive Program

Samples are heated to 55 °C for 60 minutes, then 95 °C for 10 minutes, then held at 4 °C for at least 5 minutes or until removed. The times vary slightly depending on the environment because a sensor gives active feedback to the instrument heater to ensure that proper temperatures are met.

1	Turn on the thermal block, then press the SCROLL button until the arrow (→) is next to the Gram Positive option.	→ Gram Positive Gram Negative
	Press the SELECT/CONTINUE button.	
2	The unit beeps once, and the LCD display changes as the thermal block begins equilibrating to 55 °C.	Equilibr.@ 55C GmPos
	Note: Do not load samples into the thermal block until the load prompt appears on the LCD display.	
3	When the thermal block has reached 55 °C, the unit sounds two audible beeps and the blue ACTION NEEDED LED activates. The LCD display changes to Load Samples.	Load Samples GmPos
4	After the Load Samples prompt appears, place a rack of prepared samples into the metal tube holder.	
	<i>Note: See the</i> BAX System User Guide <i>for information on preparing samples</i> .	
	Press the SELECT/CONTINUE button.	Automated Thermal Block
5	The LCD display changes to GmPos Lysis 55C .	GmPos Lysis 55C GmPos 57:08 Note: A timer in the bottom right corner counts down from 60:00 and shows the number of minutes remaining in this step.
6	After lysis at 55 °C is complete, the LCD display changes to Heating to 95C .	Heating to 95C GmPos 4:39
	No user action is required.	Note: A timer in the bottom right corner counts up

from 0:00 during the temperature change.



7 After the thermal block reaches 95 °C, the LCD Denaturing @ 95C display changes to **Denaturing @ 95C**. GmPos 7:22 No user action is required. *Note: A timer in the bottom right corner counts* down from 10:00 and shows the number of minutes remaining in this step. 8 After denaturation at 95 °C is complete, the LCD Cooling to 4C display changes to **Cooling to 4C**, and the thermal GmPos 1:45 block sounds two audible beeps to signal the change. Note: A timer in the bottom right corner counts up No user action is required. from 0:00 during the temperature change. 9 After the samples have cooled, the LCD display Sample PCR Ready changes to Sample PCR Ready, the blue ACTION GmPos 1:06 NEEDED LED activates, and the thermal block sounds Note: A timer in the bottom right corner counts up four audible beeps to signal that samples can be from 0:00 to show any additional time that removed. samples are held at 4 °C. Press the SELECT/CONTINUE button. 10 The LCD display changes to **Completed**, and the Completed thermal block sounds an audible beep to signal that GmPos 6:25 the program has been completed. Note: The timer continues to show additional time that samples are held at 4 °C. 11 Remove the cluster-tube rack and follow the instructions in the BAX System User Guide to hydrate the PCR tablets with these lysates. Press the SELECT/CONTINUE button. Note: Lysates must be maintained at 4 °C during tablet hydration. 12 The LCD display changes to Gram Positive Finished, Gram Positive and the thermal block sounds an audible beep to **Finished** signal that the program has finished. 13 Press the SELECT/CONTINUE button to end the → Gram Positive program. The LCD changes to display the program Gram Negative menu.



Run the Gram-Negative Program

Samples are heated to 37 °C for 20 minutes, then 95 °C for 10 minutes, then held at 4 °C for at least 5 minutes or until removed. The times vary slightly depending on the environment because a sensor gives active feedback to the instrument heater to ensure that proper temperatures are met.

1	Turn on the thermal block, then press the SCROLL button until the arrow (\rightarrow) is next to the Gram Negative option.	→ Gram Negative 24E
	Press the SELECT/CONTINUE button.	
2	The unit beeps once, and the LCD display changes as the thermal block begins equilibrating to 37 °C.	Equilibr.@ 37C GmNeg
	Note: Do not load samples into the thermal block until the load prompt appears on the LCD display.	
3	When the thermal block has reached 37 °C, the unit sounds two audible beeps and the blue ACTION NEEDED LED activates. The LCD display changes to Load Samples.	Load Samples GmNeg
4	After the Load Sample prompt appears, place a rack of prepared samples into the metal tube holder.	
	Note: See the BAX System User Guide for information on preparing samples.	
	Press the SELECT/CONTINUE button.	Automated Thermal Block
5	The LCD display changes to GmNeg Lysis 37C .	GmNeg Lysis 37C GmNeg 19:41
		Note: A timer in the bottom right corner counts down from 20:00 and shows the number of minutes remaining in this step.
6	After lysis at 37 °C is complete, the LCD display changes to Heating to 95C .	Heating to 95C GmNeg 4:39
	No user action is required.	Note: A timer in the bottom right corner counts up from 0:00 during the temperature change.
7	After the thermal block reaches 95 °C, the LCD display changes to Denaturing @ 95C .	Denaturing @ 95C GmNeg 8:26
	No user action is required.	Note: A timer in the bottom right corner counts down from 10:00 and shows the number of minutes remaining in this step.



After denaturation at 95 °C is complete, the LCD display changes to Cooling to 4C, and the thermal block sounds two audible beeps to signal the change.

No user action is required.

9 After the samples have cooled, the LCD display changes to Sample PCR Ready, the blue ACTION NEEDED LED activates, and the thermal block sounds four audible beeps to signal that samples can be removed.

Press the SELECT/CONTINUE button.

10 The LCD display changes to **Completed**, and the thermal block sounds an audible beep to signal that the program has been completed.

Cooling to 4C GmNeg 2:15

Note: A timer in the bottom right corner counts up from 0:00 during the temperature change.

Sample PCR Ready GmNeg 1:01

Note: A timer in the bottom right corner counts up from 0:00 to show any additional time that samples are held at 4 °C.

Completed GmNeg 4:54

Note: The timer continues to show additional time that samples are held at 4 °C.

11 Remove the cluster-tube rack and follow the instructions in the *BAX System User Guide* to hydrate the PCR tablets with these lysates.

Press the SELECT/CONTINUE button.



Note: Lysates must be maintained at 4 °C during tablet hydration.

12 The LCD display changes to Gram Negative Finished, and the thermal block sounds an audible beep to signal that the program has finished.
 13 Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.



Run the 24E Program

Samples are heated at 37 °C for 30 minutes, then removed for the addition of lysis reagents. Samples then are heated to 55 °C for 30 minutes, then 95 °C for 10 minutes, then held at 4 °C for at least 5 minutes or until removed. The times vary slightly depending on the environment because a sensor gives active feedback to the instrument heater to ensure that proper temperatures are met.



7 Remove the rack of cluster tubes from the metal tube holder.

Press the SELECT/CONTINUE button.



Note: Do not reload samples into the thermal block

until the reload prompt appears on the LCD display.

8 The unit beeps once, and the LCD display changes as the thermal block begins equilibrating to 55 °C.

> While the block is heating, follow the instructions in the BAX System User Guide to add additional lysing reagents to each sample.

- When the thermal block has reached 55 °C, the unit 9 sounds two audible beeps and the blue ACTION NEEDED LED activates. The LCD display changes to **Reload Samples**.
- 10 After the **Reload Samples** prompt appears, place the rack of samples with additional lysing reagents into the metal tube holder.

Press the SELECT/CONTINUE button.



Equilibr.@ 55C

24E



11 The LCD display changes to 55C 24E Lysis.



Note: A timer in the bottom right corner counts down from 30:00 and shows the number of minutes remaining in this step.

12 After lysis at 55 °C is complete, the LCD display changes to Heating to 95C.

No user action is required.



Note: A timer in the bottom right corner counts up from 0:00 during the temperature change.





After the thermal block reaches 95 °C, the LCD display 13 changes to Denaturing @ 95C.

No user action is required.

Denaturing @ 95C 24E 7:24

Cooling to 4C

24E

Sample PCR Ready

24E

Note: A timer in the bottom right corner counts down from 10:00 and shows the number of minutes remaining in this step.

3:44

0:56

from 0:00 to show any additional time that

Note: A timer in the bottom right corner counts up

from 0:00 during the temperature change.

Note: A timer in the bottom right corner counts up

14 After denaturation at 95 °C is complete, the LCD display changes to Cooling to 4C, and the thermal block sounds two audible beeps to signal the change.

No user action is required.

15 After samples have cooled, the LCD display changes to Sample PCR Ready, the blue ACTION NEEDED LED activates and the thermal block sounds four audible beeps to signal that samples can be removed.

Press the SELECT/CONTINUE button.

- 16 The LCD display changes to **Completed**, and the gnal that
- samples are held at 4 °C. Completed



Note: The timer continues to show additional time that samples are held at 4 °C.



Note: Lysates must be maintained at 4 °C during tablet hydration.

- 18 The LCD display changes to 24E Finished and the thermal block sounds an audible beep to signal that the program has finished.
- 24E **Finished**
- 19 Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.

 \rightarrow 24E **RT** Listeria

17 Remove the cluster-tube rack and follow the instructions in the BAX System User Guide to hydrate the PCR tablets with these lysates.

Press the SELECT/CONTINUE button.



Run the RT Listeria Program

Samples are heated to 55 °C for 30 minutes, then 95 °C for 10 minutes, then held at 4 °C for at least 5 minutes or until removed. The times vary slightly depending on the environment because a sensor gives active feedback to the instrument heater to ensure that proper temperatures are met.



7 After the thermal block reaches 95 °C, the LCD display changes to **Denaturing @ 95C**.

No user action is required.

Denaturing @ 95C RTLis 8:02

Cooling to 4C

RTLis 1:25

Note: A timer in the bottom right corner counts down from 10:00 and shows the number of minutes remaining in this step.

8 After denaturation at 95 °C is complete, the LCD display changes to **Cooling to 4C**, and the thermal block sounds two audible beeps to signal the change.

No user action is required.

9 After the samples have cooled, the LCD display changes to Sample PCR Ready, the blue ACTION NEEDED LED activates, and the thermal block sounds four audible beeps to signal that samples can be removed.

Press the SELECT/CONTINUE button.

- 10 The LCD display changes to **Completed**, and the thermal block sounds an audible beep to signal that the program has been completed.
- 11 Remove the cluster-tube rack and follow the instructions in the BAX System User Guide to hydrate the PCR tablets with these lysates.

Press the SELECT/CONTINUE button.

Note: A timer in the bottom right corner counts up from 0:00 during the temperature change.

Sample PCR Ready RTLis 0:57

Completed

RTLis 3:19

Note: A timer in the bottom right corner counts up from 0:00 to show any additional time that samples are held at 4 °C.

Note: The timer continues to show additional time that samples are held at 4 °C.



Note: Lysates must be maintained at 4 °C during tablet hydration.

- The LCD display changes to **RT Listeria Finished**, and the thermal block sounds an audible beep to signal that the program has finished.
- 13 Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.

➔ RT Listeria

RT Listeria

Finished

Gram Positive

12





Temperature Calibration Verification

The Automated Thermal Block does not require calibration when used as directed. If your laboratory requires <u>calibration verification</u> as part of your standard operating procedures, you can use the following procedure to verify the block is operating appropriately for the BAX[®] System lysis procedure which it is designed to perform.

Materials Required:

- Resistance Temperature Detector (RTD) thermometer with microprobe (e.g., VWR 61220-601 or equivalent)
- Cluster tubes used for lysis (minimum of 48)
 Note: If an RTD thermometer is not available, VWR 12777-842, Cole Palmer EW-37804-04 or similar) may be used to perform the verification. However, since results may be less accurate due to the lower resolution of the dry bath thermometer, verification with an RTD thermometer is strongly recommended.
- 1 Arrange 48 cluster tubes in a rack and fill each tube with 200 μ L of water. Poke a small hole in the cap of one cluster tube near the center of the cluster tube rack.

Note: Power is off



2 While power is still off, place the rack of cluster tubes in the black metal tube holder. Insert the microprobe of the RTD thermometer through the whole in the cluster tube cap (be sure it is in the center of the collection of tubes).

> Note: Make sure the tip of the probe touches the bottom of the tube to ensure that the probe is <u>completely immersed</u>. Hygiena[®] recommends sealing the probe with parafilm or wax to reduce evaporation at higher temperatures.

3 While pressing and holding the SELECT/CONTINUE button, turn on the power to the thermal block by toggling the on/off switch on the back panel. The LCD displays the message **Default Settings Are Now Loaded**.





Default Settings Are Now Loaded

5

Automated Thermal Block, MCH2023

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4 Continue to hold the SELECT/CONTINUE button until the LCD display changes to Set Point: off (about 15 seconds).

Note: Be sure to wait for the temperature reading of the thermometer to equilibrate before proceeding with data collection.

set point to 37 °C. The block automatically begins the heating process. Note: Be sure to wait for the temperature reading of the

thermometer to equilibrate before proceeding with data collection.

Press the SCROLL button to increase the value of the

6 After the thermal block reaches 37 °C and once the temperature has stabilized, measure the temperature of the block with an independent thermal device. Use a certified (Traceable) thermometer in your facility (e.g., NIST-Traceable thermometer VWR #12777-842, ULTRA™ #23226-658 or #23609-174, or similar).

The tolerance of the temperature variation across the block is \pm 2°C. Readings between 35 to 39 °C are acceptable.

Record the measurement for your quality systems records.

Press the SCROLL button to increase the value of the set point to 55 °C. The block automatically begins the heating process.

Note: Be sure to wait for the temperature reading of the thermometer to equilibrate before proceeding with data collection.







Plate Temp: 19C

Set Point: 37C Plate Temp: 22C

hygiend

370

Set Point: Plate Temp:

Automated Thermal Block

7 After the thermal block reaches 55 °C and once the temperature has stabilized, measure the temperature of the block with the independent measure device (as listed above or the NIST-certified thermometer in your facility). The tolerance of the temperature variation across the block is ± 2°C. Readings between 53 to 57 °C are acceptable.

Record the measurement for your quality systems records.

Press the SCROLL button to increase the value of the set point to 95 °C. The block automatically begins the heating process.

Note: Be sure to wait for the temperature reading of the thermometer to equilibrate before proceeding.

8 After the thermal block reaches 95 °C and once the temperature has stabilized, measure the temperature of the block with the independent measuring device (as listed above or any NIST-certified thermometer in your facility). The tolerance of the temperature variation across the block is ± 3°C. Readings between 92-98°C are acceptable.

Press the SELECT/CONTINUE button to decrease the set point to 4°C. The block automatically begins the cooling process.

Note: Be sure to wait for the temperature reading of the thermometer to stabilize before proceeding.











9 After the samples have cooled to 4 °C and once the temperature has stabilized, record the temperature of the block with the independent NIST-certified thermometer. The tolerance of the temperature variation across the block set to 4 °C is between 2 to 8 °C.

When finished, turn the instrument OFF. When powered back on it will initiate use of the predefined Hygiena thermal protocols.

Clean and Decontaminate the Thermal Block

Clean the Thermal Block

- Do not attempt to clean the thermal block or metal tube holder when they are hot.
- Remove dust and debris by wiping the instrument surfaces with a lint-free cloth.
- Wipe all spills or condensation with a soft cloth or paper towel, if needed.
- If needed, the casing can be wiped off with a damp cloth using mild soap or detergent.
- Do not use solvents or cleansers containing iodine or acetone, as these solutions could damage the paint or display window of the block.

Decontaminate the Thermal Block

If contamination should occur, the following steps can be performed under sterile conditions to help remove the contaminants.

- Wipe the surface of the thermal block unit with a cloth dampened with 20% bleach solution*, followed by a 70% ethanol rinse to prevent damage to the equipment.
- Soak metal tube holders in 20% bleach solution* for about 5 minutes, then rinse thoroughly with water and allow to air dry.

*An alternate cleaner designed to remove free DNA may also be investigated. A 10% bleach solution may also be used for decontamination in accordance with your laboratory SOP but may require repetition of the cleaning to ensure the removal of all amplicons.



Set Point: 4C Plate Temp: 4C





Tips and Troubleshooting

Abort a Program

The Automated Thermal Block automatically progresses through each sequential step until the program is complete. If necessary, you can cancel the program prior to completion via the **Abort** option.



Error Messages

If the power fails or any interruption occurs during a run, the LCD displays an error message.

Affected samples in the thermal block should not be used with the BAX System. Remove and dispose of these samples according to your standard operating procedures.

The letter F (Fault) appears in the lower right corner of the LCD display if an interruption occurs during any step in the program.	Denaturing @ 95C GmPos F
This fault indicator appears on the LCD display until the program completes or the program is aborted by the user.	
Affected samples should not be used with the BAX System. Remove and dispose of these samples according to your standard operating procedures.	
The Power Failure message appears when power is interrupted or fails during a run. Toggle the on/off switch on the back panel to reset the unit.	Gram Positive POWER FAILURE!
Affected samples should not be used with the BAX System. Remove and dispose of these samples according to your standard operating procedures.	



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Field of Use

The Automated Thermal Block is manufactured by Torrey Pines Scientific[®] for use with the BAX System. Please see BAX System documentation for details on Field of Use. Please read the Limitation of Warranty and Liability before using the product.

Warranty

This product is warranted by Torrey Pines Scientific to be free from defects in material and workmanship for a period of one year from the date of purchase. If repair or adjustment is necessary and has not been the result of abuse or misuse within the one-year period, correction of the defect will be made without charge.

For warranty and repair issues, contact Torrey Pines Scientific at (760) 930-9400.

Technical Support

If you have any questions or comments on the Automated Thermal Block, please contact your distributor or Hygiena at 800-863-6842 or email <u>diagnostics.support@hygiena.com</u> for technical assistance.

Contact Information

For more information, visit www.hygiena.com/contact.