

hygiena MCH2023 Automated Thermal Block Instruction **Manual**

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hygiena MCH2023 Automated Thermal Block



Product Usage Instructions

Instrument Overview

This model of the Automated Thermal Block (MCH2023) is specifically optimized for use with the cluster tubes and metal tube holder supplied with the BAX System. It is not recommended to use other tubes and holders with this model.

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

Safety Symbols and Precautions

Safety Symbols:

- **Symbol:** Indicates that you should consult the manual for further information and proceed with appropriate caution.
- **Symbol:** Indicates the presence of a hot surface or other high-temperature hazard. Proceed with appropriate caution.
- **Symbol:** Indicates the presence of an electrical shock hazard. Proceed with appropriate caution.

General Safety Information:

Safety Top ic	Information
Extreme Te mperatures	Always use the supplied AC power cord when connecting the heating block to a power source. Us e the normal care and precaution that one would use with any electrical appliance.
Power Req uirements	Always use the supplied AC power cord when connecting the heating block to a power source. Us e the normal care and precaution that one would use with any electrical appliance.

Connecting the Thermal Block

The Automated Thermal Block is pre-programmed for BAX System assays and does not require calibration or software installation when 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. Ensure the outlet is properly grounded and runs at the appropriate voltage (see specifications).
- 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.
- 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 act as 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

FAQ

Q: Can I use other tubes and holders with this model?

A: It is not recommended to use other tubes and holders with this model. It has been optimized for use with the cluster tubes and metal tube holder supplied with the BAX System.

Q: Do I need to calibrate or install software for the thermal block?

A: No, the thermal block is pre-programmed for BAX System assays and does not require calibration or software installation when used as specified.

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

General Safety Information

Safety Topic	Information
	The thermal block can reach 110 °C (230 °F), which can burn the skin if touched. To prevent injury, remember the following:
Extreme Temperatures	Always use extreme caution around the block.
A	Never leave the block accessible to others when it is hot.
<u>\mathcal{m}</u>	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 Requirement s	Always use the supplied AC power cord when connecting the heating block to a power so urce. Use the normal care and precaution that one would use with any electrical appliance.

Connecting the Thermal Block

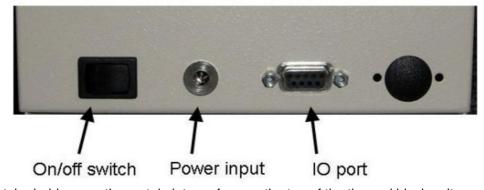
The Automated Thermal Block is pre-programmed to perform the sequential heating and cooling steps needed for BAX System assays. No calibration or software installation is required when the thermal block is used as specified.

Follow these steps to connect the thermal block:

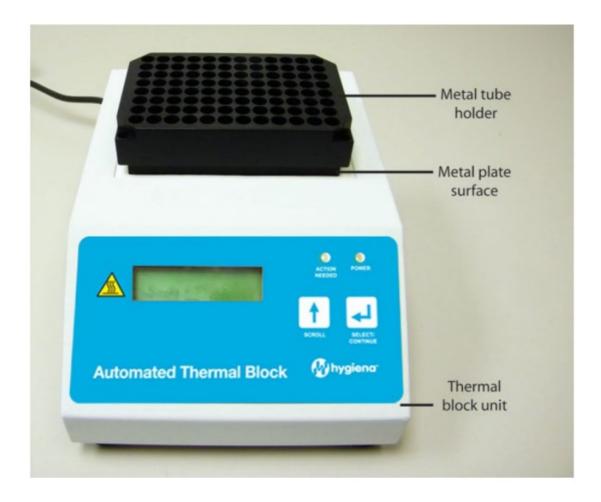
- 1. Place the thermal block unit on a level, dry laboratory workbench. Allow at least 4 inches (10 cm) on all sides of the unit for ventilation.
- 2. Insert one end of the provided power cord into the power supply and plug the other end of the power cord into a 3-wire outlet.

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.



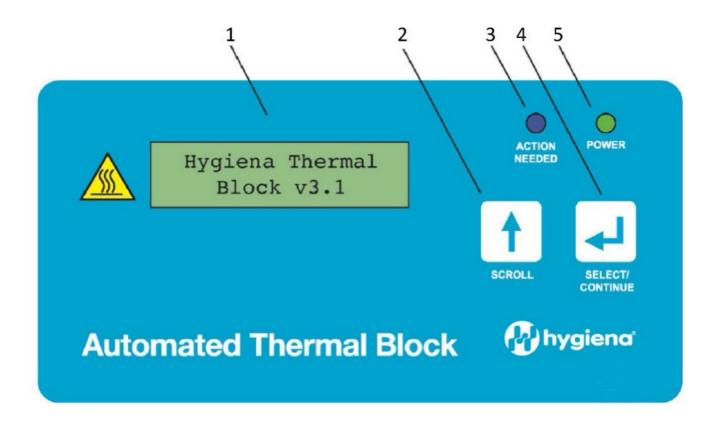
4. Seat the metal tube holder over the metal plate surface on the top of the thermal block unit.



Front Panel Display

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

- 1. **LCD**—shows the program menu, program selection, settings and instructions.
- 2. **SCROLL button**—changes the selected menu item in the LCD. An audible beep sounds when the button is pressed.
- 3. **Blue ACTION NEEDED LED**—indicates that the user must act as the program can continue. This notification is accompanied by an audible alarm.
- 4. **SELECT/CONTINUE button**—sets the menu item in the LCD 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:

- 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. Gram negative—use with gram-negative bacteria, including Salmonella, E. coli, Campylobacter, Vibrio and Cronobacter
- 3. 24E—use with Listeria 24E assays:

BAX System PCR Assay for Genus Listeria 24E	KIT2003
BAX System PCR Assay for <i>L. monocytogenes</i> 24E	KIT2002

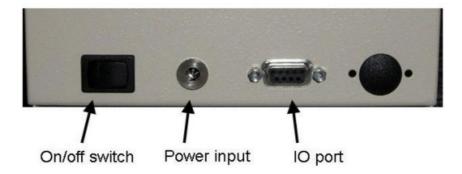
4. RT Listeria—use with real-time Listeria assays:

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

ON

Turn on the thermal block by toggling the on/off switch on the back panel of the unit.



At start-up, the LCD automatically displays the following series of messages:

• The first screen shows the version of software currently installed on the thermal block.

Hygiena Thermal Block v3.2

• The second screen shows the seg file version number and the checksum number for validation purposes.

seq file ver: 02 checksum: EE

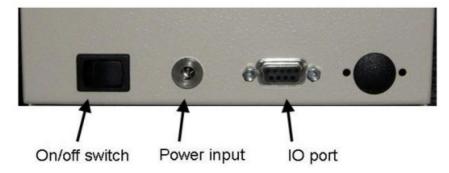
Note: A change in either of these values indicates a modification to the thermal block software. If this occurs, any validation previously performed on the instrument may no longer apply.

• The start-up sequence is complete when the LCD display shows the program menu.

→ Gram Positive Gram Negative

OFF

After finishing a run, you can either select another program or turn off the power to the unit by toggling the on/off switch on the back panel of the unit.



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.

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.



Note: See the BAX System User Guide for information on preparing samples.

Press the SELECT/CONTINUE button.

5. The LCD display changes to GmPos Lysis 55C.

Note: A timer in the bottom right corner counts down from 60:00 and shows the number of minutes remaining in this step.

GmPos Lysis 55C GmPos 57:08

6. 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.

Heating to 95C GmPos 4:39

7. After the thermal block reaches 95 °C, the LCD display changes to Denaturing @ 95C. No user action is required.

Denaturing @ 95C GmPos 7:22

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.

Cooling to 4C GmPos 1:45

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

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.

> Sample PCR Ready GmPos 1:06

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.

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

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

Completed GmPos 6:25

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.



12. The LCD display changes to Gram Positive Finished, and the thermal block sounds an audible beep to signal that the program has finished.

Gram Positive
Finished

13. Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.

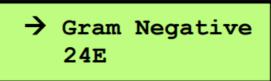
Gram Positive Gram Negative

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 (→) is next to the Gram Negative option.

Press the SELECT/CONTINUE button.



2. The unit beeps once, and the LCD display changes as the thermal block begins equilibrating to 37 °C.

Note: Do not load samples into the thermal block until the load prompt appears on the LCD display.

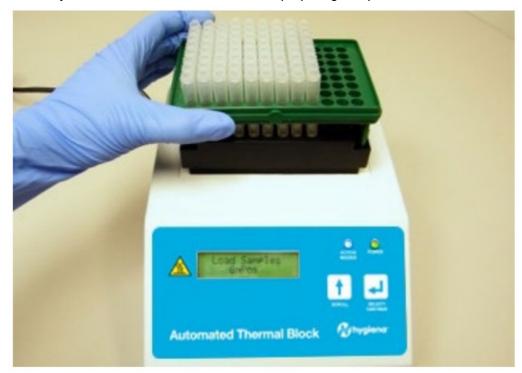
Equilibr.@ 37C GmNeg

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.

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. No user action is required.

Heating to 95C GmNeg 4:39

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. No user action is required.

Denaturing @ 95C GmNeg 8:26

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.

Cooling to 4C GmNeg 2:15

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

 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.

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.

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

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

Completed GmNeg 4:54

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.

Gram Negative **Finished**

13. Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.

→ Gram Negative 24E

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.

1. Turn on the thermal block, then press the SCROLL button until the arrow (→) is next to the 24E option. Press the SELECT/CONTINUE button.

→ 24E RT Listeria

2. The unit beeps once, and the LCD display changes as the thermal block begins equilibrating to 37 °C. **Note:** Do not load samples into the thermal block until the load prompt appears on the LCD display.

Equilibr.@ 37C 24E

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 24E

4. After the Load Samples 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.

5. The LCD display changes to 37C 24E Lysis.

37C 24E Lysis 24E 29:27

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

6. After lysis at 37 °C is complete, the blue ACTION NEEDED LED activates, and the thermal block sounds two audible beeps to signal that user action is required. The LCD display changes to Remove & Press Continue.

Remove & Press Cont.

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

Press the SELECT/CONTINUE button.



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.

Equilibr.@ 55C 24E

Note: Do not reload samples into the thermal block until the reload prompt appears on the LCD display.

9. 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 Reload Samples.

Reload Samples 24E

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.



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

55C 24E Lysis 24E 28:03

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.

Heating to 95C 24E 2:49

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

13. After the thermal block reaches 95 °C, the LCD display changes to Denaturing @ 95C. No user action is required.

Denaturing @ 95C 24E 7:24

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

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.

Cooling to 4C 24E 3:44

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

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.

Sample PCR Ready 24E 0:56

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.

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

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

Completed 24E 1:01

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.



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.

→ 24E RT Listeria

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.

1. Turn on the thermal block, then press the SCROLL button until the arrow (→) is next to the RT Listeria option. Press the SELECT/CONTINUE button.

→ RT Listeria Gram Positive

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

Note: Do not load samples into the thermal block until the load prompt appears on the LCD display.

Equilibr.@ 55C RTLis

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
RTLis

4. After the Load Samples 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.



5. The LCD display changes to RTLis Lysis 55C.

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

RTLis Lysis 55C RTLis 26:38

After lysis at 55 °C is complete, the LCD display changes to Heating to 95C.No user action is required.

Heating to 95C RTLis 2:41

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. No user action is required.

Denaturing @ 95C RTLis 8:02

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.

Cooling to 4C RTLis 1:25

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

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.

Sample PCR Ready RTLis 0:57

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.

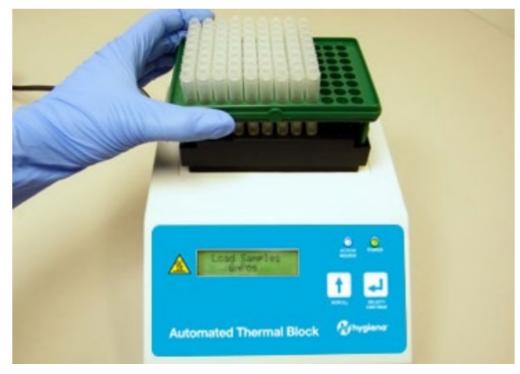
10. The LCD display changes to Completed, and the thermal block sounds an audible beep to signal that the program has been completed.

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

Completed RTLis 3:19

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 RT Listeria Finished, and the thermal block sounds an audible beep to signal that

the program has finished.

RT Listeria **Finished**

13. Press the SELECT/CONTINUE button to end the program. The LCD changes to display the program menu.



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.

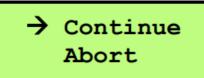
An alternate cleaner designed to remove free DNA may also be investigated. A 10% bleach solution may also be used for decontamination in accordance with your laboratory SOP but may require repetition of the cleaning to ensure the removal of all amplicons.

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.

1. While the program is running, press the SCROLL button to display the Abort menu.



2. Press the SCROLL push button until the arrow (\rightarrow) is next to the Abort option, then press the

Continue → Abort

3. The LCD display shows a message to confirm that the program was terminated.

Gram Positive
** Aborted **

4. To start another program, press the SELECT/CONTINUE button to return to the program menu.

→ Gram Positive
Gram Negative

To turn off the unit, toggle the on/off switch on the back panel.

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, 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.

Documents / Resources



hygiena MCH2023 Automated Thermal Block [pdf] Instruction Manual MCH2023 Automated Thermal Block, MCH2023, Automated Thermal Block, Thermal Block, Block



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References

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- User Manual

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