



QUIDEL®



Digital Heat Block User Manual



General Information

Quidel Contact Information

Contact Quidel Technical Support from 8:00 a.m. to 5:00 p.m. EST

Tel: 800.874.1517 (in the U.S.)
858.552.1100 (outside the U.S.)

Fax: 740.592.9820









E-mail: technicalsupport@quidel.com or contact your local distributor



Website: quidel.com

For services outside the U.S., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com.

Labels and symbols

A symbols glossary can be found at quidel.com/glossary.

| Label | Description |
|---|---|
|  | Manufacturer |
|  | <i>In vitro</i> diagnostic medical device |
|  | Consult e-labeling instructions for use |
|  | Authorized representative in the European Community |
|  | Temperature limitation |
|  | Directive 2012/19/EC on waste electrical and electronic equipment (WEEE) DO NOT throw this unit into a municipal trash bin when this unit has reached the end of its lifetime. To ensure utmost protection of the global environment and minimize pollution, please recycle this unit. |
|  | Serial Number |
|  | Catalog Number |

| Symbol | Description |
|---|--|
|  | Warning! Indicates a hazardous situation, which if not avoided, could result in injury to the Operator or a bystander (e.g., electrical shock) |
|  | Caution! Hot surface |

Brief Warnings, Precautions and Limitations

- Always operate the Heat Block on a surface that is level and dry.
- Never move the Heat Block while there is a test in progress.
- Use only the power adapter that was provided with the Heat Block.
- Do not drop the Heat Block as it could damage the unit.
- To avoid damaging the Heat Block, never place objects on top of it.

Safety Precautions

The Quidel Digital Heat Block is designed to provide safe and reliable operation when used according to this User Manual. If the Heat Block is used in a manner not specified in the User Manual, the protection provided by the equipment may be impaired.

All warnings and precautions should be followed in order to avoid unsafe actions that could potentially result in personal injury or damage to the device.



Warning!

To reduce the risk of electrical shock:

- Unplug the Heat Block before cleaning.
- Plug the Heat Block into an approved receptacle.
Note: The Heat Block 115V model will not work in 230V region unless user has a transformer.
- Do not immerse in water or cleaning solution.
- Do not attempt to open the enclosure.
- Use the appropriate power cord for the region.



Caution! Hot Surface

To reduce the risk of injury:

- Hot surfaces, especially on the Heat Block, can cause serious injury or burns. Use block lifter.
- Do not put water or liquids into the well as shock, serious injury and death may occur.

- Do not heat flammable or explosive substances as serious injury and death may occur.
- To disconnect power at any time, the AC power cord can be removed from the DC power supply as the mains disconnect.

Failure to follow the precautions mentioned above will invalidate the warranty.

To reduce the risk of environmental contamination:

- Contact Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.) for information on returning or disposing of the Heat Block.
- Clean the Heat Block per the Cleaning and Maintenance section of this User Manual prior to return or disposal.

Note: Always dispose of Heat Block and accessories in accordance with Federal, State and Local requirements.

Introduction

Please read this manual thoroughly prior to operating the instrument.

Intended Use

The Quidel Digital Heat Block is a controlled temperature heat block intended to be used for the heat lysis (95°C) step of nucleic acids extracted samples with AmpliVue® and Solana® assays. In addition, the Heat Block can be used with Lyra® assays and the 60°C step when using the Lyra® Direct HSV 1+2/VZV Assay, as well as other assays which require a heat incubation step.

Quidel's single block incubator provides a comprehensive design for a wide variety of life science research applications. Excellent temperature control can deliver accurate and reliable results.

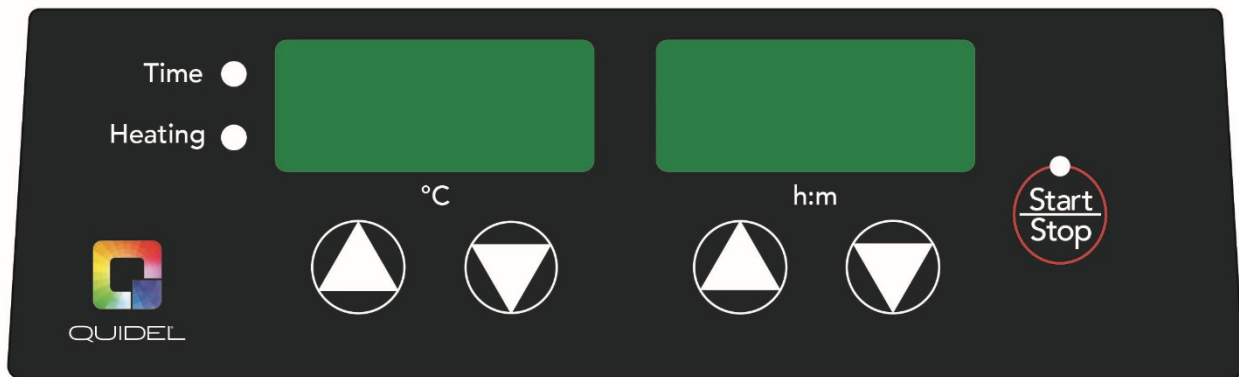
Please read this manual carefully prior to operation. Any attempt to use this instrument that is not in accordance with the manual, may cause harm or injury to the user.

Installation

Upon unpacking the Quidel Digital Heat Block, inspect for damages. Shipping damage is the responsibility of the carrier. Inspect that the following are present: User's manual, Line cord, Block Lifter, Lid.

Select a location that is dry and not subject to drafts or moving air from heating or air conditioning vents, or air blown by other equipment. Place the unit on a flat, preferably non-flammable surface. Allow sufficient room around the unit for access and cooling. Six-inch minimum on all sides is suggested. Plug the unit into a properly grounded outlet. Using the lifter, insert the block(s) into the well. The unit is now ready for use.



Controls





| | |
|------------------------|--|
| ON / OFF rocker switch | Located on back of unit. Turns primary power on and off. |
| “Start-Stop” LED, red | Used to activate or stop the unit. Illuminates when unit is in heating mode, off in temperature set mode. Note: When Start-Stop key is <u>not illuminated</u> , the heat block will be off, not actually heating and will return to room temperature. |
| “Heating” LED, red | Illuminates when the unit is in heating mode and unit is actually applying heat to the block. Note: This LED is on continuously during heat-up and cycles on and off when the unit is at the set temperature while the Start-Stop LED is illuminated red. |
| “Time” LED, green | Used to set or select time mode. This LED light indicates running Time Mode. |
| “TEMP-UP” arrow key | Raises set temperature when unit is in set mode (C°). |
| “TEMP-Down” arrow key | Lowers set temperature when unit is in set mode |
| “Timer-UP” arrow key | Raises set time when unit is in set mode (h:m, e.g., 00:01 equals 1-minute). |
| “Timer-Down” arrow key | Lowers set time when unit is in set mode. |
| “hold” mode | Keeps a constant temperature without the timer countdown. |

Operation


1. Check to ensure the heat block reaches 95°C the first time it is powered on using a traceable external thermometer. Recalibrate as necessary if it does not reach 95°C.
2. Place Quidel Digital Heat Block on a sturdy and level surface in a safe, dry place, away from laboratory traffic.
3. Ensure that the AC power switch is OFF, then plug the three-pronged power cord into a grounded three-prong AC outlet of the appropriate voltage (115V or 230V as indicated on the rating sticker near the AC cord on the back of the unit).
4. Select suitable module block and put the block into the Heat Block unit.
5. Turn the AC power ON.

6. Press the TEMP  or  arrow key (°C) to adjust to the desired temperature (95°C).




7. Press the Timer  or  arrow key (h:m) to adjust to the desired timer.

Warning: At the end of timer cycle, the Heat Block will not hold the temperature, but shut OFF and begin to cool to room temperature.

Note: To use the Heat Block in a continuous temperature hold, set the timer to 0:00. When the red-light

indicator is turned on above the  key, “hold” will be displayed in the timer window.

Note: In the ‘hold’ mode, a secondary timer will need to be used as the Heat Block will no longer countdown time.

8. Press the  key to **start** heating.
9. If one needs to reset the timer during heating, press the  key to deactivate heating.
10. Press the  key again to **start** the unit.
11. If lid is to be used, aim the shaded area on the Heat Block surface with the magnet of the lid and it will be attached to the housing. In order to remove the lid, press one hand firmly on the housing with another hand pulling the lid off.
Note: When using the dust cover lid, the tube should not extend more than 25 mm above the surface of the heating block.
Note: The lid should not be used at 95°C and will not fit when a thermometer is used with the Heat Block (See Calibration).



Calibration

Calibration allows the unit temperature display to be adjusted or matched to the temperature of a single sample or to a calibrated thermometer making an independent temperature measure of the block.











The Heat Block is calibrated at Quidel to 95°C before shipment to your facility using a standard small hole-pattern block (20 x 2.0-mL, 13mm tube; 99-D1102A). The calibration function can help you match the display temperature to your actual sample temperature to your specific application.

To calibrate the unit, first turn the unit OFF using the ON / OFF switch. Then place a thermometer of known accuracy¹ into the block thermometer hole or a thermocouple or other sensor into your sample. Make sure there is a good fit between the thermometer and the block or good contact between any sensor and sample or sensor and block.

To calibrate the Heat Block to the display, use the following procedure:

1. Press and hold the  key then simultaneously power up the unit with the ON / OFF switch.
2. You should hear a continuous beeping sound from the Heat Block, release the  key. The display on the left will show the set temperature, and the right will show “adjt.”

¹ Thermometers used for calibration purposes should have a written calibration certificate and be traceable back to NIST or some other certified body. General lab thermometers are often not accurate enough for calibration work.

3. Use the  or  arrow keys (°C) to set the desired temperature at which you want to calibrate the unit. Then press the  key.
4. Allow time (up to 30 minutes) for the unit to heat up to your set temperature and to equilibrate at this temperature. Once the unit reaches equilibrium, the LED display will show the set temperature (e.g., setting 95 degrees, the unit will show 95 when equilibrium reached).
5. After the temperature display has started flashing, read the thermometer (or sensor meter) and use the  or  arrow keys to adjust the display to the actual thermometer or sensor reading (not the difference). The display should then show the same temperature as the external thermometer. Then press the  key.
6. The unit will then begin to automatically adjust its operating temperature to your original set point with the re-calibration factor included. Once the unit reaches set point there is an audible sound. Allow sufficient time for the unit to re-equilibrate and then again compare the thermometer or sensor reading to the calibrated display. They should closely match. If not, repeat the calibration procedure.
7. Upon completion of the calibration procedure, adjust the timer by pressing the  key then use the  or  arrow keys to re-set desired time or continuous time. To reactivate the Heat Block, press the  key again.





Note #1: If the Heat Block unit is powered OFF, or after any power outages or surges, verify that the temperature reaches 95°C when the unit is powered ON again. If it does not reach 95°C recalibrate as necessary.

Note #2: Temperature should be monitored and verified using an external thermometer.

Troubleshooting Guide / Service

Problem Explanation / Solution

| Problem | Explanation / Solution |
|--------------------------------|---|
| Display / LEDs do not light up | <ol style="list-style-type: none"> 1. Check power cord and outlet 2. Check On / Off switch 3. Check fuse 4. Call service |
| Unit not heating | <ol style="list-style-type: none"> 1. Is set point below room temp 2. Is "Start-Stop" LED illuminated 3. Press "Start-Stop" key 4. Call service |
| Unit display overshoots | <ol style="list-style-type: none"> 1. This is normal when first heating up. Allow time for the Heat Block and load to equilibrate. 2. Display set point in heat-up overshoots on initial heat-up but block and sample do not overshoot. 3. See Operation section of this manual. |

| Problem | Explanation / Solution |
|---|--|
| Block or Sample temperature not same as display temperature | <ol style="list-style-type: none"> 1. Is unit in heating mode 2. Is unit sitting in draft 3. Check accuracy of thermometer 4. Is thermometer making good contact 5. Use calibration procedure to re-calibrate the unit at the desired operating temperature |
| Factory Reset | <p>User can return the Heat Block to the original factory set by pressing the two temperature arrow keys   at the same time for about 5-seconds to access the factory reset option; if the reset is successful, unit will display the 4-digit firmware version number on the left side of the display. To return to the normal display press the  key, the unit is now OFF. The digital display will now show the preset time and temperature. Press the  key again to turn the unit ON to begin heating. The unit is now reset to all calibration points set at the factory.</p> |
| Limit on Temperature Calibration | During temperature calibration, user can only input $\pm 7^\circ$ of the setting temperature; the temperature range for calibration is 0° to $\sim 150^\circ\text{C}$. For example, during temperature calibration, if the user inputs the calibration as 100°C , then the user cannot input the setting temperature above 107°C or below 93°C . |
| Error 1 | Displays when incorrect temperature calibration is entered. |
| Error 2 | In normal heating mode, if the stand-alone temperature probe identifies that the actual temperature is 10° higher than the set temperature, the unit will display this error. |
| Error 3 | If the set temperature is lower than the block chamber temperature by 10° , the unit will not function and will display this error message. |
| Error 4 | If the unit does not reach the set temperature in 2 hours, the unit will stop heating and display this error message. |

Specifications

| | |
|-----------------------------------|--|
| Temperature Range: | Ambient $+5^\circ\text{C}$ to 150°C |
| Temperature Display Resolution: | 0.1°C 4 digital LED |
| Temperature Uniformity: | $\pm 0.2^\circ\text{C}$ |
| Temperature Accuracy: | $\pm 0.3^\circ\text{C}$ |
| Temperature Controller: | Microprocessor – user calibratable |
| Factory Calibration Check Points: | 37° , 60° , 90° , 120° , 140°C |
| Timer: | 1 to 99 hours 59 minutes or continuous in 1 minute increments |
| Operating Altitude: | Not to exceed 2,000 meters |
| Control: | PI Microprocessor controller |
| I/O: | USB unidirectional |
| Dimensions: | U.S.: 8.3 x 11.4 x 4.7 inch (21 x 29 x 12 cm) Intl: 21 x 39 x 12 cm (8.3 x 15.3 x 4.7 inch) |
| Weight: | U.S.: 7.0 lbs / 3.2kg Intl: 9.6 lbs / 4.4 kg |

Specifications

| | |
|-------------|--|
| Electrical: | U.S.: 115V, 50/60 Hz, 0.5 A, Fuse 1.6 AT Intl: 230V, 50/60 Hz, 0.5 A, Fuse 1 AT |
|-------------|--|

Cleaning and Maintenance

Make sure that the Heat Block and block are cool and the power cord is disconnected before performing any cleaning or maintenance. Repair or maintenance should only be performed by an authorized service technician.

The Heat Block should be cleaned regularly. Use a damp cloth to clean the heat block. If the dirt is persistent, rub the surface of the heat block with a cloth that has been moistened with pure alcohol (isopropanol or ethanol). Do not use aggressive cleaning agents such as acetone.

The aluminum block can be removed for cleaning by using the included block lifter. For more persistent stains and for disinfecting the heat block, it is possible to clean the surface with a cloth dipped in 10% bleach solution followed by rinsing with water. The procedure can be repeated 2 to 3 times. It is also possible to use the 70% alcohol (isopropanol or ethanol) to wipe off the remaining traces of bleach. No liquids should be directly applied to the inside of the heat block. Care should be taken to avoid any application of liquids to the inside of the heat block as this can damage the internal portions of the heat block. Improper cleaning may pose a risk to the device in the long term causing cosmetic damage, and if the improper cleaning persists, possibly causing a mechanical failure.

Spillage of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas wiped with 1% bleach solution. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

For additional information regarding the compatibility of cleaning solutions that are not listed above, please contact Quidel Corporation.

Limited Warranty

Quidel Corporation warrants that this product will be free from defects in material and workmanship for a period of three (3) years from date of purchase. This warranty is valid only if the product is used for its intended purpose and within the guidelines specified in the supplied instruction manual.

Should this product require service, contact Quidel Technical Support at 800.874.1517 (in the U.S.). Products received without proper authorization will be returned. All items returned for service should be sent in the original packaging or other suitable carton, padded to avoid damage. Quidel will not be responsible for damage incurred by improper packaging.

This warranty does not cover damage caused by accident, neglect, misuse, improper service, natural forces or other causes not arising from defects in original material or workmanship. This warranty does not cover fuses, LEDs, or damage to paint or finish. Claims for transit damage should be filed with the transportation carrier.

All warranties including the implied warranty of merchantability and fitness for a particular purpose are limited in duration of 36 months from the original date of purchase.

Quidel's sole obligation under this warranty is limited to the repair or replacement, at Quidel's discretion, of a defective product. Quidel is not liable for incidental or consequential damage, commercial loss or any other damages resulting from the use of this product.

Some states do not allow limitation on the length of implied warranties or the exclusion or limitation of incidental or consequential damages. This warranty gives you specific legal rights. You may have other rights which vary from state to state.

No individual may accept for, or on behalf of Quidel, any other obligation of liability, or extend the period of this warranty.



M221 – Quidel Digital Heat Block, 115V
M222 – Quidel Digital Heat Block-230V, Intl 230V



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