

1. Purpose

- 1.1. Provides instruction for qualifying an incubator and to provide evidence that the accuracy of the temperature controller, the temperature uniformity of the device, and the temperature set point generate results within expected limits for use in the heat-treatment of GEX's B3 dosimeter products.
- 1.2. Both the calibration of the incubator's controller and the temperature map of the incubator can be considered the **Performance Verification (PV)** of the unit.
- 1.3. "Post-irradiation Heat-treatment of the GEX B3 Dosimeter Products" (Technical Report) provided the basis for the acceptance criteria, with the following objectives:
 - 1.3.1. prevent further color development of the film under normal environmental conditions, sans any additional exposure of the film to ionizing light (i.e., UV), so that a heat-treated dosimeter may be read (and re-read) within some validated period without significantly changing the measured absorbance;
 - 1.3.2. prevent the film/packaging from getting too hot to avoid appearances of surface damage to the film.
- 1.4. A successful qualification (or performance verification) of the incubator alone **is not sufficient** to validate any user's heat-treatment process. The user should conduct further tests on post-irradiated dosimeters to validate stability of responses with variable process conditions, such as timing between post-irradiation and heat-treatment, worst-case-scenario timing for post-heat-treatment reads (measurements), etc.

2. Scope

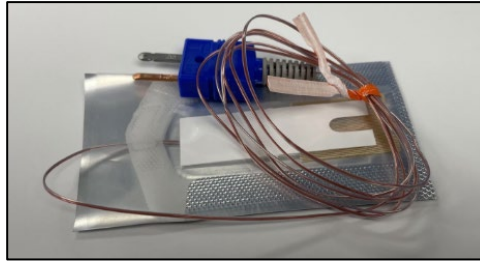
- 2.1. Any properly installed incubator shall be mapped to prove that it can heat-treat B3 film dosimeters within the acceptable temperature range.
 - 2.1.1. The procedure provides instructions for qualifying only the incubator products sold by GEX:
 - 2.1.1.1. P4900 SciGene Hybex **Micro-incubator**
 - 2.1.1.2. P4850/P4855 Memmert IF30/IF55 **Forced-Air Incubator**
 - 2.1.2. The document provides instructions for qualifying the listed incubators using only the thermocouple and probe (thermometer) products sold by GEX, including:
 - 2.1.2.1. **P4901 Digi-Sense Single-Input Thermocouple** Thermometer System with NIST-Traceable Calibration with the Cole-Parmer Type K Compact Probe (hereby called the "**Spike**" probe)



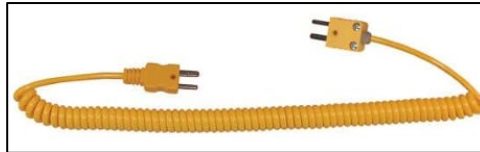


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2.1.2.2. **P4902** GEX Type T Pouched Dosimeter probe (typically not sold as part of the calibrated system)



2.1.2.3. **P4904** male-to-male Type K extension cable (typically not sold as part of the calibrated system)



2.1.2.4. If a probe product is not explicitly stated in this procedure, then any qualified probe is allowable.

3. Frequency

- 3.1. Completing this work instruction's tests are required by GEX for initial qualification of the unit for heat-treating B3 dosimeters.
- 3.2. Continued PV shall be conducted as needed for requalifying the incubator, per the user's QMS.
 - 3.2.1. GEX recommends that new units successfully complete PV once every thirty (30) days (or one (1) month) for a period of three (3) consecutively successful cycles.
 - 3.2.2. Afterwards, PV testing can reasonably be extended to once every ninety (90) days (or three (3) months).
- 3.3. GEX supplies these incubators because they are capable of being consistent performers for years of operation in laboratory conditions; however, proving that any one unit is continually operating within its required limits—within its real-world environment—is the sole responsibility of the user and that user's risk management practices.

4. Calibrating the Micro-incubator

- 4.1. Prior to the start of qualification activities, the Heat Block shall achieve a stable temperature to conduct a valid test, which typically takes no more than 15 minutes to fully warm-up from ambient. The plexiglass dust lid is intended to remain open while the incubator is on.



- 4.2. In the image above, the:
- 4.3. **Set Point temp.** is the target temperature that the incubator's internal control is trying to achieve and hold.
- 4.3.1. **GEX both uses and recommends using 58.5°C**, which is a middle point within the acceptable range and designed to meet all acceptance criteria for most users.
- 4.3.2. Users may choose an alternative Set Point temp. to achieve proper heat-treatment.
- 4.4. **Display temp.** is the real-time monitored temperature on the incubator.
- 4.4.1. The Display temp. is constantly trying to achieve and hold at the Set Point temp.
- 4.4.2. The Display temp. shall be calibrated.
- 4.5. **Measured temp.** is the real-time monitored temperature on the thermocouple.
- 4.5.1. For conformance with ISO standards, the paired thermocouple and probe shall be calibrated to a national standard.
- 4.5.2. GEX allows its technicians to utilize multiple probe products, as well as multiple methods, to calibrate the Display temp.



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- 4.6. Calculate the difference between the digital thermometer and the temperature controller to determine the adjustment value. Please see the EXAMPLE below for how to calibrate the unit.
 - 4.6.1. On the Micro-incubator, if the **Measured temp.** = 57.4°C while the **Display temp.** = 58.5°C, then the **adjustment value** is:
 - 4.6.1.1. **Measured temp. - Display temp.** = 57.4°C - 58.5°C = **-1.1°C.**
 - 4.6.2. On the Watlow temperature controller, press the up and down arrows simultaneously for 3 seconds. The left display shows “A1” and the right display shows “oPEr”.
 - 4.6.3. Press the Advance Button (green circle) 3 times until the right display shows “i.CA”. The left display shows the offset value between the controller and the thermometer when the unit was last calibrated.
 - 4.6.4. Once on the calibration screen, using the up or down arrows, add the adjustment value from above to the existing offset value shown on the controller.
 - 4.6.4.1. For example, if the existing adjustment value is found-as **0.3°C** and the current offset is **-1.1°C**, then the new offset is **-0.8°C.**
 - 4.6.5. Press the Infinity Key (∞) 2 times to exit the calibration and return to the operation display. Verify that the temperature on the thermometer matches the display. The Watlow controller is now calibrated to display the actual block temperature by offsetting the controller to agree with the measurement with the calibrated digital thermometer.
 - 4.6.6. Adjust the Set Point temp. to 58.5°C.
- 4.7. Calibrate the unit prior to temperature mapping (OQ or PV).



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4.8. Acceptance Criteria for Micro-incubator Calibration

4.8.1. Use HDWR-HEAT-VF-2 Rev-A Micro-incubator Performance Verification Form to record all test results to prove that all acceptance criteria are met.

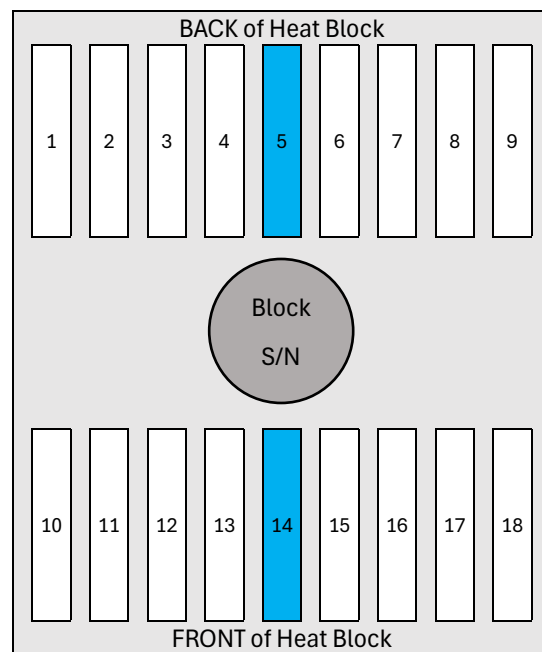
4.8.2. **ACcal-1:** $55.0^{\circ}\text{C} \leq \text{Set Point temp.} \leq 62.0^{\circ}\text{C}$

4.8.2.1. GEX recommends **Set Point temp.** = 58.5°C

4.8.3. **ACcal-2:** **Measured temp.** = **Display temp.** $\pm 0.2^{\circ}\text{C}$

4.8.3.1. Choose either **Method-1** or **Method-2** to achieve this. The thermometer shall achieve a stable temperature to conduct a valid test, which typically takes no more than 2 minutes to fully warm-up from ambient.

4.8.3.2. **Method-1:** Measured temp. shall be from a probe placed into either Slot-5 or Slot-14 (the middle slots) of the Heat-Block. The Spike probe uses the dedicated hole at the end of the slot and the P4902 uses the slot itself. See image below.





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4.8.3.3.

Method-2: Measured temp. shall be from the P4904 Type K plugged into the dedicated digital thermometer jack on the back of the Micro-Incubator. See image below.

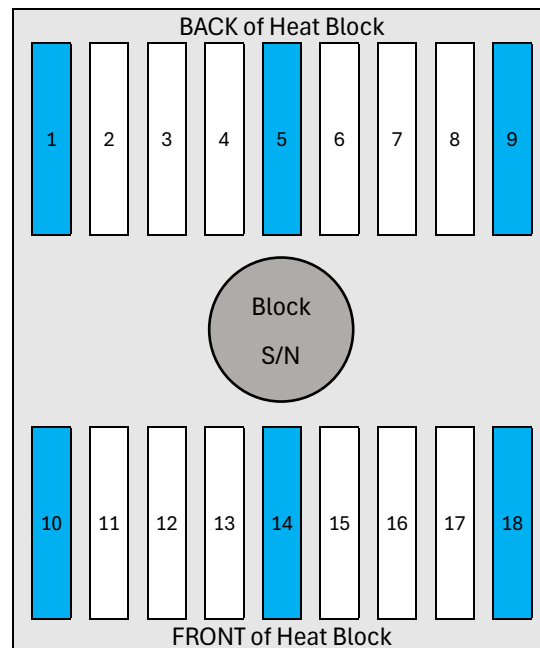




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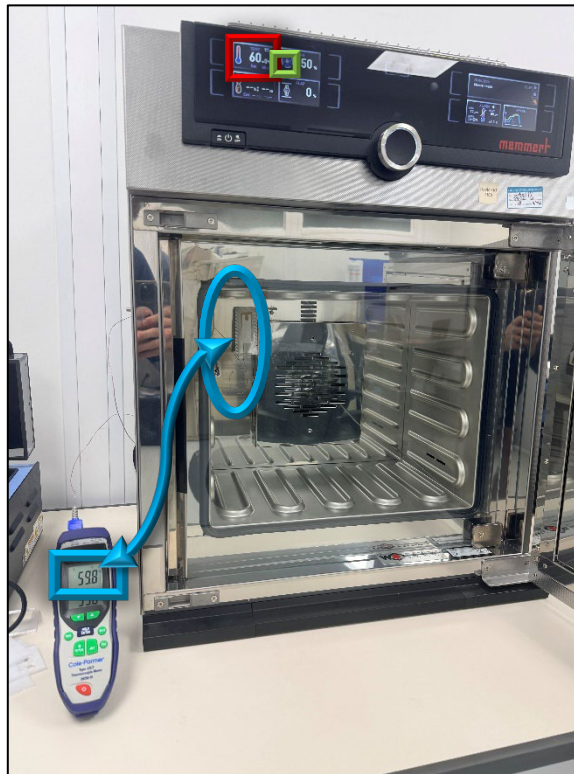
5. Temperature Mapping the Micro-incubator

- 5.1. Prior to the start of qualification activities, the Heat Block shall achieve a stable temperature to conduct a valid test, which typically takes no more than 15 minutes to fully warm-up from ambient. The plexiglass dust lid is intended to remain open while the incubator is on.
- 5.2. This map is designed to simulate what the user plans on incubating (i.e., pouches with dosimeters in them, specialty dosimetry sleeves, etc.) during routine usage.
 - 5.2.1. Note that when planning for real-world usage, dosimeters can be placed-in and removed-from the heat-block independently, without affecting the incubation of neighboring dosimeters.
- 5.3. GEX uses six (6) slots to place temperature probe for mapping the heat-block.
 - 5.3.1. The user may have different requirements; the referenced form has the capacity to record alternatives.
- 5.4. EMPTY configuration testing shall only involve the probe inside an otherwise empty incubator heat-block.
- 5.5. LOADED configuration testing shall involve the probe inside an at-capacity heat-block, as defined in the form.
- 5.6. Acceptance Criteria for Micro-incubator Temp. Mapping
 - 5.6.1. Use HDWR-HEAT-VF-2 Rev-A Micro-incubator Performance Verification Form to record all test results to prove that all acceptance criteria are met for both EMPTY and LOADED configurations.
 - 5.6.2. Use the same Set Point temp. from the earlier calibration (see above).
 - 5.6.3. **ACmap-1:** For Slots-1, 5, 9, 10, 14, and 18: each **Measured temp.** = **Set Point temp.** $\pm 2.0^{\circ}\text{C}$
 - 5.6.4. **ACmap-2:** $55.0^{\circ}\text{C} \leq \text{Measured temp.} \leq 62.0^{\circ}\text{C}$



6. Calibrating the Forced-Air Incubator

- 6.1. Prior to the start of qualification activities, the internal air shall achieve a stable temperature to conduct a valid test, which typically takes no more than 15 minutes to fully warm-up from ambient at a high fan speed ($\geq 50\%$).



- 6.2. In the image above, the:
- 6.3. **Set Point temp.** is the target temperature that the incubator's internal control is trying to achieve and hold.
- 6.3.1. **GEX both uses and recommends using 60.0°C**, which is an upper-middle point within the acceptable range and designed to meet all acceptance criteria for most users.
- 6.3.2. Users may choose an alternative Set Point temp. to achieve proper heat-treatment.
- 6.4. **Display temp.** is the real-time monitored temperature on the incubator.
- 6.4.1. The Display temp. is constantly trying to achieve and hold at the Set Point temp.
- 6.4.2. The Display temp. shall be calibrated.
- 6.5. **Measured temp.** is the real-time monitored temperature on the thermocouple.
- 6.5.1. For conformance with ISO standards, the paired thermocouple and probe shall be calibrated to a national standard.



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- 6.5.2. GEX allows its technicians to utilize multiple probe products, as well as multiple methods, to calibrate the Display temp. GEX places the tip of the probe in the air just above the grid and not directly contacting the metal.
- 6.6. Calculate the difference between the digital thermometer and the temperature controller to determine the adjustment value. Please see the EXAMPLE below for how to calibrate the unit.
- 6.6.1. Activate the adjustment setting. To do so, press the activation key on the right side of the CALIB display. The display is enlarged and shows the first calibration temperature.
- 6.6.2. Press the confirmation key repeatedly, until the calibration temperature you want is selected (whichever CalX [with X=1, 2, or 3] is at or proximate-to the Set Point temp.). For this example, we shall use Cal2 and pretend that Cal1 = 40.0°C and Cal3 = 80.0°C.
- 6.6.2.1. The calibration points shall increase in temperature: Cal1 < Cal2 < Cal3.
- 6.6.3. With the turn control, set the calibration temperature Cal2 to 60.0°C.
- 6.6.4. Save the setting by pressing the confirmation key. The corresponding calibration value is automatically highlighted.
- 6.6.5. Set the calibration value to 0.0 K and accept the setting by pressing the confirmation key.
- 6.6.6. Position the sensor of a calibrated reference instrument (thermocouple's probe) either centrally (see Zone-5 in the Temperature Mapping section below) in the appliance's working chamber or near the internal temperature sensor (twin probes protruding from the upper-left at the back of the chamber).
- 6.6.7. Close the door and, in manual mode, adjust the set temperature to 60.0°C. Wait until the appliance reaches the set temperature and displays 60.0°C.
- 6.6.8. On the Forced-air Incubator, if the **Measured temp.** = 62.6°C while the **Display temp.** = 60.0°C, then the **adjustment value** is:
- 6.6.8.1. **Measured temp.** - **Display temp.** = 62.6°C - 60.0°C = **2.6 K**.
- 6.6.9. In the SETUP, adjust the calibration value Cal2 to **+2.6 K** and save the setting by pressing the confirmation key.
- 6.6.10. After the calibration procedure, the temperature measured by the reference instrument should now also be 60.0°C
- 6.7. Calibrate the unit prior to temperature mapping (OQ or PV).



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6.8. Acceptance Criteria for Forced-air Incubator Calibration

6.8.1. Use HDWR-HEAT-VF-1 Forced-air Incubator Performance Verification Form to record all test results to prove that all acceptance criteria are met.

6.8.2. **ACcal-1:** $55.0^{\circ}\text{C} \leq \text{Set Point temp.} \leq 62.0^{\circ}\text{C}$

6.8.2.1. GEX recommends **Set Point temp.** = 60.0°C

6.8.3. **ACcal-2:** **Measured temp.** = **Display temp.** $\pm 0.5^{\circ}\text{C}$

6.8.3.1. Choose either **Method-1** or **Method-2** to achieve this. The thermometer shall achieve a stable temperature with both the glass door and the thermal (exterior) door latched closed to conduct a valid test, which typically takes no more than 5 minutes to fully warm-up from ambient. The images below all have the thermocouple's cable running through the purpose-built probe port (see red arrow).

6.8.3.2. **Method-1:** Measured temp. shall be from a probe positioned centrally in the appliance's working chamber, which is defined in the Temperature Mapping section as Zone-5. Note that the thermal door is open in the images below to provide visibility; a valid test requires that this door be closed.

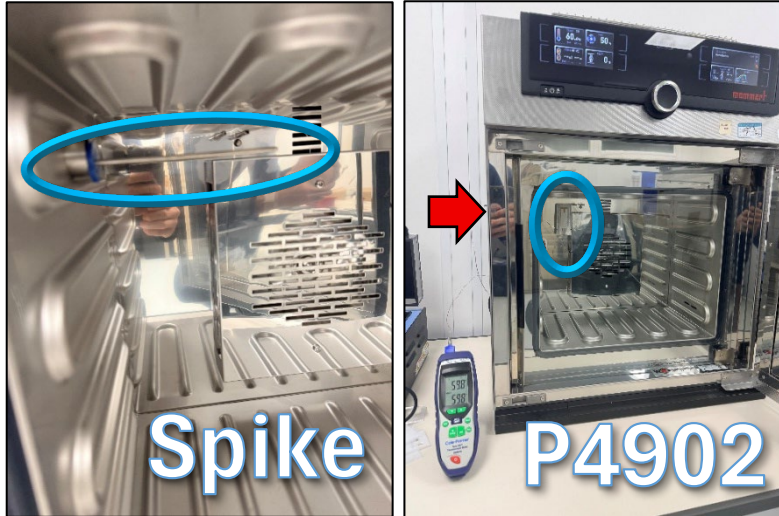




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6.8.3.3.

Method-2: Measured temp. shall be from a probe positioned near the ceiling, like where the incubator's internal temperature sensor is (twin probes protruding from the back wall) or—in the case of the Spike probe (see image below)—protruding deep into the compartment straight from the port.





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7. Temperature Mapping the Forced-air Incubator

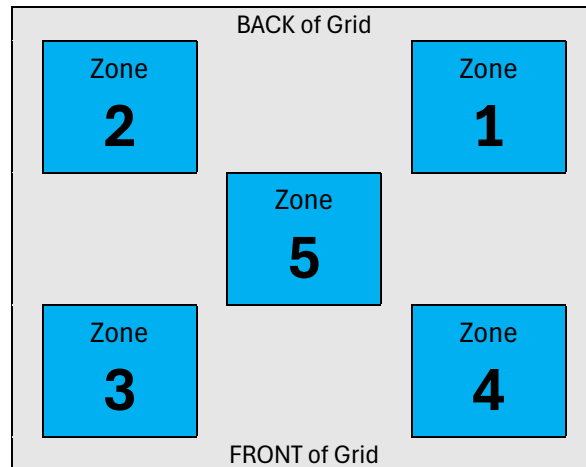
- 7.1. Prior to the start of qualification activities, the internal air shall achieve a stable temperature to conduct a valid test, which typically takes no more than 15 minutes to fully warm-up from ambient at a high fan speed ($\geq 50\%$).
- 7.2. This map is designed to simulate what the user plans on incubating (i.e., dosimeters, bare film strips, pouches with dosimeters in them, papers with dosimeters on them, cards, substrates, etc.) during routine usage, including considerations for how much is present and how it is all configured at any one time on the grid.
 - 7.2.1. Note that when planning for real-world usage, opening the doors will drop the temperature of the chamber and this action can affect the incubation efficiency of the film.
 - 7.2.2. To increase incubation efficiency, the fan should be set to the highest speed possible before dosimeters start gaining lift and fluttering around; dosimeters should not be allowed to become unstable and fall to the floor of the incubator.
- 7.3. Note that adhesive tape is typically required to hold the probe (either the Spike or the P4902) in each position.
 - 7.3.1. GEX places the tip of the probe in the air just above the grid and not directly contacting the metal.
- 7.4. GEX uses five (5) imaginary zones to place the temperature probe (i.e., the tip of the probe) for mapping (see image below), regardless of how the chamber is loaded with objects that obstruct airflow.
 - 7.4.1. The user may have different requirements; the referenced form has the capacity to record alternatives.
- 7.5. EMPTY configuration testing shall only involve the probe inside an otherwise empty incubator.
- 7.6. LOADED configuration testing shall involve the probe inside an at-capacity grid, as detailed/illustrated by the user in the HDWR-HEAT-VF-1 Forced-air Incubator Performance Verification Form.



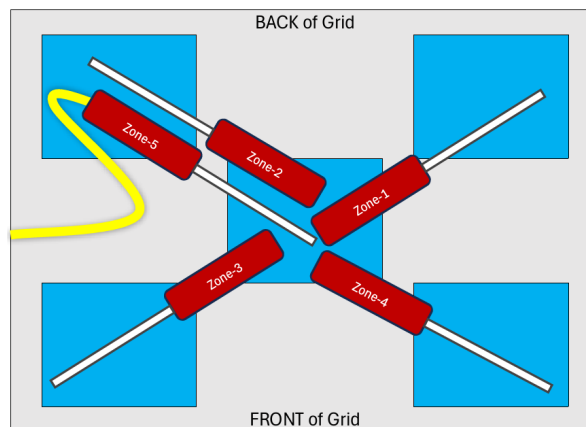
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7.7. Acceptance Criteria for Forced-air Incubator Temp. Mapping

- 7.7.1. Use HDWR-HEAT-VF-1 Forced-air Incubator Performance Verification Form to record all test results to prove that all acceptance criteria are met for both EMPTY and LOADED configurations.
- 7.7.2. Use the same Set Point temp. from the earlier calibration (see above).
- 7.7.3. **ACmap-1:** For Zones-1, 2, 3, 4, and 5: each **Measured temp.** = **Set Point temp.** $\pm 2.0^{\circ}\text{C}$
- 7.7.4. **ACmap-2:** $55.0^{\circ}\text{C} \leq \text{Measured temp.} \leq 62.0^{\circ}\text{C}$



- 7.7.5. The image below has an EXAMPLE of how to map the area above the grid with the Spike probe.



Date	Change Description	Revision
01-MAY-2026	Document replaces GEX #100-276, 100-123; initial release. ECO 75147	A

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