

Heat Treatment Incubator IQ/OQ Test Procedure

GEX Doc# 100-276

1.0 PURPOSE

To provide explicit 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 B3 dosimeters.

2.0 SCOPE

Any incubator to be used for the heat-treatment of GEX B3 dosimeters.

Note: Users may modify acceptance criteria for models not listed at their discretion.

3.0 FREQUENCY

- 3.1 As needed for initial qualification of the unit for use in heat treatment of B3 dosimeters.
- 3.2 As needed for requalification of the incubator after any major servicing of the heating element.

4.0 MATERIALS

- 4.1 Incubator
- 4.2 Timer
- 4.3 P4901 Digital Thermometer or equivalent (calibrated) and included male/male thermocouple wire.
- 4.4 P4902 B3 Dosimeter Package Probe or equivalent
- 4.5 40 pouches of WINdose or DoseStix dosimeters
- 4.6 Masking tape or equivalent
- 4.7 PC with MS Excel

5.0 PREREQUISITES

- 5.1 The user has the necessary documents (see Section 9 – Associated Documents) that contain the installation and usage instructions for the incubators, or has written standard operating procedures to use during this test.
- 5.2 The equipment has been installed in accordance with the documents referred to in Section 5.1.
- 5.3 The P4901 and P4902 devices have been received in working condition and are calibrated.
- 5.4 The incubator has been turned on and has been operating for a minimum of 4 hours / 2 hours (P4850/P4900 respectively).

6.0 OVERVIEW

The test objective is to verify the performance of the incubator installed at the end-use site. This test will verify the accuracy of the display temperature at the set point using a calibrated digital thermometer (calibration verification). This test will also verify the minimum, maximum, and overall range of temperature in the incubator are within expected limits at positions that represent where the dosimeters will be placed (performance verification).

7.0 RATIONALE

7.1 Calibration Verification:

- 7.1.1 The incubators are not supplied with a Certificate of Calibration for the temperature controllers. Calibration verification of the temperature controllers using a calibrated digital thermometer is required until the temperature controller is calibrated.

7.2 Performance Verification:

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7.2.1 Temperature Uniformity

7.2.1.1 A specification for temperature uniformity is provided for each device. The device should be capable of operating within the specification.

7.2.1.2 A more uniform heat-treatment process that yields overall lower measurement uncertainty for B3 dosimetry.

7.2.2 Temperature Minimum and Maximum

7.2.2.1 The minimum temperature for heat-treatment of B3 dosimeters should greater than or equal to 58.0°C, because a lower temperature may not be sufficient to fully stabilize the dosimeter response.

7.2.2.2 The maximum temperature for heat-treatment of B3 dosimeters should not exceed 62.0 °C to avoid an increased risk of damage to the films in the treatment process.

8.0 PROCEDURE

8.1 Open *GEX Doc# 100-277, Incubator IQOQ Test Form* in MS Excel or equivalent. Use the (a) tab to record the measurements for the P4850 incubator test and the (b) tab for recording the P4900 incubator measurements. The worksheets have been validated by GEX with the respective acceptance criteria integrated in to each. For more detail on acceptance criteria see Section 8.7.

8.2 Enter the header information in rows 2 through 5.

8.3 Follow the instructions below, and complete one Test Form for each incubator.

8.4 See Section 8.6 to review the acceptance criteria for all tests described below.

8.5 P4850 Forced Air Incubator (or equivalent)

8.5.1 *Calibration Verification*

8.5.1.1 The objective is to verify the P4850 Incubator display temperature using a calibrated device.

8.5.1.2 Record the temperature controller set point in cell C8. The recommended set point for first trial is 60.0°C.

8.5.1.3 Insert the male T-Type thermocouple of the *P4902 B3 Dosimeter Package Probe* into the female T-Type port on the *P4901 Digital Thermometer*. Turn on the power to the P4901 using the switch on the side of the device.

8.5.1.4 Open the door of the incubator, and place the P4902 probe within 4cm of the in-situ thermocouple inside the P4850 incubator in the bottom center of the unit.

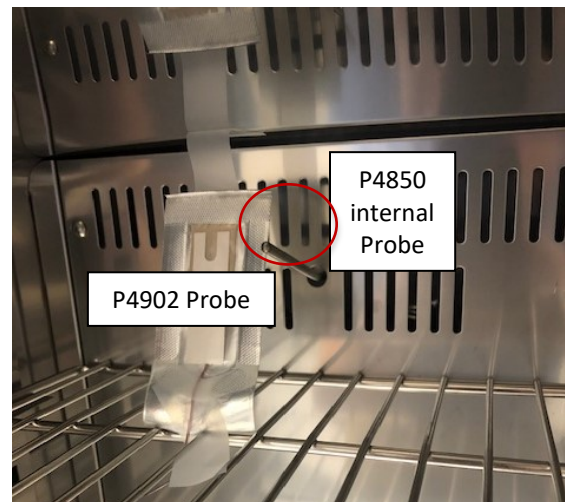
8.5.1.5 Use masking tape to secure the end of the P4902 B3 Dosimeter Package Probe to the body of incubator (ceiling, floor or walls). Do not attach the P4902 directly to the P4850 internal probe; doing so may interfere with the device. See image to the right.

8.5.1.6 Carefully feed the wire of the P4902 out of the doorway and close the glass and outer doors securely.

8.5.1.7 Set the timer to count down, and let the P4902 probe dwell for 15 minutes.

8.5.1.8 On the Test Form, record the temperature displayed on the temperature controller of the incubator into the cell for “Displayed Temp”, cell D8.

8.5.1.9 Record the temperature of the P4901 display into the cell for “Measured Temperature”, cell G8.



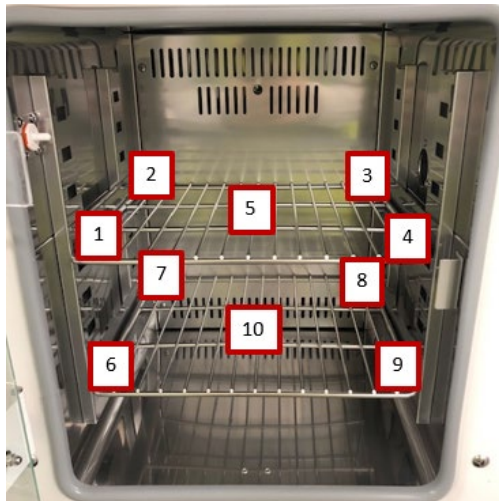
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- 8.5.1.10 After entering these values, the Test Form will calculate if the accuracy of the incubator's temperature controller meets acceptance criteria according to Section 8.7 below. The Pass or Fail result is displayed in cell I-8.
- 8.5.1.11 If the test result is "FAIL" do not continue with testing.
 - 8.5.1.11.1 Mark out the empty cells for the next Section (cells D12 to D29 and H12 to H29). Sign and date the Test Form.
 - 8.5.1.11.2 Adjust the offset of the temperature offset of the controller using the temperature displayed on the P4901 as the calibrated reference temperature to determine the offset. The manufacturer user guide for the incubator will provide instruction for executing this.
 - 8.5.1.11.3 Review the placement of the P4902 and repeat all of Section 8.5.1 to try again.
 - 8.5.1.11.4 If you experience repeated failure, contact GEX Customer Service at cs@gexcorp.com for assistance.

8.5.2 Performance Verification

- 8.5.2.1 The objective is to map the temperature uniformity to ensure that the temperature variation keeps the minimum and maximum with the range required for B3 heat-treatment, and that the incubator is working to specification.
- 8.5.2.2 A total of 5 positions on each of the 2 shelves will be measured. The device will be tested with and without a load of dosimeters on each shelf.
- 8.5.2.3 The test requires placing the P4902 probe in 10 different locations within the incubator to test the uniformity of temperature.



- 8.5.2.4 First, test the empty incubator.
 - 8.5.2.4.1 Place the probe into position and secure with small pieces of masking tape.
 - 8.5.2.4.2 Carefully feed the wire of the P4902 out of the doorway, and close the glass and outer doors securely. Be sure that probe is secured in position after moving the wire before closing the outer door.
 - 8.5.2.4.3 Let the P4902 probe dwell for 15 minutes.
 - 8.5.2.4.4 Record the temperature of the P4901 display into cell G12 of the Test Form.
 - 8.5.2.4.5 Repeat the steps in 8.5.2.4 for the remaining 9 positions, recording each result in the appropriate cell of the Test Form.
- 8.5.2.5 Next, test the loaded incubator.
 - 8.5.2.5.1 Place 20 pouches of B3 dosimeters loosely on each of the two pieces of thin, unprinted white paper.
 - 8.5.2.5.2 Slide one piece of paper onto each shelf in the incubator.

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8.5.2.5.3 Repeat steps 8.5.2.4 for all 10 positions.

8.5.2.6 See Section 8.7 below for acceptance criteria.

8.5.2.7 If there is a failure of any criteria, assess if any adjustment to the set temperature of the incubator can be made which may ensure a passing result on a repeat of the test.

8.5.2.8 Review the procedure for errors and repeat.

8.5.2.9 If you experience repeated failure, contact GEX Customer Service at cs@gexcorp.com for assistance.

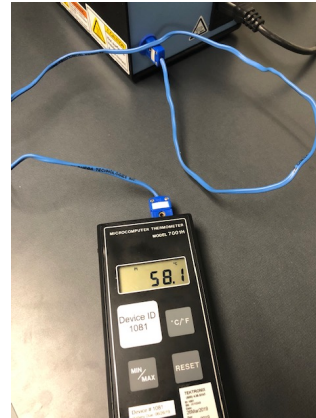
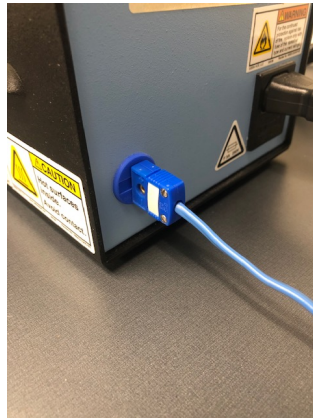
8.6 P4900 Microincubator

8.6.1 *Calibration Verification*

8.6.1.1 The objective is to verify the P4900 Incubator display temperature using a calibrated device.

8.6.1.2 Record the temperature controller set point in cell C8. The recommended set point for first trial is 59.0°C.

8.6.1.3 Insert the one end of the male/male T-type thermocouple female T-Type port on the *P4901 Digital Thermometer*.



8.6.1.4 Attach the other male end of the wire into the female T-Type port on the back of the *P4900 Microincubator*.

8.6.1.5 Set the timer to count down and let the P4902 probe dwell for 5 minutes.

8.6.1.6 On the Test Form, record the temperature displayed on the temperature controller of the incubator into the cell for “Displayed Temp”, cell D8.

8.6.1.7 Then record the temperature of the P4901 display into the cell for “Measured Temperature”, cell G8.

8.6.1.8 After entering these values, the Test Form will calculate if the accuracy of the incubator’s temperature controller meets acceptance criteria according to Section 8.7 below. The Pass or Fail result is displayed in cell I-8.

8.6.1.8.1 Mark out the empty cells for the next Section (cells D13 to D22 and H13 to H22). Sign and date the Test Form.

8.6.1.8.2 If failure continues, adjust the offset of the temperature offset of the controller using the temperature displayed on the P4901 as the calibrated reference temperature to determine the offset. The manufacturer user guide for the incubator will provide instruction for executing this.

8.6.1.8.3 Repeat all of Section 8.6.1 to try again.

8.6.1.8.4 If you experience repeated failure, contact GEX Customer Service at cs@gexcorp.com for assistance.

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8.6.2 Performance Verification

8.6.2.1 The objective is to map the temperature uniformity to ensure that the temperature variation keeps the minimum and maximum with the range required for B3 heat-treatment, and that the incubator is working to specification.

8.6.2.2 A total of 18 slot positions in the aluminum heat-block of the P4900 will be tested, and the device both with and without a load of dosimeters in all the other positions.

8.6.2.3 Start at the back-left and work towards the front-right.

8.6.2.4 All testing is completed with the lid open. The lid is only closed when the P4900 is not in use as a safety precaution.

8.6.2.5 First, test the empty incubator.

8.6.2.5.1 Place the probe into #1 position.

8.6.2.5.2 Set the timer to count down and let the P4902 probe dwell for 5 minutes.

8.6.2.5.3 Record the temperature of the P4901 display into cell G12 of the Test Form.

8.6.2.5.4 Repeat all the steps in 8.6.2.5 for the remaining 17 positions, recording each result in the appropriate cell of the test form.

8.6.2.6 Next, test the loaded incubator.

8.6.2.6.1 Insert a B3 dosimeter package into positions 2 through 18 of the heat-block of the P4900.

8.6.2.6.2 Repeat all the steps in 8.6.2.5: place the P4902 probe into position 2 and the dummy dosimeter from position 2 into position 1.

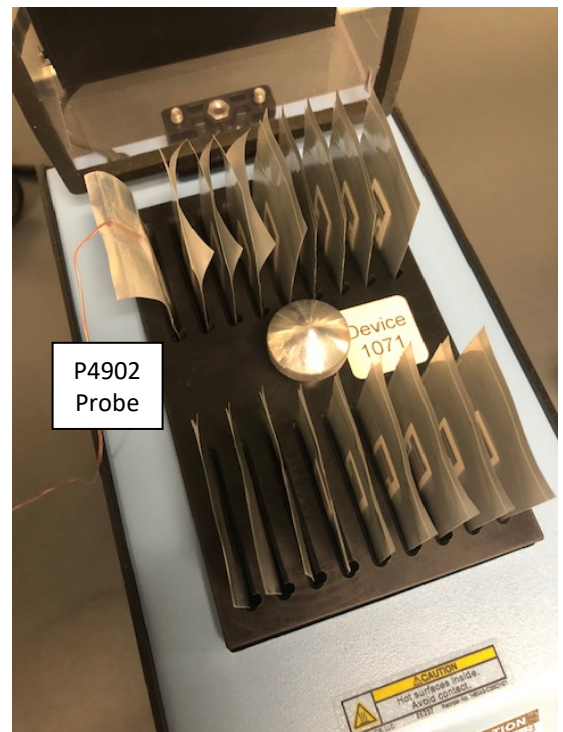
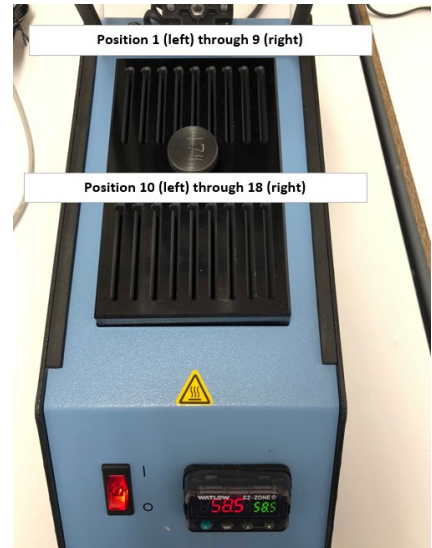
8.6.2.6.3 Repeat until all 18 positions have been measured.

8.6.2.6.4 See Section 8.7 below for acceptance criteria.

8.6.2.6.5 If there is a failure of any criteria, assess if any adjustment to the set temperature of the incubator can be made which may ensure a passing result on a repeat of the test.

8.6.2.6.6 Review the procedure for errors and repeat.

8.6.2.6.7 If you experience repeated failure, contact GEX Customer Service at cs@gexcorp.com for assistance.



8.7 Acceptance Criteria

8.7.1 P4850 Forced Air Incubator

8.7.1.1 Calibration Verification

8.7.1.1.1 Measured Temperature (cell G8) must be $\pm 0.5^{\circ}\text{C}$ from the Displayed Temperature (cell D8).

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8.7.1.2 *Performance Verification (empty and loaded)*

8.7.1.2.1 The overall minimum temperature must be greater than or equal to 58.0°C.

8.7.1.2.2 The overall maximum temperature must be less than or equal to 62.0°C.

8.7.1.2.3 The range must not exceed 2.0°C.

8.7.2 P4900 Microincubator

8.7.2.1 *Calibration Verification*

8.7.2.1.1 Measured Temperature (cell G8) must be $\pm 0.2^\circ\text{C}$ from the Displayed Temperature (cell D8).

8.7.2.2 *Performance Verification (empty and loaded)*

8.7.2.2.1 The overall minimum temperature must be greater than or equal to 58.0°C.

8.7.2.2.2 The overall maximum temperature must be less than or equal to 62.0°C.

8.7.2.2.3 The range must not exceed 1.0°C.

8.8 Enter your name below the signature line, and then sign and date the Test Form(s).

8.9 Obtain a review by a qualified reviewer, whom also enters their name, and sign and date the Test Form(s).

9.0 ASSOCIATED DOCUMENTS

- VWR Forced Air Incubator User Guide
- SciGene Microincubator User Guide
- GEX Doc# 100-123, P4900 Microincubator Product Specifications and Usage
- GEX Doc# 100-142, P4850 Forced Air Incubator Product Specifications & Usage
- GEX Doc# 100-277, Incubator IQOQ Test Form

10.0 REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/30/19	Initial release.	A

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