DESCRIPTION

The P4900 is a top loading micro-incubator with 18 dosimeter wells designed specifically to heat treat B3 DoseStix and B3 WINdose dosimeters. The aluminum heating block incubator provides highly uniform temperature conditions (±0.5°C) that transfer heat to the dosimeters much faster than a typical convection or forced-air incubator and eliminates the temperature swings experienced while loading and unloading a typical convection or forced-air incubator.

APPLICATION

P4900 Micro Incubator with the 18-position custom heat block is specifically for heat treatment of B3 DoseStix and WINdose dosimeters in their individual factory packaging.

SPECIFICATIONS

Physical Specifications

Incubator:

Item Dimensions:	Packaging Dimensions:	Gross Weight:
12.0 (L) x 6.0 (W) x 8.0 (H) in.	15.0 (L) x 15.0 (W) x 10.5 (H) in.	5.3 lbs.

Material:	Metal with plastic lid
Color:	Light blue front and top, black sides, translucent lid
Printing:	Hybex Microsample Incubator, SciGene
Packaging:	Triple boxed, cardboard
Electrical:	115V or 220V AC; 250 W
Temperature Range:	Ambient +5°C to 99°C
Temperature Regulation:	±0.2°C
Heat up Time:	>5°C/ min
Temperature Controller:	Digital PID, single loop
Temperature Display:	Actual or Set Temperature LED
Thermometer Output:	T-type Thermocouple

Aluminum Heat Block:

Item Dimensions:	Packaging Dimensions:	Gross Weight:
6.0 (L) x 3.0 (W) x 2.25 (H) in.	10.0 (L) x 10.0 (L) x 6.5 (H) in.	4.9 lbs

Material:	Anodized aluminum
Mechanical:	Demountable for cleanup
	18 individual dosimeter package capacity – B3 WINdose or DoseStix
Color:	Black
Packaging:	Cardboard box
Maximum Temperature Variation for all Slots	±0.5°C

Timer:

Item Dimensions	Packaging Dimensions	Net Weight
2.5 (L) x 1.2 (W) in.	Included with incubator	0.4 lbs.

Alarm:	Audible
Functions:	Count-down, Count-up, Clock, Stopwatch, Memory
Display:	1.3 (H) cm, 6-digit LCD
Resolution:	1 second
Range:	24 hours to 1 second
Accuracy:	0.01%

Included Components:

- Incubator base unit
- Aluminum heat block
- Digital timer

Accessories:

- GEX Part# P4901 Digital Thermometer – used to verify the temperature controller display and for using the P4902 Probe.
- GEX Part# P4902 B3 Probe – thermocouple packaged in between two DoseStix dosimeters to test the temperature in any of the 18 wells of the heating block.

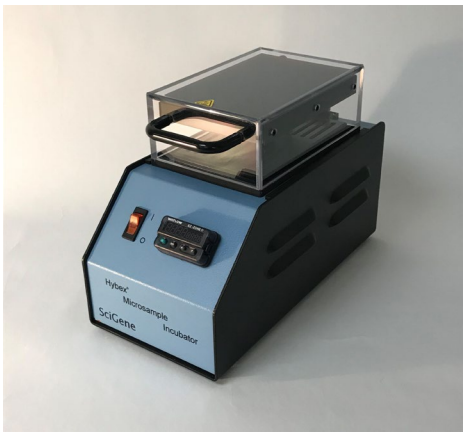
Packaging:

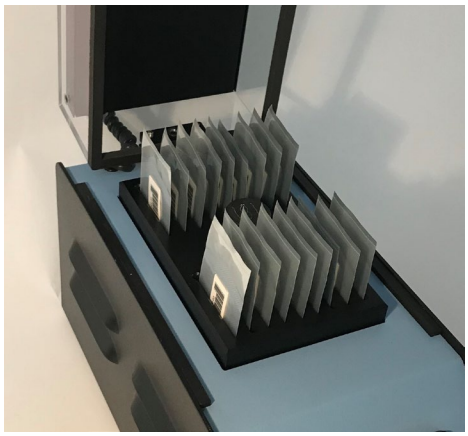
Delivered in two separate cardboard boxes. One containing the heat block and the other containing the incubator and timer.

Storage:

Store the device in a cool and dry area. Store the heat block separately. Do not ship with the heat block inside of the incubator or damage to the incubator may result.

PRODUCT PHOTOS



GENERAL INFORMATION

The system is comprised of a heating base unit that houses the custom 18-well anodized aluminum heat block and a portable, digital countdown timer. The incubator base unit has an integrated digital temperature display with temperature control and on/off switch.

The unit is equipped with back panel jack for connection to a digital thermometer using a T-type thermocouple for verification of the unit's actual versus displayed temperature. The T-type thermocouple and the one used by the controller to monitor actual temperature terminate in the long probe which is located in the center of the incubator and protrudes up inside the aluminum heat block. Refer to the 'Calibration & Maintenance' section below for details on calibration verification.

INSTALLATION

1. Set the device on a stable, flat surface with unobstructed airflow around the incubator.
2. Open the lid and insert the heat bock. The block will fit in either direction (180° rotation).
3. Plug the unit into an appropriate power source. The two types offered are 110V and 220V models and the power source must match the voltage. Refer to the SciGene User Manual delivered with the product for more details.
4. After powering on the unit, the set temperature can be adjusted by pressing 'SET' button and the 'UP ARROW' or 'DOWN ARROW' buttons together.

Note: Refer to the temperature controller calibration method described below in the 'Calibration' section for important information before first use.

USAGE

Determining Heat-Treatment Process Parameters

Different time and temperature settings for heat treatment of GEX B3 dosimeters can and have been successfully implemented. Some users have qualified and use slightly different settings than others. The P4900 Microincubator is delivered with a Set Point of 58.5°C which is the most widely used treatment temperature for this device. For more information on determining and validating heat treatment parameters refer to *GEX Doc# 100-201, Post Irradiation Heat Treatment of B3 Dosimeters – Technical Information Report*.

Usage Procedure

1) For most applications, the incubator remains powered on at all times. If necessary, turn on the power and wait for the temperature of the aluminum block to reach the set point and the unit to fully equilibrate.
2) Open the lid and insert the dosimeters. Leave the lid open while the dosimeters are actively being heat-treated.
3) Start the timer to countdown the defined dwell-time for the dosimeters (e.g., 5 minutes).
4) Remove the dosimeters after the dwell-time period has elapsed.
5) Close the lid when not in use.

QUALIFICATION

Installation and Operational Qualification (IQ/OQ):

The P4900 calibration of the temperature controller is verified and the heat block for the specific incubator is tested for temperature uniformity at GEX prior to shipment. However, it is the user's responsibility to verify the equipment's performance after it is installed at the user's site. Refer to *GEX Doc# 100-276, Heat Treatment Incubator IQOQ Test Procedure* for details on IQ and OQ for complete instruction.

Performance Qualification (PQ):

GEX currently provides no explicit procedure for execution of PQ. Each user must define the limits to test when conducting performance qualification of the heat-treatment process and must consider the impacts of the dosimeter retrieval requirements and dosimeter handling procedure for the site for which qualification will be performed. GEX suggests that users should validate the 'Process for Routine Dosimetry' as they would any other process. Users should also assess whether the process for dosimetry tests used in Irradiator IQ/OQ/PQ (processes such as product dose mapping and dosimetry-related irradiator qualification activities) will vary significantly from routine dosimetry and consider in their qualification of heat-treatment. For example, if routine dosimeters will always be heat-treated within 2 hours of irradiation but dosimeters from Product Qualification Dose Mapping are not typically heat-treated until the next day, each condition may need to be considered in the protocol.

CALIBRATION & MAINTENANCE

Maintenance:

General good practices for care and cleaning are the only recommendations. The heat block may be disassembled and cleaned if desired or deemed necessary, but no specific timescale is determinable for recommendation.

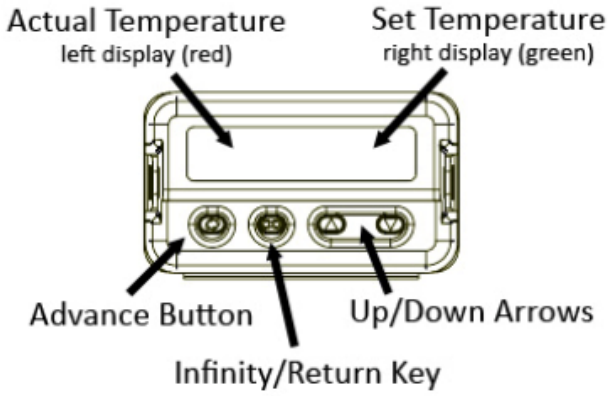
Calibration Frequency:

- The Watlow temperature controller on the unit should be calibrated annually at a minimum.
- The separate digital timer that GEX provides with the unit should be recalibrated or replaced every 1 or 2 years.

When to re-calibrate the temperature controller:

Re-calibration is recommended if the actual displayed temperature on the Watlow controller is found to differ by more than 1.0°C from a connected NIST-certified digital thermometer.

Calibration instructions for Hybex with EZ-Zone Controller



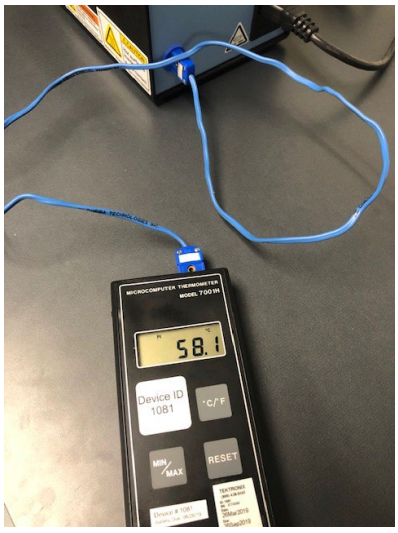
Definitions:

Actual temperature: temperature shown on the Hybex display indicating current conditions (left display/red)

Set temperature: temperature programmed into the Hybex controller by the user (right display/green)

Instructions:

1) Set the temperature on the controller to 58.5°C and allow to the temperature to stabilize for 15 minutes.
2) Use a calibrated digital thermometer, such as GEX product #P4901. Using the T-type cable provided with the digital thermometer, plug one end of the cable into the blue receptacle found on the back panel of the Hybex unit and the other end into a calibrated digital thermometer.



3) Turn on the thermometer. Allow 1 minute for the thermometer to stabilize. The actual temperature of the block will be displayed.

4) Calculate the difference in the temperature shown on the Watlow controller and on the digital thermometer. For example, if the controller displays 58.5°C and the digital thermometer displays 59.8°C, the difference (offset) is 1.3°C.

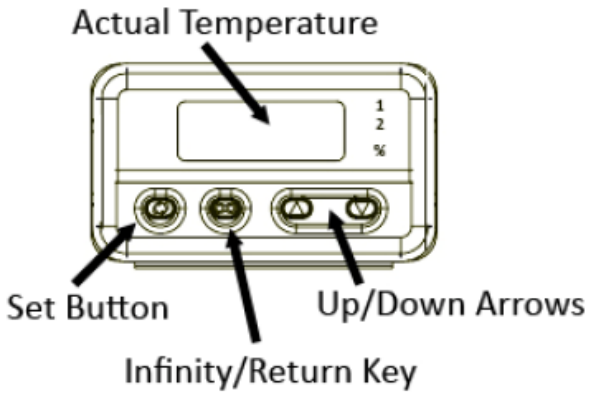
5) On the Watlow temperature controller, press the up and down arrows simultaneously for 3 seconds. The left display shows "**A1**" and the right display shows "**oPEr**".

6) 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.

7) Use the up or down arrow to adjust the offset value to the temperature difference calculated in Step 4. For example, if the controller shows a temperature 1.3°C lower than the thermometer, adjust the offset by adding 1.3 to the value shown.

8) Press the Infinity Key (∞) twice (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.

Calibration instructions for Hybex with Watlow SD31 Controller



Definitions:

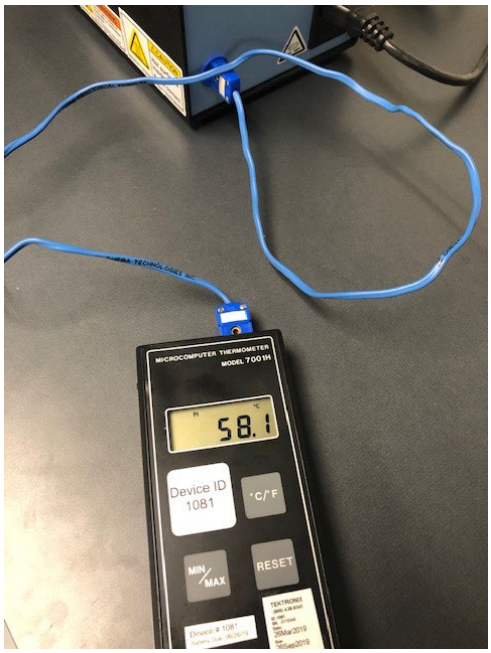
Actual temperature: temperature shown on the Hybex display indicating current conditions

Set temperature: temperature programmed into the Hybex controller by the user (hold down the SET button to view)

Instructions:

1) Set the temperature on the controller to 58.5°C and allow to the temperature to stabilize for 15 minutes.

2) Use a calibrated digital thermometer, such as GEX product #P4901. Using the T-type cable provided with the digital thermometer, plug one end of the cable into the blue receptacle found on the back panel of the Hybex unit and the other end into a calibrated digital thermometer.



3) Turn on the thermometer. Allow 1 minute for the thermometer to stabilize. The actual temperature of the block will be displayed.

4) Calculate the difference in the temperature shown on the Watlow controller and on the digital thermometer. For example, if the controller displays 58.5°C and the digital thermometer displays 59.8°C, the difference (offset) is 1.3°C.

5) On the temperature controller, press the Infinity Key (∞) for 3 seconds until "OPEN" appears.

6) Press down the arrow 4 times until "Cal" appears.

7) Press and hold the SET key. The existing offset value between the controller and digital thermometer is displayed.

8) Press and hold the SET key and use the up/down arrows to adjust the offset value to the temperature difference calculated in Step 4. For example, if the controller shows a temperature 1.3°C lower than the thermometer, adjust the offset by adding 1.3 to the value shown.

9) Press the Infinity Key (∞) 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

PRECAUTIONS

- Do not heat-treat more than 1 package per well in the heat block: maximum 18 packages in one incubator at a time.
- The surface of the heat block is very hot (about 60°C). When not in use keep the lid closed to prevent accidental contact.
- The aluminum block should be kept inside the cavity of the incubator at all times and should only be removed for periodic cleaning or servicing.
- To remove the heat block, turn off the power to the unit and allow the heat block to cool to room temperature. This may take several hours.

WARRANTY

Warranty:

1-year manufacturer's warranty. User modifications are not warranted and are the sole responsibility of the user. See the manufacturer warranty information for more details. The P4900 is provided to GEX for resale under the Hybex label owned by SciGene, Inc., Sunnyvale, CA. Please contact GEX for warranty and technical support.

RELATED DOCUMENTS

- GEX Doc #100-125, Digital Thermometer PSU
- GEX Doc# 100-201, Post Irradiation Heat Treatment of B3 Dosimeter Products – Technical Report
- GEX Doc# 100-276, Heat Treatment Incubator IQOQ Test Procedure

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/04/2020	Formatted to new PSU template. Major revision to fit the template and for clarity of original intent. Removed old section "Heat Treatment Method Comparison" as this information will be located in Doc# 100-201 instead. Changed recommended set point to 59.5°C to ensure no position would ever fall below 58.0°C even at the limits of the uncertainty of the calibration of the temperature controller – it has an accuracy of +/-1°C. ECO 70506.	A
09/29/2020	Usage section; changed specs imperial units – the products are designed in those units. Added links to documents on website. Changed heat treatment language to refer user to 100-201 for details – no information other than general info and the factory set point are now discussed in this document. ECO 10046.	B
01/18/2023	Added calibration instructions and image for the Hybex with the EZ-Zone Watlow temperature controller. Added calibration instructions and image for the Hybex with the SD31 Watlow temperature controller. Added Digital Thermometer PSU document link. ECO 70627.	C