MesaLabs

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MesaLabs

EZTest® Incubator

OPERATION MANUAL

DECLARATION OF CONFORMITY

(In accordance with EN 45014 and ISO/IEC Guide 22)

We (manufacturer),

Mesa Labs
10 Evergreen Drive
Bozeman, MT 59718 USA

Declare under our sole responsibility that the product:

Model Name: Biological Indicator Incubator
Model Number: 1410

to which this declaration relates meets the following standards:

Safety: CAN/CSA-C22.2 No. 61010-1-04
CAN/CSA-C22.2 No. 61010-2-10:04
UL Std. No. 61010-1 (2nd Edition)

EMI/EMC: EN 61326-1 Class A
EN 61000-3-2 Class A
EN 61000-3-3

and is in conformity with the provisions of the **Low Voltage Directive 73/23/EEC** *and the* **EMC Directive 89/336/EEC**.

Year of CE Marking: 2011

Authorized by:

John Verzuh
Director of Quality and Regulatory Affairs
Mesa Labs, Bozeman Manufacturing Facility

CE

Date: 30-August-2011

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Introduction

The Mesa Labs biological indicator incubator is designed for convenient and effective incubation of self-contained biological indicators requiring incubation temperatures of 37°C, 57°C, or 60°C. The incubator features a built-in thermometer with LED display, 13 incubation cavities, and an integrated activation (crushing) cavity.

A self-contained biological indicator consists of a capped thermoplastic culturing vial containing a glass media ampoule and a carrier inoculated with bacterial spores. Upon removal from the sterilizer, the indicator is activated by flexing the plastic culturing vial to crush the inner glass ampoule which allows the growth medium to contact the spore carrier. The activated indicator is then incubated for a specified length of time and observed for color change of the growth medium. If the medium turns yellow during incubation, the test is positive indicating growth and inadequate sterilization.

Safety Information

Handle with caution. The surface of the incubator may become hot to the touch.

The incubator has been designed with function, reliability, and safety in mind. It is the user's responsibility to install it in conformance with local electrical codes. For safe operation, please pay attention to the alert boxes throughout the manual.

Warning

Refer to manual.

Caution

Cautions alert you to potential equipment damage and hazards.

Note

Notes alert you to pertinent facts and conditions.

Use Only as Directed

- Indoor use only.
- Temperature 10°C to 35°C.
- Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 35°C.
- Main power supply voltage fluctuations not to exceed ±10% of the nominal voltage.
- Installation class II service.
- Polution-Degree 2 environments.
- Altitude less than 2000m.

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Specifications

Incubator

Catalog Number	I1410	
Overall Dimensions	Width	3.5 in / 9 cm
	Height	2.0 in / 5.08 cm
	Depth	4.0 in / 10.2 cm
	Weight	0.89 lb / 0.4 kg
Incubation Cavities	Number	13
	Diameter	.375 in / .94 cm
	Depth	1 in / 2.54 cm
Thermometer	Accuracy	+ / - 1ºC
Electrical Ratings (for use with certified class 2 power supply)	Volts	12VDC
	Watts	18.0
	Amps	1500 mA
Operating Range	Temperature	37ºC / 57ºC / 60ºC
Environmental Conditions	Ambient Temperature	10ºC - 35ºC
	Relative Humidity	20% - 80% Non-condensing
Conformance	*CSA/C/US, CE, RoHS, FCC Part 15 Class A, ICES-003 Class A*	

Power Supply

Catalog Number	P6-1000
Rated Input Voltage	100 – 240VAC
Input Voltage Range	90 – 264VAC
Rated Frequency	50-60Hz
Rated Input Current	1.0A
Output Voltage	12VDC
Max Output Current	2.5A
Max Output Wattage	30W
Safety Approvals	UL/cUL, GS, CCC, RCM
EMC/EMI	FCC class B, CE, VCC I class II
RoHS Compliant	Yes
Storage Temperature	-10°C – 70°C
Storage Humidity	10 – 90%
Operating Temperature	0 – 40°C
Operating Relative Humidity	20 – 80%

Installation and Warm Up

The incubator is designed for continuous operation and does not have a power switch. The incubator will power on when it is plugged into a power source.

Note: the incubator must be installed in a location where temperature is maintained between **10°C** (50°F) and **35°C** (95°F).

1. Remove the incubator from its packaging.
2. Unpack the power supply. The power supply includes four interchangeable blades (plugs). Select the appropriate blades for your region and attach the blades to the power supply.
3. Plug the power supply into a power source.
4. Insert the small connector from the power supply into the matching receptical in the back of the incubator (*see Figure 1*).
5. The incubator will automatically power on and perform a self-test. Upon completion, the installed firmware revision will be displayed on the LED screen for two seconds.
6. The incubator will begin its warm-up phase. During this time the configured temperature setpoint will fade in and out on the LED screen.
7. The incubator is ready to use when the configured setpoint is no longer fading in and out, and the LED screen displays the current operating temperature of the incubator.

Note: it may take approximately 15 minutes for the incubator to warm up to operating temperature, depending on the selected incubation temperature and the temperature of the environment in which the incubator is installed.

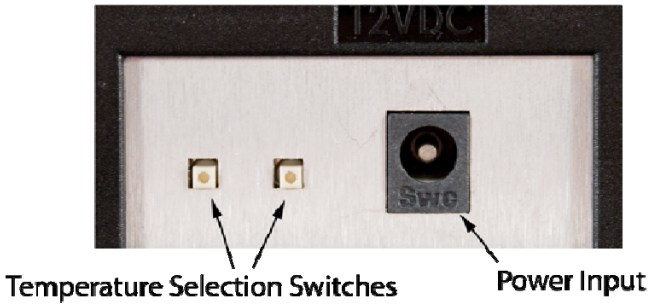
Temperature Selection

The incubator can be configured to operate at 37°C for biological indicators containing *Bacillus atrophaeus*, or 57°C or 60°C for biological indicators containing *Geobacillus stearothermophilus*. The incubator is initially configured to operate at 60°C.

Caution: failure to set the correct incubation temperature will yield invalid test results. It is not possible to incubate at multiple temperatures simultaneously. Refer to the instructions for use for your biological indicators to select the appropriate incubation temperature.

1. With the incubator powered on, simultaneously press and hold the two small buttons on the rear of the incubator (*see Figure 1*) for ~2 seconds until the currently selected temperature setpoint blinks on the LED display.
2. Release the buttons, then press either button repeatedly to toggle between the available temperature setpoints (37°C, 57°C, or 60°C).
3. When the desired temperature setpoint is blinking on the display, press and hold both buttons for ~2 seconds.
4. The configured setpoint will fade in and out on the LED screen until the incubator has reached temperature, upon which the actual temperature of the incubator will be displayed.

Figure 1 - Rear of Incubator



Warranty

Mesa Labs expressly warrants the Model 1410 biological indicator incubator manufactured by it as set forth herein. Mesa Labs makes no other warranties, either express or implied. No warranty as to merchantability or fitness for a particular purpose shall apply. In addition, the following shall constitute the exclusive remedies of buyer for any breach by Mesa Labs of its warranty hereunder.

Material and Workmanship: Mesa Labs warrants the Model 1410 incubator manufactured by Mesa Labs shall be free from defects in material and workmanship, under normal use and service, for a period of fifteen (15) months from the date the product shipped from Mesa Labs. If any part of the equipment is returned within this time and found by Mesa Labs to be defective in workmanship or material, it will be replaced or repaired, free of charge and returned F.O.B. your plant. Any equipment or part thereof so replaced or repaired shall be warranted by Mesa Labs for the remainder of the original warranty period. All replacements or repairs necessitated by inadequate preventive maintenance, or by normal wear and usage, or deterioration under unsuitable environmental conditions shall be at Buyer's expense. Buyer may incur service charge for evaluation of returned equipment not found to be defective. Mesa Labs shall not be obligated to pay any charges incurred by Buyer except as may be agreed upon in writing in advance by Mesa Labs.

Limitation of Remedy: Mesa Labs shall not be liable for damages caused by delay in performance. The sole and exclusive remedy for breach of contract shall be limited to repair or replacement under the standard warranty clause. In no case shall Mesa Labs liability exceed the price to buyer of the specific goods manufactured by Mesa Labs giving rise to the cause of action. Buyer agrees that in no event shall Mesa Labs liability extend to include incidental or consequential damages.

Service

The incubator is not field-servicable. In the event of an incubator malfunction, please contact your dealer immediately.

When requesting service, please have ready the model and serial number of the incubator. The model and serial number are located on the bottom of the unit.

Prior to returning any materials, a Return Goods Authorization (RGA) must be obtained from your dealer. Any materials returned without an RGA will be refused.

Operation

Note: refer to the instructions for use supplied with your biological indicators for information on processing, incubation, interpretation of results, and using positive controls.

When the incubator has reached the configured temperature, the actual temperature of the incubator will be shown on the LED display, indicating that the unit is ready to accept biological indicators. Verify that the temperature displayed is within the allowable range for your biological indicator before proceeding (see the instructions for use supplied with your biological indicators).

Biological Indicator Activation

Prior to incubation, the biological indicator must be activated by crushing its internal glass medium ampoule. This allows the color-change medium from the ampoule to contact the spore carrier.

WARNING: allow a processed BI to cool for at least 10 minutes upon removal from the sterilizer. Failure to do so may cause the glass medium ampoule to burst during activation, resulting in injury from hot liquid or flying debris.

The incubator contains an activation (crushing) cavity to simplify activation (*see Figure 2*). Place the processed or positive control biological indicator into the left side of the activation cavity and flex the indicator to the right until the glass ampoule breaks.

Note: you may have to grip the incubator by the base while activating a BI so that it does not tip over.

Incubation

To confirm adequate sterilization (negative result), self-contained biological indicators must be incubated for the appropriate length of time (“incubation time”). Please refer to the instructions for use that came with your biological indicators for the proper incubation time.

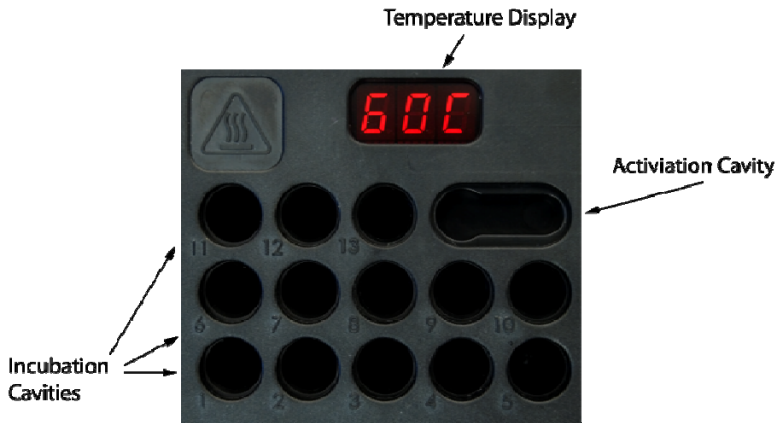
Immediately upon activation, place the indicator into one of the thirteen numbered incubation cavities (*see Figure 2*). Record the incubation start time and cavity number.

Observe the color of the growth medium in the BI at regular intervals during incubation. A color change to yellow during the incubation time indicates bacterial growth (positive test). If the incubation time expires and no color change to yellow is observed, this indicates a negative test.

Caution: if a positive control does not grow, do not use the remaining units from the box and contact your dealer immediately. A positive control that does not turn yellow is a serious problem. Fortunately, the causes are few: a grossly malfunctioning incubator, inadvertent sterilization of the control vial, inadvertent sterilization of the box of indicators, or improper storage. If the control is negative because of one of the latter two causes, do not use any of the other biological indicators from the same box.

Dispose of positive or negative BIs immediately per the instructions for use that accompany each box of indicators, or per your organization's policy.

Figure 2 – Top of Incubator



Maintenance & Service

The incubator requires no maintenance other than cleaning as necessary.

Cleaning

1. Unplug the incubator before cleaning.
2. To clean the exterior, use a cloth dampened with isopropyl alcohol.
3. To clean the incubation and activation cavities, use a cotton swab dampened with isopropyl alcohol.

WARNING: DO NOT IMMERSE THE UNIT IN ANY LIQUID AND DO NOT SPRAY OR POUR LIQUID DIRECTLY ONTO THE UNIT. DOING SO MAY DAMAGE THE INCUBATOR AND VOID YOUR WARRANTY.

Replacement Parts

Description	Quantity Required	Part Number
Power Supply	1	P6-1000

Temperature Verification

The incubator, including the LED temperature display, is factory calibrated using a NIST traceable temperature standard and does not require user calibration.

Incubation temperature can be verified by placing an NIST traceable thermometer into one of the incubation cavities and allowing 30 minutes for temperature stabilization. The temperature reading should be within +/- 2°C of the incubator set-point temperature.