

EZTest[®] Incubator

OPERATION MANUAL



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Introduction

The EZTest[®] Incubator is designed for 37°C (gas) or 57°C (steam) incubation of EZTest biological indicators. EZTest self-contained biological indicators consist of bacterial spores of *Geobacillus stearothermophilus* inoculated onto a paper carrier which is placed into a thermoplastic vial that serves as a culture tube. A small glass ampoule containing sterile culture medium and color indicator is also contained in the vial.

Please read the instructions carefully.

Warranty

SGM Biotech, Inc. warrants that if a product manufactured by SGM Biotech, Inc. and sold within the continental United States or Canada proves to be defective in material or construction, SGM Biotech, Inc. will provide you, without charge, for a period of ninety (90) days, the labor, and a period of one (1) year, the parts, necessary to remedy any such defect. Outside the continental United States and Canada, the warranty period shall commence either six (6) months following the date the product is sold by SGM Biotech, Inc. or on the date it is purchased by the original retail consumer, whichever date occurs first.

All warranty inspections and repairs must be performed by and parts obtained from an authorized SGM Biotech dealer or SGM Biotech, Inc. The name of the authorized SGM Biotech, Inc. dealer nearest you may be obtained by calling (406) 585-9535 or writing to:

SGM Biotech, Inc.
10 Evergreen Drive, Suite E
Bozeman, MT 59715 USA
FAX: (406) 585-9219
EMAIL: cust-service@sgmbiotech.com
WWW: <http://www.sgmbiotech.com>

SGM Biotech, Inc's sole obligation with respect to its product shall be to repair or replace the product. Under no circumstances shall it be liable for incidental or consequential damage.

THE WARRANTY STATED HEREIN IS THE SOLE WARRANTY APPLICABLE TO SGM BIOTECH, INC. PRODUCTS. SGM BIOTECH EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR USE.

If this equipment is not used in a manner specified by SGM Biotech, Inc., the protection provided by the equipment may be impaired.

Ordering Procedure

Please refer to the specification label on the underside of the incubator for the complete model and serial number of your incubator when requesting service, replacement parts, or in any correspondence concerning this unit.

All parts listed herein may be ordered from the SGM Biotech, Inc. dealer from whom you purchased this unit. When service or replacement parts are needed we ask that you check first with your dealer. If the dealer cannot handle your request, then contact our Customer Service Department by phone at (406) 585-9535 or e-mail to cust-service@sgmbiotech.com.

Prior to returning any materials to SGM Biotech, Inc., please contact our Customer Service Department for a "Return Goods Authorization" number (RGA). Material returned without a RGA number will be refused.

Safety Information

The EZTest biological indicator 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.

Specifications

Incubator

Catalog Number	1401	
Overall Dimensions	Width	3.5 in / 9 cm
	Height	2.0 in / 5.8 cm
	Depth	4.0 in / 10.2 cm
	Weight	0.89 lb / 0.4 kg
Well Dimensions	Number	14
	Diameter	.375 in / .94 cm
	Depth	1 in / 2.54 cm
Thermometer Well Dimensions	Number	1
	Diameter	.28 in / 0.71 cm
	Depth	1 in / 2.54 cm
Electrical Ratings	Volts	12VAC
	Watts	12.0
	Amps	1000 mA
	Frequency	50 - 60 Hz
	Phase	1
Operating Range	Temperature	37°C / 57°C
Environmental Conditions	Ambient Temperature	17°C - 27°C
	Relative Humidity	20% - 80% Non-condensing

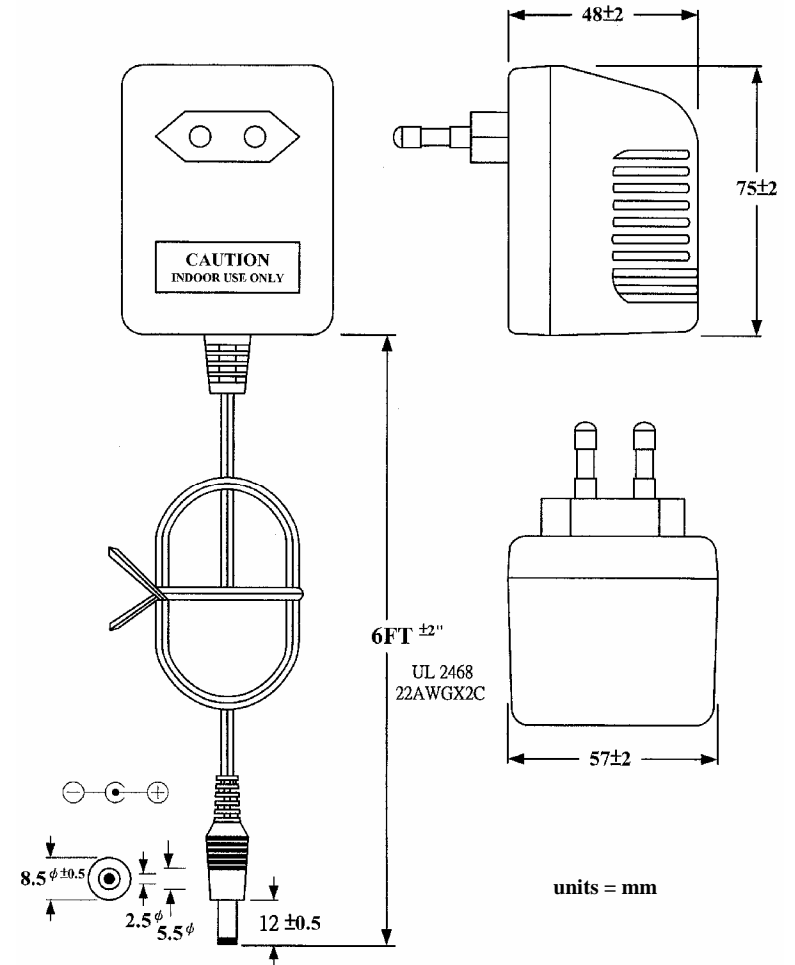
Power Pack

Catalog Number	P1-1000	P2-1000
Where Applicable	U.S.	Europe
Primary Exciting Current	120mA max	100mA max
	120 VAC	230 VAC
	60 Hz	50 Hz
Secondary No Load Voltage	17.1 ± 5% VDC	17.8 ± 5% VDC
Secondary Voltage Load	12 VDC ± 5% 1000 mA	
Hi-Potential Pri. to Secondary	AC 1500V	AC 3750V
Test Secondary to Core	AC 500 V	
Temperature Rise	75° C Maximum	
Output Conductor	AWG #22	

Model 1401

Parts & Diagrams

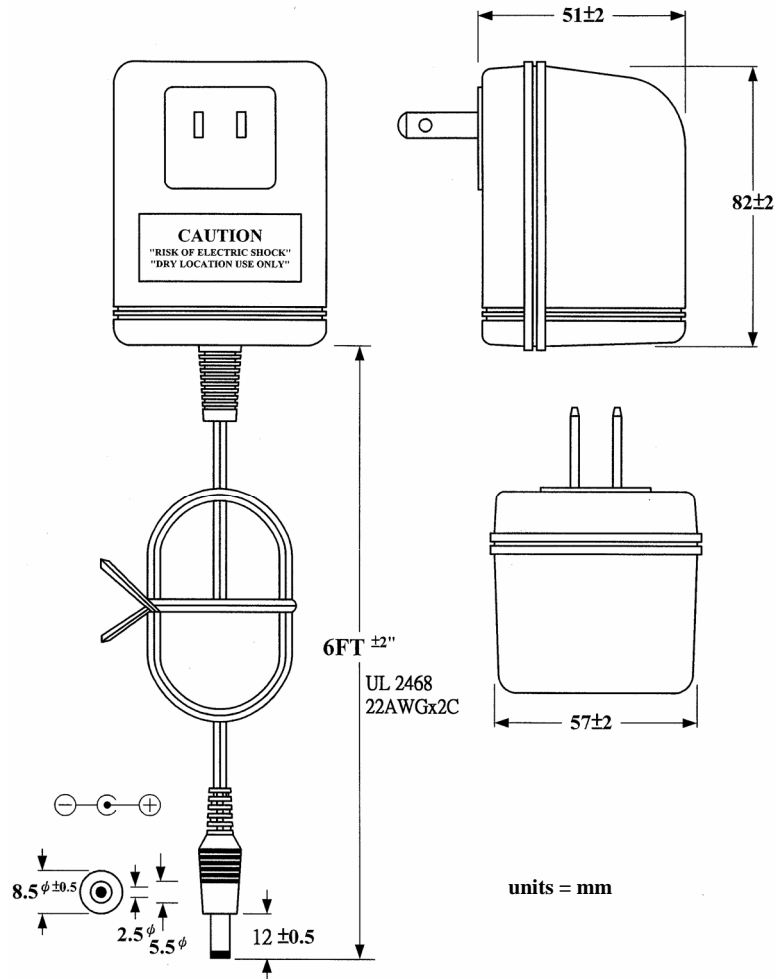
Power Pack – P2-1000 - European



Model 1401

Parts & Diagrams

Power Pack – P1-1000 - United States



Model 1401

Installation



Note:
Incubator
can run at
only one of
the
temperatures
at a time.

1. Remove incubator from packaging.
2. **Select temperature by setting the slide switch located on the back of the incubator. This switch can be set at either 37°C for gas or 57°C for steam.**
3. Remove thermometer from casing.
4. Remove power pack from packaging.
5. Insert small connector from power pack into the receptacle in the back of incubator.
6. Plug power pack unit into wall.
7. Place thermometer into the small hole in the center of the third row.
8. Press the O/I toggle switch located on the back of unit to turn incubator on. Red light should illuminate. Once red light turns to green, incubator has reached the selected incubation temperature.

Use Only as Directed

- Indoor use only.
- Temperature 5°C to 37°C.
- Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 37°C.
- Main power supply voltage fluctuations not to exceed ±10% of the nominal voltage.
- Installation class II service.
- Pollution-Degree 2 environments.
- Altitude less than 2000m.

Model 1401

Operation for Steam - 57°C

Make sure that the slide switch on the back of the incubator is set to the 57°C position. Upon start-up, let incubator run until red light has changed to green (~ 25 - 45 minutes) - this indicates that it has reached the temperature setpoint of 57°C.



Warning:
Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid or flying debris.

1. Remove the EZTest biological indicator (BI) from the sterilizer and allow to cool for at least ten minutes.
2. Activate the BI by placing it into a plastic crusher in an upright position, and gently squeezing the crusher to break the glass ampoule.
3. Immediately place the activated BI into the incubator and incubate for 24 hours.
4. Examine the BI at regular intervals for a color change from purple to yellow (i.e. 8, 12, 18, and 24 hours).

Growth is indicated by a color change of the BI media from purple to yellow.

Interpretation



Note: This incubator is designed for use only with EZTest or comparable sized biological indicators.

The EZTest Steam culture medium has a pH indicator added to it which appears purple. If the medium remains purple following proper incubation, this indicates adequate sterilization. If the process was not effective, the spores will grow and turn the medium yellow. Note: If any units show signs of a visual color change prior to use, they should not be used and should be disposed of properly.

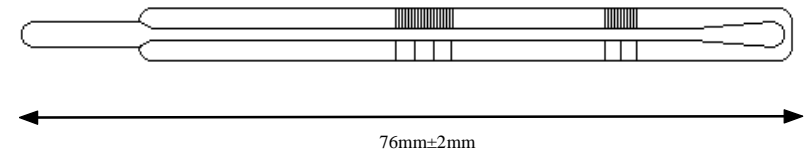
Act on a positive test (a color change to yellow) as soon as the color change is noted. Color change to yellow is to be interpreted as “inadequate sterilization”. Always retest the sterilizer with several EZTest biological indicators throughout the test load. EZTest biological indicators can be subcultured if identification of positive growth is desired.

Parts & Diagrams

Replacement Parts

Description	Quantity Required	Part Number
Power Pack (US)	1	P1-1000
Power Pack (Europe)	1	P2-1000
Thermometer	1	I14/T

Thermometer



Maintenance & Servicing

Maintenance



Do not immerse the unit.

1. Unplug the incubator before performing any maintenance.

DO NOT IMMERSE THE UNIT IN ANY LIQUID

2. To clean the unit, wipe with a cloth dampened with isopropyl alcohol.
3. To clean the wells, use a cotton swab dampened with isopropyl alcohol.

Service and Repair

This unit is pre-calibrated by the manufacturer and is not field serviceable. Contact SGM Biotech, Inc. if service is required.

Interpretation (continued)

To test a **positive growth control**, place an activated, **unprocessed** EZTest indicator into the incubator. Examine the positive indicator at regular intervals such as 4, 8, 12, 18 and 24 hours. A yellow color is expected as evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of properly. If the positive control does not grow, do not use the units from this box and contact your dealer.



Caution: Dispose of biological indicators in accordance with your facility's policies. You may wish to autoclave any positive indicators at 121°C for no less than 30 minutes.

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 in the same box. Dispose of the contents of the box by autoclaving at 121°C for no less than 30 minutes after confirmation of test.

Incubation Read Out

The recommended incubation time for steam is 24 hours. The manufacturer of the biological indicators has performed the FDA protocol for determining the incubation read out time and the data meets the FDA criteria after 24 hours of incubation.

Operation for Gas - 37°C

Make sure that the slide switch on the back of the unit is set to the 37°C position. Upon start-up, let incubator run until the red light has changed to green (~ 20 - 30 minutes) - this indicates that it has reached the temperature setpoint of 37°C.



Note: This incubator is designed for use only with EZTest or comparable sized biological indicators.

1. Remove the EZTest biological indicator (BI) from the sterilizer
2. Activate the BI by placing it into a plastic crusher in an upright position, and gently squeezing the crusher to break the glass ampoule.
3. Immediately place the activated BI into the incubator and incubate for 48 hours.
4. Examine the BI at regular intervals for a color change from red/orange to yellow (i.e. 18, 24, or 48 hours).

Growth is indicated by a color change of the BI media from red/orange to yellow.

Interpretation

The EZTest Gas culture medium has a pH indicator added to it which appears red/orange. If the medium remains red after proper incubation, this indicates adequate sterilization. If the process was not effective, the spores will grow and turn the medium yellow. Note: if any units show signs of color change prior to use, they should not be used and should be disposed of properly.

Act on a positive test (a color change to yellow) as soon as the color change is noted. Color change to yellow is to be interpreted as “inadequate sterilization.” Always retest the sterilizer with several EZTest biological indicators throughout the test load. EZTest biological indicators can be subcultured if identification of positive growth is desired.

Interpretation (continued)



Caution: Dispose of biological indicators in accordance with your facility's policies. You may wish to autoclave any positive indicators at 121°C for no less than 30 minutes.

To test a **positive growth control**, place an activated, **unprocessed** EZTest indicator into the incubator. Examine the positive indicator at regular intervals such as 18 and 24 hours. A yellow color is expected as evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of properly. If the positive control does not grow, do not use the units from this box and contact your dealer.

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 in the same box. Dispose of the contents of the box by autoclaving at 121°C for no less than 30 minutes after confirmation of test.

Incubation Read Out

The recommended incubation time for gas is 48 hours. The manufacturer of the biological indicators has performed the FDA protocol for determining the incubation readout time and the data meets the FDA criteria after 48 hours of incubation.