How To Fill Out ProSure® Mailers

ProSure®
Sterilizer Monitoring Service

INSTRUCTIONS FOR USE:

1. Remove test pouch from the pocket marked “Test Strip”.
2. Place the test pouch in the sterilizer.
3. Sterilize load according to normal procedure.
4. After processing, place test pouch inside envelope and seal. Mail to the lab for culturing.
5. Last envelope? Contact your medical supplier to reorder. #3910 - 12 tests, #3926 - 26 tests, #3952 - 52 tests.

EDM3 SOLUTIONS
HealthLink® A Family of Medical Products

1-844-494-4147 www.edmthree.com

Sterilization Information

Laboratory is not responsible for invalid test due to incomplete or inaccurate information

MUST COMPLETE FOR EVERY TEST

Customer account # _____
(Leave blank if first sterilizer test)

Sterilizer Serial # _____

Date of Test: _____

COMPLETE FOR FIRST TEST OR ANY CHANGES

☐ Steam ☐ Vapor ☐ Dry Heat ☐ EO

Dr. / Office name _____

Specialty _____

Address: _____

City: _____ State: ____ Zip: _____

Phone: _____

Primary Contact: _____

E-mail or Fax: _____

Brand: _____ Model # _____

Distributor: _____

1 **“GREEN BOX”** - information **NEEDED** to be filled out for every customer.

2 **CUSTOMER ACCOUNT No.** - the number located at the top of your results page. It is **SPECIFIC TO EACH AUTOCLAVE**. If you have more than one autoclave, you will have a Customer Account No. for each autoclave.

! FIRST TIME USERS - If testing an autoclave for the first time and/or you are a new customer, ***leave the “Customer Account” section blank***. You will receive your Customer Account No. with your first results.

3 **STERILIZER SERIAL No.** - A unique ID number specific to an autoclave (not a model #).

NOTE: If your Sterilizer Serial # does not correlate with the correct Customer Account #, it may delay your test results.

4 **DATE OF TEST** - Date ProSure® test was taken.

5 **“SECTION 5”** - only to be lled out if:

- Testing an autoclave for the rst time
- You have changes to any information. ***Indicate information that needs only to be updated.***

For product information and technical assistance, contact EDM3 at **1-800-638-2625**

3611 St Johns Bluff Rd. South, Suite 1
Jacksonville, Florida 32224

EDM3 SOLUTIONS

HealthLink®
A Family of Medical Products

Biological Indicator Monitoring Log Book for

- EZ-Test®
- ProSure® Mailers

For product information and technical assistance,
contact EDM3 at **1-800-638-2625**

3611 St Johns Bluff Rd. South, Suite 1
Jacksonville, Florida 32224

A-1040

Table of Contents:

Dear Customer,

Thank you for participating in EDM3/HealthLink's sterilization monitoring service. The use of Biological Indicators is an essential component of an effective infection control program. We have enclosed a certificate of participation so that your patients and staff are aware of your vigilance in this area.

We have also included the following items to assist you in successful implementation of your Biological Indicator program:

1. Instructions on how to use our EZ-Test and ProSure® products.
2. A table listing specific Professional Organization guidelines for use.
3. A technical bulletin to guide you in determining the frequency of use of your biological indicator (a minimum of once per week).
4. For regulatory compliance, we have also included a biological monitoring log book to allow you to keep a record of your results. When you receive test results from HealthLink, keep them in your log book for third party verification.

Again, thank you for using our program. If you have any questions, please feel free to call us at (800) 638-2625.

Sincerely,

Your friends at EDM3.

EDM3 SOLUTIONS HealthLink® A Family of Medical Products

Professional Organization Guidelines for Sterilization Monitoring

Accepted practice guidelines for Sterilization Monitoring				
Control Category	**AAMI**	**ASHCSP**	**AORN**	**CDC**
Load Control for Steam	At least weekly, each load of implantables	Daily, each load of implantables	Daily, each load of implantables	At least weekly, each load of implantables
Load Control for EO	Each cycle	Each cycle	Each cycle	At least weekly, each load of implantables
Pack Control	Within each package	Placed on and/ or within each package	Inside each package, including items being flashed	Inside large packages

Equipment Control				
Bowie-Dick Type Test	Daily	Daily	-	-
Mechanical	Each Load	Each Load	Each Load	-
Exposure Control	Printed on or affixed to all packages	Placed on and/ or within each package	Outside each package	Outside each package
Record Keeping Control	Yes	Yes	Yes	-

AAMI - Association for Advancement of Medical Instruments.
ASHCSP - American Society for Healthcare Central Service Providers
AORN - Association of Operating Room Nurses
CDC - Center for Disease Control and Prevention

Load Control - Biological Indicator (BI).
Pack Control - Chemical Indicator within the pack.
Exposure Control - Visible Chemical Indicator on outside of the package.
Chart from Infection Control & Sterilization Technology, June 1997

Frequency of Use for Biological Indicators

How often should you test your autoclave to verify that it is working properly? Did you know that changes in water quality and/or pressure may have a direct effect on steam quality in steam sterilizers. Monitoring of autoclaves each day of use can help ensure that load failures are limited to one day or one load and are as isolated as possible. While autoclaves are very effective at rendering pathogenic organisms non-infectious, it is important to remember that steam has to actually contact surfaces to sterilize them.

How do you know...?

Healthcare workers and patients are at risk of exposure to a variety of pathogenic microorganisms. Infections may be transmitted through several routes, including direct contact with blood, body fluids and oral/respiratory secretions; indirect contact with contaminated instruments, operatory equipment or environmental surfaces; or contact with airborne contaminants present in either droplet spatter or aerosols of oral and respiratory fluids. Infection via any of these routes requires that all three of the following conditions be present to form "the chain of infection":

1. a susceptible host
2. a pathogen with sufficient infectivity and numbers to cause infection
3. a portal through which the pathogen may enter the host[1].

Effective infection control strategies are intended to break one or more of these "links" in the chain, thereby reducing the risk of or completely preventing infection. A key component in this link-breaking process is the proper use of sterilizers (autoclaves) which serve as a vital step toward eliminating the 'pathogen links' in the chain of infection.

Biological Indicators (BI's) are designed to ensure that sterilization equipment is functioning properly.

Governmental agencies such as The Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Association (OSHA) recommend the use of BI's for monitoring sterilization cycles. The CDC states, "... proper functioning of sterilization cycles should be verified by the periodic use (at least weekly) of biologic indicators (i.e., spore tests). Heat sensitive chemical indicators (e.g., those that change color after exposure to heat) alone do not ensure the adequacy of sterilization cycle..."[1] OSHA relies on guidelines published by the CDC as a widely recognized and accepted standard to be followed by employers in carrying out their responsibilities under the Occupational Safety and Health Act.

Sterilizer manufacturers also recognize the importance of routine testing of sterilizers and autoclaves. They also recommend that a biological spore test indicator should be used weekly in a representative sterilizer load for sterilization assurance.

So, how often should you test your autoclave with Biological Indicators?

EMD3 recommends testing with a Biological Indicator each day of autoclave use to ensure that it is working properly!! However, as you have seen above, the minimum acceptable standard frequency is weekly monitoring. By performing these tests at recommended intervals, you can protect your staff, customers and/or patients from infection as well as avoid serious liability concerns!

1 CDC. Recommended infection control practices for dentistry. MMWR 1993;41:1-12

EZ-Test Biological Indicator Instructions For Use

Indications: Intended for steam sterilization. 121° C gravity and 121-135° C prevacuum cycles.
Storage: Store 60-80° F (15-27° C), 30-70% relative humidity. Protect from freezing, sterilants, and light. **Do not refrigerate.**

Description: EZ-Test® is intended for use in the monitoring of saturated steam sterilization cycles. Each EZ-Test® vial contains a spore disc impregnated with *Geobacillus stearothermophilus* (ATCC 7953) spores and a culture medium encased in a glass ampoule with Bromocresol Purple as a pH indicator. The acid production associated with growth causes a change in color of the media from purple to yellow, facilitating the detection of growth.

Frequency of Testing: For greatest control of sterilized goods we recommend that a EZ-Test® Biological Indicator be included with every load.

Precaution: Do not use damaged or expired vials. Since EZ-Test® contains live cultures, vials should be handled with care.

Disposal: Sterilize all positive and expired units prior to disposal. Sterilize by steam at 121°C for not less than 30 minutes.

Instructions For Use:

Exposure: Place one or more EZ-Test® vials in a horizontal position in the most difficult to sterilize locations (e.g., near drain). Run a normal cycle for the sterilizer. Remove the vials and verify that the chemical indicator on the vial label has changed color.

Caution: After sterilization, handle unit with care. Contents of the ampoule are hot and under pressure. Failure to allow sufficient cooling time (10-15 minutes) may result in the bursting of the ampoule. **Always wear appropriate safety gear (gloves and safety glasses) when handling sterilized units.**

Activation:
1. Allow vial to cool.
2. Crush the media ampoule by squeezing the sides of the plastic tube.
3. Inspect the unit to make sure that the media has been released from the ampoule and the spore strip is in contact with the released media.

Incubation: Place the processed vial(s) and an unprocessed (control) vial in a vertical position in an incubator maintaining 55-60°C for 24 hours.

Monitoring: You may begin monitoring the incubated vials after 12-24 hours. Record requested information for each run in the monitoring log book . All positive vials should be recorded and disposed of immediately. Do not continue to incubate positive units. Final negative results can be made after 24 hours and recorded in the monitoring log book. Dispose of vials in biohazard container.

NOTE: Do not continue to incubate vials once they turn yellow.

Interpretation:

Control Vial: The control vial should exhibit turbidity and/or a color change to or toward yellow. If the control vial does not show signs of growth, consider the test invalid.

Test Vial: A failed sterilization cycle is indicated by turbidity and/or a color change to or toward yellow. A test vial that retains its original purple color indicates that sterilization parameters have been met.

ProSure® Spore Strips
Instructions For Use

Each envelope contains a test strip and a control strip, which have been impregnated with approximately one million Bacillus atrophaeus spores (ATCC 9372) for use with dry heat and ethylene oxide sterilizers, and one hundred thousand *Geobacillus stearothermophilus* spores (ATCC 7953) for testing steam and chemical vapor sterilizers).

1. Remove blue bag containing the "Test Strip" from open side of envelope.
2. ***DO NOT OPEN BLUE GLASSINE BAG!!***
3. Place blue glassine bag containing test strip in the sterilizer along with load to be sterilized near the center of the load. DO NOT immerse the strip in liquid.
4. Run the load according to normal procedure. (Consult operator's manual for correct temperature and time settings.)
5. Record the information requested on back of envelope as well as information requested on log sheet.
6. After sterilization cycle is complete, place the blue bag back into the envelope and seal the flap.
7. Mail the pre-addressed return envelope back to EDM3.
8. When you receive your test result from EDM3, circle the test result (growth or no growth) in the appropriate area in the log sheet.

Biological Monitoring Log for EZ-Test® and ProSure® Mailer Biological Indicators

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IMPORTANT: Be sure to record all information requested in table below for the type of test used.

Date of Test	Circle Type of Spore Test Used	Sterilizer ID	Load ID	BI Lot # / Exp. Date	Date & Time Out of Incubator and Initials **EZ-Test**	Date & Time Out of Incubator and Initials **EZ-Test**	Type of Sterilization (check one) **ProSure**	Cycle Length/ Temperature **ProSure**	Test Results (circle one)	Control Results (circle one)
	EZ-Test **ProSure**				Date In ______ Time In ______ Initials _______	Date Out _____ Time Out ____ Initials _______	Steam _______ Dry Heat _____ Chemiclave __	Minutes ______ Temp ºC _____	Growth No Growth	Growth No Growth
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