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# Ensure Log Book

IN-OFFICE BIOLOGICAL MONITORING SYSTEM

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Log Book Start Date:

\_\_\_\_\_  
YYYY/MM/DD

Log Book End Date:

\_\_\_\_\_  
YYYY/MM/DD



# In-Office Steam Biological Monitoring System

## Monitoring Frequency:

For optimum control of sterilized goods, many Federal and Provincial guidelines recommend that biological indicators are used to monitor every sterilizer daily.

Routine monitoring should be performed according to the recommendations of your leading infection control authorities and local regulatory guidelines/recommendations

Monitoring use is the responsibility of each institution or user.

## Instructions for Use:

**CAUTION: After sterilization, the contents of the Ensure biological indicator are hot and under pressure. Always allow to cool at least 10 minutes. Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.**

### A. Exposure:

1. Remove an appropriate number of Ensure BI vials from the box.
2. Identify the indicators by labeling pertinent process information.
3. It is recommended that at least two BI's be used per cycle.
4. Place the Ensure biological indicators in a horizontal position with representative materials to be sterilized. These materials should be placed within the load as recommended by the sterilizer manufacturer.
5. Select the appropriate cycle and process the load.
6. Remove from the sterilizer and allow to cool for at least 10 minutes.
7. The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes exposed from unexposed units.

**NOTE:** a black color does not indicate acceptable sterilization.

### B. Incubation:

Any microbiological incubator that is adjusted for 55 to 60°C will satisfy the incubation conditions for the Ensure BI. To activate the media, place the indicator in an upright position in a vial crusher. Gently crush the vial in the vial crusher to break the inside glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

### C. Interpretation:

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1. Examine the indicator at regular intervals for any color change (i.e. 8, 12, 18 and 24 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
2. Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate hospital or clinic personnel (i.e. Infection Control). Always retest the sterilizer with several Ensure biological indicators placed throughout the test load. Ensure biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from SciCan.
3. The incubation time is 24 hours (meets the US FDA/RIT protocol).
4. Record the results.
5. Dispose of all used Ensure biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

### Use of Controls:

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- A. As a positive growth control, place an activated, un-sterilized Ensure biological indicator in each incubator on a daily basis. Mark the control vial with a "C"
- B. Examine the positive indicator at regular intervals (i.e. 4, 8, 12, 18 and 24 hours). The yellow color is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of as mentioned above.
- C. If the positive control does not grow, do not use the units from this box. Contact SciCan.

### Storage:

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- A. Store Ensure biological indicators at room temperature. Do not desiccate (dry out).
- B. Do not store these indicators near sterilants or other chemicals.
- C. The biological indicators have a 24 month shelf life which is clearly designated on each box. Rotate your stock accordingly.

**NOTE:** Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

**1**  
Date

**2**  
Identify the sterilizer that is being tested\*

**3**  
Initial and indicate the date and time the vials are being placed in the incubator.

Date	Sterilizer #	Date In Time In (Initials)	Date Out Time Out (Initials)	Results Sterilized Vial (Circle One)	Results Control Vial (Circle One)
Nov 3, 2009	Statim 2000 #1	Nov 3, 2009, 9:30 am HR	Nov 4, 2009, 10:30 am JP	+ (yellow) Lot: S391 (purple)	+ (yellow) Lot: S391 - (purple)
				+ (yellow) Lot: - (purple)	+ (yellow) Lot: - (purple)
Nov 3, 2009	Statim 2000 #2	Nov 4, 2009, 11:30 am JP	Nov 5, 2009, 11:30 am RS	+ (yellow) Lot: S391 (purple)	+ (yellow) Lot: S391 - (purple)
				+ (yellow) Lot: - (purple)	+ (yellow) Lot: - (purple)

**4**  
Initial and indicate the date and time the vials have been checked and removed from the incubator.

**5**  
Circle the results of the sterilized vial and indicate the lot code of the vial sterilized

**6**  
Circle the results of the control vial and indicate the lot code of the control vial used

\* If your facility uses multiple of one type of sterilizer, the sterilizers should be identified appropriately (Eg. STATIM 2000 #1, STATIM 2000 #2)

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**Reorder Numbers:**  
SCI-BI25, Ensure Biological Indicators (Box of 25)  
SCI-BI100, Ensure Biological Indicators (Box of 100)  
SCI-BINC, Ensure Incubator  
SCI-BILOG, Ensure Biological System Log Book  
SCI-134, Ensure Chemical Indicators (250 count)

SciCan Ltd.  
1440 Don Mills Road  
Toronto ON Canada M3B 3P9  
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USA: 1-800-572-1211  
[www.scican.com](http://www.scican.com)

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Biological Monitoring System



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SCI-BI100, Ensure Biological Indicators (Box of 100)  
SCI-BINC, Ensure Incubator  
SCI-BILOG, Ensure Biological System Log Book  
SCI-134, Ensure Chemical Indicators (250 count)

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**Reorder Numbers:**  
SCI-BI25, Ensure Biological Indicators (Box of 25)  
SCI-BI100, Ensure Biological Indicators (Box of 100)  
SCI-BINC, Ensure Incubator  
SCI-BILOG, Ensure Biological System Log Book  
SCI-134, Ensure Chemical Indicators (250 count)

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USA: 1-800-572-1211  
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Biological Monitoring System



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