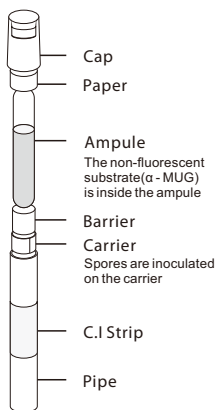


ULTRA SUPER RAPID / SUPER RAPID / RAPID BIOLOGICAL INDICATORS FOR STEAM STERILIZATION PROCESSES



TYPE: LBS020/LBS060/LBS180

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators for monitoring steam sterilization consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator and fluorogenic substrates. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 with a population level of $\geq 10^6$ is located at the bottom closed end of the pipe. A barrier is positioned like a plug between the carrier and the ampule.

The LBS020 / LBS060 / LBS180 Rapid Biological Indicator, when used with an automatic reader (incubation temperature 54-60°C), provides a fluorescence test result in a short period (LBS020-20 minutes; LBS060-60 minutes; LBS180-180 minutes) with an accuracy of $\geq 97\%$. As an option the user can continue the incubation for 48 hours in order to confirm visually the stability or color change of the culture medium.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

INDICATIONS FOR USE

The LBS020 is utilized to monitor sterilization efficacy of gravity displacement or vacuum-assisted steam processes at 132°C to 135°C.

The LBS060 / LBS180 is utilized to monitor sterilization efficacy of gravity displacement or vacuum-assisted steam processes at 121°C to 135°C.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^6$ per carrier	RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.		
Resistance	D value at 121 °C \pm 1 °C ≥ 1.5 mins. Z value ≥ 6 °C.		
Dimensions	10.9 mm (cap diameter), 8.6 mm (pipe diameter), 57 mm (height)		

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 24 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBS BIs from the box, reseal the box, and check each BI for:
 - Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a suitable test pack which is representative of the load.
3. Place this test pack in the most challenging area of the sterilizer and run the sterilization program as usual.
4. After sterilization is complete, remove from the sterilizer and allow the pack and biological indicator to cool for a sufficient time, at least 5 minutes.
5. Retrieve the BIs from the test load and press down the cap to seal the vent hole.
6. After exposure to steam, the chemical indicator strip changes from pink to black. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; black does not indicate successful sterilization.
7. Recheck each BI for:
 - Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.
 Dispose of any questionable units. Results obtained from damaged units should be considered suspect.
8. Place the BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.
9. After a certain incubation time (LBS020-20 minutes; LBS060-60 minutes; LBS180-180 minutes), the automatic reader will display the fluorescence test result. The automatic reader displays "—" indicating a negative result for the BI, and "+" indicates a positive result for the BI. If necessary, continue to incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.
 ISO 11138-3:2017 Sterilization of healthcare products-Biological indicators-Part 3 Biological indicators for moist heat sterilization processes.
 ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.
 ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive (automatic reader displays "+"). If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBS BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.

Vacuum-assisted steam processes includes pre-vacuum and dynamic-air-removal saturated steam sterilization processes



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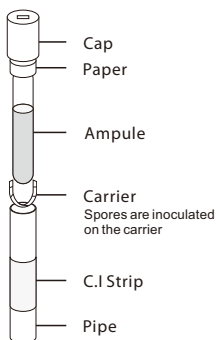


BIOLOGICAL INDICATORS FOR STEAM STERILIZATION PROCESSES



TYPE: LBS144/LBS288

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators for monitoring steam sterilization consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearotherophilus* ATCC 7953 with a population level of $\geq 10^5$ is located at the bottom closed end of the pipe.

The LBS144 / LBS288 Biological Indicator, when used with an incubator (incubation temperature 54-60°C), provides a test result after 24 hours(LBS144) or 48hours(LBS288) with an accuracy of $\geq 97\%$.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

INDICATIONS FOR USE

The LBS144 / LBS288 is utilized to monitor steam sterilization processes efficacy at 121°C to 135°C.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^5$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	D value at 121 °C \pm 1 °C \geq 1.5 mins. Z value \geq 6 °C.
Dimensions	10.9 mm (cap diameter) , 8.8 mm (pipe diameter), 46 mm (height)

STORAGE AND SHELF LIFE

- 10°C to 30°C, 30% to 80% Relative Humidity.
- Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
- Shelf life: 36 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBS BIs from the box, reseal the box, and check each BI for:
 - Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a suitable test pack which is representative of the load.
3. Place this test pack in the most challenging area of the sterilizer and run the sterilization program as usual.
4. After sterilization is complete, remove from the sterilizer and allow the pack and biological indicator to cool for a sufficient time, at least 5 minutes.
5. Retrieve the BIs from the test load.
6. After exposure to steam, the chemical indicator strip changes from pink to black. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; black does not indicate successful sterilization.
7. Recheck each BI for:
 - Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.
 Dispose of any questionable units. Results obtained from damaged units should be considered suspect.
8. Place the BI in an upright position, compress the plastic pipe in the crushing device to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.
9. Incubate for 24 hours(LBS144) or 48hours(LBS288) to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.
 ISO 11138-3:2017 Sterilization of healthcare products-Biological indicators-Part 3 Biological indicators for moist heat sterilization processes.
 ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.
 ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive. If the Positive Control as does not show signs of growth, consider the test invalid.
 Short excursions outside the range of temperature recommended will not impact the performance of the LBS BIs.
 Do not use after the expiration date. Do not refrigerate.
 Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.
 If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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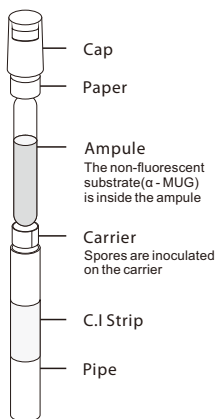


ULTRA SUPER RAPID / SUPER RAPID / RAPID BIOLOGICAL INDICATORS FOR PLASMA OR VAPORIZED HYDROGEN PEROXIDE STERILIZATION PROCESSES



TYPE: LBH020/LBH060/LBH180

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution. A crushable media ampule which contains modified culture medium with a pH indicator and fluorogenic substrates. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 with a population level of $\geq 10^6$ is located at the bottom closed end of the pipe.

The LBH020 / LBH060 / LBH180 Rapid Biological Indicator, when used with an automatic reader (incubation temperature 54-60°C), provides a fluorescence test result in a short period (LBH020-20 minutes; LBH060-60 minutes; LBH180-180 minutes) with an accuracy of $\geq 97\%$. As an option the user can continue the incubation for 48 hours in order to confirm visually the stability or color change of the culture medium.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

INDICATIONS FOR USE

The LBH020 / LBH060 / LBH180 is utilized to monitor the efficacy of H₂O₂ plasma sterilization cycles.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^6$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	50 °C \pm 0.5 °C, H ₂ O ₂ 2.3 \pm 0.4 mg/L, D value: 20~80s.
Dimensions	10.9 mm (cap diameter), 8.6 mm (pipe diameter), 57 mm (height)

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 24 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBH BIs from the box, reseal the box, and check each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a horizontal position with representative materials which is representative of the load.

3. Place the BI in the most challenging area of the sterilizer and run the sterilization program as usual.

4. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load and press down the cap to seal the vent hole.

5. After exposure to V H₂O₂, the chemical indicator strip changes from green to yellow. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; yellow does not indicate successful sterilization.

6. Recheck each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

Dispose of any questionable units. Results obtained from damaged units should be considered suspect.

7. Place the BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.

8. After a certain incubation time (LBH020-20 minutes; LBH060-60 minutes; LBH180-180 minutes), the automatic reader will display the fluorescence test result. The automatic reader displays "—" indicating a negative result for the BI, and "+" indicates a positive result for the BI. If necessary, continue to incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.

BI Premarket Notification [510(k)], Submissions, issued October 4, 2007

ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive (automatic reader displays "+"). If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBH BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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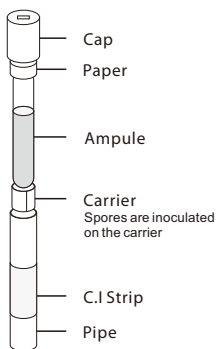


BIOLOGICAL INDICATORS FOR PLASMA OR VAPORIZED HYDROGEN PEROXIDE STERILIZATION PROCESSES



TYPE: LBH144/LBH288

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 with a population level of $\geq 10^5$ is located at the bottom closed end of the pipe.

The LBH144/LBH288 Biological Indicator, when used with an incubator (incubation temperature 54-60°C), provides a test result after 24 hours (LBH144) or 48 hours (LBH288).

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

INDICATIONS FOR USE

The LBH144 /LBH288 is utilized to monitor the efficacy of H₂O₂ plasma sterilization cycles.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^5$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	50 °C \pm 0.5 °C , H ₂ O ₂ 2.3 \pm 0.4 mg/L, D value: 5~80s.
Dimensions	10.9 mm (cap diameter), 8.8 mm (pipe diameter), 46 mm (height)

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 36 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBH BIs from the box, reseal the box, and check each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a horizontal position with representative materials which is representative of the load.

3. Place the BI in the most challenging area of the sterilizer and run the sterilization program as usual.

4. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load.

5. After exposure to V H₂O₂, the chemical indicator strip changes from green to yellow. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; yellow does not indicate successful sterilization.

6. Recheck each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

Dispose of any questionable units. Results obtained from damaged units should be considered suspect.

7. Place the BI in an upright position, compress the plastic pipe in the crushing device to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.

8. Incubate for 24 hours (LBH144) or 48 hours (LBH288) to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.

BI Premarket Notification [510(k)], Submissions, issued October 4, 2007

ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive. If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBH BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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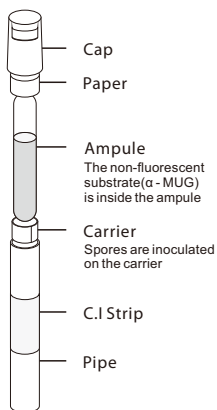


ULTRA SUPER RAPID / SUPER RAPID BIOLOGICAL INDICATORS FOR LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZATION PROCESSES



TYPE: LBF020/LBF060

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution. A crushable media ampule which contains modified culture medium with a pH indicator and fluorogenic substrates. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 with a population level of $\geq 10^6$ is located at the bottom closed end of the pipe.

The LBF020 / LBF060 Rapid Biological Indicator, when used with an automatic reader (incubation temperature 54-60°C), provides a fluorescence test result in a short period (LBF020-20 minutes; LBF060-60 minutes) with an accuracy of $\geq 97\%$. As an option the user can continue the incubation for 48 hours in order to confirm visually the stability or color change of the culture medium.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a horizontal position with representative materials which is representative of the load.

3. Place the BI in the most challenging area of the sterilizer and run the sterilization program as usual.

4. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load and press down the cap to seal the vent hole.

5. After exposure to FORM, the chemical indicator strip changes from red to green. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; green does not indicate successful sterilization.

6. Recheck each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

Dispose of any questionable units. Results obtained from damaged units should be considered suspect.

7. Place the BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.

8. After a certain incubation time (LBF020-20 minutes; LBF060-60 minutes), the automatic reader will display the fluorescence test result. The automatic reader displays "—" indicating a negative result for the BI, and "+" indicates a positive result for the BI. If necessary, continue to incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

INDICATIONS FOR USE

The LBF020 / LBF060 is utilized to monitor the Formaldehyde Sterilization Processes.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^6$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	60 °C \pm 0.5 °C , Form 1.0 \pm 0.01 mol/L, D value: ≥ 6 min.
Dimensions	10.9 mm (cap diameter), 8.6 mm (pipe diameter), 57 mm (height)

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 24 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBF BIs from the box, reseal the box, and check each BI for:

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.

ISO 11138-5:2017 Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes.

BI Premarket Notification [510(k)], Submissions, issued October 4, 2007

ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive (automatic reader displays "+"). If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBF BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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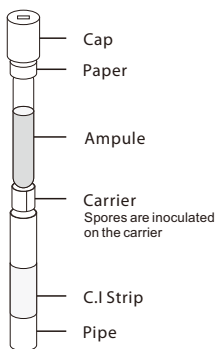


BIOLOGICAL INDICATORS FOR LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZATION PROCESSES



TYPE: LBF144/LBF288

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 with a population level of $\geq 10^5$ is located at the bottom closed end of the pipe.

The LBF144 / LBF288 Biological Indicator, when used with an incubator (incubation temperature 54-60°C), provides a test result in a short period (LBF144-24 hours; LBF288-48 hours) with an accuracy of $\geq 97\%$.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

INDICATIONS FOR USE

The LBF144 / LBF288 is utilized to monitor the Formaldehyde Sterilization Processes.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^5$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	60 °C \pm 0.5 °C, Form 1.0 \pm 0.01 mol/L, D value: ≥ 6 min.
Dimensions	10.9 mm (cap diameter), 8.8 mm (pipe diameter), 46 mm (height)

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 36 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBF BIs from the box, reseal the box, and check each BI for:
 - Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI in a horizontal position with representative materials which is representative of the load.

3. Place the BI in the most challenging area of the sterilizer and run the sterilization program as usual.

4. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load and press down the cap to seal the vent hole.

5. After exposure to FORM, the chemical indicator strip changes from red to green. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; green does not indicate successful sterilization.

6. Recheck each BI for:

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

Dispose of any questionable units. Results obtained from damaged units should be considered suspect.

7. Place the BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.

8. Incubate for 24 hours (LBF144) or 48 hours (LBF288) to observe the biological culture results. If the color of the culture medium changes from purple to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (purple), the BI is negative.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.

ISO 11138-5:2017 Sterilization of health care products-Biological indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes.

BI Premarket Notification [510(k)], Submissions, issued October 4, 2007

ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive (automatic reader displays "+"). If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBF BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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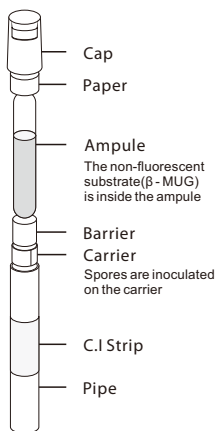


SUPER RAPID BIOLOGICAL INDICATORS FOR ETHYLENE OXIDE STERILIZATION PROCESSES



TYPE: LBE180

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators for monitoring ethylene oxide sterilization consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator and fluorogenic substrates. The modified culture medium will change from the initial Blue color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Bacillus atrophaeus* ATCC 9372 with a population level of $\geq 10^6$ is located at the bottom closed end of the pipe.

A barrier is positioned like a plug between the carrier and the ampule. The LBE180 Rapid Biological Indicator, when used with an automatic reader (incubation temperature 35-39°C), provides a fluorescence test result in a short period (LBE180-180 minutes) with an accuracy of $\geq 97\%$. As an option the user can continue the incubation for 48 hours in order to confirm visually the stability or color change of the culture medium.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

- Missing or damaged components including cap, cap filter, spore strip, medium ampule and plastic pipe. Dispose of any damaged or questionable units.

2. Identify the BIs by labeling with process information, place the BI inside representative materials to be sterilized or within the chamber directly.

3. Place this test packages in the most challenging area of the sterilizer and run the sterilization program as usual.

4. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load and press down the cap to seal the vent hole.

5. After exposure to EO, the chemical indicator strip changes from pink to brown. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; brown does not indicate successful sterilization.

6. Recheck each BI for:
- Indication of a damaged ampule including low medium fill volume, wet or dried medium inside pipe, spore strip appearing wet or discolored.

Dispose of any questionable units. Results obtained from damaged units should be considered suspect.

7. Place the BI in an upright position, compress the plastic pipe in the crushing cavity of the reader to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.

8. After a certain incubation time (LBE180-180 minutes), the automatic reader will display the fluorescence test result. The automatic reader displays "—", indicating a negative result for the BI, and "+ " indicates a positive result for the BI. If necessary, continue to incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from blue to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (blue), the BI is negative.

INDICATIONS FOR USE

The LBE180 is utilized to monitor ethylene oxide sterilization.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^6$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product
Resistance	54°C, 100% EO gas 600 mg/L \pm 30 mg/L, RH 60% \pm 10%. D value \geq 2.0 min
Dimensions	10.9 mm (cap diameter), 8.6 mm (pipe diameter), 57 mm (height)

STORAGE AND SHELF LIFE

1. Store at room temperature.
2. Keep away from sunlight, Protect from sterilizing agent and radioactive sources, Do not dry.
3. Shelf life: 24 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove an appropriate number of LBE BIs from the box, reseal the box, and check each BI for:

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.

ISO 11138-2:2017 Sterilization of health care products-Biological indicators-Part 2: Biological indicators for ethylene oxide sterilization processes.

ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.

ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive (automatic reader displays "+"). If the Positive Control as does not show signs of growth, consider the test invalid.

Short excursions outside the range of temperature recommended will not impact the performance of the LBE BIs.

Do not use after the expiration date. Do not refrigerate.

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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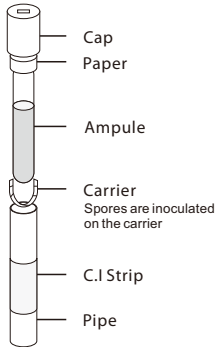


BIOLOGICAL INDICATORS FOR ETHYLENE OXIDE STERILIZATION PROCESSES



TYPE: LBE288

VERSION: 2024.06.28



PRODUCT DESCRIPTION

Self-Contained Biological Indicators for monitoring ethylene oxide sterilization consist of:

A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution.

A crushable media ampule which contains modified culture medium with a pH indicator. The modified culture medium will change from the initial Blue color to Yellow in the presence of bacterial growth.

An inoculated carrier of *Bacillus atrophaeus* ATCC 9372 with a population level of $\geq 10^6$ is located at the bottom closed end of the pipe.

The Biological Indicator, when used with an incubator (incubation temperature 35-39°C), provides a biological culture result after 48 hours.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.

2. Keep away from sunlight, Keep Dry, Protect from sterilizing agent and radioactive sources.
3. Shelf life: 36 months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Place BIs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized or within the chamber directly. Package or wrap product as usual, if applicable.
2. Locate the test packages or BIs in areas most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.
3. After sterilization is complete, remove from the sterilizer and retrieve the BIs from the test load.
4. After exposure to EO, the chemical indicator strip changes from pink to brown. The purpose of the chemical indicator strip is to distinguish whether the BI has been used; brown does not indicate successful sterilization.
5. Place the BI in an upright position, compress the plastic pipe in the crushing device to break the glass ampule. Confirm that the spore strip at the bottom of the BI is fully saturated with the culture medium; Be careful not to let the culture medium come into contact with the filter paper on the cap and incubate the indicator in the automatic reader. Use an unsterilized BI at least once per day or at every new batch of indicators and process it as above as a positive control tube.
6. Incubate for 48 hours to observe the biological culture results. If the color of the culture medium changes from blue to yellow, it indicates a positive result. If the color of the culture medium remains unchanged (blue), the BI is negative.

INDICATIONS FOR USE

The Self - Contained Biological Indicators are utilized to monitor EO sterilization process efficacy.

PERFORMANCE CHARACTERISTICS

Population	$\geq 1.0 \times 10^6$ per carrier
RIT	$\geq 97\%$
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Resistance	D value at 54 °C ± 1 °C, 60% RH $\pm 10\%$ RH, 600 mg/L ± 30 mg/L ≥ 2.0 mins The EO D value range is based on the requirements outlined in the ISO 11138-2. The EO D value is determined using 100% EO.
Dimensions	10.9 mm (cap diameter), 8.8 mm (pipe diameter), 46 mm (height)

MONITORING FREQUENCY

For greatest control of sterilized goods it is recommended that a minimum of ten (10) BIs be included with every load.

STORAGE AND SHELF LIFE

1. 10°C to 30°C, 30% to 80% Relative Humidity.

COMPLIANCE

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.
ISO 11138-2:2017 Sterilization of health care products-Biological indicators-Part 2: Biological indicators for ethylene oxide sterilization processes.
ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.
ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

NOTE

The Positive Control BI should show positive. If the Positive Control as does not show signs of growth, consider the test invalid.
Short excursions outside the range of temperature recommended will not impact the performance of the BIs.
Do not use after the expiration date. Do not refrigerate.
Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.
If the incubation time exceeds 48 hours, ensure that the culture solution does not evaporate by sealing the holes on the cap.



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