What to do if a processed Biological Indicator (BI) shows a positive fluorescence result?





Regarding the load

Do not release the load. Follow your institution's policies and applicable standards, such as ANSI/AAMI ST79, which recommends initiating a recall of items processed since the last known negative BI result, especially when implants are involved.



Regarding the sterilizer

Keep the sterilizer out of service until the cause has been identified and corrected, and satisfactory results are obtained from a new BI test.

Fluorescence reading is the result.
A positive fluorescence result is a positive result. Do not wait for visual confirmation. Take immediate action.

Investigate the cause

Review these four areas with the sterilization team and document your findings.

Sterilization cycle

- Review the display and printout: the cycle must be complete, with no interruptions or alarms.
- Compare cycle parameters with those validated for use with the BI: temperature, pressure, exposure time, humidity (EO), or sterilant concentration (EO, H_2O_2, LTSF).
- Verify that the chemical indicators in the load have changed color as expected.

Sterilizer and sterilant

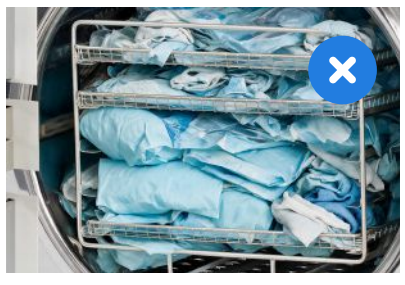
- Perform a Bowie-Dick test (pre-vacuum steam) and leak test; compare results with previous records.
- Review calibration records and the chamber temperature profile.
- Ensure steam traps and filters are clean, and verify steam quality to rule out water carryover or superheating (steam, LTSF).
- Verify that the sterilant is within its shelf life and that the container indicator shows its initial color (EO, H_2O_2, LTSF).

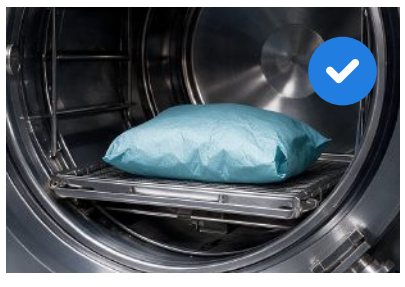
BI and auto-reader

- Run a positive control from the same lot; it must yield a positive result.
- Verify that the BI is within its shelf life, has been stored according to the label instructions, and that the chemical indicator on the label has changed color as expected.
- Ensure the time between processing and activation is within the limit specified in the IFU, with the ampoule intact and the cap lowered.
- Select the correct reading program before crushing the ampoule.
- If a PCD was used, verify that it has been validated by Terragene.

Load and packaging

- Ensure packaging is compatible with the process and packages are assembled correctly.
- Avoid overloading: the load volume must not exceed the sterilizer manufacturer's recommendations.
- Verify that the load and BI are positioned according to standard procedures.





Before using the sterilizer again

1. 
   Correct the identified cause.
2. 
   Repeat the BI test, including the positive control from the same lot.
3. 
   Return the sterilizer to service only after satisfactory results are obtained, and document the investigation.

Best practices for reliable readings

- Activate the BI only after 10 minutes have elapsed and the auto-reader is available.
- Use the recommended ampoule crusher and shake the BI to ensure the growth medium comes into contact with the spores.
- Do not remove the BI before the result is obtained or re-incubate it for a second rapid reading.
- Keep the auto-reader firmware up to date using the BioUpdate tool.

Optional verification

Extended incubation may be performed as an additional verification of the fluorescence reading, in accordance with the IFU. It does not change the actions required for the load or the sterilizer based on the fluorescence result.



Technical Support

Contact Terragene at customer.service@terragene.com or visit terragene.com/customer-services/.

IMPORTANT: This guide provides general information about product use but does not replace the official Instructions for Use (IFU) or packaging labels. Always read and follow the complete instructions, warnings, and safety guidelines provided with the product.

Other Useful Resources

Visit our YouTube channel to learn more about how to use our products.

Scan to discover all our solutions