POTENTIAL CAUSES OF A POSITIVE BIOLOGICAL INDICATOR

In the event of a positive BI, it must be assumed that the cycle load was not sterilized, and that the sterilizer has malfunctioned, until a full investigation has proven otherwise. Immediate steps must be taken to take the sterilizer out of service, quarantine the cycle load and begin look-back procedures.

A single positive BI (i.e. failed spore test) does not necessarily indicate sterilizer malfunction, especially if all other process indicators demonstrate sterilizer effectiveness. The most common cause of a positive BI is operator error.

Monitoring of physical indicators involves checking the gauges, displays or printouts of the sterilizer for cycle time, temperature and pressure, which must be documented. Since these physical parameters can be observed during the sterilization cycle, they may be the first indication of a problem.

COMMON OPERATOR ERRORS	OBSERVATION
Overloading the sterilizer	Most common cause: overloading increases the heat-up time and prevents penetration of the sterilizing agent to the center of the sterilizer load
Incorrect packaging	Too densely packed
Incorrect loading	• Heavier packages not on the bottom • Inadequate space between peel pouches to allow for expansion of steam • Plastic side of pouches not facing one direction • Stacking trays on top of each other impedes air removal and sterilant
Using pouches that are too small	Prevents adequate air removal and penetration of the sterilant
Using excessively large packaging	Obstructs the penetration of moisture and steam sterilant
Mixing multiple complex products within the same sterilizer load	Prevents penetration of steam into complex items (e.g. hollow areas)

COMMON OPERATOR ERRORS	OBSERVATION
Inadequate exposure time	Incorrect exposure time chosen or interruption in the cycle
Choosing the incorrect cycle load parameters	Example - running an unwrapped cycle for a wrapped load. Follow manufacturers' instructions for use (MIFU)
Failure to preheat the sterilizer (if indicated)	An initial 5-minute cycle (if as per usual MIFU) helps to get rid of any air pockets in the sterilizer jacket. An improperly heated sterilizer could yield a false Bowie-Dick test failure
Interruption of the cycle (electrical or other)	Ensure electrical cord is not damaged and is fully seated in the outlet. A circuit break could also be the cause
Distilled water not used	Impurities in tap water can damage gaskets and cause poor quality steam
Chamber drain strainer not kept clean	Strainer may be clogged
Unwanted condensation	Condensation can get trapped in the jacket of the autoclave, leading to cold spots at the base of the autoclave. Check the steam traps on the autoclave
Load directly covering the chamber drain port	Impedes air removal and prevents steam penetration
Failure to ensure that vacuum pulses were working by checking the printer readouts	Checking physical monitors allows for checking functionality before running the full cycle
Failure to check that cycle time, temperature and pressure reached the parameters recommended by the sterilizer manufacturer	Check functionality before running the cycle The temperature is taken at one location in the sterilizer, but that same temperature may not have been achieved throughout the sterilizer chamber or inside all the packs in the load. To know whether steam penetrated to the inside of the packs, you rely on the internal CI
Peel pouches not stored in a cool dry place	Heat and moisture can compromise the CI (i.e. become defective)
Confusing the BI test strip with the control strip	Control strip should always be positive
Expired BI lot number	Can cause an invalid result
Misinterpretation of the BI test result	BI was read incorrectly

COMMON OPERATOR ERRORS	OBSERVATION
Incorrectly placing the BI PCD in the load	E.g. an additional pack was placed on the PCD
Choosing the incorrect BI PCD for the load	Does not emulate the current load conditions
Failing to crush the BI test vial before placing in the incubator	Invalidates the test
BI not incubated at the proper temperature and for the appropriate time	Invalidates the test
COMMON EQUIPMENT ERRORS	**OBSERVATION**
Leaking of air or steam	Verify you had proper air removal by re-checking the daily Bowie-Dick test cycle Spores and bacteria can survive at 134°C (273°F) in air pockets
Inadequate time at required sustained temperature	Out-of-calibration temperature gauge, clogged chamber drain Ensure the distilled water tank is not empty Check for a leak
General mechanical breakdown: • gasket seal is broken • out-of-calibration pressure gauges and controllers • plugged or faulty control valves • variations in steam pressure due to clogged filters	Ensure regular schedule of preventive maintenance including software upgrades