

Instructions for Validation of Autoclaves

- A. Validation of autoclaves may be accomplished by the following methods:
1. Autoclave tape applied to the outside of all packs to validate that the correct temperature was reached within the autoclave.*
 2. OK Sterilization Monitor Strips with standard reference color placed into each double wrapped pack for validation of sterilization. Reliable white to black pressure steam reactive ink indicates complete penetration of the pack by pure steam pressure.*
 3. Items autoclaved in sterilization pouches utilize the color indicators located on the pouch to verify that the appropriate temperature has been achieved.
 4. Autoclaves validated each quarter using the Steris method of verification.**
 5. Autoclaves with a pre-vacuum stage validated each quarter using the Daily Air Removal Test (DART®).
 6. Packs with indicators that fail to change color should be re-packed and autoclaved again. If the pack continues to fail to sterilize or any validation method fails a repeat test, the autoclaved should be serviced.
- B. Instructions for use of the Steris Biological Indicators
1. Remove the appropriate number of Verify biological/chemical indicators.
 2. Label the indicators according to the cycles on the autoclave. **Always** run a control specimen (specimen not autoclaved). This allows for visualizing the actual color change processes that take place.
 3. Place one or more indicators in autoclave and run on selected cycles
 4. After sterilization is complete, allow indicators a few minutes to cool. Observe the chemical process exposure indicator on the outside of each vial. Steam should turn the indicator to brown. If the chemical process indicator is unchanged, sterilization may not have occurred.
 5. If the proper color change did occur, place the indicator in the Verify activator and seal. The indicator is properly sealed when the cap is pushed down to the second black bar on the label.

Note: If the verify indicator is not going to be incubated immediately, it is recommended that it not be activated, but kept in a sealed condition at room temperature for up to 2 hours.

6. To activate, push or pull the indicator completely through the restricted space on the activator. The indicator is properly activated when the growth medium is released from the crushed ampule and is in contact with the spore disk.
7. Place activated indicators in the incubator (Precision, Thelco model 6) on the 5th floor (N548). The temperature of the incubator should be between 55-59°C.
8. Check indicators the morning after and at 24 hours for steam test results. Indicators positive for growth will often be evident prior to recommended incubation time. If the test indicators begin to show turbidity and/or a color change from deep blue to bright yellow, sterility has not been achieved. If sterility has been achieved, the test indicator will show neither color change nor turbidity. Thus, the growth medium will remain deep blue.
9. Record results as pass or fail on the autoclave validation log located in the validation notebook. Initial and date the surgery maintenance log sheet, and dispose of processed indicators in red biohazard barrels.
10. If the autoclave/sterilization process has failed the validation test, repeat the test within 24 hours. If a second failure occurs, immediate service of the unit is required. For more information, see package insert of Steris Indicators.

- C. Instructions for use of the Daily Air Removal Test (DART®)
1. If the sterilizer is not already at operating temperature, bring the unit up to operating conditions (270°F-274°F) by running a preliminary non-processing cycle.
 2. Place or hang DART® so that it is oriented as low as possible directly over the drain opening in an empty chamber.
 3. Operate a standard pre-vacuum cycle (270°F) with exposure time set for between 3.5 and 4.0 minutes. **FOR BEST RESULTS EXPOSURE TIMES SHOULD NOT EXCEED 4 MINUTES; DRYING TIMES DO NOT AFFECT RESULTS.**
 4. After completion of the test cycle, place the indicator window on a flat surface so the tube section overhangs. Vertically flex the tube portion so the window cracks at the breakaway point. Remove the indicator strip from the window. Discard the empty window and tube.
 5. Interpret the results as follows:
 - i. **Pass**- Indicated by a uniform black color on the indicator bars.
 - ii. **Fail**- Indicated by a color response other than black; **dark brown, light brown or the original yellow color is unacceptable.**
NOTE: If the first test fails, the sterilizer can still be qualified by generating two consecutive acceptable results. Check the recording chart to insure that the cycle parameters have been met. If unacceptable results are indicated from Test #2 or #3, it is recommended that the sterilizer not be used in the vacuum mode until it has been serviced and requalified.
 6. After interpreting the result, record the result as pass or fail on the autoclave Validation log.

*can only verify that autoclave has reached normal operating temperatures for decontamination, but cannot measure the length of time spent at the temperature.

**verifies that autoclave reached adequate temperatures for long enough to kill microorganisms.

Autoclave Validation Results Log (Quarterly)

Department: _____ Room #: _____

Autoclave Model: _____

Contact person: _____

Biological Indicator Validation

Person conducting test	Date of Autoclaving and Incubation	Cycle Selected and Temperature	Cycle Time	Incubation Time (Hours)	Lot Number and Expiration Date	Results Pass or Fail

DART® Validation

Person conducting test	Date of Test	Results Pass or Fail	Attach Test Strip here

OK Sterilization Monitor Strips



JA Wester – www.jawebster.com product # 07-8089871

https://www1.fishersci.com/wps/portal/PRODUCTDETAIL?productId=641913&catalogId=29103&pos=20&catCode=HC_SC&fromCat=yes&keepSessionSearchOutPut=true&brCategoryId=57689&hlpi=false&fromSearch=

Products available for purchase through Steris – www.steris.com

Verify® Self-Contained Biological Indicators



Verify Self-Contained Biological Indicators (SCBIs) are for use in monitoring steam sterilization (250°F (121°C) gravity, 270°F (132°C) prevacuum, 270°F (132°C) gravity flash) and ethylene oxide (EO) sterilization processes. Each SCBI is completely self-contained within a vial and contains a disc inoculated with dual spore species (*Geobacillus stearothermophilus* and *Bacillus atrophaeus*) and an ampule of specially formulated soybean casein digest growth medium with a pH indicator. The vial label contains a process indicator for steam and EO.

- 24-hour final results for steam sterilization
- 48-hour final results for EO sterilization
- Sturdy design prevents premature activation
- Steam and EO chemical indicators on every vial
- Easy to read blue to yellow color change indicates growth

Product Number	Description	Quantity
S3061	Verify Self-Contained Biological Indicator	Box (50 SCBIs)
S3075	Vial Activator Set	Each

Dart® Daily Air Removal Test



The Dart Daily Air Removal Test is an easy and accurate way to test air removal and steam penetration in prevacuum steam sterilizers.

This easy to use product is a light weight, compact, one piece system that is pre-assembled and ready for use. It eliminates the need to spend time folding towels and preparing packs necessary for traditional Bowie Dick Test Packs.

- Results are immediately visible and easy to read through the clear vial.
- The indicator strip is easy to retrieve and can be stored as a permanent record.
- Most important, the Dart Daily Air Removal Test is reproducible. The inconsistencies associated with traditional Bowie Dick Test Packs are eliminated.

Dart Daily Air Removal Test –an innovative concept for evaluating air removal efficacy in prevacuum steam sterilizers that is only from STERIS Corporation.

Product Number	Description	Quantity
NB215	Dart Daily Air Removal Test Pack	Pack (10 tests)
NB113	Dart Daily Air Removal Test Case	Case (10 packs)
NB224	Dart Record Forms Box	Box (100 sheets)