

In-Office Biological Monitoring of Table-top Steam Sterilizers

Processing

- Record the sterilizer number, load number, and processing date on the BI label. Per CDC dental guidelines, steam sterilizers should be BI tested at least weekly, and every load that contains an implant.



- Place the BI inside a sterilization self-seal pouch, or wrapped cassette, whichever is representative of the load being routinely processed. Include a SteamPlus™ Integrating Indicator to create a process challenge device test pack (PCD). Label the PCD with the sterilizer number, load number, date, and "PCD." For pouches, write on the plastic side only. Pictured is an example of a pouch PCD.



- Place the PCD in the most challenging area of chamber (i.e. The bottom shelf near the door over the drain for large sterilizers; center of the load and towards the front for table-top units). Run the PCD in a chamber that is loaded with instruments to be processed.



- Process the load using your normal instrument cycle selection.



- Allow the load to cool to room temperature before removing and opening the PCD. Confirm that the external process indicators have changed color (pouch or indicator tape). Remove the BI and confirm that the process indicator stripe on the label has turned from blue to brown. Report any failed results immediately to a supervisor.



- Remove the SteamPlus™ Integrating Indicator and confirm that the dark bar has fully entered the SAFE area. SAFE area indicates parameters for sterilization have been met and the load can be released (except for implants). If the dark bar has not entered the SAFE area, do not release the load and report failed results immediately to a supervisor.



Activation and Incubation

- Activate the test BI within 8 hours of processing. Be sure to wear safety glasses when handling and crushing the BI. Carefully crush the inner media tube using the built-in incubator crusher or separate crusher. Select another unprocessed BI from the same lot number for use as the control. Label it with the date and the letter "C", and crush it.

- Incubate the test and control BIs together at 55° to 60°C for the time indicated (check IFU). Check the test BI for spore growth (visual color change from purple to yellow) at regular intervals (i.e. 3, 5 and 8 hours).



Test Results

- Observe the color of the test BI after full incubation. If the BI is purple (-), proper sterilization has occurred and the test passed. If the test BI is yellow (+), the spores survived and the test failed. Report failed results immediately to a supervisor.



Use of Controls

- Observe the color of the control (unprocessed) BI after full incubation. If the control BI is yellow (+), the control test passed showing the spores are viable. If the control BI is purple (-), it indicates the spores are non-viable and the control test failed. Report failed results immediately to a supervisor.

Record Results

- Record sterilization results into a record keeping notebook and retain according to timeline policy established by the facility. Enter test date, sterilizer number, load number, and incubation date.



Ordering Information

Ref. #	Description	Quantity
CBMS10	ConFirm™ 24 Starter Kit (24hr) (25 BIs, Incubator, Record Keeper)	Each
CSBI25	ConFirm™ 24 Biological Indicators (24hr)	25/Box
C10SK	ConFirm™ 10 Starter Kit (Incubator, Record Keeper)	Each
C10BI25	ConFirm™ 10 Biological Indicators (10hr)	25/Box
SSI-100	SteamPlus™ Integrating Indicator 4 in x 0.75 in Strip (10.2 cm x 1.9 cm)	100/Pack
SSI-1000	SteamPlus™ Integrating Indicator 4 in x 0.75 in Strip (10.2 cm x 1.9 cm)	1000/Pack

Ref. #	Description	Quantity
NDB-601	55°-60° C Dry Block Incubator w/Crusher* with Record Notebook	Each
STLF18mm	Lead-free Steam Indicator Tape* 0.75 in x 60 yd (18mm x 55mm) (also available in 24mm width)	Each
SCS	Duo-Check™ Sterilization Pouch With Type 1 Process Indicators 3.5 in x 9 in (other sizes available)	200/Pack
SCS2	Sure-Check™ Sterilization Pouch With Type 4 Process Indicators 3.5 in x 9 in (other sizes available)	200/Pack
CRK02	ConFirm™ Record Keeper	Each

*Dry Block Incubator made in China
*Lead-free Steam Indicator Tape made in Canada

Storage & Disposal of BIs

- Store at controlled room temperature as defined by USP.
- Do not store near sterilants or other chemicals. Do not refrigerate.
- Do not use beyond stated shelf-life which is indicated on each box.
- Negative (no growth) BIs can be disposed of as normal waste; however, positive BIs (growth) should be autoclaved at 250°F/121°C for at least 30 minutes prior to disposal.

For more information call us at (800) 722-1529, or visit us at HuFriedyGroup.com.

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