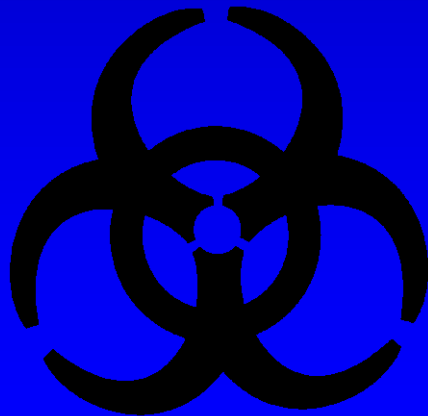


Process Control Devices For autoclaves

in Collaboration with
Al-Essa Medical & Scientific Equipment Co. W.L.L



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Brief report

The use of a process challenge device in dental office gravity displacement tabletop sterilizers



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Key Words:

Sterility assurance
Biological indicator
Process challenge device
Dental instrument sterilization
Chemical indicators

There is evidence that dental office sterilizers often fail to pass the challenge of a biological indicator test. The use of a class 5 integrating indicator in each load could reduce the risk of instruments being released when all parameters for sterilization have not been met.

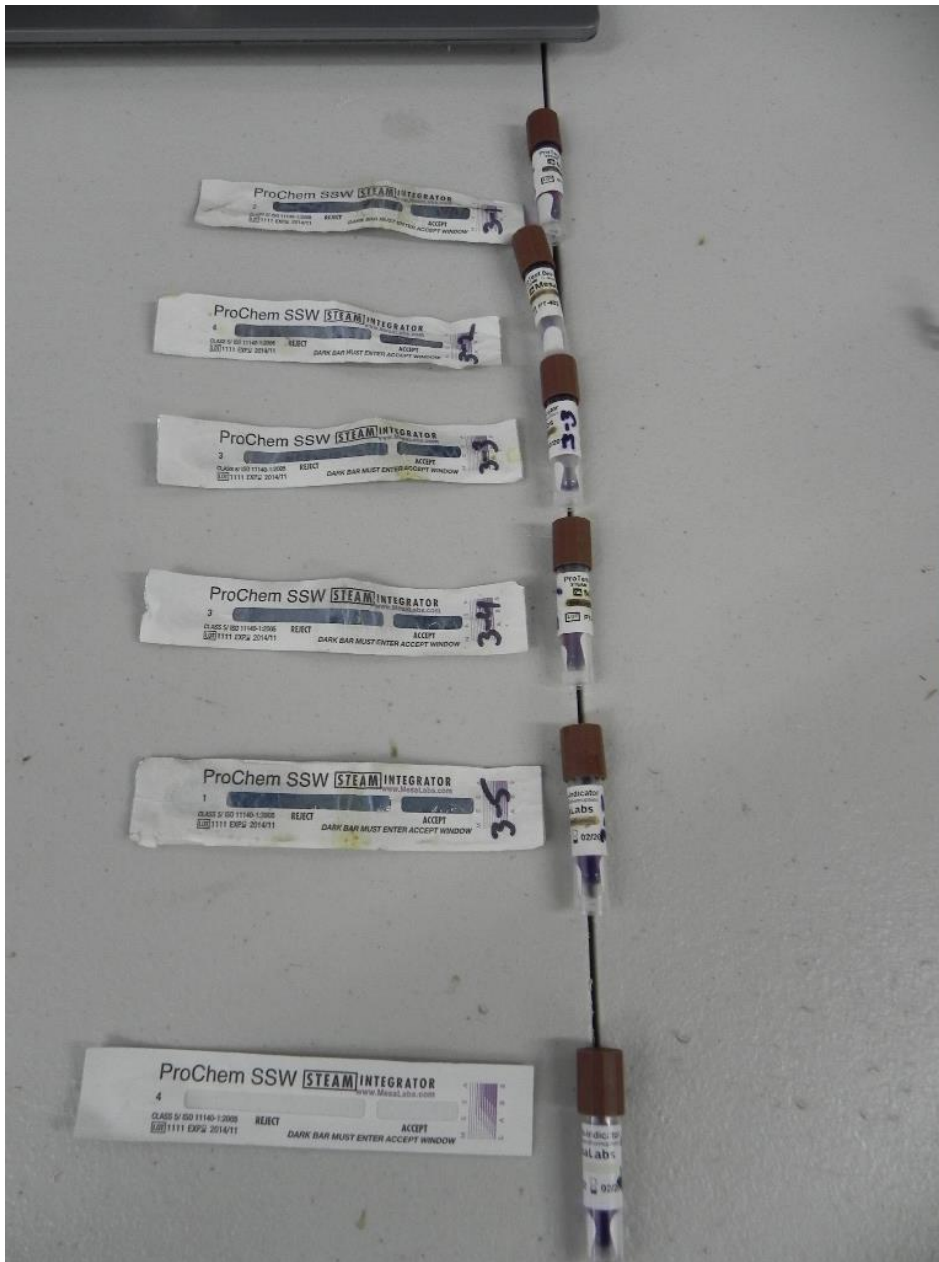
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Table 2
CI types

Class	Type	Performance requirements
1	Process indicators	Intended for use with individual units (eg, packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. These indicators are also referred to as external CIs.
2	Indicators for use in specific tests	Intended for use in specific test procedures (eg, Bowie-Dick test) as defined in relevant sterilizer/sterilization standards. See 10.7.6 for recommendations on the use of these indicators. See also ANSI/AAMI/ISO 11140-5, Sterilization of health care products—chemical indicators, part 5: class 2 indicators for Bowie-Dick air removal test sheets and packs.
3	Single-variable indicators	Designed to react to 1 of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.
4	Multivariable indicators	Designed to react to 2 or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.
5	Integrating indicators	Designed to react to all critical variables, with the stated values generated to be equivalent to or exceed the performance requirements given in the ISO 11138 series for BIs.
6	Emulating indicators	Chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values generated from the critical variables of the specific sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.


NOTE: Food and Drug Administration recognition of chemical indicators is limited to class 1 process indicators, class 2 indicators for use with special tests, and CIs with resistance characteristics consistent with the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators, issued December 19, 2003.

Adapted from ANSI/AAMI ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities, Association for the Advancement of Medical Instrumentation, 2013.



Class 5 Integrators


UNEXPOSED



ProChem SSE Emulator
STEAM 135°C (275°F) - 3.5 MIN CLASS 6
132°C (270°F) - 4 MIN
GREEN = PASS [LOT] 000001

A purple progress bar is shown at the bottom of the label, which is nearly full, indicating that the emulators have not been exposed to steam.


FAIL



ProChem SSE Emulator
STEAM 135°C (275°F) - 3.5 MIN CLASS 6
132°C (270°F) - 4 MIN
GREEN = PASS [LOT] 000001

A purple progress bar is shown at the bottom of the label, which is nearly full, indicating that the emulators have not been exposed to steam.


FAIL



ProChem SSE Emulator
STEAM 135°C (275°F) - 3.5 MIN CLASS 6
132°C (270°F) - 4 MIN
GREEN = PASS [LOT] 000001

A purple progress bar is shown at the bottom of the label, which is nearly full, indicating that the emulators have not been exposed to steam.

PASS



ProChem SSE Emulator
STEAM 135°C (275°F) - 3.5 MIN CLASS 6
132°C (270°F) - 4 MIN
GREEN = PASS [LOT] 000001

A green progress bar is shown at the bottom of the label, which is nearly full, indicating that the emulators have been successfully exposed to steam.


Class 6
Emulators



3M
Attest™
Steam Pack

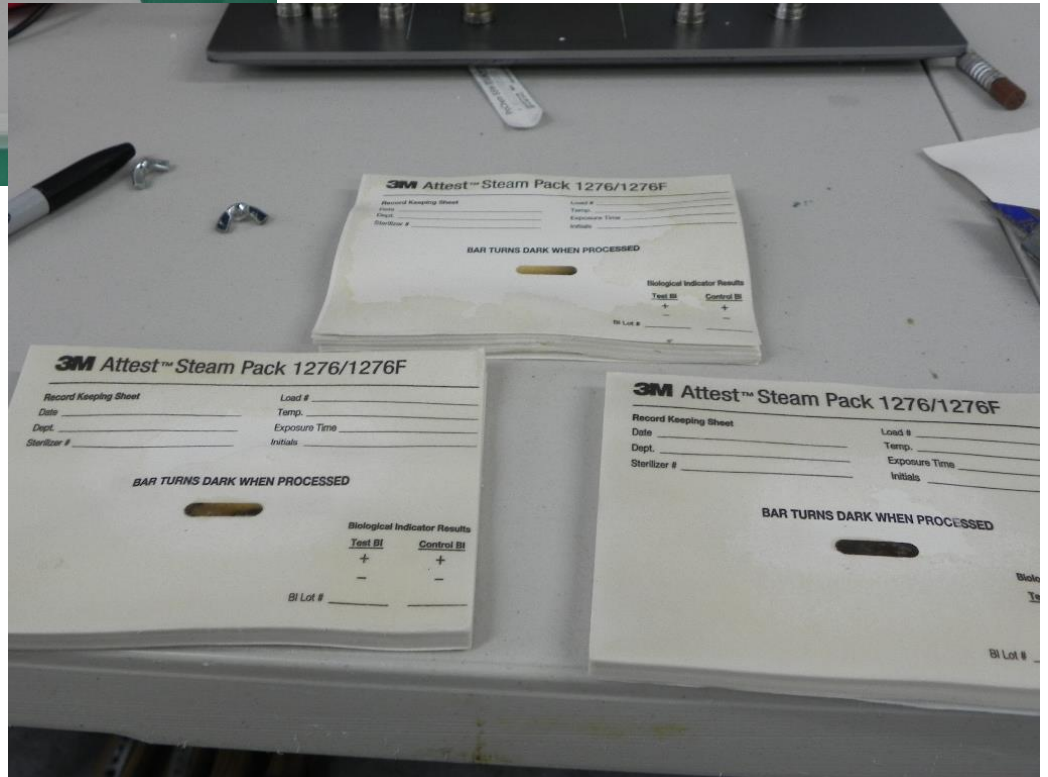
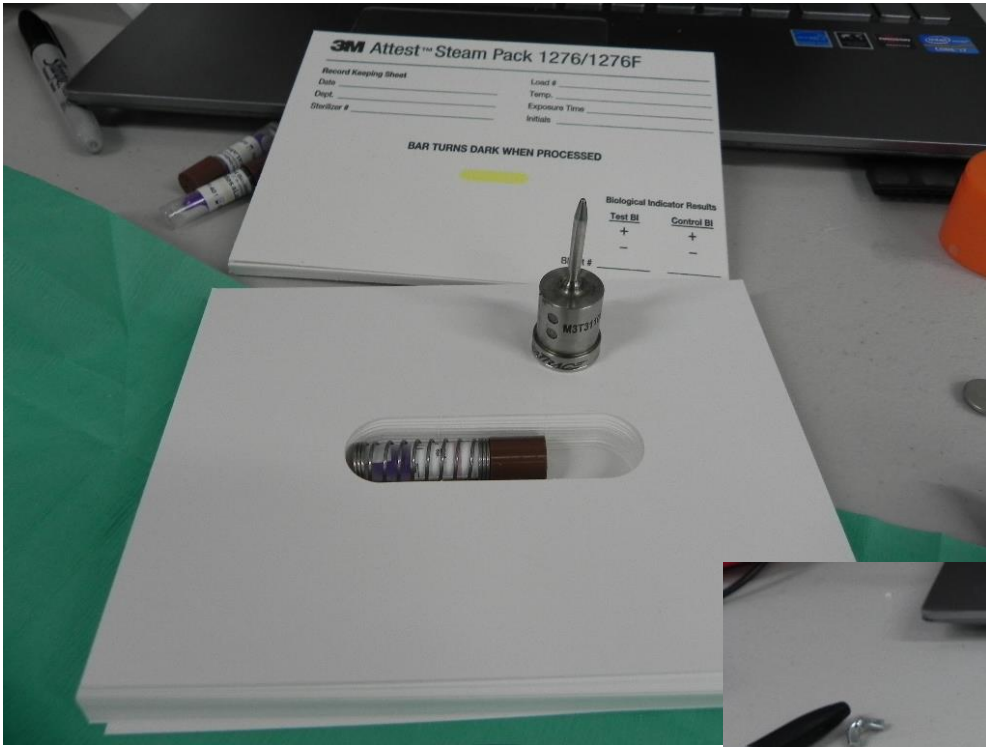


This Side Up in Sterilizer

 **2016-04Jl**

U.S. Patent No. 4,636,472
and foreign counterparts.

1276





Process Control Device

Future Health Systems Unit 2 Run 2

Thermal Mapping/Microbiological PCD Efficacy Test February 4 2014

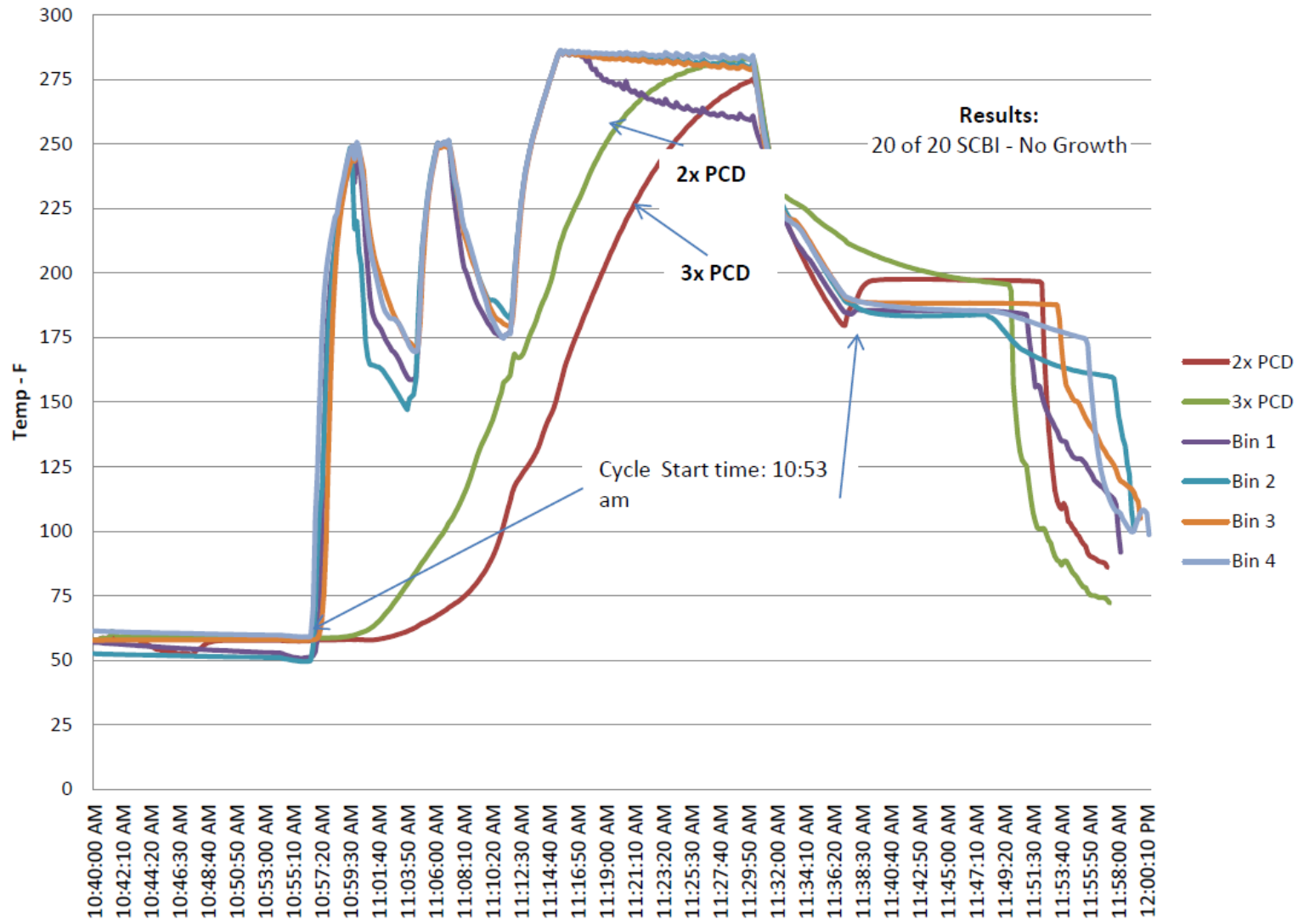




Photo 22- Bin 1 Run 2 Pretreatment



Photo 23 - Bin 2 Run 2 Pretreatment



Photo 24 - Bin 3 Run 2 Pretreatment



Photo 25 - Bin 4 Run 2 Pretreatment





