# Standard Operating Procedure

## Steam Sterilizer Daily Routine Biological Monitoring

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### OBJECTIVES

To provide guidelines for Medical Device Reprocessing staff for the use of Biological Indicators (BI) for the daily routine quality assurance testing of sterilizers.

### APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

**Note**: Site specific procedures shall be developed and followed based on the specific equipment that is used.

### ELEMENTS

1. Routine biological monitoring shall be done

    1.1 Routine biological monitoring with the use of a Process Challenging Device (PCD) shall be done daily in the first load of the day. A biological indicator contained within a PCD shall be used to test the sterilizer for each type of cycle used (e.g. prevaccum, gravity) and at the shortest exposure time, according to the sterilizer manufacturer's recommendations.

2. Materials required

    2.1 Site specific process challenging device (PCD) compatible with the type of sterilizer and cycle being tested.

3. Procedure

    3.1 Each day a processed BI is incubated, activate and incubate one non processed BI, referred to as a control. This control BI serves to prove there are viable spores in the BI to be killed and proper functioning of the incubator. The control BI shall be from the same lot number as the processed BI.

    The control BI is to be incubated according to the manufacturer's instructions for use.

    **Note**: Documentation of the control BI test will be done as per site specific documentation requirements.

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3.2 Load sterilizer cart with prepared items according to the correct procedure as per Steam Sterilization Policy.

3.3 Place the BI PCD on the bottom shelf of a loaded sterilizer cart in the spot closest to the sterilizer drain. Run the cycle that needs routine biological testing.

3.4 Once cycle is complete remove the BI PCD and let cool as per manufacturer's instructions for use.

3.5 Incubate the BI as per manufacturer's instructions for use.

3.6 Interpret BI results and document as per site specific documentation requirements. Documentation shall include but is not limited to the following:

- date and time of sterilization;
- sterilizer number and cycle number;
- users identifier (initials, unique ID number).

**Note**: If a positive BI test result is noted, notify direct report immediately. Initiate process for failed BI, see SOP A1.30 Management of Positive Biological Indicator (BI) or failed Sterilization Mode

3.7 Dispose of Control BI and test BI according to MIFU and health care setting's policies and SOP's.

## DEFINITIONS

None

## REFERENCES

- Non-Alberta Health Services documents
  - Canadian Standards Association. (2018). *Canadian medical device reprocessing* (CAN/CSA Z314-18, sections 11, 16, and 4).
  - PCD manufacturer's instructions for use
  - Steam Sterilizer manufacturer's instructions for use
  - BI Incubator manufacturer's instructions for use

## VERSION HISTORY

| Date | Action taken |
|---|---|
| July 2018 | Initial approval |
| March 2020 | Last updated |
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