

Operational Qualification for Autoclave

Approvals:

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Date: 17JAN14

Reviewer: Dr. Maggie Bryans

Date: 18JAN14

1. Purpose:

- 1.1. Proper use of BTSure biological indicators to carry out an operational qualification of an autoclave.

2. Scope:

- 2.1. To validate the ability of a laboratory autoclave to sterilize.

3. Responsibilities:

- 3.1. It is the responsibility of the course instructor/lab assistant to ensure that this SOP is performed as directed and to update the procedure when necessary.
- 3.2. It is the responsibility of the students/technicians to follow the SOP as described and to inform the instructor about any deviations or problems that may occur while performing the procedure.

4. References:

- 4.1. BTSure Biological Indicator manufacturer instructions
- 4.2. Autoclave SOP
- 4.3. Incubator or water bath SOP

5. Definitions: N/A

6. Precautions:

- 6.1. The contents of the BTSure biological indicator is extremely hot and under pressure after autoclaving. It may burst and cause burns. Allow at least 10 minutes to cool before handling it.
- 6.2. Always wear the appropriate personnel protective equipment.

7. Materials:

- 7.1. BTSure biological indicator unit(s)
- 7.2. BTSure crusher
- 7.3. autoclave
- 7.4. incubator (55-60°C) or water bath
- 7.5. small beaker
- 7.6. aluminum foil
- 7.7. permanent marker

8. Procedure:

- 8.1. Remove an appropriate number of BTSure units from the box.
- 8.2. Remove one unit for each area of the autoclave to be tested and one additional unit to be used as a positive control (this one will not be placed in the autoclave).
- 8.3. Label indicators with appropriate information.
- 8.4. Place each unit in a small beaker so that they lay horizontally in the bottom of the beaker. Use a separate beaker for each BTSure unit.
- 8.5. Cover the beakers with aluminum foil. **Note:** If a flash cycle is selected the goods should be unwrapped. If the come up time is less than one minute a three minute exposure cycle may have to be extended to four minutes to ensure the BI is killed.
- 8.6. Place the beakers inside the autoclave except the positive control.

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- 8.6.1. One of the beakers should be situated so that it is directly over or next to the drain. **Note:** The area surrounding the drain is the coolest part of the autoclave and considered to be the least effective area for sterilization.
- 8.7. Operate the autoclave per autoclave SOP.
- 8.8. Remove the beakers from the autoclave. Allow indicators to cool for at least 10 minutes.
- 8.9. Remove the biological indicators from the beakers.
- 8.10. Observe the color change (blue to black) of the chemical indicator on the BTSure Label. **Note:** Color change indicates exposure to steam. It does not indicate acceptable sterilization.
- 8.11. **Incubation**
 - 8.11.1. Place an indicator into the crusher in an upright position and squeeze the crusher to break the glass ampoule. This will allow the strip to be immersed in the media.
 - 8.11.2. Repeat the crushing with each additional indicator including the positive control.
 - 8.11.3. Immediately place the indicators (including the positive control) into the incubator or water bath.
 - 8.11.4. Incubate at 55 to 60°C for at least 48 hours.
- 8.12. **Interpretation**
 - 8.12.1. During the incubation examine the indicators at regular intervals starting approximately at 4 hours, and again at approximately 8, 12, 18, and 24 hours for any change in color. Record results on the Autoclave Monitoring Form.
 - 8.12.1.1. The positive control tube should change from purple media to yellow. If it does not, the study is invalid and needs to be repeated with a new lot of indicators.
 - 8.12.1.2. The sample indicators should not change color. No color change (media remains purple) indicates adequate sterilization.
 - 8.12.1.3. If the sample indicators turn yellow this indicates bacterial growth and an investigation will need to be conducted. This may include re-performing the autoclave cycle.
 - 8.12.2. Report any indication of bacterial growth to instructor or lab manager.
 - 8.12.3. Dispose all used BTSure tubes in a biohazard receptacle when finished.

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9. Attachments:

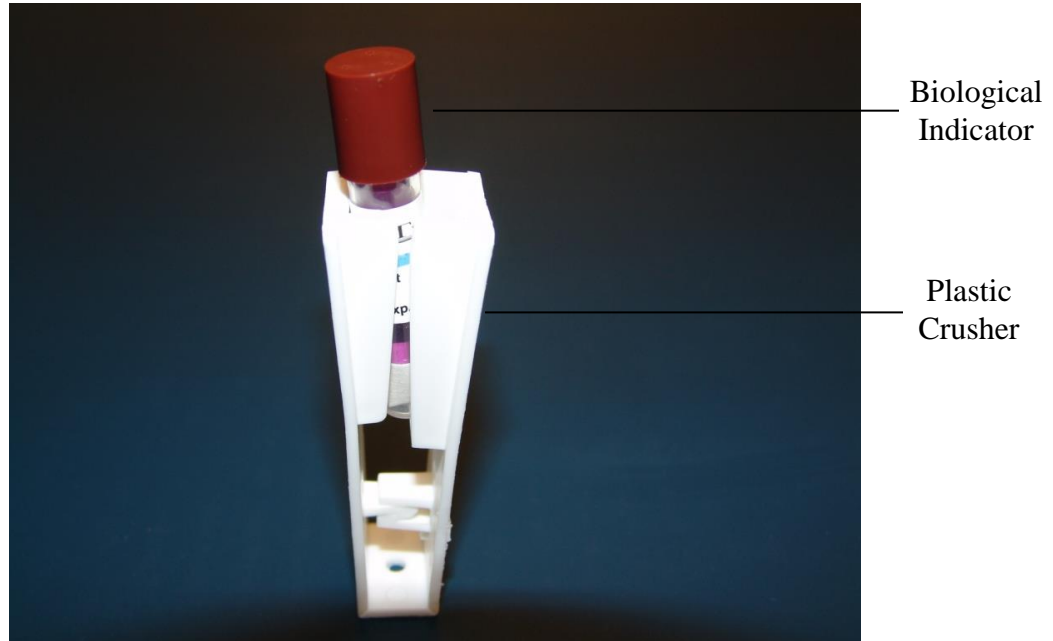


Figure 1: BTSure Biological Indicator in Plastic Crusher

10. History:

| <i>Revision Number</i> | <i>Effective Date</i> | <i>Preparer</i> | <i>Description of Change</i> |
|------------------------|-----------------------|----------------------------|--|
| 0 | 25JAN06 | Hope Townes and Kari Britt | Initial release |
| 1 | 20JUL06 | Bob O'Brien | Added photograph and disposal information. |
| 2 | 20AUG06 | Bob O'Brien | Added interval hours for examination. |
| 3 | 12FEB07 | Bob O'Brien | Updated date format. |
| 4 | 11APR08 | Bob O'Brien | College name change |
| 5 | 15OCT09 | Sonia Wallman | Additional information to purpose and scope. |
| 6 | 10AUG10 | Kari Britt | Added data table. Made formatting edits throughout. |
| 7 | 17JAN14 | Jason McMillan | Additional information to purpose and interpretation, college name change. |