

Vaporized hydrogen peroxide sterilization cycle validation

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Abstract

Sterilization cycle performance are proven adequate during validation and it should be done in accordance to current international standards to guarantee that all critical parameters were met. Low temperature sterilization using vaporized hydrogen peroxide do not have a specific standard published yet and to validate the sterilization cycles from this type of equipment, ISO 14937, the base standard for all sterilization cycle validation, should be followed. This standard uses biological indicator (BI) as an instrument for equipment performance evaluation and its cycle configuration must be according to half cycle approach. Since most of the manufactures do not have this option available for the performance evaluation, cycles will canceled when the half cycle has been reached and the plasma phase concluded, when applicable. Since the US FDA is the only independent organism that has some type of product registration, equipments and self contained BIs that have been approved by them will be used in this study only.

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Guidelines

ISO 14937:2009 should be followed

Before start

Equipment must have been calibrated and passed thru preventive maintenance in the past month. Manufacturer must have concluded equipment installation and operational qualification.

Protocol

Empty cycle performance evaluation for equipments with plasma and 2 diffusion

Step 1.

1. Install a sterilization agent leak monitor on top of the equipment;
2. Place inside of a small tyvek pouch one BI and one chemical indicator (CI)
3. Place three tyvek pouches with BIs and CIs as follows:
 - one right below sterilization agent entrance
 - one in the middle of the chamber

- one in the distal point from sterilization agent entrance
- 4. Select the sterilization cycle that will be evaluated;
- 5. Monitor continuously the cycle;
- 6. When the first plasma phase is finished, after the end of the first diffusion, abort the cycle;
- 7. Open the door right after it is cleared by the equipment control;
- 8. Record the sterilization agent concentration from the monitor;
- 9. Remove the three pouches, taking out the BIs and CIs;
- 10. Incubate the BIs immediately;
- 11. Repeat the procedure two more times.

Empty cycle performance evaluation for equipments without plasma and 4 diffusion

Step 2.

1. Install a sterilization agent leak monitor on top of the equipment;
2. Place inside of a small tyvek pouch one BI and one chemical indicator (CI)
3. Place three tyvek pouches with BIs and CIs as follows:
 - one right below sterilization agent entrance
 - one in the middle of the chamber
 - one in the distal point from sterilization agent entrance
4. Select the sterilization cycle that will be evaluated;
5. Monitor continuously the cycle;
6. At the end of the second diffusion, right after the gas removal, abort the cycle;
7. Open the door right after it is cleared by the equipment control;
8. Record the sterilization agent concentration from the monitor;
9. Remove the three pouches, taking out the BIs and CIs;
10. Incubate the BIs immediately;
11. Repeat the procedure two more times.

Warnings

Instructions for use of the low temperature vaporized hydrogen peroxide sterilization equipment manufacturer must be followed