Influences of Residual Moisture remaining in instruments on Vaporized Hydrogen Peroxide Sterilization Process

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Introduction

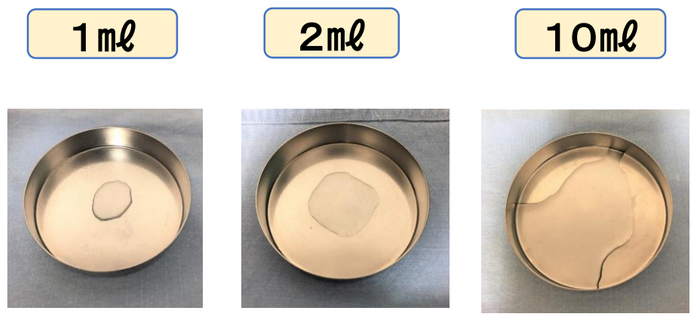
The continued development of new surgical methods and technologies has resulted in reusable medical devices that are more complex and present greater reprocessing challenges. In addition to cleaning and sterilization, proper drying of instruments has become more difficult because of complex structures such as narrow lumen devices as well as more heavy and complex designs such as orthopedic power tools. Insufficient time available for drying between cleaning and sterilization, especially for loaner instruments, increases the possibility of moisture remaining on/in instruments that are placed in the sterilization chamber.

We conducted a series of experiments to determine the effect of residual moisture on sterilization efficacy on a number of surgical instruments.

Experiment #1

Method

- 1mL, 2mL, or 10mL of sterile water was placed in stainless steel petri dishes and packaged in separate sterilization pouches.
- Each package was processed in a vaporized hydrogen peroxide sterilizer.
- Each volume of water was tested 4 times, and the number of cycle cancellations was recorded.



Result

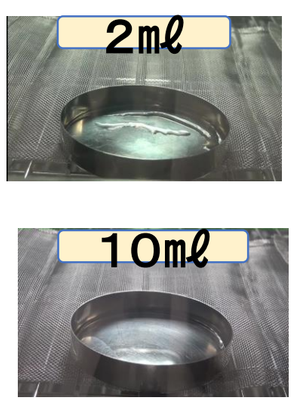
All four cycles cancelled in the presence of 2mL and 10mL water while only one out of four cycles cancelled in the presence of 1mL water.

	1mℓ	2mℓ	10mℓ
# of Cancellations	× × × ○	○ ○ ○ ○	○ ○ ○ ○

Experiment #2

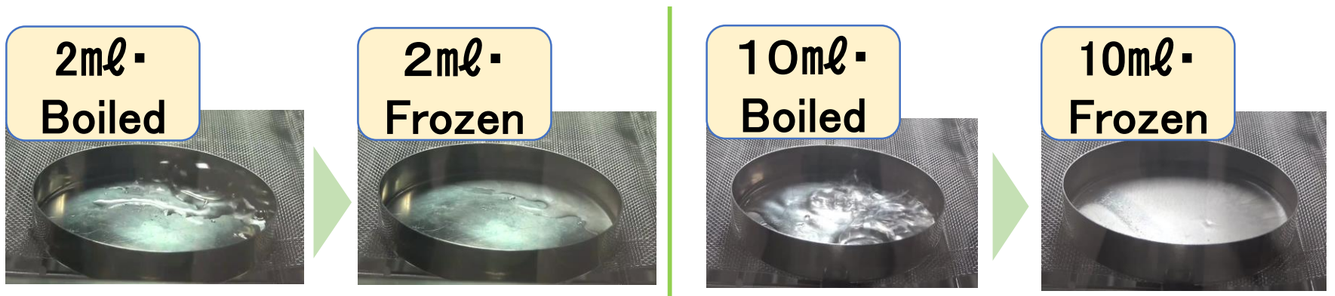
Method

- Observation windows in the chamber door allowed observation of the effects of the cycle vacuum on the water in the petri dishes.
- The effects of the process on 2mL and 10mL samples in canceled cycles was photographed.



Result

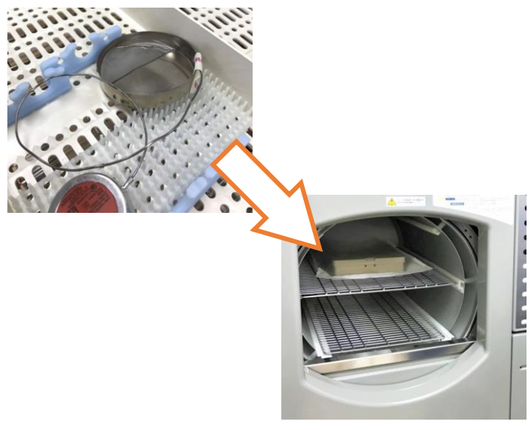
Water boiling followed by freezing was observed and recorded for both 2mL and 10mL before the cycle was cancelled.



Experiment #3

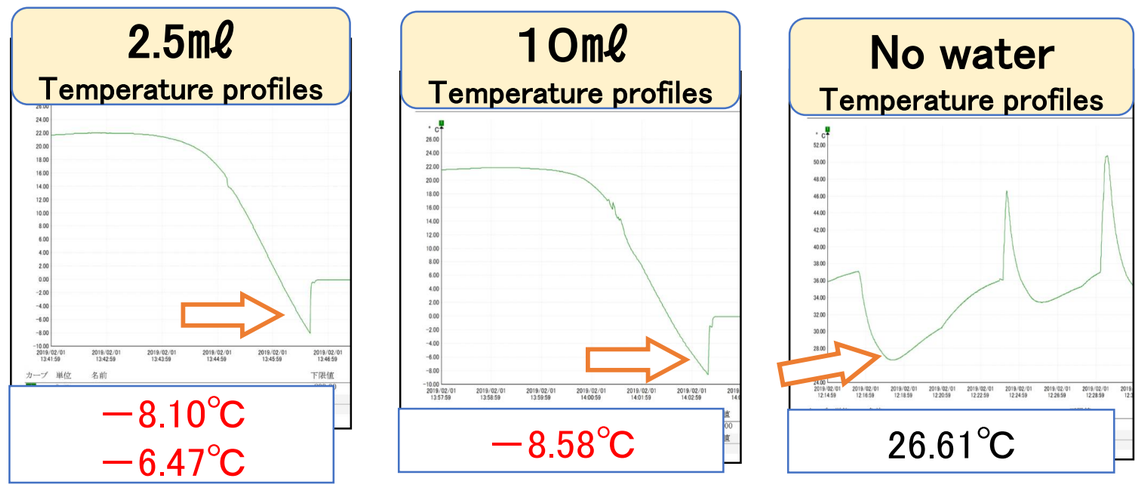
Method

The temperature profiles of the processes for the 2.5mL and 10mL samples of sterile water, as well as processes containing no water, were recorded by data loggers and compared.



Result

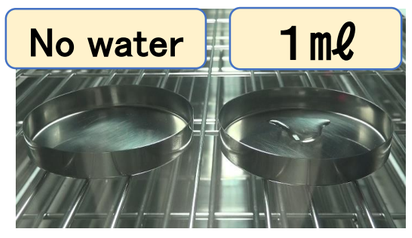
The minimum temperature for the 2.5mL and 10mL water samples was dropped to less than -8 degree centigrade. The processes without water had a minimum temperature of 26 degree centigrade.



Experiment #4

Method

- Baseline data for processes that did not cancel was obtained by running
- 3 replicate cycles containing no water, and 3 replicate cycles with 1mL water samples.



Result

Condensation of hydrogen peroxide was observed during the first three sterilant injections, out of the four in each process. This phenomenon was observed in all three tests performed.

Conclusion

This study suggested the possibility of a **sterility failure** because of **residual moisture remaining in instruments**. Residual moisture or condensation of hydrogen peroxide could result in insufficient exposure to the sterilant.

While most vaporized hydrogen peroxide sterilizers will automatically cancel the cycle if water is present, this study implies that a **small amount of water may not trigger the auto-cancelation** and may lead to a sterility failure. Thus **sufficient drying time** between cleaning and sterilization is very important.