

WHITE PAPER - HIGHLIGHTS

HOTLINE® Blood and Fluid Warmer: Sustained Performance and Safety

Hypothermia Introduction

Keeping surgical patients normothermic is an important objective to prevent the known morbidities associated with unintended perioperative hypothermia, which occurs when core body temperature falls below 36°C. Research shows that even mild hypothermia can be associated with significant morbidity and mortality, including surgical site infections, myocardial ischemia, prolongation of drug effects, bleeding diatheses, and increased morbidity, mortality, and expense.²

Unintended perioperative hypothermia can be caused by a number of factors, including administration of cold intravenous blood or fluids, exposed surgical cavities, cold operating theater temperatures, and administration of anesthesia. The induction of anesthesia causes the smooth muscle in veins and arteries to vasodilate, allowing the warm blood to flow from the core out to the cool periphery, returning cool blood from the periphery back to the core. This produces a rapid drop in patient core temperature up to 1.6°C in the first hour.^{2,7,8}

Performance of HOTLINE® Blood and Fluid Warmer: Maintaining Normothermia

Blood and fluid warmers play a significant role in preventing unintended perioperative hypothermia. Administration of normothermic fluids, rather than cold or inadequately warmed fluids, may reduce both the incidence and complications associated with hypothermia.³

For the past two decades, the Level 1® HOTLINE® blood and fluid warmer has played an integral part in the prevention of perioperative hypothermia in over 30 million surgeries. With its unique technology, the HOTLINE® blood and fluid warmer provides consistent normothermic performance across a range of routine flow rates.⁹ Essential to the performance of the HOTLINE® blood and fluid warmer is the design of the system that is comprised of a warmer with a pump to circulate warmth-transferring fluid and a disposable fluid warming set with unique, triple-lumen construction. The triple-lumen construction allows blood or fluid to travel through the sterile center

lumen of the warming set to the patient while a layer of 42°C circulating solution envelops the entire length of the sterile fluid pathway, keeping blood and fluids warm all the way to the patient.

Established Safety: HOTLINE® Blood and Fluid Warmer

In the past several years, the importance of safety and high maintenance standards has received attention due to concerns about the potential for blood and fluid warming systems to act as reservoirs for nosocomial pathogens. Water-based systems in particular have been targeted. However, the evidence used to support the argument that water-based systems may act as reservoirs for pathogens comes largely from an article that looked at this potential problem in water baths such as sinks, ice and ice machines, and dialysis water.⁴ Of the water-based devices evaluated within the context of the article, most were not accompanied by manufacturer maintenance protocols leading the authors to suggest that “it would be prudent to develop policies for the routine cleaning, disinfection, and changing of water in water baths used to thaw or warm blood products.” This suggestion is in line with what has already been established by the maintenance protocol in place for the HOTLINE® blood and fluid warmers.

What this concern over pathogens does highlight is the critical importance of implementing maintenance protocols that are developed and followed for sustained system performance. Of critical importance for any type of system is not its warming technology but that the system is accompanied by a clear, specific protocol for routine cleaning and disinfection to sustain ongoing high quality and safe performance.

Antimicrobial Effectiveness Study

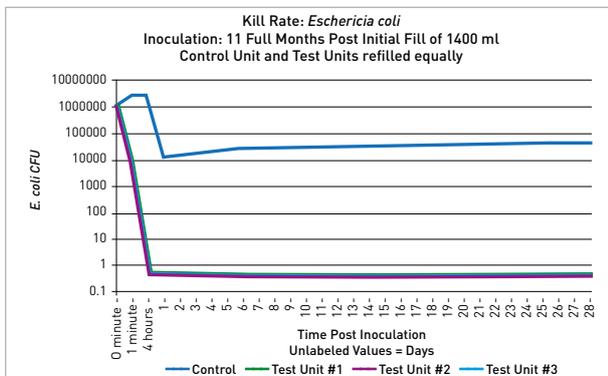
Smiths Medical undertook an in-depth, year-long microbiological study to validate and support the long-term antimicrobial effectiveness of 0.3% H₂O₂ solution within the fluid reservoir of HOTLINE® blood and fluid warmers.^{5,6} A protocol to test this solution was derived from a targeted investigation to test H₂O₂ antimicrobial effectiveness against contamination challenges of three specific bacteria: *Escherichia coli*, *Pseudomonas aeruginosa*, and

Bacillus subtilis. The three bacteria were chosen for their ability to thrive in low-nutrient water-borne environments.

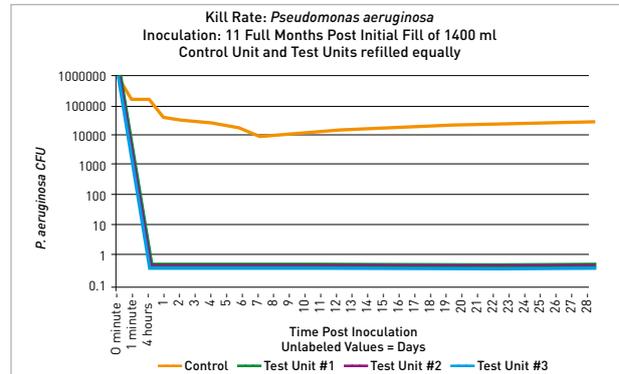
To evaluate the antimicrobial effectiveness of 0.3% H₂O₂ over an extended period of time, the study followed the maintenance protocols established in the HOTLINE® Operator's Manuals. This includes the instructions on "topping off" the reservoir with the same solution as necessary. To simulate extended, normal use, HOTLINE® blood and fluid warmers were filled with 1400mL of 0.3% H₂O₂ and allowed to run 8 hours per day, 5 days per week, for up to 12 months. At predetermined time periods, the 0.3% H₂O₂ fluid reservoirs were challenged by introducing high colony forming unit ($\geq 1 \times 10^6$ CFU) populations of each *B. subtilis*, *E. coli*, and *P. aeruginosa*. Immediately after CFUs were introduced, followed by hourly, then daily, and finally weekly intervals, the 0.3% H₂O₂ fluid reservoir solutions were sampled and tested for viable populations of test organisms.

Antimicrobial effectiveness results of 0.3% H₂O₂ are available in the figures shown here. Results clearly indicate the 0.3% H₂O₂ solution provides fast and sustained antimicrobial activity for the HOTLINE® blood and fluid warmer for up to 12 months.

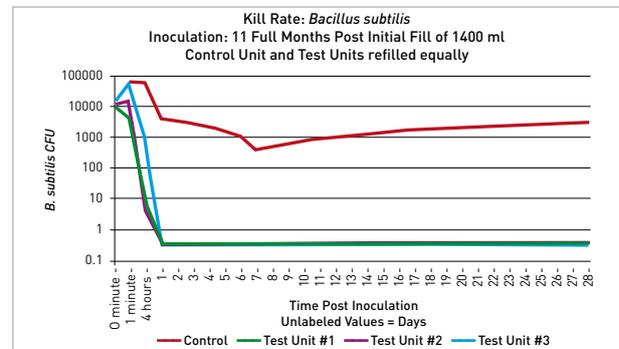
Challenge Results – *Escherichia coli*: Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use.



Challenge Results – *Pseudomonas aeruginosa*: Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use.



Challenge Results – *Bacillus subtilis*: Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use.



Conclusion – Maintenance Protocols Validated

As confirmed by the data presented above, when maintained properly, 0.3% hydrogen peroxide (H₂O₂) solution not only kills microorganisms, but provides a residual effect after disinfection and continues to provide a barrier against recontamination. The disinfection and maintenance protocols listed in the HOTLINE® Operator's Manuals, therefore, may be used confidently to maintain a microbial free environment in HOTLINE® blood and fluid warmers.

References

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