

WHITE PAPER

HOTLINE® Blood and Fluid Warmer: Sustained Performance and Safety

ABSTRACT

Keeping surgical patients normothermic is an important objective to prevent the known morbidities associated with unintended perioperative hypothermia. Blood and fluid warmers play a significant role in preventing unintended perioperative hypothermia. The HOTLINE® blood and fluid warmer offers a safe, reliable, and proven technology to warm and deliver blood and fluids at routine, gravity flow rates to improve patient outcomes by maintaining normothermia. With its unique triple lumen HOTLINE® fluid warming set, the HOTLINE® blood and fluid warmer is the only blood and fluid warming system that eliminates patient line cool-down and delivers consistently warmed fluids at the point of patient connection. Well-established maintenance protocols provide clear and easy to follow instructions on sustained quality performance over time. Recent results from a study that looked at the long-term antimicrobial effectiveness of 0.3% hydrogen peroxide (H₂O₂) used as a bactericidal agent within the fluid reservoir of HOTLINE® blood and fluid warmers show that the solution not only kills microorganisms but also provides a residual effect after disinfection and continues to provide a barrier against recontamination.^{1,2,3} These results validate the disinfection and maintenance protocols listed in the HOTLINE® Operator's Manuals, and provide additional evidence that the HOTLINE® blood and fluid warmers are safe and can maintain a microbial free environment over time.

INTRODUCTION

Keeping surgical patients normothermic is an important objective to prevent the known morbidities associated with unintended perioperative hypothermia, which occurs when the body's core temperature falls below 36°C. Unintended perioperative hypothermia has been called a frequent, preventable complication of surgery.⁴ Among the 51 million inpatient⁵ and 34.7 million ambulatory surgeries⁶ occurring annually in the United States, it is estimated that 50-90% suffer from accidental hypothermia.⁷

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. As patient temperature declines, peripheral vessels vasoconstrict to keep warm blood near the core, protecting the vital organs. The induction of anesthesia causes the smooth muscle in veins and arteries to vasodilate and allows the warm blood to flow from the core out to the cold periphery, and sends cold blood from the periphery back to the core. This produces a rapid drop in patient core temperature of 1.0-1.5°C in the first hour.^{4,8,9}

Research has shown that even mild hypothermia can have significant effects on patient outcomes. Adverse consequences of unintended perioperative hypothermia include surgical site infections, myocardial ischemia, prolongation of drug effects, bleeding diatheses, and increased morbidity, mortality, and expense.⁹

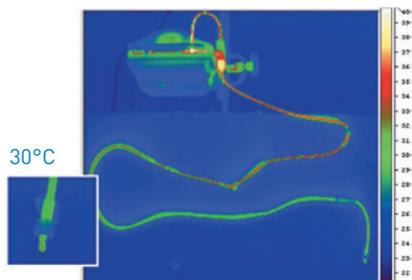


Based on the adverse outcomes of even mild perioperative hypothermia, a trend is emerging globally to adopt national quality initiatives related to improving patient care through temperature management. In the United States, the Department of Health & Human Services has identified reduction of surgical site infections and surgical complications as a top national priority.¹⁰ Specific initiatives in the US include the Surgical Care Improvement Project (SCIP), a project sponsored by the Centers for Medicare and Medicaid Services (CMS) in collaboration with other partners, aimed at improving surgical care by significantly reducing surgical complications. One of the evidence-based elements of SCIP is perioperative temperature management, which is considered a process measure designed to improve normothermia for all patients undergoing surgical procedures under general or neuraxial anesthesia lasting 60 minutes or greater in duration.¹¹ Similar to SCIP, the UK National Institute for Health and Clinical Excellence (NICE) has instituted guidance advocating for the management of inadvertent perioperative hypothermia.¹²

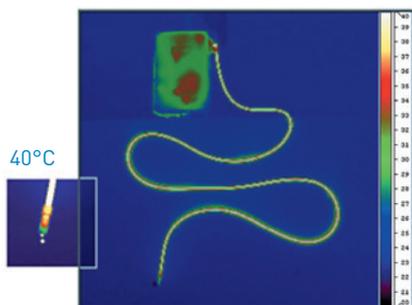
Blood and fluid warmers play a significant role in preventing unintended perioperative hypothermia. Administration of cold or inadequately warmed intravenous fluids contributes to hypothermia, whereas administration of normothermic fluids may reduce both the incidence and complications of hypothermia.¹³ For optimal performance, blood and fluid warmers need to meet safety standards similar to those required for other medical equipment as well as undergo regular maintenance to sustain high quality performance over time. In the past several years, the importance of safety and high maintenance standards has received attention due to concerns about the potential for these systems to act as reservoirs for microbial pathogens.

HOTLINE® Blood & Fluid Warmers deliver fluids above normothermic temperatures all the way to the patient

Conventional Fluid Warmer

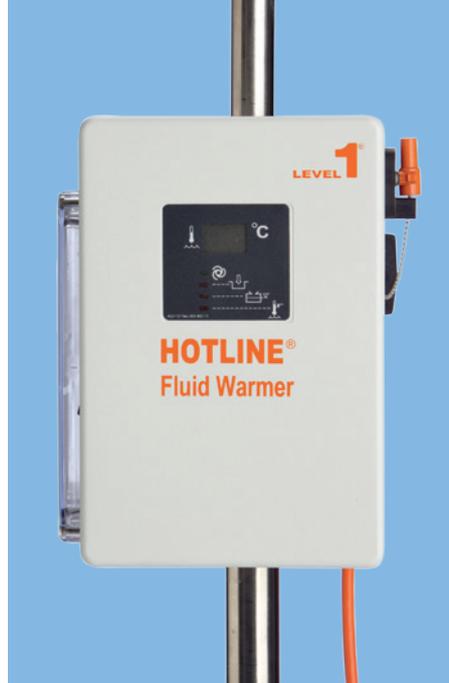


HOTLINE® Blood and Fluid Warmer



Ambient Temperature: 20°C
Fluid Input Temperature: 20°C

For the past two decades, Smiths Medical 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 outperforms other conventional blood and fluid warmer systems in its ability to provide consistent normothermic performance across a range of routine flow rates.¹⁴ The HOTLINE® blood and fluid warmer system also has a strong established safety record, in addition to a well-defined and clear protocol for maintenance to sustain high quality performance and antimicrobial effectiveness.^{14, 15}



Part I of this article summarizes the well-established data on the performance and safety of the HOTLINE® blood and fluid warmer that distinguishes it from other blood and fluid warmer systems. Part II focuses on device maintenance, with particular attention to addressing the more recent concerns raised over fluid reservoirs as a potential source of nosocomial pathogens. Along with describing the clearly written and well established protocol for HOTLINE® blood and fluid warmer maintenance, this article provides new data from a study undertaken to examine the validity of the maintenance protocol. The aim of this article is to provide healthcare providers objective evidence supporting the safe, effective, and sustained use of the HOTLINE® blood and fluid warmer.

PART I PERFORMANCE OF HOTLINE® BLOOD AND FLUID WARMER: MAINTAINING NORMOTHERMIA

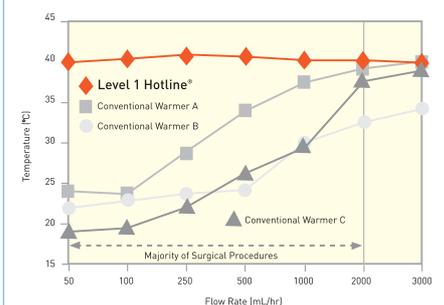
The most important factor when choosing a blood and fluid warmer is performance. More specifically, it is imperative that a blood and fluid warmer is able to deliver fluids at normothermic routine flow rates given the majority of routine surgical procedures use flow rates <2 L/hr.¹⁶

The HOTLINE® blood and fluid warmer is designed for use with the HOTLINE® fluid warming set. The integrated design of the HOTLINE® blood and fluid warmer and HOTLINE® fluid warming set allows intravenous blood and fluids to be delivered to the patient at normothermic gravity flow rates from KVO – 5 L/hr. The HOTLINE® blood and fluid warmer employs a safe, recirculating solution heating system that is inherently free of “hot spots”. The operating temperature for the standard HOTLINE® blood and fluid warmer is 42°C. For patients

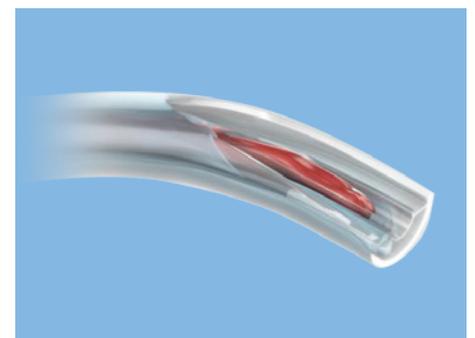
who may not be able to tolerate a 42°C infusion, HOTLINE® units with operating temperatures of 38°C and 40°C are also available.

The HOTLINE® blood and fluid warmer has demonstrated the most consistent normothermic blood and fluid delivery performance across a range of fluid warmers (figure 1).¹⁴ It achieves this by utilizing a unique triple lumen fluid warming set, which maintains a layer of 42°C recirculating solution around the sterile fluid pathway, keeping blood and fluids warm all the way to the patient.

Figure 1



Essential to the performance of the HOTLINE® blood and fluid warmer is the unique 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 HOTLINE® fluid warming set to the patient as heated circulating fluid flows through the two outer lumens, which envelops the center lumen in warmth.



As previously described, the HOTLINE® warmer maintains the circulating fluid temperature at 42°C to deliver blood or fluids to the patient at a temperature able to maintain normothermia. Because the outer and central lumens are separate, circulating fluid never comes in contact with blood or fluid, and therefore presents no risk of cross-contamination and is an essential safety feature to the HOTLINE® blood and fluid warmer.

Unlike the HOTLINE® blood and fluid warmer, conventional fluid warming systems suffer from cool-down between the warmer and the patient connection, particularly at lower routine flow rates. In these systems, active warming ceases after blood or fluid has passed through the conventional warmer heater, which allows fluid to cool in the intravenous line before being delivered to the patient.

ESTABLISHED SAFETY: HOTLINE® BLOOD AND FLUID WARMER

Safety standards for medical equipment are rigorous and essential for the protection of clinicians and patients. The HOTLINE® blood and fluid warmer has gone through extensive testing to meet clinical expectations for performance as well as being a safe tool within the perioperative environment. The HOTLINE® blood and fluid warmer meets all electrical safety and biocompatibility standards, complying with IEC 60601-1:2005. Furthermore the HOTLINE® blood and fluid warmer has been tested by TÜV SÜD America Inc., a nationally recognized technical laboratory, to meet requirements for product safety.

BUILT-IN SAFETY FEATURES

Alarms

Designed with both audio and visual alarms, the HOTLINE® blood and fluid warmer actively alerts the user if the following scenarios occur: reservoir temperature exceeds 43.1°C, reservoir volume is below the minimum level, or HOTLINE® fluid warming set is missing or improperly installed. These alarm modes are indicated via the following mediums:

- The green Operating LED on the display panel turns off
- The red Check Disposables LED on the display panel illuminates
- The audible alarm sounds and repeats approximately every two seconds
- The recirculating solution stops circulating

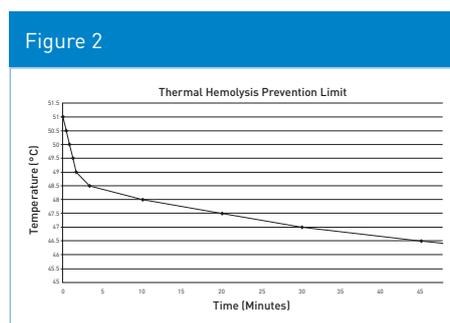
Air Protection

Smiths Medical offers the L-10 HOTLINE® gas vent, which is intended to vent outgassed micro bubbles from HOTLINE® L-series fluid warming sets. The L-10 HOTLINE® gas vent is connected directly to the distal end of the HOTLINE® L-series fluid warming sets via standard Luer fitting.

MANUFACTURING

HOTLINE® fluid warming sets are individually packaged single-use disposables that contain a sterile fluid path and are 100% tested on the manufacturing floor – both the

intravenous lumen and recirculating solution lumens. The closed loop HOTLINE® fluid warming sets are pressure tested to 300 mm/Hg to confirm an uncompromised fluid pathway.



INDUSTRY GUIDELINES

HOTLINE® blood and fluid warmers are designed to stay well below the limit for heat-caused hemolysis – that is, the alteration, dissolution, or destruction of red blood cells. Per the standard, blood would have to be exposed to a temperature of 46°C for 60 minutes to alter the properties of the cells. Fluid in the HOTLINE® fluid warming set is never exposed to dangerous temperatures while the HOTLINE® blood and fluid warmer is operating. Figure 2, taken from the Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers (ASTM Standard F2172-02) supports this claim.¹⁷

Further evidence that the HOTLINE® blood and fluid warming system is a clinically safe tool for the perioperative environment can be gleaned from a review Smiths Medical undertook of safety complaints between 1 January 2009 and 31 March 2013. A comparison of the total number of complaints in the last four years versus the sales of disposables (representing the potential number of uses) over the same time period resulted in a yield rate of 0.01%, demonstrating minimal dissatisfaction.¹⁴ This provides further evidence that the HOTLINE® blood and fluid warming system is a clinically safe tool for the perioperative environment. Furthermore, this supports the notion that the vast majority of HOTLINE® blood and fluid warming system users follow recommended maintenance protocols enabling long-term device performance and functionality.

PART II

MAINTENANCE: HOTLINE® BLOOD AND FLUID WARMER

In general, equipment maintenance in healthcare settings is a necessary and critical step to sustained product performance and effective patient treatment. Anesthesia gas machines,

heart-lung bypass machines, mechanical ventilators, and patient monitors are a few examples of hospital products that require regular (monthly, semi-annual, annual) preventative maintenance to improve equipment life and avoid unplanned maintenance expenses. Preventative maintenance is required for all serviceable medical devices for sustainable performance.

Blood and fluid warmers also require regular preventive maintenance. To meet this requirement, the HOTLINE® blood and fluid warmer includes a clear and detailed maintenance protocol in its Operator's Manual that provides guidance on how to sustain product performance.¹⁵ The protocol recommends disinfecting the reservoir and changing the recirculating solution every 30 days or every 12 months based on the recirculating solution used for the HOTLINE® warmer. Table 1 summarizes the disinfection and maintenance protocols stated in the HOTLINE® Operator's Manual.

Recirculating Solution	Preparation	Maintenance
0.3% Hydrogen Peroxide Solution	Mix 140 ml of 3% hydrogen peroxide with 1,260 ml of distilled water	Replace solution and disinfect reservoir every 12 months
Distilled Water	Use distilled water	Replace solution and disinfect reservoir every 30 days
35% Isopropyl Alcohol Solution	Mix 700 ml of 70% isopropyl alcohol with 700 ml of distilled water	Replace solution and disinfect reservoir every 30 days

Adherence to this protocol has demonstrated the sustained quality performance of the HOTLINE® blood and fluid warmer.^{1, 2, 3} Over the past several years, however, concerns have been raised regarding 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 by Rutala and Weber that looked at this potential problem in water baths such as sinks, ice and ice machines, and dialysis water.¹⁸ The article did not look at recirculating baths for heating purposes nor did it examine the HOTLINE® blood and fluid warmer or any other blood and fluid warmers in particular. 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 warmer system as described previously.

What this concern over pathogens does highlight is the critical importance of implementing maintenance protocols that are developed and followed for sustained system performance. Although water-based systems may seem at higher risk of acting as a reservoir for these pathogens, evidence shows that even dry heat fluid warmers and their disposable sets are not inherently free of gram-positive or gram-negative bacterium and have been linked to *Staphylococcus epidermidis*, *Serratia marcescens*, and *Staphylococcus warneri*.¹⁹ Of critical importance for any type of system is not its warming technology (e.g., water bath, dry heat) but that the system is accompanied by a clear, specific protocol for routine cleaning and disinfection to sustain ongoing high quality and safe performance.

The HOTLINE® blood and fluid warmer meet this standard requirement. The Operator’s Manual provides a detailed maintenance section for ongoing quality and safe performance. In light of the ongoing debate and concern over the potential for nosocomial pathogens,



however, Smiths undertook an in-depth microbiological study to validate the maintenance protocols set forth in the HOTLINE® blood and fluid warmer Operator’s Manual. The scope of the microbiology study includes data specific to 0.3% hydrogen peroxide (H₂O₂) as it represents a worst case scenario from a planned maintenance perspective (annual v. 30 days). Furthermore, the suggested annual maintenance for 0.3% H₂O₂ is the most recent protocol added to the HOTLINE® Operator’s Manual maintenance instructions and, as such, yields the most current data to support the sustained effective use of

the HOTLINE® blood and fluid warmer. Distilled water and 35% Isopropyl alcohol are also well-established circulating solutions based on over two decades of use but are not detailed in this article.

VALIDATION OF MAINTENANCE PROTOCOL: ANTIMICROBIAL EFFECTIVENESS STUDY

Smiths Medical conducted a year-long study to determine the long-term antimicrobial effectiveness of 0.3% H₂O₂ solution used as a bactericidal agent within the fluid reservoir of HOTLINE® blood and fluid warmers.^{2,3} Hydrogen peroxide is well known for its high oxidative and biocidal efficiency. In addition, unlike other chemical substances, hydrogen peroxide does not produce toxic residues or gasses.

REGULATORY REQUIREMENTS

The study satisfies regulatory recommended requirements by the Food and Drug Administration (FDA) to develop antimicrobial maintenance instructions that are clear and easy to follow, as well as to test the methods under worst case scenarios to demonstrate that the instructions, if properly followed, will provide safe, sustained, contamination-free, long-term use and reuse. Although no national or international regulatory requirements exist specific to the application of antimicrobial maintenance in a medical device fluid reservoir environment, the FDA released on May 2, 2011 a comprehensive draft guidance for a similar application entitled Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling which states that adequate reprocessing and handling of reusable medical devices is vital to protecting patient safety.²⁰ When final, this document will supersede the previous FDA document released in 1996 Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.²¹

ANTIMICROBIAL EFFECTIVENESS STUDY

The purpose of this study was to evaluate the long-term antimicrobial effectiveness of 0.3% H₂O₂ used as a bactericidal agent within the fluid reservoir of HOTLINE® blood and fluid warmers. A protocol to test this solution was developed at Ethide Laboratories in Coventry, RI. Ethide Laboratories is a well-established, ISO 13485 certified laboratory that has provided customized microbiology services to the medical device industry for over 50 years. A testing protocol was derived from targeted investigation in which the researchers studied possible contamination risks. The final protocol provided a study series 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. *E. coli* and *P. aeruginosa* are common environmental bacteria with tolerance of a wide variety of physical conditions, including pH and temperature. *B. subtilis*, a common spore-former, is especially resistant to adverse environmental factors.

Methods

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 on when and how to disinfect the reservoir and change the recirculating solution. 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. Once daily, the fluid warming set was replaced on each unit with the fluid reservoir “topped off” with the same 0.3% H₂O₂ solution when the solution level approached the “minimum” operating level.

At predetermined time periods (0, 30, and 60 days followed by 3, 6, 9, and 11 months) the 0.3% H₂O₂ fluid reservoirs were challenged by introducing high colony forming unit ($\geq 1 \times 10^4$ CFU) populations of each *Bacillus subtilis*, *Escherichia coli*, and *Pseudomonas aeruginosa*. Immediately after CFUs were introduced, followed by hourly, then daily, and finally weekly intervals for up to one month, the 0.3% H₂O₂ fluid reservoir solutions were sampled and the sample solutions were tested for viable populations of the test organisms.

Actual test methods used in the study followed the 2002 best practice guidance of US Pharmacopeia 25, 2002 Antimicrobial Effectiveness Testing.²²

Results

Results of the disinfection rate of 0.3% H₂O₂ are available in the figures shown here. Results are shown for disinfection capability immediately (0 months) and 12 months after inoculation. The test units were initially filled with 0.3% H₂O₂ and refilled (“topped off”) per Smiths Medical recommended instructions for a period up to 12 months with additional 0.3% H₂O₂ solution. The figures clearly indicate the 0.3% H₂O₂ solution provides fast and sustaining antimicrobial activity for the HOTLINE® blood and fluid warmer.

CHALLENGE RESULTS – ESCHERICHIA COLI

- Consistent evidence of disinfection activity beginning within minutes (figure 3 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent 100% disinfection capability against *E. coli* within 4 hours of challenge inoculation (figure 3 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use (figure 4 – Bacteria Kill Rate 12 months Post Initial Fill of 1400ml 0.3% H₂O₂).

Figure 3

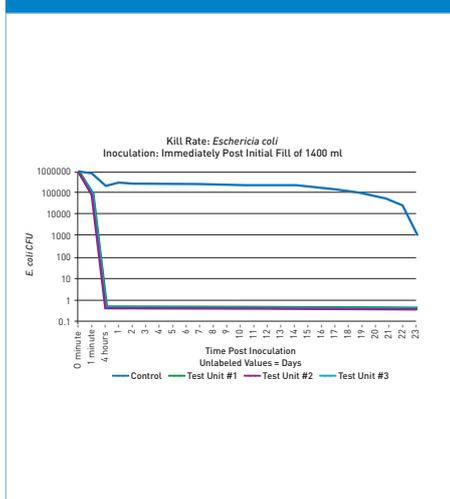
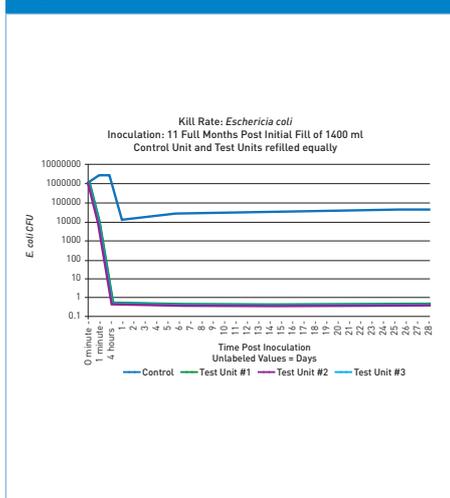


Figure 4



CHALLENGE RESULTS – PSEUDOMONAS AERUGINOSA

- Consistent evidence of disinfection activity beginning within seconds to minutes (figure 5 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent 100% disinfection capability against *P. aeruginosa* within 4 hours of challenge inoculation (figure 5 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use (figure 6 – Bacteria Kill Rate 12 months Post Initial Fill of 1400ml 0.3% H₂O₂).

Figure 5

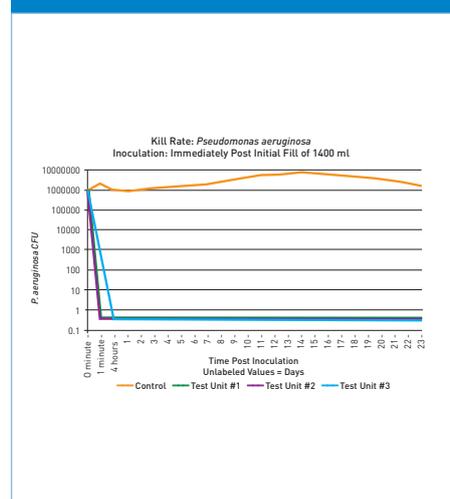
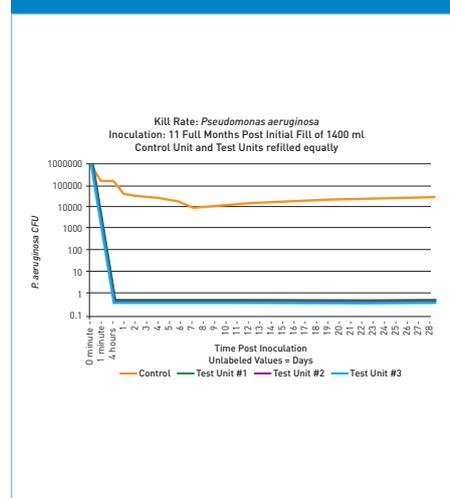


Figure 6



CHALLENGE RESULTS – BACILLUS SUBTILIS

- Consistent evidence of spore disinfection activity beginning within 4 hours (figure 7 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent 100% disinfection capability against *B. subtilis* within 24 hours of challenge inoculation (figure 7 – Bacteria Kill Rate Immediately Post Initial Fill of 1400ml 0.3% H₂O₂).
- Consistent repeatability of 100% disinfection capability for up to 12 months of sustained use (figure 8 – Bacteria Kill Rate 12 months Post Initial Fill of 1400ml 0.3% H₂O₂).

Figure 7

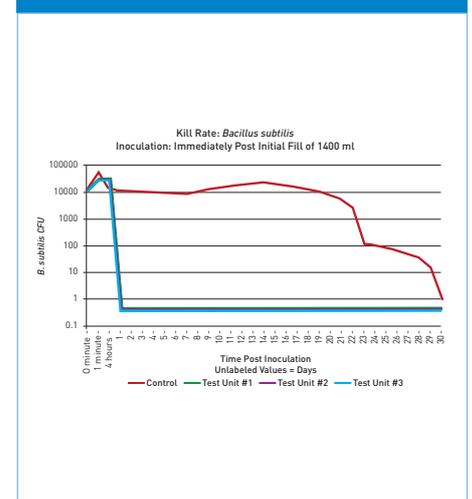
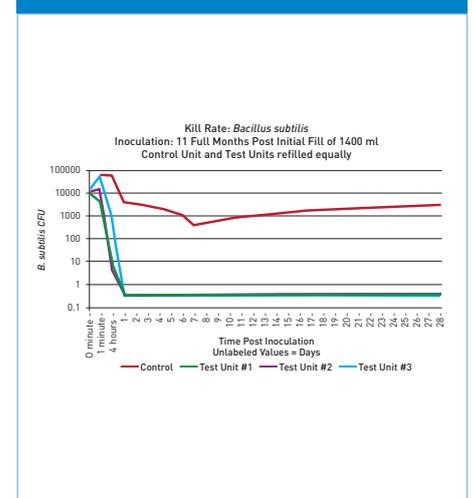


Figure 8



CONCLUSION – MAINTENANCE PROTOCOLS VALIDATED

The study shows that with proper attention to solution care and maintenance, microbial contamination may be prevented in the HOTLINE® blood and fluid warmer system. As such, the study validates the maintenance protocols established in the HOTLINE® Operator's Manuals. These protocols

provide instructions for use of the correct 0.3% hydrogen peroxide (H₂O₂) solution, the correct initial fill volume, and the recommended refilling or 'topping off' procedure when indicated by operational levels (see Table 1). As confirmed by the data presented above, when maintained properly, the 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.

SUMMARY

The HOTLINE® blood and fluid warmer offers a safe, reliable and proven technology to warm and deliver blood and fluid at gravity flow rates to improve patient outcomes and maintain normothermia. With its unique triple lumen HOTLINE® fluid warming set, the HOTLINE® blood and fluid warmer is the only blood and fluid warmer system that eliminates patient line cool-down and delivers

consistently warmed fluids at the point of patient connection. Well established maintenance protocols provide clear and easy to follow instructions on sustained quality performance over time. Recent results from a study that looked at the long-term antimicrobial effectiveness of 0.3% hydrogen peroxide used as a bactericidal agent within the fluid reservoir of HOTLINE® blood and fluid warmers show that the solution not only kills microorganisms but

also provides a residual effect after disinfection and continues to provide a barrier against recontamination. These results validate the disinfection and maintenance protocols listed in the HOTLINE® Operator's Manuals, and provide additional evidence that the HOTLINE® blood and fluid warmers are safe and can maintain a microbial free environment over time.

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For further information on the HOTLINE® Blood and Fluid Warmer
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