EXECUTIVE SUMMARY

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Test 1: Ward-based Washer Disinfectors & CPD based Washer Disinfectors

Due to the increasing *Clostridium difficile* infections, the recent virulence of the microorganism, and knowing that bedpans are processed in washer disinfectors based on the ward or in the central processing department of hospitals, this study was to determine the cleaning efficacy and the *C. difficile* spore killing ability of such washer disinfectors.

During this study, the ArjoHuntleigh Tornado was evaluated as the ward-based washer disinfecter. The Steris Reliance 444 washer disinfecter was the CPD-WD.

This testing utilized Ultra-Violet Visible Marker (UVM), Test Object Surgical Instrument (TOSI), Artificial Test Soil (ATS), and autoclaved stool/urine that was inoculated with *C.difficile* spores.

The results indicated that the CPD-WD was able not only to adequately clean the bedpans of organic soil, but also to completely inactivate the 6 logs of *C. difficile* spores placed in sealed ampules inside the CPD-WD. The ward-based WD did not demonstrate adequate cleaning, and upon further investigation, it was determined that installation errors were responsible for the inadequate cleaning.

It was also determined that the thermal conditions of the Ward-based WD did not adequately inactivate *C difficile* spores. This is not unexpected as a washer disinfecter is designed to disinfect (thermal conditions of 85°C for 1 minute) and would not be adequate to kill a spore.

Conclusion:

The results of the study indicate that user testing of the efficacy of washer disinfecters is critical to ensure appropriate functionality.

Ward-based WD’s still provide an effective means of disposing of fecal waste from bedpans without generating aerosols. Although the currently accepted thermal decontamination parameter for all bedpan WDs (ie, 80°C for 1 minute) is appropriate for killing vegetative bacteria, these temperatures are not adequate to kill *C difficile* spores on bedpans.

The article indicated that manufacturers may be able to make adjustments to bedpan washers to achieve conditions that will effectively eliminate *C. difficile* spores.
Test 2 – Phase 1: [Data not yet published]

Baseline Testing – ArjoHuntleigh Tornado with Intensive Cycle

Based on the results and conclusions of Test 1 above, additional testing was undertaken to determine if the ArjoHuntleigh Tornado bedpan washer disinfector, using its current intensive program, is sufficient to eliminate *C. difficile* spores from bedpans or whether alterations to the cycle parameters are needed.

This testing utilized the same test methods outlined in Alfa et al (2008) consisting of autoclaved stool that was inoculated with *C. difficile* spores and dried onto bedpans to assess the cleaning cycle. Cryovials containing the feces/*C. difficile* spore mix were used to test the *C. difficile* spore killing ability of the thermal conditions of the Tornado.

Conclusion:

Although the bedpans were visibly clean and achieved ~ a 4 Log$_{10}$ reduction of spores on the surface of the bedpans, the Tornado intensive program was not able to completely eradicate spores from the bedpans.

The low reduction of spores in the cryovials (< 2 Log$_{10}$ reduction in spore level) confirmed that the thermal conditions of the Tornado were not adequate to kill *C. difficile* spores efficiently. This is not unexpected as the thermal conditions are 85°C for 1 minute in this cycle.

Test 2 – Phase 2: [Data not yet published]

**ArjoHuntleigh Tornado with modified Intensive Cycle and specially formulated ArjoHuntleigh detergents**

Based on the results and conclusions of Test 2 – Phase 1 above, additional testing was undertaken to determine if the ArjoHuntleigh Tornado bedpan washer disinfector, using a modified cleaning program and detergent, is sufficient to eliminate *C. difficile* spores from bedpans.

The same test method used in Test 2 Phase 1 was used for Phase 2. The thermal temperatures in the phase were modified to 95°C for 300 seconds. An enzymatic formulation and a new proprietary alkaline detergent formulation (SUREWash C.d.) were tested in conjunction with a modified Intensive cycle that included a higher temperature and longer wash time.

Conclusion:

**Enzymatic detergent testing:**

Although the thermal conditions of the ArjoHuntleigh Tornado are not sufficient to completely kill the *C. difficile* spores in the cryovials, the modified intensive cycle, used in conjunction with the Enzymatic detergent was successful in achieving complete surface disinfection. However,
the bedpans did not appear visibly clean despite the fact that no *C. difficile* spores were detected on the surface of the bedpans. The use of the enzymatic detergent and modified intensive cycle would not be acceptable.

**Alkaline detergent (SUREWash C.d.)**

Although the thermal conditions of the ArjoHuntleigh Tornado are not sufficient to completely kill the *C. difficile* spores in the cryovials, the modified intensive cycle, used in conjunction with the proprietary alkaline detergent was successful in achieving bedpans that were visibly clean and had no detectable *C.difficile* spores; however, the volume of water used for the modified Intensive cycle was considered too excessive for routine use (~ 60 L per cycle).

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<tr>
<th>Test 2 – Phase 3: [Data not yet published]</th>
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<tbody>
<tr>
<td>ArjoHuntleigh Tornado with regular Intensive Cycle and 45 mLs of ArjoHuntleigh alkaline detergent (SUREWash C.d.) per cycle</td>
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<td>Based on the results and conclusions of Test 2 – Phase 2 above, additional testing was undertaken to determine if the ArjoHuntleigh Tornado bedpan washer disinfector, using a regular Intensive cycle at 85°C for 60 seconds, and the new proprietary alkaline detergent (SUREWash C.D.) is sufficient to eliminate <em>C. difficile</em> spores from bedpans.</td>
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<td>The same test method used in Test 2 Phase 1 was used for Phase 3.</td>
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<td>Conclusion:</td>
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<td><strong>Alkaline detergent (SUREWash C.d.)</strong></td>
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<td>The thermal conditions of the ArjoHuntleigh Tornado are not sufficient to completely kill the <em>C. difficile</em> spores in the cryovials (assesses only thermal effect). The regular Intensive cycle with 45 mLs of the proprietary alkaline detergent (SUREWash C.d.) was successful in achieving bedpans that were visibly clean and had no detectable <em>C.difficile</em> spores.</td>
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<td>Thus the combination of the proprietary alkaline detergent (SUREWash C.d.) and the regular intensive cycle thermal conditions provided a validated solution to the problem of adequate reprocessing of bedpans that takes into account the unique conditions needed to address <em>C.difficile</em> spores.</td>
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