

**WHITE PAPER REPORT**  
**Study #05-21-03**

**Sterilization of Dental and Medical Instruments in the  
STATIM 2000S and 5000S Cassette Autoclaves**

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**EXECUTIVE SUMMARY**

In this 2003 Indiana University study, the STATIM 2000S and STATIM 5000S cassette autoclaves were modified to incorporate an embedded thermocouple boiler configuration and special development software (PCD-1.7A). The units were tested to validate pre-sterilization cycle steam purges, which are needed to kill high levels of *Geobacillus stearothermophilus* spores (a bacteria most resistant to sterilization by steam). Various medical, dental and ophthalmic handpieces were inoculated with the test spores.

Using the standard 134°C half-cycle in both the STATIM 2000S and STATIM 5000S cassette autoclaves, results demonstrated that the three pre-sterilization purges killed the high levels of *Geobacillus stearothermophilus* spores placed in the instruments tested.

**METHODS:** Internal sites on a dental high-speed handpiece and several medical instruments were inoculated with at least one million spores of *Geobacillus stearothermophilus* in 10% sheep's blood per test instrument and then left to dry at room temperature overnight. The next day, instruments were wrapped individually in paper/plastic peel pouches and or left unwrapped. Three of each type of instrument was then distributed within a full load of "filler" hand instruments to achieve maximum loads in the sterilizing cassette of a STATIM 2000S and a STATIM 5000S cassette autoclave.

The instruments were processed in triplicate runs through a sterilization half-cycle of 134°C for 1 min. 45 sec. (half the regular 3.5-minute cycle) preceded by 3, 4 or 6 pre-sterilization cycle purges. Each run contained a spore strip of *Geobacillus stearothermophilus* containing at least one million spores. The test instruments and the spore strips were then incubated in a Tryptic-soy broth at 56°C for three weeks to recover any live spores. Positive and negative cultures were confirmed.

**RESULTS:** Live spores were recovered from all the positive control instruments and no contaminants were detected from culturing the negative control instruments. Since each test and positive control instrument was inoculated with 10 microliters of the spores-blood

suspension, it was confirmed that each instrument was challenged with at least one million spores.

No live spores were detected from any of the wrapped or unwrapped test instruments in either the STATIM 2000S or the STATIM 5000S cassette autoclaves when using half-cycles with three pre-sterilization purges.

Thus the data indicated that three pre-sterilization purges killed high levels of *Geobacillus stearothermophilus* spores placed in the dental and medical instruments processed in the STATIM 2000S and STATIM 5000S's sterilization half-cycle of 134°C.

## **INSTRUMENTS USED IN THE STUDY:**

### **Dental instruments**

- KaVo GENTLEforce 7000C
- Kavo - Gentle Power Lux 25 LPA
- W&H -Trend LS, WD-56
- W&H -Trend HS, YC-95RM
- KaVo Super-Torque LUX/640 B
- KaVo-INTRAmatic LUX3, 20 LH
- KaVo- Gentleforce 7000C
- NSK-PANA Air
- NSK-ATL118040
- NSK - Ti-Max
- STAR-430 SWL
- Sirona-T1 Classic, S 40 L
- Sirona-T1 Control, TC3
- Midwest Tradition
- Bein - Air - Bora L

### **B&L Ophthalmology instruments**

- |  |           |
|--|-----------|
| • Gimble irrigating cannula 30g        | E4894     |
| • Lasik cannula                        | E4989     |
| • Gillis irrigating-aspirating cannula | E4932     |
| • Nichamin hydrossection cannula 26g   | E4421 H   |
| • Irrigating-aspirating handpiece      | MVS 1063C |

### **Rudolf Medizintechnik GmbH Endoscope accessories**

- Trocar sleeve, arthroscopy, 2 rotating stop cocks  
(1.7 mm dia x 104 mm length #10-0008-00)
- Trocar sleeve, hysteroscopy diagnostic sheath, 1 fixed stop cock  
(2.7 mm dia x 302 mm length #10-0049-00)

### **Alcon Ophthalmic handpiece**

- NeoSonix Phaco handpiece

**Miltex Medical Instruments**

- Frazier needle 26-778
- Yeoman biopsy forceps with rotating shaft 28-304
- Kerrison rongeur 18-1994
- Frazier-Ferguson tube 19-570
- Yankauer suction tube 2-104SS
- Menghini biopsy needle 13-150

**Becton Dickinson**

- Needle, 30G1

**Medical Workshop**

- Hockeystick Forceps, membrane peeling mw-1925