ETS (Electronic Test System) in a university hospital: Diagnostics beyond the BDT!

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1. Introduction
In 2002 the ETS was tested at the Central Sterilization Department of the University Medical Centre Utrecht. A comparison was made between the ETS and a disposable BD testpack. Our conclusion was that the ETS was equivalent or better in detecting fails. Furthermore a trend analysis of the Decision Value showed that maintenance improved the sterilizer performance.

2. Purpose
To establish that a trend-analysis of ETS Decision Values can be used in evaluating the performance of the sterilizer.
To establish if the ETS can be used as load control.

3. Materials
- Steamsterilizer #3 and #5 (815 L, SA 6.9.12-81, 1998, Sanamij, Netherlands). The sterilizers are validated annually according to EN 285 & EN 554.
- Sterilization cycles #2 (BDtest 3.0 min 134°C) and #3 (3.0 min. 134 °C) were used. These cycles are identical except for the drying phase.
- ETS 4008 sensing units #1285 + #1390 and #1280 + #1393, ETS 4009 data converter, ETS 4010 software version 1.1 rev 4.0.39 and 4.0.4 (3M Laboratories (Europe), Germany).

4. Methods
ETS was used in two sterilizers in normal production cycles. These sterilizers were validated before and after the investigation. Validation was performed according to EN285 and EN554. During one day the measurements were carried out in an empty chamber (BD), with a full load of laminate pouches (LP) and with a full load of instrument trays (IT). LP load was approx. 300 pouches (total mass of baskets and load approx. 45 kg). IT load was 20 instrument trays (total mass of baskets and load approx. 150 kg).
One ETS was used in each measurement cycle. The mean Decision Value was calculated for each load type.

5. Results
- Decision Values are load dependent. The lowest Decision Value is found in an empty chamber, the highest in a full load of instrument trays. The difference between the mean Decision Values of empty chamber, full load laminate and full load instrument trays is significant.
- ETS results of BD test cycle differ from results in phase 1: the % of fails increased from 1.6% to 29%! This was not shown in the disposable BD testpack.

6. Discussion
A slight change in cycle design (jacket temperature was raised at an earlier time in the cycle) might be responsible for the change in ETS empty chamber results.
Validation of the sterilizers showed that the results did not differ from the validation results in previous years.
The Decision Value and algorithm had been changed in between the phase 1 and phase 2. This change did not affect the sensitivity of the PASS/FAIL decision.

7. Conclusions
- Empty chamber with ETS is still a worst case load.
- ETS can be used as a diagnostic tool.
- Due to the high % fails a trend analysis of the Decision Values did not show significant results.

8. Recommendations
- Further investigation into the effect of jacket temperature on BDT fails is necessary.
- ETS will be used in daily routine BD test and in troubleshooting.

References
(1) Philip A de Vries & Peter de Haas, Through the looking glass, IASSM/EFFISS conference 2003, Dublin.
(2) 3M_Technical_Report_of_ETS_enhanced_compatibility_algorithm