3M 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.(1)

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

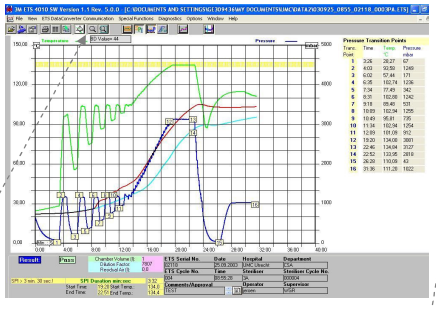
- Steamsterilizer #3 and #5 (815 L, SA 6.9.12-H, 1998, Sanamij, Netherlands). The sterilizers are validated annually according to EN 285 & EN 554.
- Sterilization cycles #2 (BDtest 3.0 min 134 °C) and #3 (3.0 min. 134 °C) were used. These cycles are identical except for the drying phase.
- ETS 4008 sensing units #1285 + #1390 and #1280 + 1393, ETS 4009 data converter, ETS 4010 software version1.1 rev 4.0.39 and 4.0.4 (3M Laboratories (Europe), Germany).
- Disposable BD testpack (ISP 2000, Interster International, Netherlands).

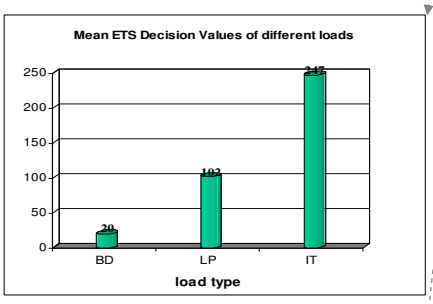
4. Methods

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.

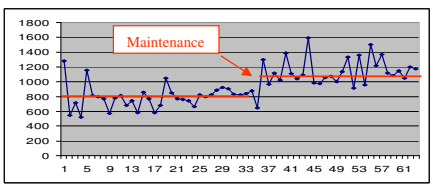
During one day the measurements were carried out in an empty chamber (BD), with a full load of laminate pouches (LP) and with a full load of instrument trays (IT). LP load was approx. 300 pouches (total mass of baskets and load approx. 45 kg). IT load was 20 instrument trays (total mass of baskets and load approx. 150 kg).

One ETS was used in each measurement cycle. The mean Decision Value was calculated for each load type.

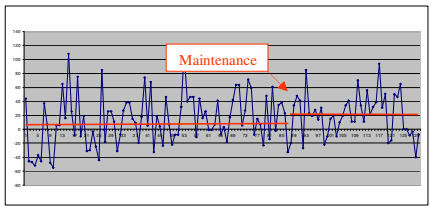




Phase 1	Time	Cycle	Load	# tests	% Fail	% early warning
Jan 2002 - April 2002	06:00	Warm-up cycle	Empty	123	-	-
	06:20	Leak-rate test cycle	Empty	123	0	-
	06:35	BD test cycle	BD testpack	123	0	-
	08 - 21	Extra BD test cycle	BD testpack + ETS	123	0	-
	08 - 21	Extra Leak-rate test cycle	Empty + ETS	123	1.6	1.6
	08 - 21	Production cycle 1....n	Hospital load	123	0	-
Phase 2	**Time**	**Cycle**	**Load**	**# tests**	**% Fail**	**% early warning**
Sept 2003 - April 2004	06:00	Warm-up cycle	Empty	124	-	-
	06:20	Leak-rate test cycle	Empty	124	0	-
	06:35	BD test cycle	BD testpack	124	0	-
	08 - 21	Extra BD test cycle	ETS	124	29	40
	08 - 21	Production cycle 1....n	Hospital load	-	-	-
	08 - 21	Production cycle + ETS	Laminate pouches + ETS	50	4	6
			Instrument trays + ETS	41	2	0



Change in sterilizer performance and DV due to maintenance in phase 1. (1)



Change in sterilizer performance and DV due to maintenance in phase 2

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.

What is the "Decision Value"?

A dimensionless number derived from measured values indicating the level of residual air or NCG in or entering the chamber. DV has values from minus infinity (fail), to plus infinity (pass). The greater the number the lower the residual air level and therefore the more efficient the air removal stage.

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 (2).

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/EFHSS conference 2003, Dublin.

(2) 3M_Technical_Report_of_ETS_enhanced_compatibility_algorithm

Acknowledgements

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