

The standard helix test in hospital sterilisers

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Rijksinstituut
voor Volksgezondheid
en Milieu



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National Institute for Public Health and the Environment

- Our mission is to benefit people, society and the environment, matching our expertise, knowledge and research with that of colleagues from around the world
 - 1400 employees
 - 100 M€
- Vaccine production
- Advise to Ministry and Inspectorate; research based
- Environment

Dutch Ministry of Public Health

In the year 2000 the Dutch Health Care Inspectorate checked the compliance of hospital CSSDs with the “Decree on sterilized medical devices in hospitals”

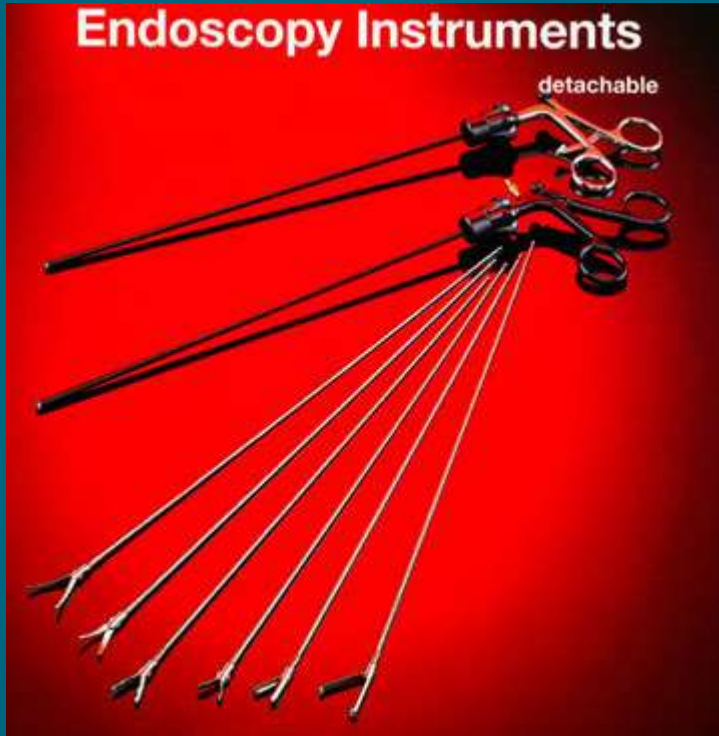
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Health Care Inspectorate

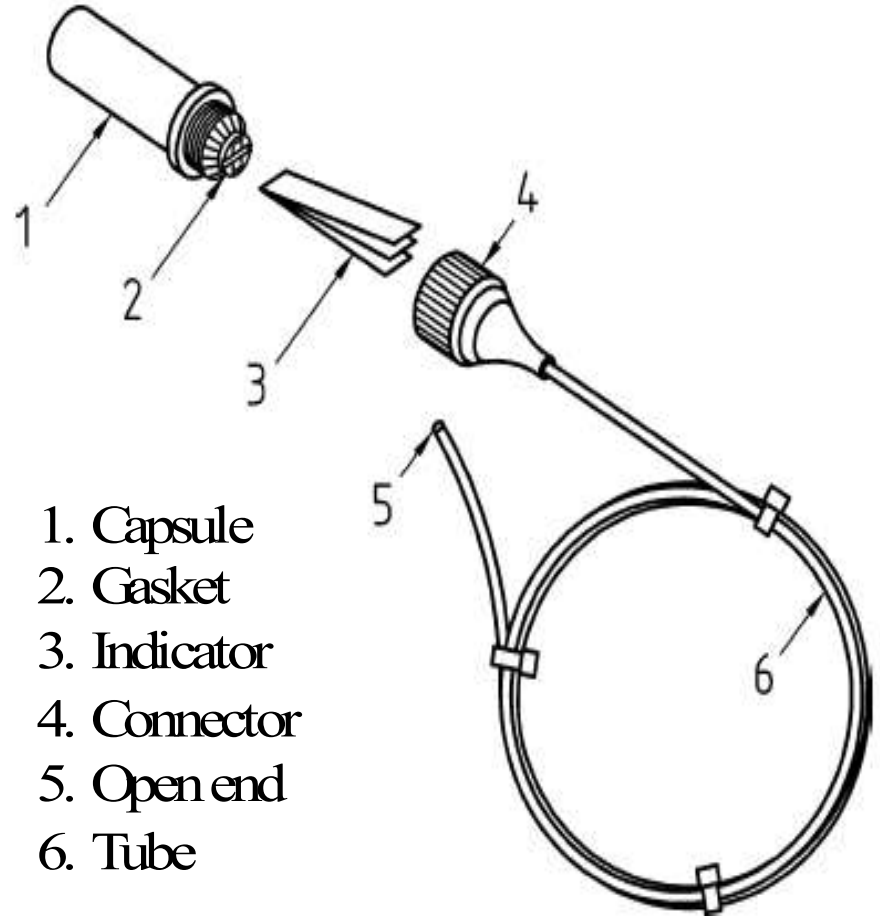
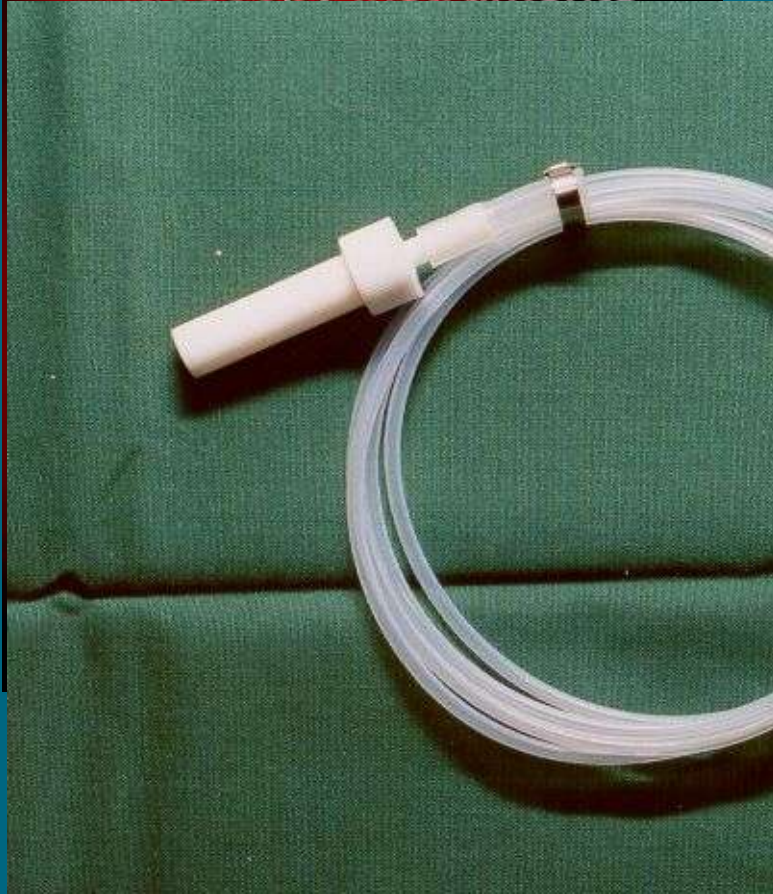
- Recommendation to reconsider the use of the Bowie & Dick test for daily testing and annual validation of the steam sterilisers
 - Textiles are not sterilized by the CSSD
 - Lumen devices are sterilized; more and more
 - From literature; lumen is harder to sterilize than textile pack
 - National guidelines prescribe the use of helix test since 1997, whenever hollow devices are sterilized
 - Helix test is standard challenge test for small steam sterilisers, ETO-sterilisers and LTSF-sterilisers

How to test for steam penetration?



How to test for steam penetration?

Endoscopy Instruments



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Reason for the study

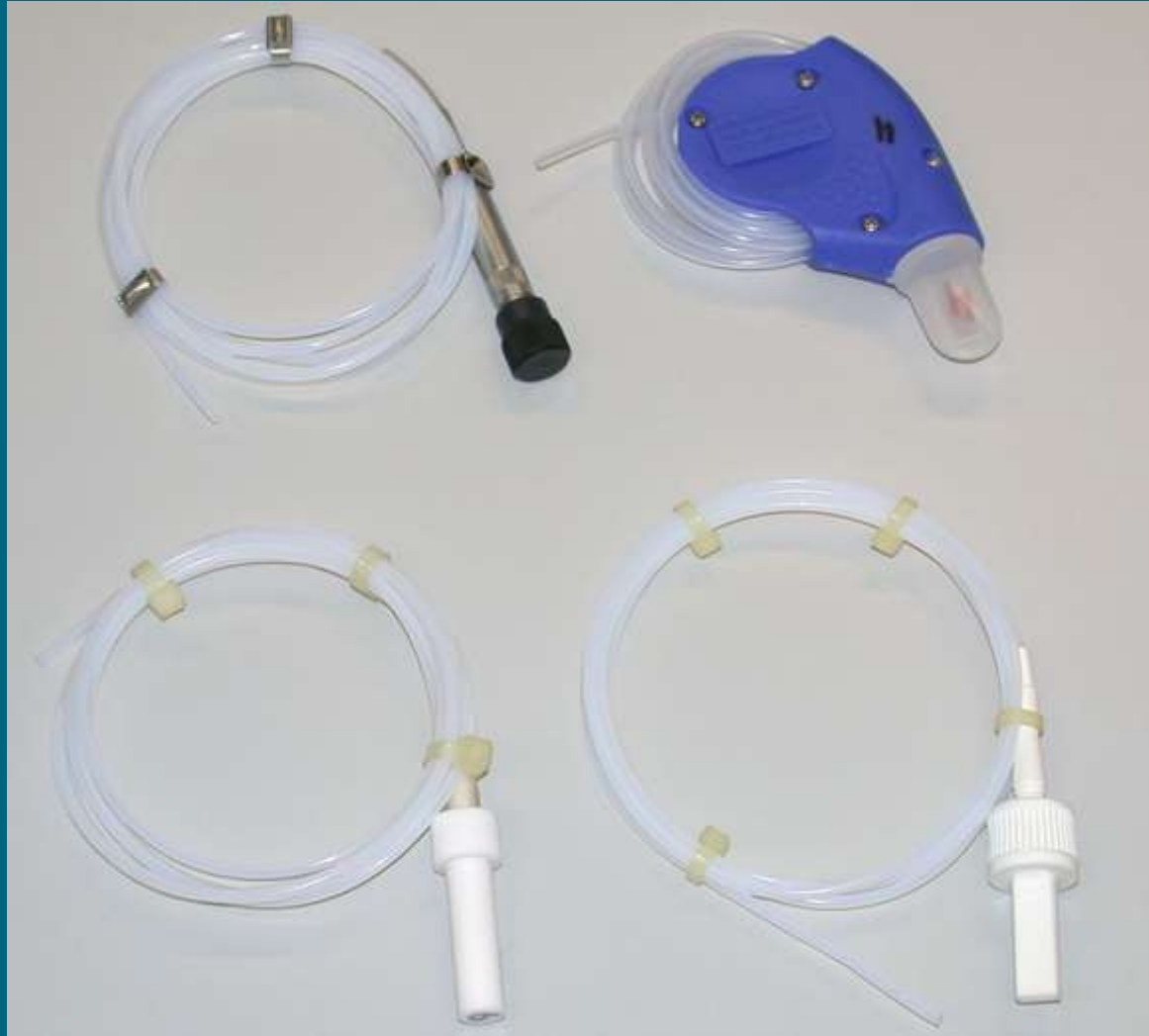
- Impression that recommendation from the Health Care Inspectorate was not followed
- A few experimental tests in two hospital sterilisers
 - Bowie & Dick test showed no problems
 - Helix test failed
- Are these results representative for the sterilisers in the Dutch autoclaves?
 - The Dutch Health Care Inspectorate asked RIVM to look into this matter

Design of the study

- Suppliers of the helix test listed
- Sample of the test helices requested
 - Declaration of conformity with EN867-5
- Verify the critical specifications
- Usable test helices selected and purchased
- Program of tests developed
- Visits to hospitals scheduled
- Hospitals visited and the tests performed
- Analyses of the results and report writing

Selection of test helices

- Conformity to EN867-5 or equivalent
- Critical specifications
 - Length and diameter of tube
 - Ratio volume capsule / volume tube



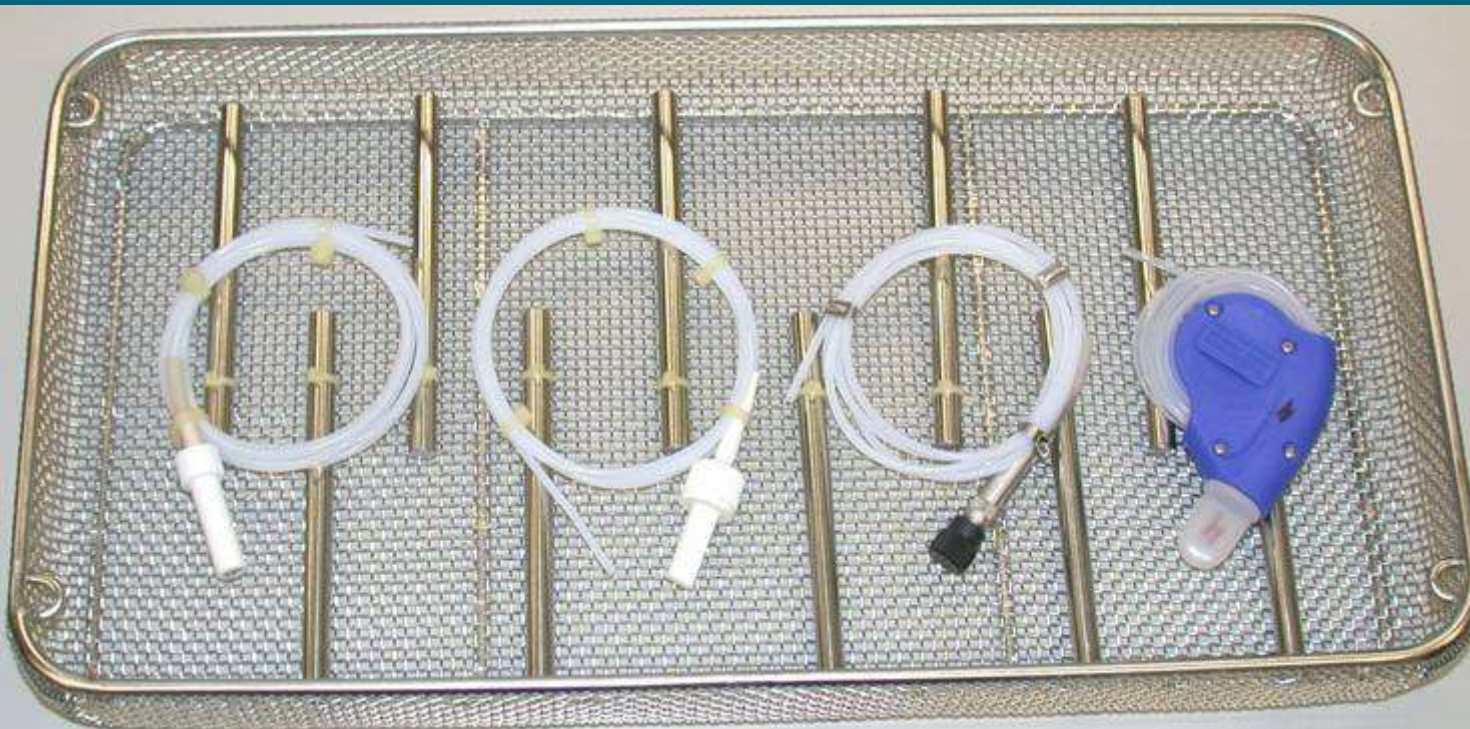
Test loads (1)

- Test helices in empty steriliser chamber
 - B&D test cycle (sterilisation time set to 3 minutes)
 - Perform as the daily test
 - Disposable B&D test pack included in the cycle



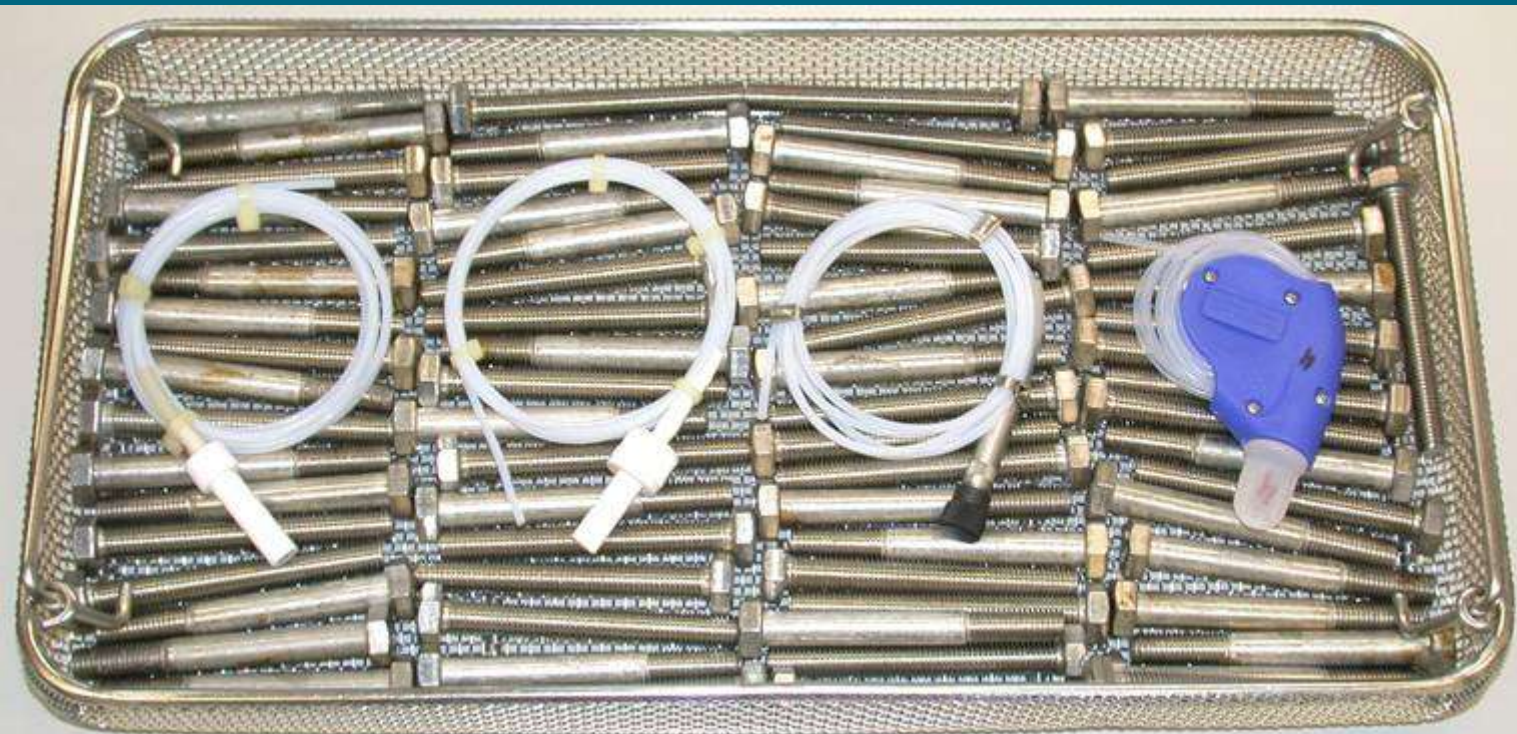
Test loads (2)

- Test helices added to an light instrument tray (2 kg); double layer wrapped
 - B&D test cycle
 - Steriliser chamber otherwise empty
 - Model for a light instrument tray with hollow instruments



Test loads (3)

- Test helices added to an heavy instrument tray (8.5 kg); double wrapped
 - Tray added to a full load and half load
 - Normal production sterilisation cycle (holding time 4 minutes)
 - Model for heavy instrument tray with hollow instruments



Test loads (4)

- Test helices individually sealed in double paper-laminate pouches
 - Added to a full load and half load
 - Placed on the bottom shelf of the steriliser
 - Normal production sterilisation cycle (holding time 4 minutes)
 - Model for routine / batch test



Attention!



- Dedicated chemical indicator for the test helix
- Position of the chemical indicator in the capsule
- Test helix dry
- Test helix at room temperature

Results; critical parameters of helix

	Tube length (mm)	Tube internal diameter (mm)	Ratio volume tube / capsule (%)	Tube material	Capsule material
Requirement in EN867-5	1500 ± 15	2,0 ± 0,1	6 ± 1	Teflon	Teflon
Helix A	1510	2,0	8,4 ± 0,5	Teflon	Plastic
Helix B	1510	2,0	3,2 ± 0,2	Teflon	Teflon
Helix C	1510	2,0	7,5 ± 0,6	Teflon	Metal
Helix D1	1500	2,0	7,5 ± 0,5	Teflon	Plastic
Helix D2	1500	2,0	7,8 ± 0,4	Teflon	Plastic

Results; critical parameters of helix

- Non of the helices is in full conformance; to the letter of the standard EN867-5
- But, alternative materials are allowed according to standard
- Therefore also mass and dimensions may be altered
- Does it make a lot of difference in practical situation?

Results, helix test overall

Hospital id.	Type ster process	B & D test	Helix test performed as daily test in B&D test cycle				Helices added in a 2 kg instrument tray processed in B&D test cycle				Helices double wrapped in see through pouches added to a full load, processed in standard cycle				Helices double wrapped in see through pouches added to a half load, processed in standard cycle				Helices added in a 8.5 kg instrument tray, tray added to a full load, processed in standard cycle				Helices added in a 8.5 kg instrument tray, tray added to a half load, processed in standard cycle				Total number of positive results per type of helix				Percentage positive results per hospital
			Helix A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	
1	A	+	-	+	+	+	-	-	-	-	-	+	+	+	-	+	-	+	+	+	-	+	-	-	-	-	1	4	2	4	46
2	C	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+	+	5	4	4	6	79
3	A	+	-	-	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0	1	1	0	8
4	B	+	+	+	-	+	-	-	-	-	-	-	-	-	Test not performed				-	-	-	-	-	-	-	-	1	1	0	1	15
5	B	+	+	+	+	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	2	1	1	1	21
6	D	+	+	+	-	+	+	-	+	+	+	-	-	+	+	-	-	+	+	-	-	+	+	-	-	+	6	1	1	6	58
7	B	+	+	-	-	+	+	-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	+	5	0	0	2	29
8	A	+	+	+	+	+	-	-	-	+	+	+	+	+	+	-	+	+	+	+	+	-	+	+	-	+	5	3	3	6	71
9	C	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	6	6	6	6	100
10	B	+	+	-	+	+	+	-	-	+	+	-	-	-	+	-	-	+	+	-	-	+	+	-	-	+	6	0	1	5	50
11	A	+	+	+	+	+	-	-	+	-	+	+	+	+	-	-	-	+	-	-	-	+	-	-	-	-	2	2	3	4	46
12	D	+	+	+	-	+	+	-	-	-	+	-	-	+	+	-	-	+	+	-	-	+	+	-	-	-	6	1	0	4	46
13	C	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	-	+	+	+	+	+	6	6	4	6	92
14	A	+	+	+	+	+	+	-	+	-	+	+	-	+	+	+	+	+	+	+	-	+	+	-	+	+	6	4	4	5	79
15	B	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+	-	+	-	5	4	6	5	83
16	A	+	-	+	+	+	-	-	-	-	-	-	-	+	-	+	-	-	-	-	+	-	-	-	-	+	0	2	2	3	29
17	A	+	+	-	-	-	-	-	-	-	-	+	+	+	-	+	+	+	-	+	+	+	+	-	-	+	2	3	3	4	50
18	A	+	+	+	+	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	5	4	5	6	83
19	C	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+	+	6	5	6	6	96
20	C	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	6	5	5	5	88
Number of positive test results			17	16	15	18	11	4	7	9	13	13	10	15	14	11	10	15	13	8	7	15	13	5	8	13					



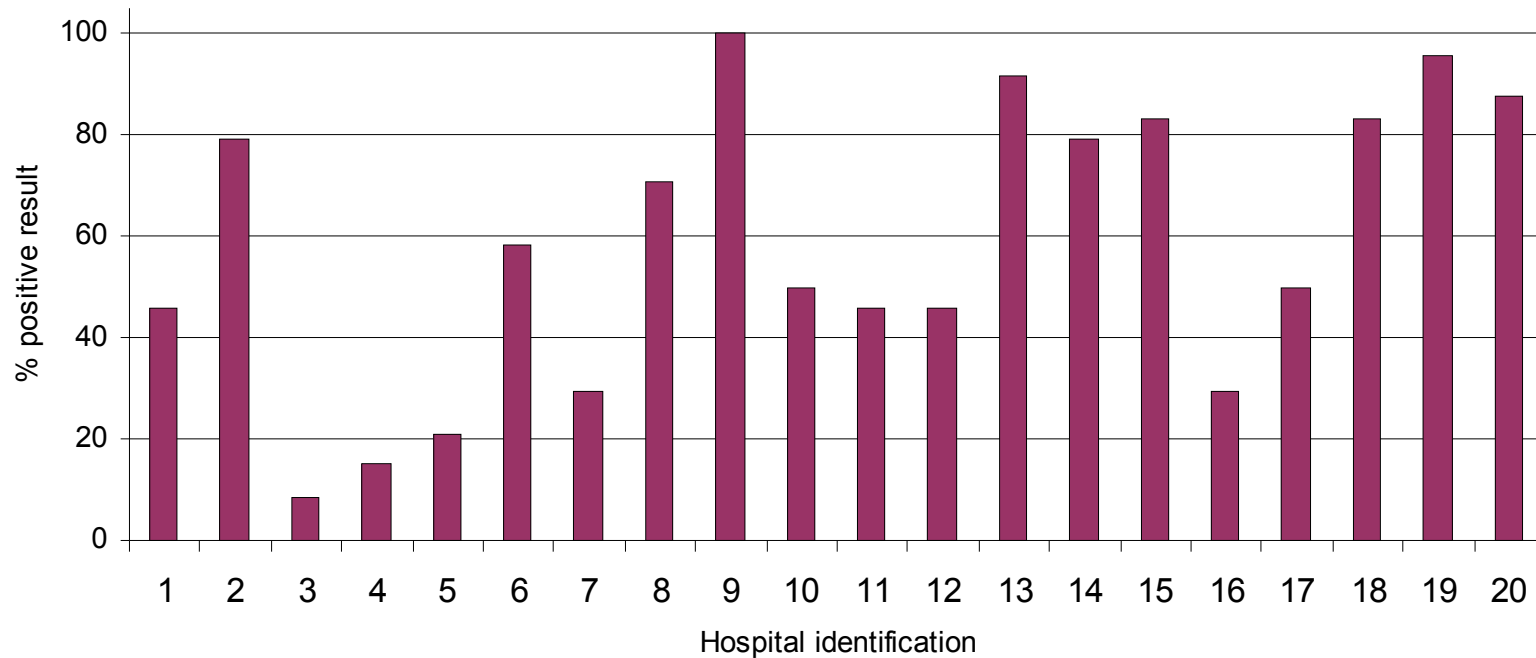
Results, helix test overall

- 20 hospitals
- 4 types of helix
- 6 test settings
- In 1 hospital, one test setting not performed
- 476 indicator test results
- 59% positive (variance 8% - 100%)

- 20 results from Bowie & Dick,
plus 40 retrospective
- 100% positive

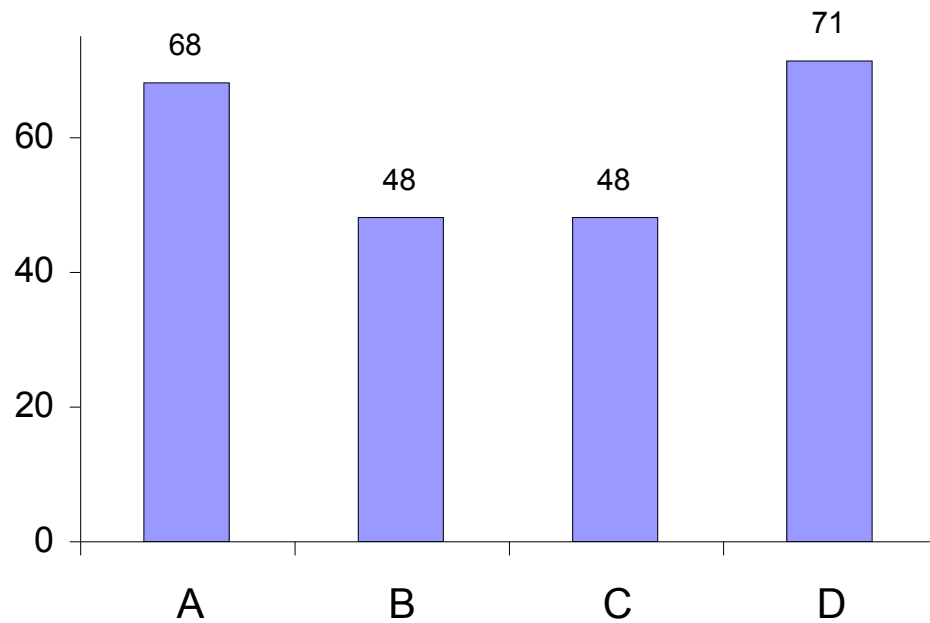
Results, helix test overall

Percentage positive test results per hospital



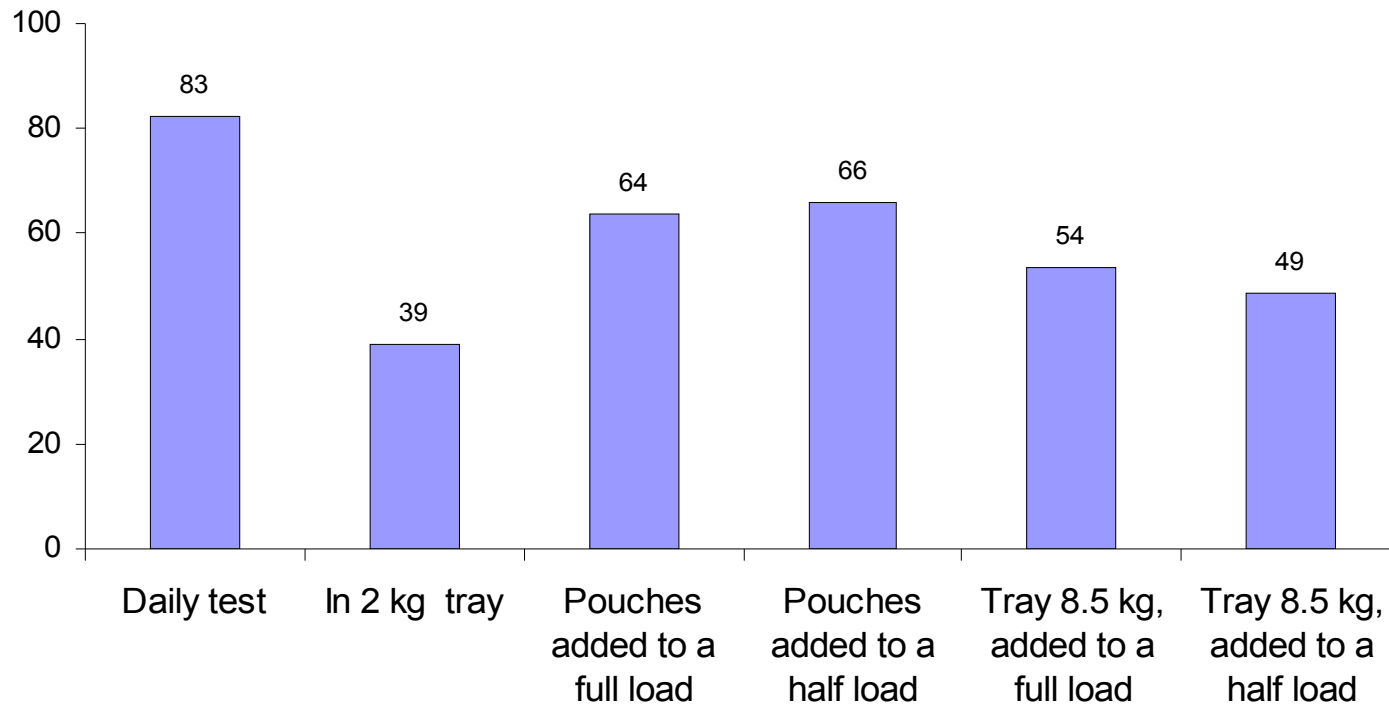
Results, helix type

Percentage positive results per helix type



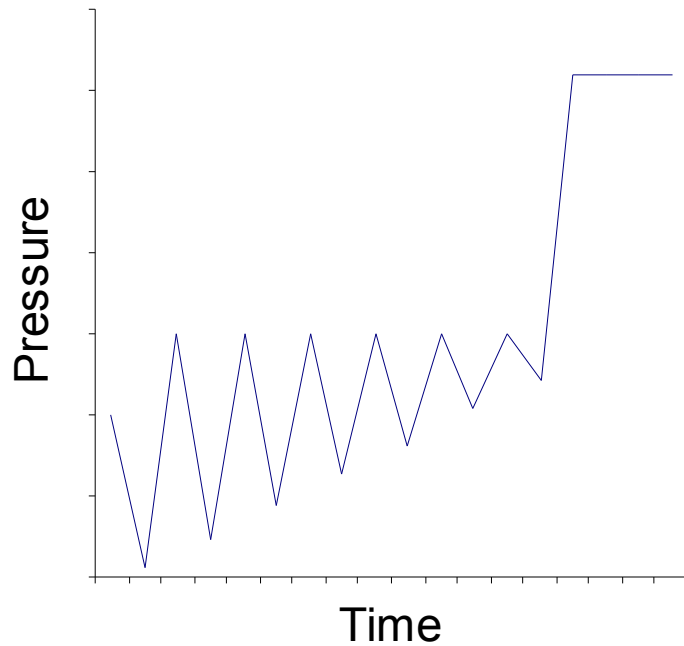
Results, test setting

Percentage positive results per test setting

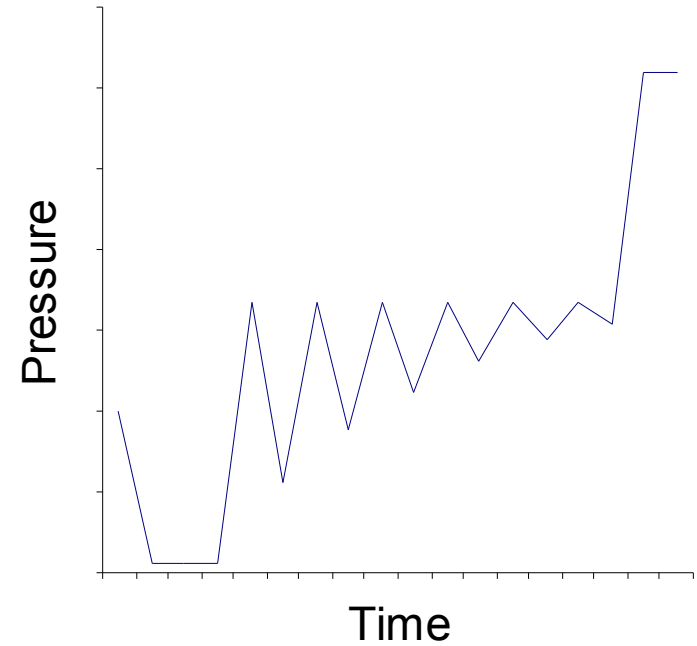


Results, cycle type

Cycle type A

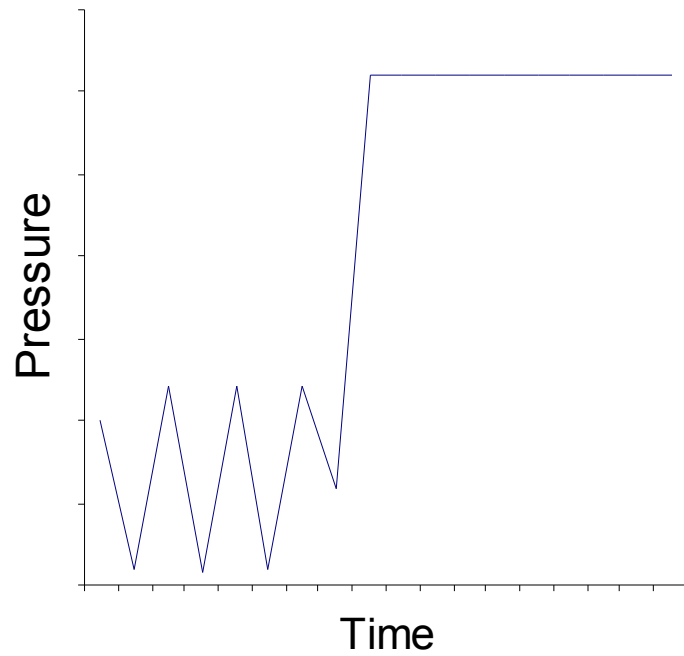


Cycle type B

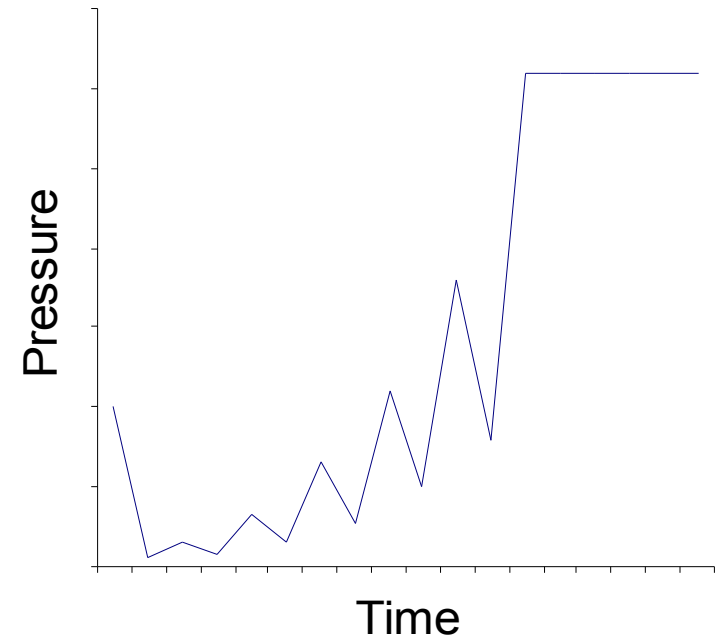


Results, cycle type

Cycle type C

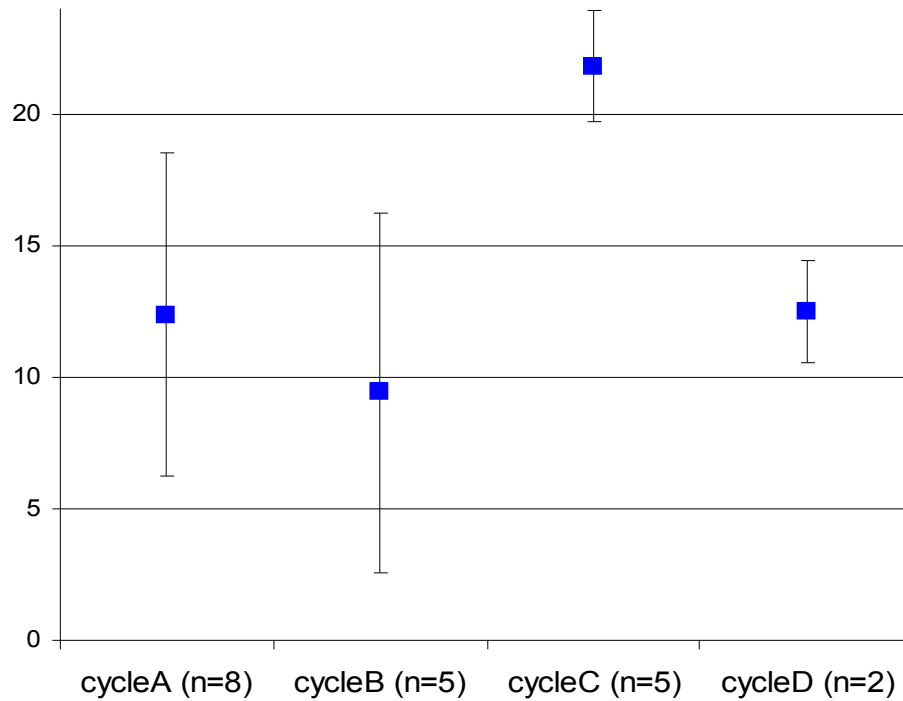


Cycle type D



Results, cycle type

Average number positive results per sterilisation cycle type



Results, indicators



Summary

- Different types of helices give different results
 - Helix type B and C generally the most critical.
 - Check which type of helix is the most critical in your steriliser.
- Different test loads give different results
 - Light weight instrument tray generally the most critical.
- The test result is cycle dependent
 - Generally the 'classical' three pulse vacuum gives the best results.
- Bowie & Dick test; 100% positive results!
- Helix test gives positive results in 59% of the tests.
- The goal of the study is confirmed.

Advice given to the hospitals

Taking into account that:

- The Bowie & Dick test is no longer representative for the steriliser loads in Dutch CSSDs.
- The helix test is the standard worse case challenge for small steam sterilisers (EN13060).
- Hospital sterilizers are clearly not capable of passing the helix test in all test settings.

Advice given to the hospitals

We recommend to:

- Monitor, batch-wise or continuously the non-condensable gas content of the steam (e.g. EN285-method, air-detector, Vapocontrol).
- Use the test helix added to a double wrapped instrument tray with a mass of 2 kg as a standard test load during validation.
- Modify the steam supply and/or the sterilisation cycle, where necessary.
- Perform the daily steam penetration test using the test helix added to a double wrapped instrument tray with a mass of 2 kg.

Advice given to the hospitals

- Do the Bowie & Dick test when textile packs are routinely sterilised.
- Alternatively, instead of the daily test, sterilise a test helix, double wrapped in see-through pouches, with every sterilisation cycle and use the test result for batch release.

