

- steam steriliser
- performance evaluation
- helix test

# Performance Evaluation of Hospital Steam Sterilisers Using the European Helix Test

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**The Bowie & Dick test is used by manufacturers of steam sterilisers to design the sterilisation cycle in line with the requirements of the European standard for large steam sterilisers, EN285. Hospitals use it as the reference load in operational qualification and re-qualification and as the daily steam penetration test.**

**However, textile packs are rarely sterilised in hospitals and complicated laparoscopic instruments provide a new challenge to the sterilisation cycle. It is time to review the value of the Bowie & Dick test in light of the items that are nowadays sterilised and perhaps choose another type of reference device for the design and qualification of large steam sterilisers (1).**

**The Dutch National Institute for Public Health and the Environment conducted a study in 20 hospitals to determine whether the sterilisers are capable of passing the standard helix test according to EN867-5 (2). All sterilisers passed the Bowie & Dick test but of the 476 tests conducted with the helix 41% failed. The study shows that the ability of the steriliser to pass the helix test depends on the test conditions and the type of air removal. An air removal stage of the sterilisation cycle that is suitable to remove the air from a textile pack is not necessarily suitable for the air removal from hollow devices.**

## Introduction

The general opinion is that it is mandatory to test the performance of the steam sterilisers in hospitals once a day, using the Bowie & Dick test. In the Netherlands the "Decree on sterilisation of medical devices in hospitals" requires that the hospital shall use adequate equipment to sterilise the medical devices and the performance of the equipment shall be veri-

fied on a regular basis. Neither the necessary test methods nor the frequency of the test are specified in the decree. The Dutch Health Care Inspectorate (IGZ) expects hospitals to perform a daily steam penetration test that is a representative challenge to the sterilisation process.

Practical test procedures are given in standards and guidelines. The European standard EN554 on validation and routine monitoring requires a daily steam penetration test where saturated steam is used and the efficacy of the process depends on air removal. The draft ISO standard ISO/CD 17665, which is going to replace EN 554 in time, requires a steam penetration test to be carried out at "specified intervals". The nature of the steam penetration test is not specified in either document. It may be a test based on a textile pack e.g. Bowie & Dick test or based on a tubular device e.g. a test helix. These requirements for a steam penetration test to be performed, are historically interpreted, by the users of sterilisers, as an obligation to perform the Bowie & Dick test.

The Bowie & Dick test is prescribed in the type test procedure for steam sterilisers that are build in compliance with EN285. The Bowie & Dick test pack as specified in EN285 is often considered to be "the most difficult to sterilise object". If the steriliser is capable of providing sufficient steam penetration into this test pack it is generally assumed that the steriliser is capable of sterilising all types of loads and items. The design of the sterilisation cycles operated in Dutch hospitals is for the larger part based on the achievement of steam penetration in this "worst case" standard textile test pack. However, literature and national guidance documents indicate that the Bowie & Dick test

pack is not the general applicable worst case load.

a. The specifications of the most difficult to sterilise textile pack seem to depend on the steriliser chamber size. CEN TC102 has re-defined the "standard" test pack for steam sterilisers with a chamber volume of 1 standard unit. A pack less high than the standard Bowie & Dick test pack seems to be a greater challenge for the smaller models of large steam sterilisers.

b. To test whether steam penetration in hollow devices is sufficient the European standard for small steam sterilisers (EN13060:2004) requires the standard helix test to be performed.

c. Recommendations to conduct the helix test are found in guidance documents for healthcare from Germany, the Netherlands and the UK.

d. A published study from Gömann [3] shows that the Bowie & Dick test is less of a challenge than the standard helix test.

In 2000 IGZ expressed her concern about the lack of consideration given by the hospitals to the relevance of the daily steam penetration test. The fact that textile is no longer sterilised makes the use of the textile standard test pack for the Bowie & Dick test, or paper pack alternatives, obsolete.

Since the publication of the report by IGZ a few hospitals have experimented with the helix test; all with negative results. To determine whether these observations were purely accidental or that the Dutch

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sterilisation cycles are by design not adequate for the sterilisation of hollow medical devices, IGZ has asked the RIVM to visit 20 hospitals and perform the standard helix test on site. This paper describes the design of the study, the results and the recommendations derived from the results.

## Materials and methods

### Selection of helices

The helix is made from a long narrow tube that is closed at one end with a capsule, designed to receive a chemical or biological indicator. The tube is curled up, hence the name "helix". Figure 1 shows a schematic representation.

In principle the length and diameter of the tube, the materials of the capsule and the internal volume of the capsule could be varied indefinitely. For this study helices were selected that, according to the manufacturer, fulfil the requirements in the European standard EN867-5 (2). This standard clearly specifies the materials and dimensions of the different components. The standard allows for the use of other materials of demonstrated equivalence. At the start of the study five companies were known at the RIVM as suppliers of a test helix for autoclaves. A request for a sample of the helix, fulfilling the requirements of the standard, was sent to these firms. On receipt of the sample, the critical parameters length and internal diameter of the tube, volume of the chemical indicator and the capsule volume were verified by measurement. The volumes of the tube and the capsule were measured gravimetrically using distilled water and a calibrated balance. The measurements were taken seven times and the average values were calculated. The free capsule volume is defined in EN867-5 as the capsule volume minus the volume of the chemical indicator.

### Test loads

The tests were performed with the selected test helices in six different settings. These settings were:

#### 1. Helices non-wrapped, in an empty steriliser chamber

The helices were processed using the Bowie & Dick test cycle. This setting is

identical to the setting in which the daily Bowie & Dick test is performed. The Bowie & Dick test cycle on the steriliser is typically programmed with a shorter holding time than the standard cycle, to prevent over exposure of the chemical indicator that is used in the test. For comparison the usual alternative test for the Bowie & Dick test (disposable pack) was processed at the same time.

#### 2. Helices added to a light instrument tray

The total mass of the tray was 2 kg. The tray was double wrapped in non-woven and/or paper, as indicated by the hospital's protocols. All the test helices were processed together in a single tray (see figure 2) using the Bowie & Dick test cycle.

#### 3/4. Helices double wrapped in see through pouches.

Each helix was double wrapped in see through pouches. Each pouch was sealed. The pouches were added to a full production load and a half production load respectively. The pouches were positioned on the bottom shelf. The helices were processed using the standard 134°C sterilisation cycle. The holding time of the cycle was not adjusted to match the maximum allowed exposure time of the chemical indicator.

#### 5/6. Helices added to a heavy instrument tray

The total mass of the instrument tray was 8,5 kg. The tray was double wrapped in non-woven and/or paper, as indicated by the hospital's protocols. All the test helices were processed together in a single tray

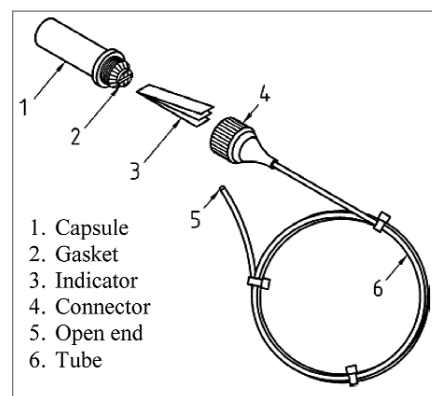


Fig. 1: Helix construction

(see figure 3). The tray was added to a full production load and a half production load respectively. The tray was positioned on the bottom shelf next to the unloading door. The helices were processed using the standard 134°C sterilisation cycle. The holding time of the cycle was not adjusted to match the maximum allowed exposure time of the chemical indicator.

The helices in the see through pouches and the heavy instrument tray were processed together in the same cycle.

### Procedure

The tests were performed using the sterilisers in the CSSD of 20 different hospitals.

Preceding the visit to the hospital the helices were prepared by placing the chemical indicator in the capsules. The indicator was folded so that the printed side was in-

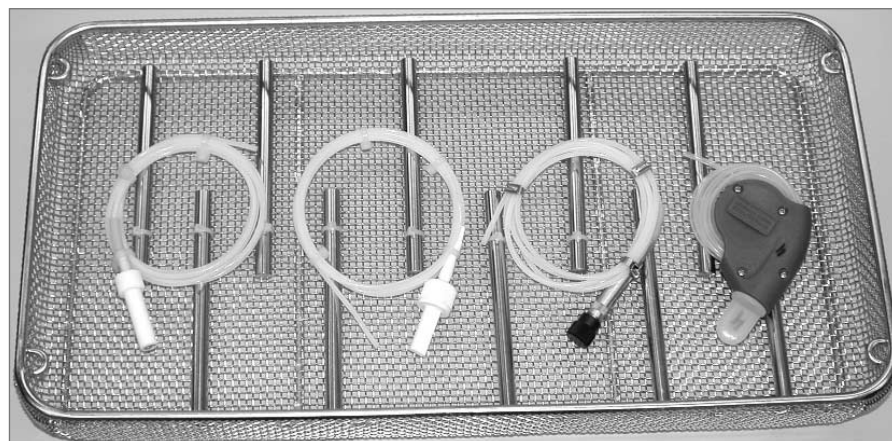


Fig. 2: Test load with a mass of 2 kg

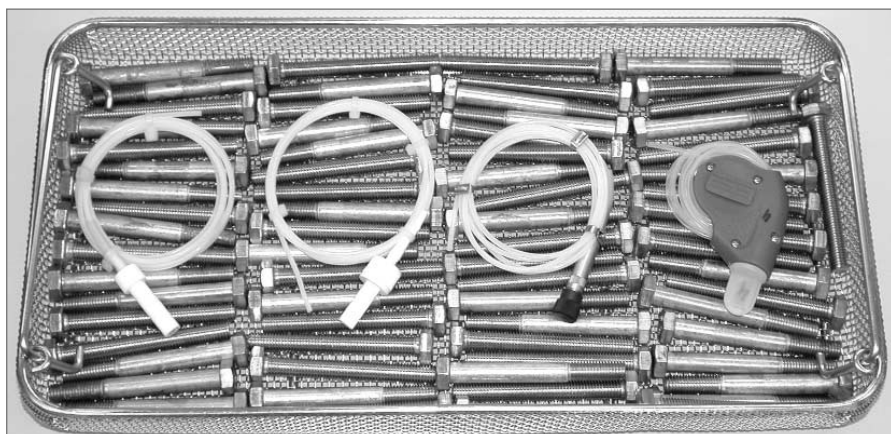


Fig. 3: Test load with a mass of 8,5 kg

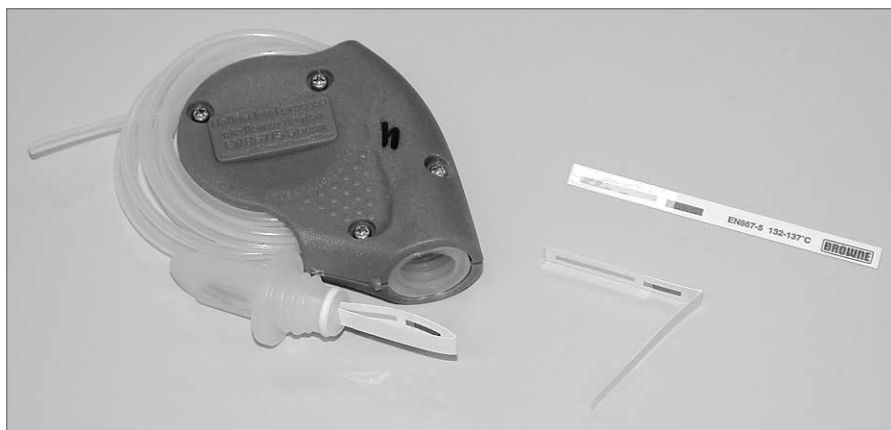


Fig. 4: Position of the chemical indicator in the capsule

side the fold. The indicator was positioned in the capsule so that the printed part of the indicator was farthest away from the point of entry of the steam. This was not necessarily in line with the instructions of the manufacturer. See figure 4 for an example of the position of an indicator in the capsule. The capsules were screwed on to the helices, but not tightened, to preserve the flexibility of the rubber gasket. The helices were stored and transported in an aluminium flight case. The relative humidity in the case was reduced by silicagel desiccant in a container that was closed with a piece of non woven sheet material that allowed for the entry of moisture but prevented the spillage of the desiccant. The indicators were kept in double zipper bags that were stored in the case.

On site the helices were taken out of the case, the capsules tightened and added in the test loads as described above. The test loads and helices were at ambient temperature before they were put into the steriliser. Once loaded into the steriliser the door was closed as soon as possible and the sterilisation cycle was started.

At the end of the sterilisation cycle the helices were taken out of the steriliser and the indicators recovered from the capsules. The results of the tests were observed and noted. The test result was noted as "positive" when the colour change of the indicator was complete. The capsules were screwed on to the helices but not tightened, to allow for the evaporation of residual moisture. The helices were used once per test site.

To preserve the test results, the exposed indicators were scanned into a computer.

On each site the results of the Bowie & Dick test of the day of the visit and the day six months before the visit were observed and noted. Some indicators may invert the colour change if the colour change was not entirely completed. When observed directly after the sterilisation cycle the colour change may appear to be complete, but the colour change may partly reverse in time. This may be an indication of sub-optimum steam penetration.

We also asked the hospital whether the steam quality, in particular the amount of non-condensable gasses, had been tested.

## Results and conclusions

### Selection of test helices

Four out of five suppliers provided a sample of the helix and the chemical indicator. One of these companies supplied two different helices, giving five helices in total.

Table 1 gives the results from the verification measurements of the critical specifications of the helices.

The helices D1 and D2 were provided by different suppliers. The design and materials used seemed to be identical. There was no significant difference in the critical specifications. Therefore only the helix of one of the suppliers was used in the practical tests.

None of the helices met the specifications given in the European standard for the ratio of the internal volume of the tube and the free capsule volume.

The free capsule volume of the helices A, C, D1 and D2 was too large. One may expect that these helices will give an early positive result. The materials used for the construction of helix B are as required by the standard. The free capsule volume, however, is too small. One may expect an early negative result with this helix.

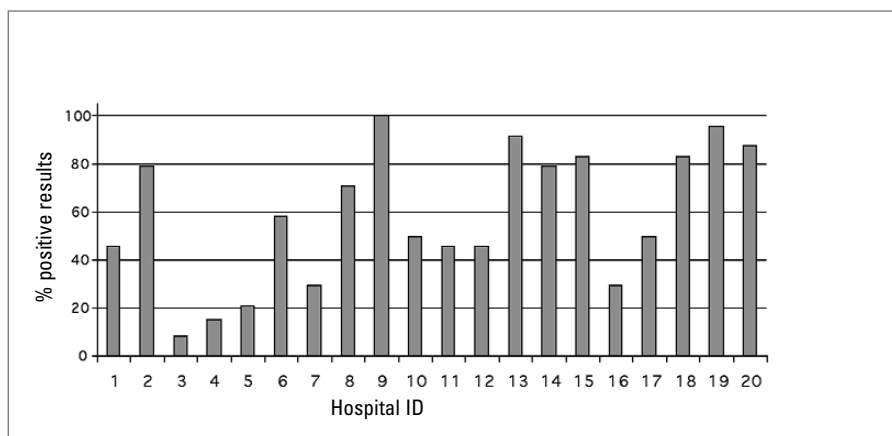
The standard allows for the use of other materials of demonstrated equivalence. None of the manufacturers supplied any information about the equivalence of their product with the reference helix.

### Practical tests

The tests were performed in the CSSD of 20 hospitals. In one hospital one of the test

|                         | Tube length (mm) | Tube internal diameter (mm) | Ratio volume tube/capsule (%) | Tube material | Capsule material |
|-------------------------|------------------|-----------------------------|-------------------------------|---------------|------------------|
| Requirement in EN 867-5 | 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          |

**Table 1:** Critical specifications of the helices



**Fig. 5:** Percentage positive test results per hospital

settings (helices wrapped in double see-through pouches, added to a half steriliser load) could not be performed for logistic reasons. For the other test sites 24 test results were obtained, which adds up to a total of 476 test results. Per helix type 119 test results were available for analysis. Table 2 gives an overview of all individual test results. Figure 5 gives a graphical representation of the percentage of positive test results per hospital.

A positive test result is the complete colour change of the chemical indicator. Per hospital the number of positive test results varied from 8% to 100%.

The Bowie & Dick tests performed by the hospitals on the day of the visit, the tests performed six months before the visit, as well as the Bowie & Dick tests performed during the visit as part of this study all showed a "pass".

At first glance the test results given in table 2 seem to be little systematic. The

result of a particular helix type in a particular test setting seems to have little value to predict the result of the helix type in a different test setting. Some helix types gave a positive result in a particular test setting, but not on all sites. The reversed situation also occurred. Based on earlier tests one would expect a negative result, while the actual result was positive.

The results were analysed by grouping them in different manners, in order to show trends.

**Relation test results and type of helix**

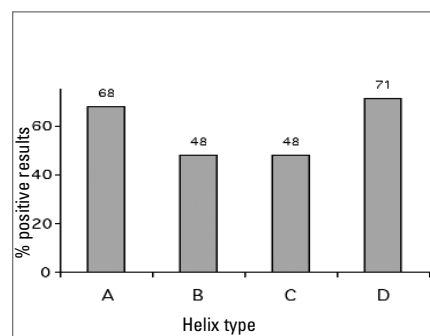
Out of the 119 test results that were obtained for each helix type, the number of positive results per helix type is determined. Figure 6 gives the graphical representation of the results. When used in the same sterilisation cycle the different helices do not necessarily give an identical result. Helices B and C turned out to be more

critical, i.e. giving significantly less positive results, than the helices A and D.

Table 2 shows that in a number of tests one or more helices gave a positive result while during the same sterilisation cycle one or more of the other helices showed a negative result. The test result shall be reliable primarily for positive results. In other words, a positive result must be a true positive result, thus giving confidence that the sterilisation process was effective and gave sufficient steam penetration in the load. As a consequence, a particular type of helix shall not give a positive result, while during the same sterilisation cycle another type of helix gives a negative result. For each of the four helix types the number of positive results is counted, under the condition that in the same test setting another type of helix gave a negative result. The average of these counts over all hospital visits gives an indication of the probability that the particular type of helix may give a false positive result. Figure 7 gives a graphical representation of the average number of false positives and the standard deviation.

The differences between helices A and D and the helices B and C are not significant.

From the 80 test results that were obtained for each test setting (79 for the helices wrapped in double see through pouches, added to a half load), the number of positive results was counted. Figure 8 gives the graphical representation of these results. As was expected the tests performed in the different test settings gave a variation in the test results. The number of positives in the test setting "Daily test" is significantly higher than the number of positive results in the



**Fig. 6:** Relation test results and type of helix

| Hospital ID                     | Type of sterilisation process | B & D test | Helix test performed as daily test in B & D test cycle |    |    |    | Helices (H.) added to a 2 kg instrument tray processed in B&D test cycle |   |   |   | H. double wrapped in see through pouches added to a full load, processed in standard cycle |    |    |    | H. double wrapped in see through pouches added to a half load, processed in standard cycle |    |    |    | H. added to an 8.5 kg instrument tray, tray added to a full load, processed in standard cycle |   |   |    | H. added to an 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 of positive results per hospital |  |
|---------------------------------|-------------------------------|------------|--|----|----|----|--|---|---|---|--|----|----|----|--|----|----|----|---|---|---|----|---|---|---|----|--|---|---|---|---|--|
|                                 |                               |            | 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 |   |  |
|                                 |                               |            | Helix  |    |    |    |  |   |   |   |  |    |    |    |  |    |    |    |   |   |   |    |   |   |   |    |  |   |   |   |   |  |
| 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 |  |   |   |   |   |  |

**Table 2:** Overview of individual test results

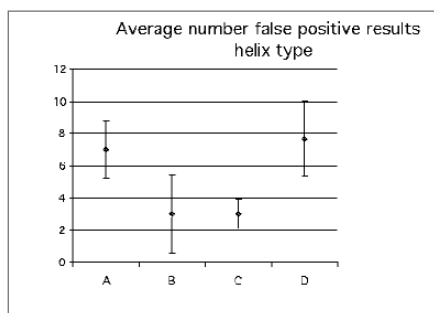


Fig. 7: Average number of false positive results per type of helix

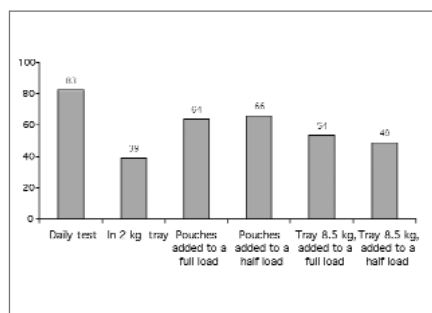


Fig. 8: Percentage of positive results per test setting

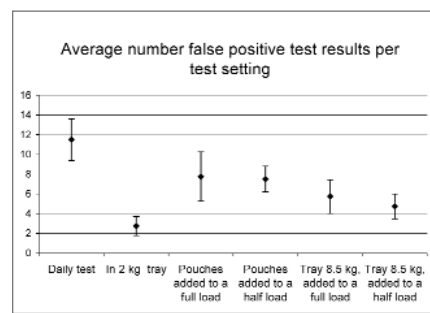


Fig. 9: Average number of false positive results per test setting

other test settings. The results from "In 2 kg tray" are not significantly lower than the results in both "Tray 8.5 kg" test settings. The results are however significantly lower than the results from the tests performed in the test setting "Pouches". The small difference between the test settings "Pouches added to a full load" and "Pouches added to a half load" is not significant. This indicates that the test result from helices wrapped in see-through pouches is little influenced by the amount of load in the steriliser chamber. The same conclusion can be drawn from the results from the helices added to the 8.5 kg trays.

Table 2 shows that a particular type of helix gave a positive result in one or more test settings while this type of helix gave a negative result in one or more of the other test settings. For each of the six test settings the number of positive results for a particular type of helix is counted, under the condition that in another test setting this helix gave a negative result. This is done for all the helix types. The average of these counts over all hospital visits gives an indication of the probability that a particular test setting may give a false positive result. Figure 9 gives a graphical representation of the average number of false positives and the standard deviation.

The chance to obtain a false positive result when the helix test is performed in the test setting "daily test" is significantly higher when compared to the other test settings. The change to obtain a false positive result in the test setting "In 2 kg tray" is significantly lower when compared to the test settings where the helix is double wrapped in see through

pouches. The differences between the test setting "In 2 kg tray" and both test setting "In 8.5 kg tray" are not significant. Where the sterilisation cycle is designed to pass the helix test when the helix is added to a 2 kg instrument tray, there is only a small change that a positive result is a false positive.

#### Relation test results and type of sterilisation process

The sterilisation cycles that are in use in the different hospitals are all of a different design. However, they can be divided into four types. Figure 10 shows a schematic presentation of the four different sterilisation cycle types. In the sterilisers from a particular brand usually the same sterilisation cycle is applied. Minor differences in the pressure of the vacuum and steam pulses are noted from steriliser to steriliser.

Sterilisation cycle A is used on 8 locations, cycles B and C on 5 sites each and cycle type D was used in 2 of 20 hospitals. The results of the helix test seem to depend on the type of sterilisation cycle that is applied. Figure 11 shows the average number of positive results and the standard deviation.

The sterilisers in which sterilisation cycle type C is used give, on average, the most positive results. The only hospital that gave 100% positive test results used a type C sterilisation cycle. The sterilisation cycle types A and B show a large variation in positive results in the different test sites. The hospital with the lowest number of positive test results (2 out of 24) used a type A sterilisation cycle. On another site, a type A sterilisation cycle gave 20 positive results.

#### Relation test results and type of chemical indicator

Few problems were encountered when reading the test results from the chemical indicators. The difference between a positive and a negative result was clear in almost every case. The indicator provided by one of the manufactures has the advantage that the colours for the non-processed indicator (bright yellow) and the processed indicator (dark blue) are distinctly different. The other manufacturers provided indicators that do not give such a distinct difference in colour. The colour change is more graduate and it is more difficult to establish whether the end point has been reached. Fortunately these indicators are printed in a checked pattern, which helps to see a gradient in the colour change. Fig 12 shows the different phases in colour change of the indicators. The bottom row shows the end colour for both types of indicator.

A relation between the test results and the type of indicator could not be established because the indicator is an integral part of the helix. Each type of helix has its own type of indicator, specified by the manufacturer. A different indicator shall not be used. The results of the helix test depend partly on the properties of the indicator. The dimensions of the indicator are important because the indicator reduces the internal volume of the capsule. Variations in the volume of the indicator lead to variations in the volume of the capsule. In theory the internal volume of the capsule will influence the sensitivity of the test. The sensitivity of the indicator for temperature and saturation level of the steam as well as the reaction time were unknown to us. One may expect that these un-

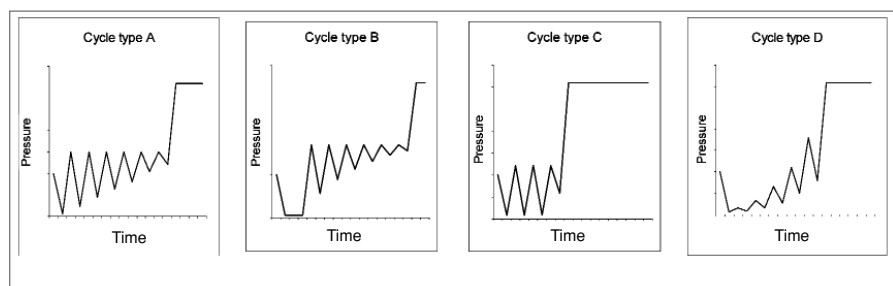


Fig. 10: Presentation of the types of sterilisation cycle

known factors are partly responsible for the variations in the test results between the different helix types.

### Conclusions and recommendations

Despite the fact that more and more hollow instruments and medical devices with lumens are used and reprocessed, until now the helix test is not used to demonstrate the efficacy of the sterilisation process for these types of loads in Dutch hospitals.

This study shows that the helix test cannot be performed satisfactory in one or more test settings in practically all sterilisers. Only on one site the sterilisers were able to give a positive result for all helices in all of the test settings. Only 59% of all the tests gave a positive result, where the Bowie & Dick test gave a positive result in all cases. In this respect the study confirms the results of the study from Gömann et al [3].

However, this was to be expected. The sterilisation processes as used in the Dutch hospitals are designed to give full steam penetration in the 'worst case load' named Bowie & Dick test pack. The sterilisation of hollow devices is not given due consideration at type testing of new sterilisers, nor during performance qualification.

Taking into account that more and more laparoscopic instruments and very few textile packs are sterilised in hospital sterilisers, the Bowie & Dick test is no longer representative for the steriliser loads. The sterilisation processes should be designed and tuned for the sterilisation of hollow instruments. The European standard for small steam sterilisers promotes the standard helix (EN867-5) as the test object when hollow instruments are ster-

ilised. Therefore it seems logical to use the same test device as a reference object for the design and monitoring of the sterilisation process in large steam sterilisers.

The European standard EN867-5 gives requirements for the materials and dimensions of the parts of the test helix. It is allowed to use different materials under the condition that the helix gives an identical performance as the reference helix described in the standard. Despite the claim from the manufacturers that their helices fulfil the requirements of the standard, the helices do not give an identical result when exposed to the same sterilisation process. This may be explained by the fact that the critical specification of the helices deviate from those of the reference helix. One of the helices used in this study is made from the materials specified in the standard, but the free capsule volume is too small. The capsule of one helix is made of metal, thus having different heat transmission characteristics than a plastic capsule. The metal capsule will rapidly heat up from the outside. One may expect that these differences in construction influence the sensitivity of the helix test for remaining air, non-condensable gasses and rate of temperature change. Another unknown parameter is the specifications of the chemical indicator that is used in the helix. The sensitivity of the indicators for remaining air and other non condensable gasses, as well as the optimum sterilisation temperature and holding time are unknown. These factors may have influenced the outcome of the helix test. Within the limits of this study it was not possible to study these aspects.

As expected, the test setting had an influence on the result of the test. Firstly, the packaging in which the helices were placed gave resistance to air-removal and steam penetration. Secondly, for the he-

lices that were added to a light or heavy instrument tray the amount of non-condensable gasses in the steam may play an important role. In these test loads a relatively large amount of steam will condense in the surroundings of the helices. The non-condensable gasses that enter the test load with the steam will not condense. In this way the amount of non-condensable gasses in the steam surrounding the helices is concentrated. The non-condensable gasses surrounding the helices will be carried into the helices with the steam. As a result of the relative large amount of non-condensable gases the indicator will not give a complete colour change and the test will fail.

The test results obtained in this study show a relation between the test result, the type of helix, the test setting and the type of sterilisation cycle. In general helix B or C added to an instrument tray with a mass of 2 kg proved to be the most critical combination, with the smallest change of false positive test results.

In the report (4) that has been presented to the Dutch hospitals and steriliser manufacturers, the RIVM gives the following recommendations:

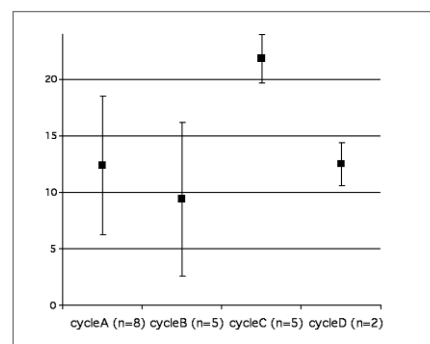


Fig. 11: Relation test results and type of sterilisation cycle

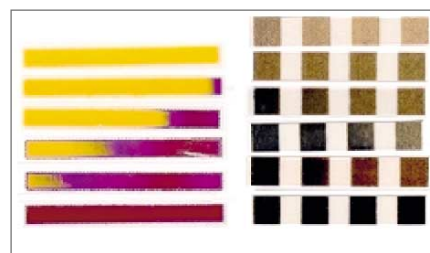


Fig. 12: Phases in colour change of the chemical indicators

Considering that:

- the Bowie & Dick test pack is not a good representative for hollow instruments and therefore should no longer be considered as the worst case test load
- the helix test sets the standard for small steam sterilisers that are mainly used in areas where the nature of the medical treatment carries relatively little risk to acquire an infection when compared to the nature of the treatment given in hospitals
- the steam sterilisers in the majority of the Dutch hospitals are not capable of getting a positive helix test in all test settings
- the helices from different suppliers do not give identical results when used in the same test setting
- although it is required by the Dutch law for hospital sterilisation, the steam quality is not routinely monitored.

It is recommended to:

- perform the helix test, as part of the validation procedure. The helix shall be added to an instrument tray with a mass of 2 kg, double wrapped and exposed to the Bowie & Dick test cycle
- perform the helix test as the daily steam penetration test. The helix shall be added to an instrument tray with a mass of 2 kg, double wrapped and exposed to the Bowie & Dick test cycle
- alternatively, instead of the daily test, add a helix, double wrapped in see-through pouches, to every steriliser load and use the result of the test for parametric release of the load. The holding time of the sterilisation cycle shall not exceed maximum allowed exposure time of the chemical indicator
- perform the test several times with all helices available on the market and which, according to the manufacturer fulfil the requirements of EN867-5, un-

less it is already established which type of helix is the most critical for the test setting and the given sterilisation cycle

- perform the Bowie & Dick test if textile packs are routinely sterilised
- monitor the concentration of non-condensable gasses when the helix test does not give positive results. Several methods are described (5). \*

## References

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