Keywords
- Inter-hospital trials
- washer-disinfectors
- cleaning performance
- test instruments

Inter-Hospital Trials to Determine Minimal Cleaning Performance According to the Guideline by DGKH, DGSV and AKI

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In order to implement the coming EN ISO 15883 in practice, a working group consisting of members of the German Society for Hospital Hygiene (DGKH), the German Society for Sterilisation Supply (DGSV) and of the Working Group Instrument Reprocessing (AKI)[3], worked out and published the "Guideline of the DGKH, DGSV and AKI Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices as Well as Advice on Selecting Washer-Disinfectors (WD)" Part 1[4]. Parallel to working on the Guideline, a test method was elaborated which facilitated an assessment of the performance of WDs. In an inter-hospital trial conducted in 18 hospitals, the practicability and meaningfulness of the test method was investigated. It became clear that the pre-determined benchmark value was not achieved by all the WDs. For 13 WDs the results were in the vicinity of the hazard value (> 50 µg), and immediate measures for improving washing performance had to be taken. From these 13, four gave results, which were above the threshold value, and it was necessary to remove these WDs from active duty until they could be positively requalified, i.e. they should on no account be further used for routine reprocessing. Five of the participants of the inter-hospital test attained the benchmark value.

Although the sensitivity of the semi-quantitative Biuret/BCA method used in the tests is fairly low, it can be presumed that the test method is sufficient for the moment to identify WDs with poor cleaning quality, and to monitor the quality of the measures carried out here.

Introduction

Legal and normative background of the Guideline

The obligation to provide quality-assured reprocessing of medical devices for medical institutions arises both indirectly and directly from the laws, directives, standards, guidelines and recommendations mentioned here (1–5). The Guideline of the DGKH, the DGSV and the AKI gives the user practical working recommendations. The part of the Guideline worked out so far (part 1) concerns itself with the preconditions for validation in health care facilities and gives advice on the evaluation of structural-technical and organisational preconditions for the user, as well as necessary information from the manufacturer of the WD to the user, and from the user to the manufacturer.

Validation is carried out according to prEN ISO 15883 and includes the installation qualification, the operational qualification and the performance qualification of the WD. For the performance qualification, four criteria were taken into account: washing, disinfection, drying and the rinsing-off of process chemicals. Here the distinction was made between WDs complying with the standard and those WDs already in use but not fulfilling the basic requirements of the standard, which should be qualified for further use. For the latter, it should be proven that by a corresponding surveillance an assured operation is possible and the performance requirements are met.

Method to evaluate cleaning according to the Guideline

To evaluate cleaning performance two different methods were used: the use of test instruments with a defined soil **(A)** and the use of instruments contaminated by actual use **(B)**. Both methods should be applied.

A. Test instruments

PrEN ISO 15833 refers to a method using artificially contaminated instruments for the performance tests to determine a particular minimum cleaning performance. To practically attain an idea of required minimum performance, instruments contaminated with a defined soil (prepared according to standardised working instructions in a qualified laboratory) are added to the reference load to be tested (7).

Heparinised sheep's blood made coagulable by the addition of protamine sulphate is used, because this soil has a wide consensus and the best relation to the practical situation.

B. Instruments soiled by actual use

The second method evaluates cleaning performance using instruments contaminated during actual use in the predetermined reference loadings. This is the only way to take into account the factors affecting cleaning after use in the operating theatre, during transport for reprocessing, possible pre-cleaning and loading of the WD itself. This article does not further investigate this method.

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Contamination of the test instruments

Heparinised sheep's blood made coagulable with protamine sulphate was used as the test soil. The sheep's blood should not be older than one week, and should be kept cool until use.

The contamination of the haemostatic clamps (Crile) as test instruments should take place in a suitable laboratory. The heparinised sheep's blood (Acila GMN®, Möhrfelden, Germany) used to contaminate the instruments was diluted by 10% using bidistilled water. The sheep's blood solution was then made coagulable by adding 1.5 IU protamine sulphate (Acila GMN) per 1ml. Then 100µl of this solution was pipetted into the joint of each instrument. The test instrument was then opened and closed five times in order to spread the contamination evenly. After contamination, a maximum of 20 test instruments were laid in the open position in a sieve basket. The sieve basket of test instruments was dried for an hour at 45 °C in a drying cabinet.

Each test instrument was closed after drying and put singly in a polyethylene bag. The air was removed from the polyethylene bag and it was tightly sealed before sending to the hospitals.

Tests on the ageing of the contamination and alteration of its cleaning behaviour

The defined contamination of test instruments in the hospitals is not really practicable, so it should be carried out beforehand in a suitable laboratory. Until the process tests can take place, possible influences and their effects on the test soil, due to varying transport times and temperatures, type of packing, and possible mechanical effects, should be considered, and those that affect the cleanability of instruments and blood solubilityshould especially be investigated.

In a test model, we investigated blood solubility in relation to the respective storage conditions (8). Here 25 µl of a 1:1 mixture of reactivated heparinised sheep's blood (Acila GMN) and bidistilled water, was pipetted onto 4 cm^2 pieces of filter paper (54 altogether) – these were the test objects. They were then dried at 40 °C for an hour. These prepared filter papers were stored under the following conditions:

a) In an open polyethylene bag, at room temperature

b) In a partly ventilated polyethylene bag at room temperature

c) In a dessicator at room temperature

Blood solubility was investigated after 1, 3, 5, 7 and 15 days, as follows. Three test objects at a time were stirred on a magnetic stirrer at 200 rpm at 20 °C for 5 mins. in 20 ml fully demineralised water, or in 20 ml fully demineralised water whose pH had been adjusted to pH 11 with sodium hydroxide solution. The test objects were then removed, dried and extracted for 15 mins. with 2 ml 1% SDS solution (adjusted to pH 11 with NaOH), and the extract was used for double determination in the OPA analysis (400 µl + 2 ml OPA reagent) (Uvikon 931, Kontron Instruments). The percentage of residual contamination of the filter papers was calculated from the extinction. For each determination of three identically treated filter papers the deviation of the residual contamination was always less than ± 1 %.

After contamination and drying at 40 °C in a drying cabinet, the average residual contamination for the three filter papers, treated with fully demineralised water as described above was 41 %, and for those treated with alkalised water at pH 11, an average residual contamination of 6% was found. The results from the varying storage conditions are displayed in fig. 1.

Storage of blood in air causes it to turn increasingly brown within a few days. The solubility in water – a) FDW – is considerably reduced. Storage in a polyethylene bag shows less brown discolouration, and the water-solubility reduces noticeably more slowly. An end-point determination of the filter papers stored in the dessicator was made after 15 days. No difference in blood solubility was found between the first and fifteenth days.

The storage conditions have a noticeably smaller influence on blood solubility in alkaline conditions, although there is a slight reduction in blood solubility when storage occurs open to the air. There is also a minute deviation in the blood solubility of filter papers from the alkaline solution after 15 days in the dessicator. The alterations in solubility characteristics of blood are obviously mainly caused by air humidity.

Thus it can be presumed that instruments contaminated with the aforementioned soil which are then dried, packed in polyethylene bags (which are evacuated of air or contain a drying-agent bag – silica gel), can be safely used to test cleaning performance within 14 days.

Procedure in the hospitals

In each hospital taking part in the inter-hospital trial, a total of three process cycles were tested. Instruments were used which had been contaminated during actual use, with all the specific influencing factors **(B)**. After a maximum disposal time the instruments were put in the loading carrier in predetermined positions. For each process cycle there was an addition of at least one test instrument contaminated with a defined soil **(A)** per sieve basket, but at least 10 instruments per process cycle load. The test instruments were removed for evaluation and assessment after interrupting the programme before the disinfection phase.

Before the inter-hospital trial took place, each participating hospital was given a questionnaire to determine WD type, chemicals used and to ensure the possibility of interrupting the process before the disinfection phase. The parameters of the reprocessing processes were recorded using data-loggers, and the type of load was documented. A form to record instrument positions was sent to each participant with the test instruments, so that they could record the position of the test instruments within the WD.

Initially the evaluation of cleaning performance was undertaken visually and documented by the participants in the inter-hospital trial. After this the instruments were allowed to dry on the air at room temperature, packed in polyethylene bags with a unique code and then sent to the test laboratory.

Testing the instruments using the Biuret/BCA method

For the semi-quantitative protein test, samples were taken by sluicing the joints with 1% sodium dodecylsulphate solution (SDS). To test cleaning processes with a cleaning stage temperature of greater than 60 °C (before thermal disinfection), the Guideline recommends adjusting the 1 % SDS solution to pH11 with

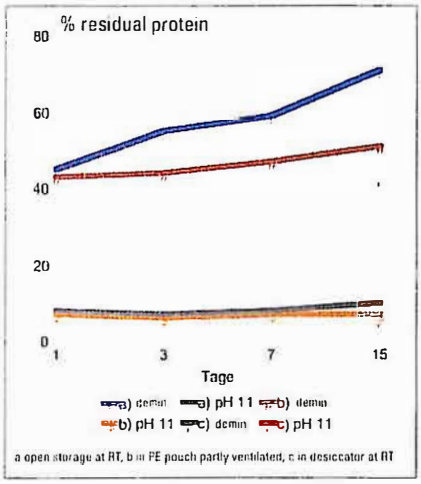

Fig. 1 Changes in the cleaning behaviour of the test soil (blood) expressed in percent of the residual contamination with respect to the duration and conditions of storage

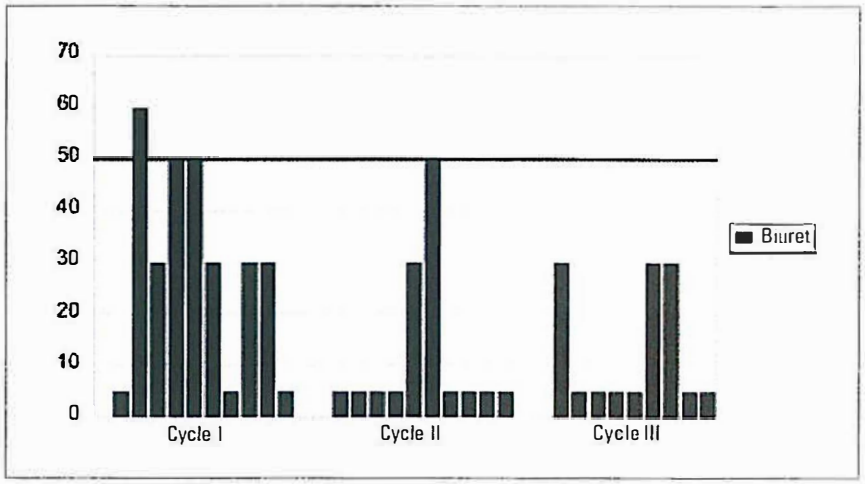

Fig. 2: Results of the Biuret/BCA determination in µg/ml eluate for the participant who subjected instruments 3 to 10 of each WD load to ultrasound treatment.

sodium hydroxide solution. Thus the reduction of the recovery rate caused by temperature denaturation is somewhat compensated. For this inter-hospital trial however, all the samples were obtained with alkalised SDS solution. For sampling, each instrument was put into a 50 ml beaker (tall type, e. g. article C123.1, Carl Roth GmbH, Karlsruhe, Germany) and 2 ml SDS solution were pipetted into the joint area.

The beaker was then held tilted so that the instrument, which was held firmly at the beaker rim, was wetted up to just above the joint. The joint was then opened and closed as widely as possible in the solution five times. The instruments were left to soak for 10 mins. in the beaker after which the procedure was repeated in the same solution. The process was repeated a third time and then 1 ml of the solution was transferred to the test kit for protein determination based on semi-quantitative determination (Miele, Gütersloh, Germany) (9).

The assessment was carried out according to the acceptance criteria of the Guideline:

Limit value: All test instruments must be optically clean. As well as optical cleanliness of the test instruments, the protein content of the eluate from a particular test instrument must not reach or exceed 100 µg protein (as bovine serum albumin) per ml eluate.

Hazard value: Values above 50 µg protein (as bovine serum albumin) per ml eluate from a particular test instrument.

Benchmark: a maximum of 50 µg protein (as bovine serum albumin) per ml eluate from a particular test instrument.

Results of the inter-hospital trial

The completed forms recording instrument positions showed that participants had placed the instruments within the WDs in various different ways. In most cases 10 test instruments were added to each of three loads in a WD, running the same process cycle each time. Some participants put each of the three loads of instruments into separate WDs running the same process cycle. Two participants each made use of two different programmes, and one participant used the ultrasound system integrated into the WD for treatment of some of the instruments. The results of the Biuret/BCA determination for the latter participant are displayed in figure 2. Here the first two instruments of each load had been placed in the upper level of the loading carrier and were thus not subjected to ultrasound treatment.

The ultrasound treatment is not convincing, as the results show, because even with this treatment there was little change in the range of results. In general this participant's results were at or below the benchmark, except for one slight deviation.

One participant programmed different washing temperatures for the process cycle with an alkaline cleaning stage. The first cycle was run at 50 °C, the third at 70 °C. The results from all three cycles (shown in figure 3) point to the necessity of process optimisation. Cycle III, run at a washing temperature of 70 °C, i. e. in the denaturing and fixing range, seems to have exerted a definitely unfavourable effect on the results. Apart from this participant, another seven of the eighteen participants used an alkaline detergent. Two of these seven used them at denaturing temperatures of over 65 °C. These two produced noticeably poorer results – altogether 9 results above 50 µg/ml – than the other five participants who altogether produced only 5 results above 50 µg/ml. The fixing effect became obvious particularly in the joint area which is difficult to control visually.

The comprehensive evaluation of all the participants is shown in figure 4. Here the number of instruments is shown per participant exhibiting > 50 µg protein per ml eluate (as equivalent bovine serum albumin). All in all it can be seen that the number of results above 50 µg/ml eluate decreases from Cycle I to Cycle III. Some participants obviously noticed visually inadequate results on the first load, and then made sure improvements were introduced for the further loads. Such im-

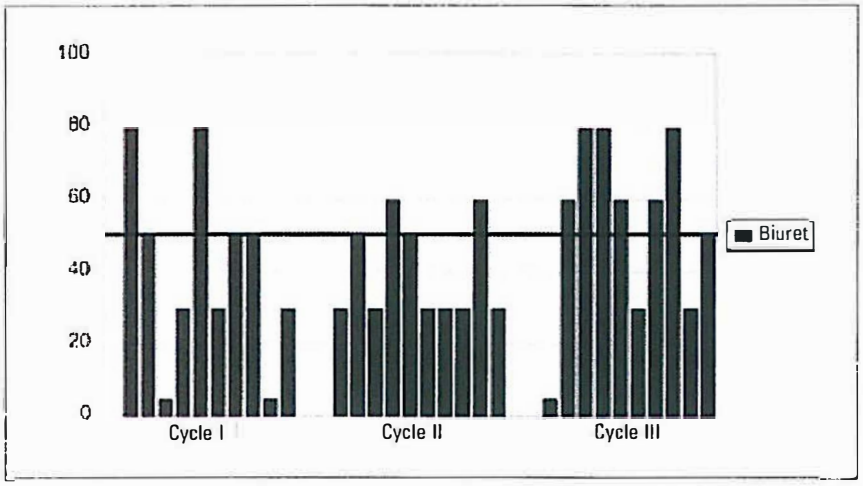

Fig. 3: Results (µg/ml) from the participant using an alkaline detergent for Cycle I at 50 °C, and for Cycle III at 70 °C, where the denaturing effect has a negative influence.

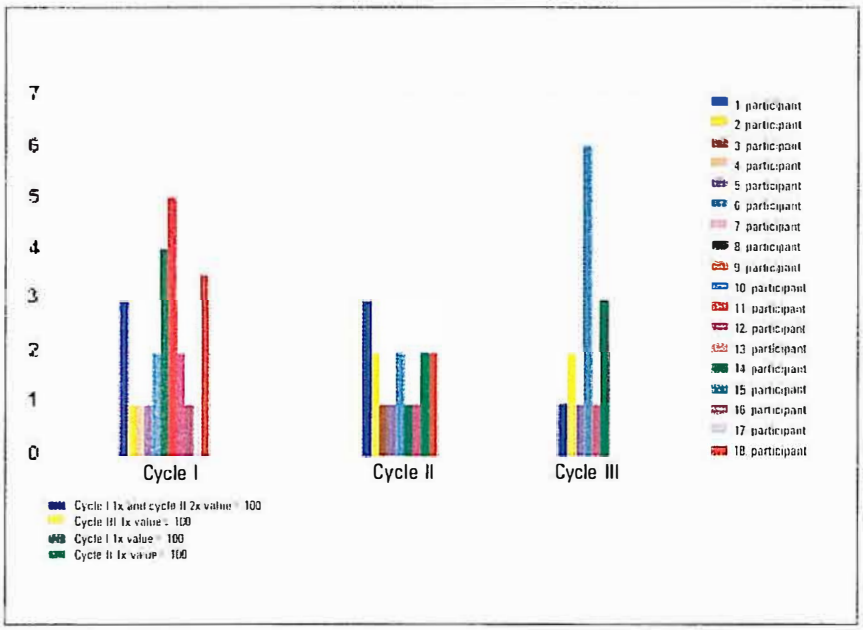

Fig. 4: The number of test instruments showing results > 50 µg/ml eluate for each of three loads of 10 instruments for each of the 18 inter-hospital trial participants; as well as four participants with results ≥100 µg/ml.

provements could be made for example simply by positioning the instruments more carefully.

The participants had checked the instruments visually on the spot and had documented their results. If the Biuret/BCA values ≥ 50 µg/ml are compared with the visual results, it can be seen that in 55.4 % of cases there was a good correlation, whereas in 44.6 % in this range of Biuret/BCA results, no residual soil was noted by visual checking. This is almost certainly due to the restricted possibility of checking the joint areas.

Out of 18 participants, the five participants 7, 9, 10, 13 and 15 attained the benchmark of ≤ 50 µg/ml eluate for all instruments and all three loads. Thirteen participants had results above the benchmark value of 50 µg/ml eluate for all 30 instruments. Here four participants – 3, 4, 16, 17 – only produced one single result that was above the benchmark, whereas the remaining nine participants produced several or even many results above the benchmark.

Participant number 11 produced a result above 50 µg/ml eluate only in the first load. The explanation is that it is technically impossible for the cleaning solution to reach unfavourably placed test instruments, e.g. in a perforated tin basket which causes a spray shadow, or when instruments are placed too close together. Perforated tin baskets should therefore be no longer permitted in instrument reprocessing in WDs.

According to the Guideline, nine of the thirteen participants producing results > 50 µg should be allowed to continue using their WD, but must make improvements in order to attain results < 50 µg. Participants 1, 2, 8 and 14 produced results of 100 µg/ml eluate, although no technical difficulties which could have caused spray shadows were present, as had been the case with participant 11. According to the Guideline these reprocessing processes should no longer be routinely used, until their serious deficiencies will have been eliminated.

Ten participants out of eighteen used a mildly alkaline detergent pH range of 10 and lower. The results from the thirty instruments for each participant vary considerably here, and range from no result above 50 µg/ml up to 7 results above the benchmark. This large range of deviation cannot be explained by process design; it is therefore probable that in these cases the washing mechanics are the relevant factor.

Amongst the WDs there were three tunnel WDs, used by participants 1, 4 and 18, with 1, 7 and 5 results obtained from the thirty instruments above the benchmark.

Discussion

The results of the inter-hospital trial give a first impression of what sort of results can be expected in practice, when investigating the minimum cleaning performance with this test method within the context of performance qualification. Further evaluations will follow which will take in-

to account the recorded positions of the instruments in the sieve baskets and also of an additionally conducted test for the presence of haemoglobin.

Although the sensitivity of the semi-quantitative Biuret/BCA method used here must be recognised as rather low, it can be said that the evaluation scheme is sufficient for the moment, with this method which easily identifies WDs with poor cleaning quality and allows monitoring of the quality of the processes carried out. Two thirds of the participants produced results above the Guideline's fixed benchmark and should accordingly make concerted efforts to improve their cleaning performance results. One third of these participants, however, had only one single poor result, so that it should be relatively easy to improve results to reach an acceptable level.

Half of the participants will have to make a considerable effort to optimise results, and if necessary may have to conduct in-depth monitoring of the exact technical conditions of washing, including collaboration with the WD manufacturer. The aim of validation is to attain acceptable results and to ensure that they are always attained. This appears to be possible using the test method described in the Guideline, augmented by the testing of instruments actually used and contaminated by routine use the results of which will no doubt lead to further consequences. The practical user should not be over-challenged, but it is obvious that urgent standardisation of process performance must be undertaken. Alibi results, i. e. those obtained from tests not related to the practical situation, should be avoided. Future evaluations will be published. ⁂

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For references, please refer to p. 110