

Comparative assessment of various automated processes following prEN/ISO 15883-1

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prEN/ISO 15883-1 Annex B

B.2.6.2 Surgical instruments

One instrument tray with:

- 20 Mayo scissors, curved, 14 cm, stainless steel, polished clean, not lubricated;
- 20 forceps, Crile, curved, 14 cm, stainless steel, polished clean, not lubricated.

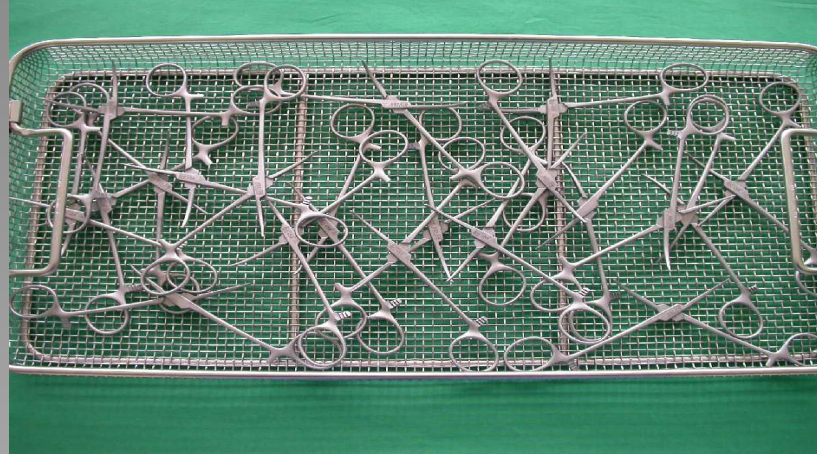
B.2.8.2 Surgical instruments

Load the WD with the test instruments on their tray. If the WD can take additional instrument trays, fill it with clean surgical instruments on their trays according to the manufacturers instructions. If the WD can take more than four but less than nine instrument trays simultaneously, two of these should be with test instruments according to B.2.7.2. If it can take more than eight trays simultaneously, three of these should be with test instruments according to B.2.7.2.

B.2.9.2 Acceptance

For the cleaning efficiency of the WD to be deemed acceptable at least 95% of all test objects for each test object type under test should be clean.

Investigations Following the Standards prEN/ISO 15883-1



BH 145R
(lower sieve basket)



BH 425R
(upper sieve basket)

Contamination of the artery clamps with 100µl coagulable sheep blood



First Investigations



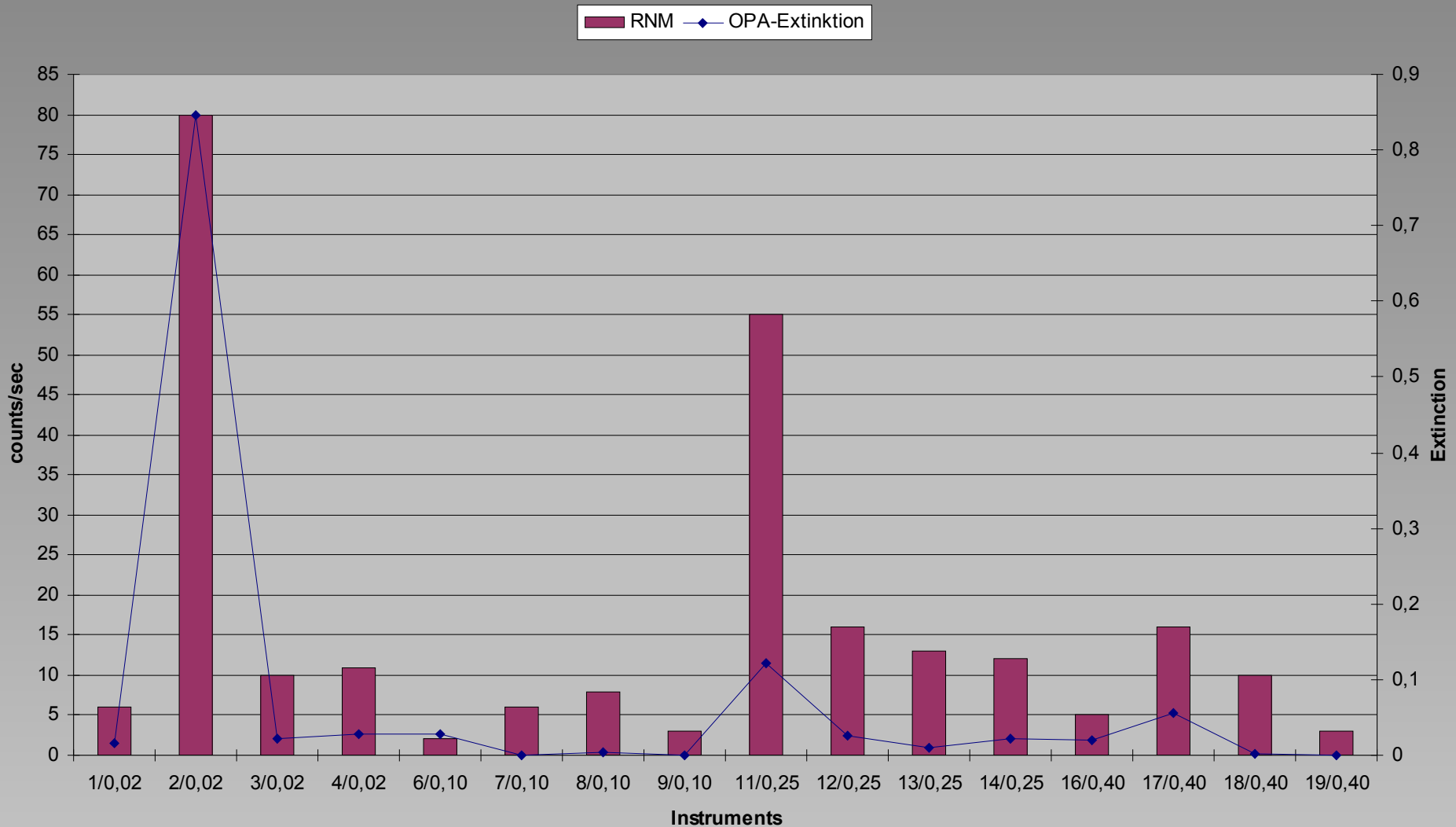
Correlation of the Radionuclide Method with the OPA-Method

The radionuclide method can only be used in the laboratory, but the results of the tests are not influenced by the quality of the recovery procedure. Therefore the experiments in practice have been performed with the Biuret- and modified OPA-Method

Radionuclide method

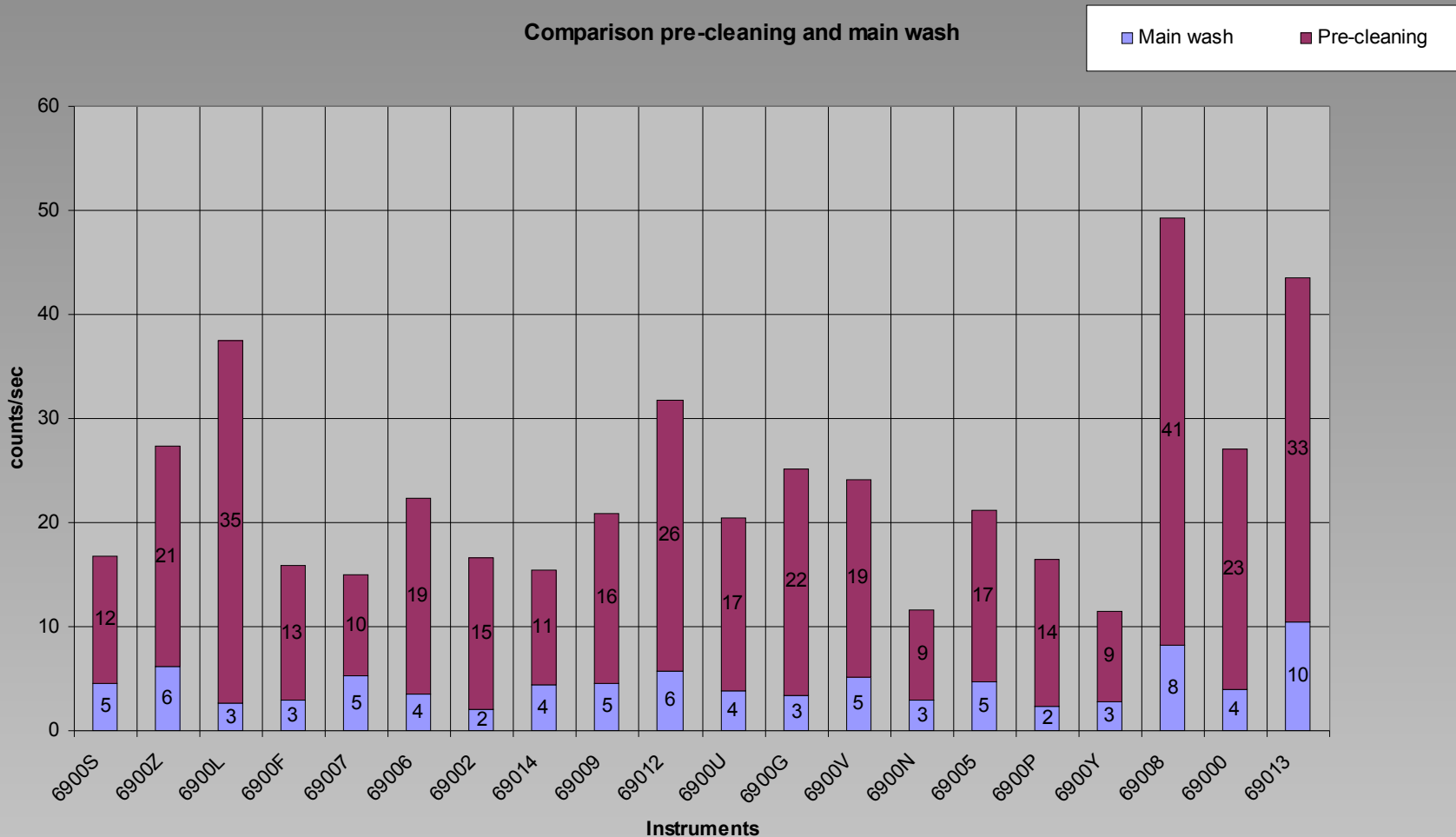
- Standardized in-vitro contamination
- Quantification of residues
- Detection of critical spots
- Method for validation of cleaning behavior
- The results of RNM and OPA- method correlate

Correlation between RNM- and OPA-Method

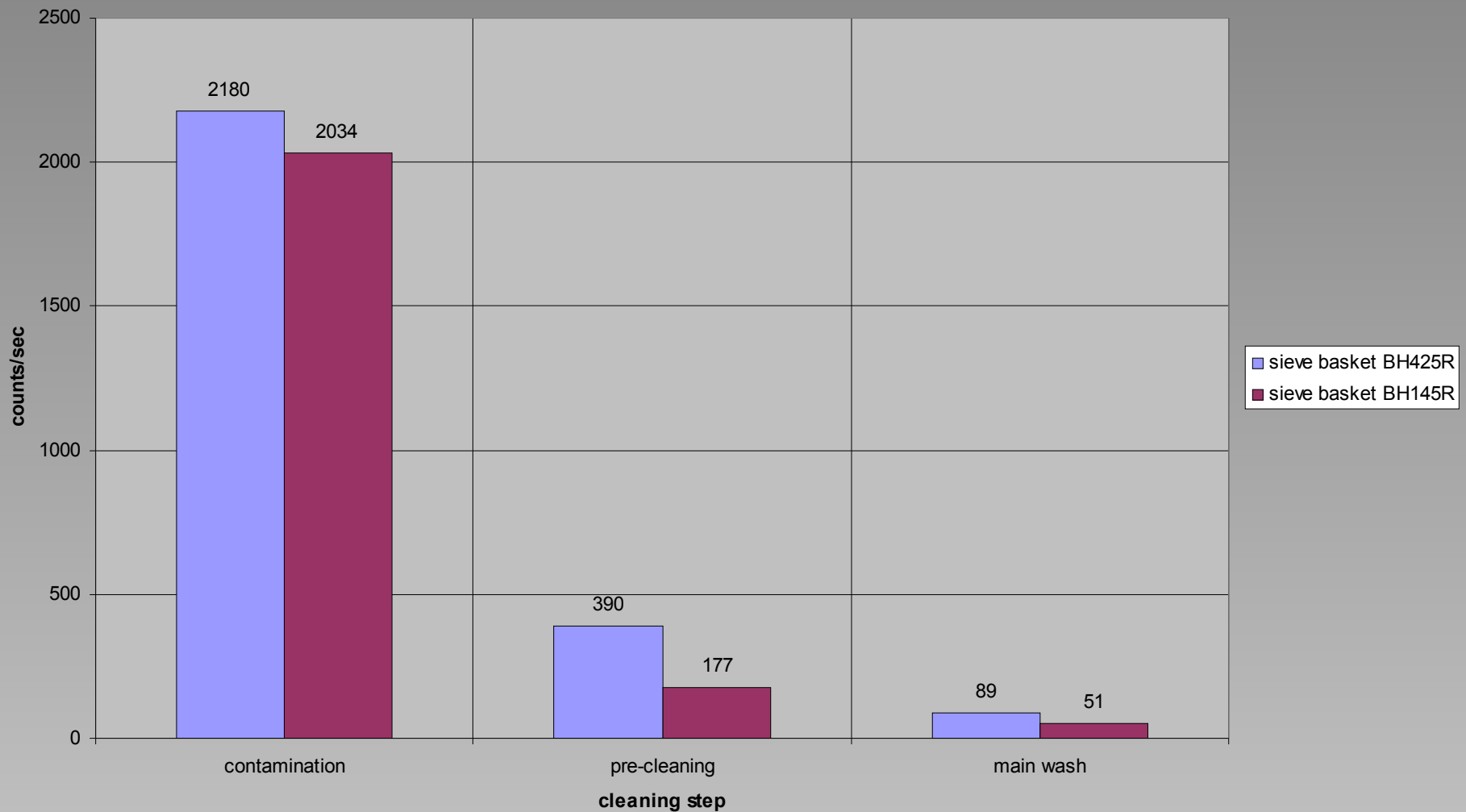


Influence of the pre-cleaning

Initial contamination of each instrument was 120 counts/sec



Influence of the pre-cleaning



Oxivario Programme

- 2 min cold pre-wash using tap water
- Drainage
- 5 min wash at 55°C using 0,5% alkaline detergent
- Drainage
- 5 min wash at 55°C using 0,5% alkaline detergent and an oxidative additive 0,35%
- 1 min neutralisation at 38°C using an acid additive (0,1 %) based on citric acid
- Drainage
- 1 min intermediate rinse
- Drainage
- 1 min intermediate rinse

Investigated detergents

Alkaline detergent A (phosphate, disodium- and potassium-metasilicate, tenside-free, with and without an oxidative additive B (hydrogen peroxide solution somewhat less than 30%) in the second wash step

Also the oxidative additive was tested in different concentrations (0,175 % and 0,35 %)

Alkaline detergent C (sodium phosphate, sodium silicate, potassium hydroxide, tenside-free) with and without an oxidative additive D (hydrogen peroxide solution somewhat more than 30%) in the second wash step at a concentration of 0,35%

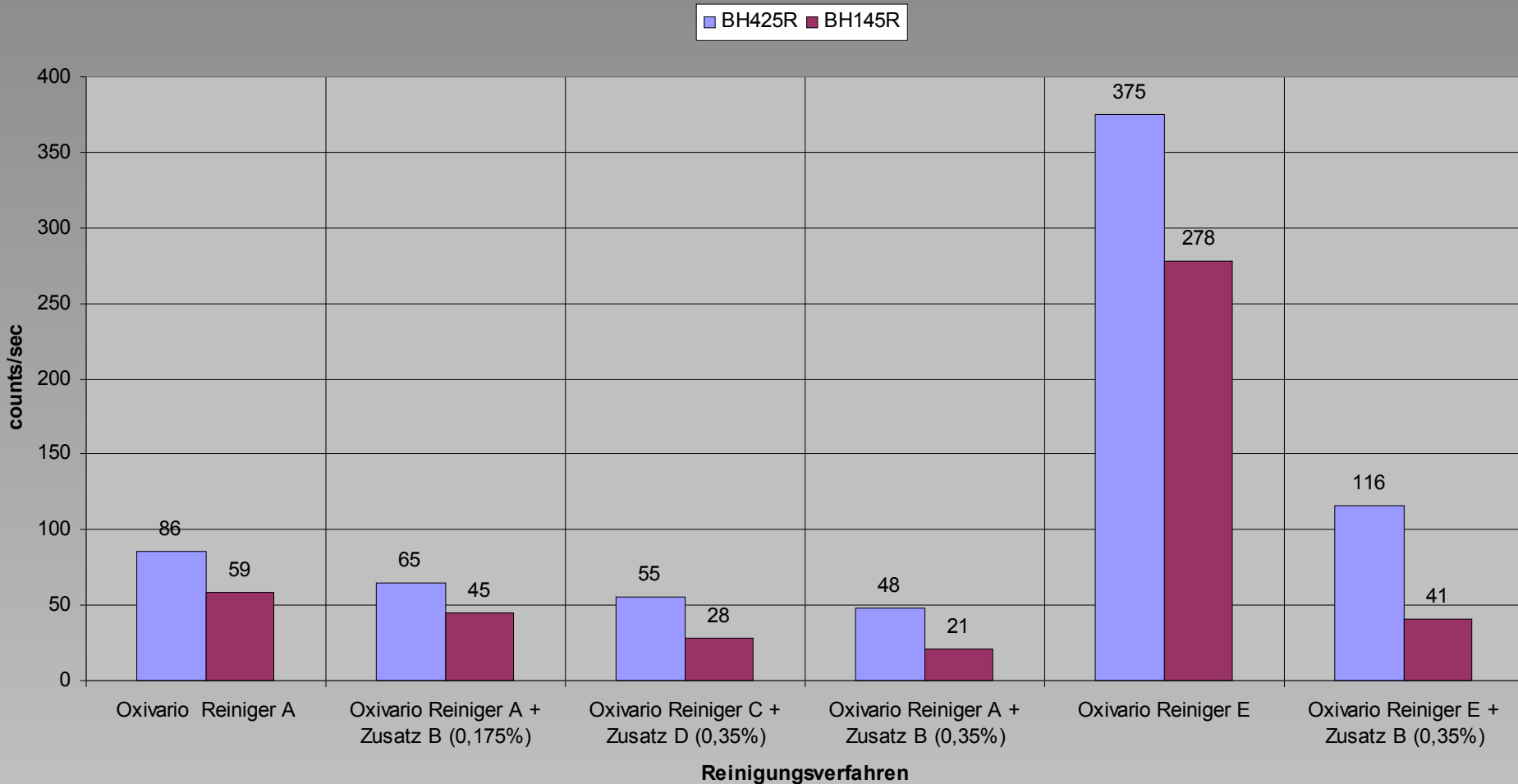
Mildly alkaline detergent E (enzymes, tenside, caustic potash solution) with and without oxidative additive B

pH-values of the applied concentrations of detergents

Detergent and concentration	pH-value
Alkaline detergent A 0,5%	11,2
Alkaline detergent A 0,5% & H ₂ O ₂ 0,175% (oxidative additive B)	10,9
Alkaline detergent A 0,5% & H ₂ O ₂ 0,35% (oxidative additive B)	10,4
Alkaline detergent B 0,5% & H ₂ O ₂ 0,35% (oxidative additive D)	11,1
Alkaline detergent E 0,5%	9,8
Alkaline detergent E 0,5% & H ₂ O ₂ 0,35% (oxidative additive B)	9,2

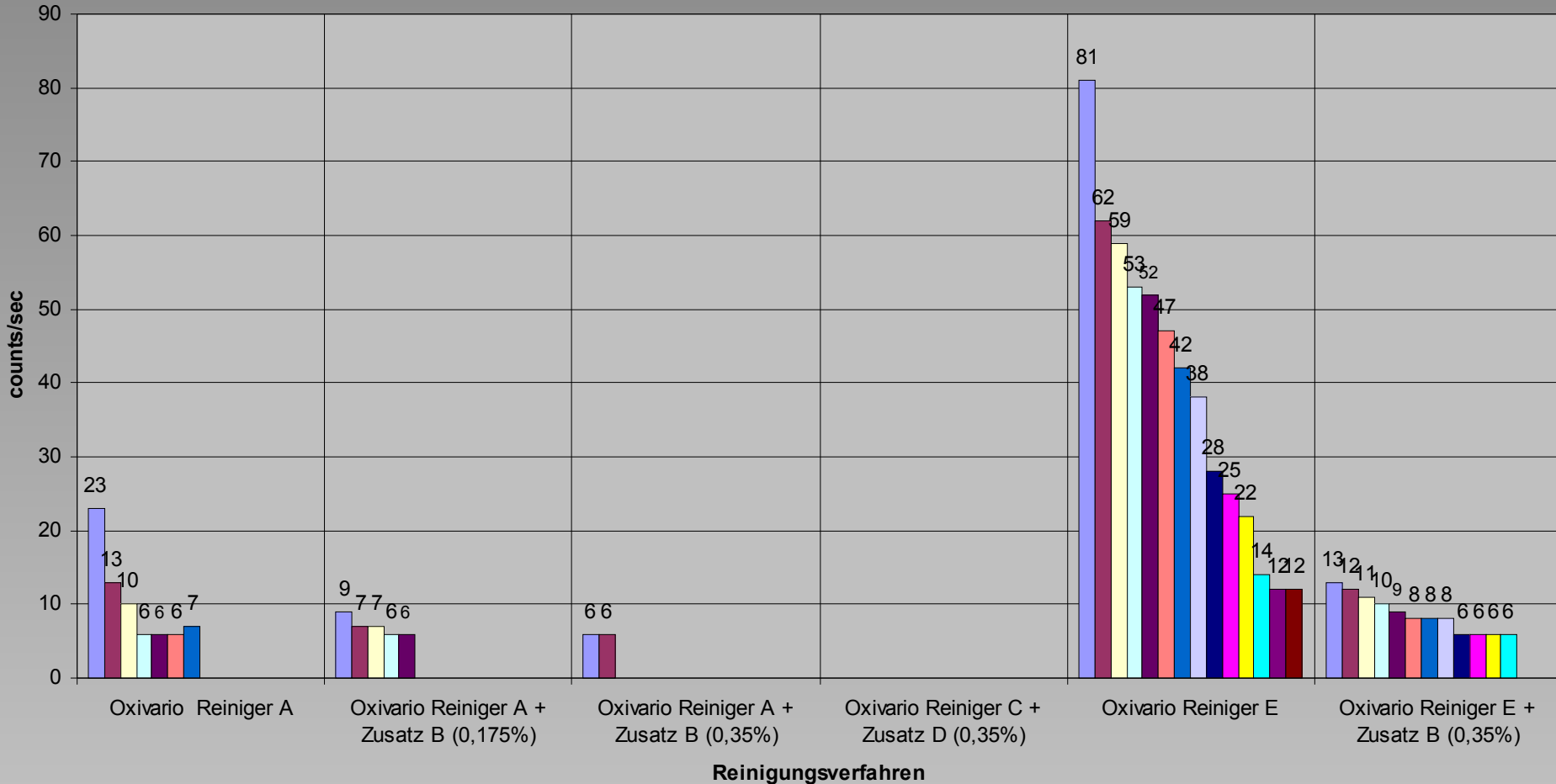
Reduced cycle investigations:

Reinigungsverhalten im verkürzten Zyklus



Reduced cycle investigations:

Anzahl der Klemmen über dem Grenzwert



Discussion (1)

The test method described in the standard prEN/ISO 15883, when combined with the RNM, proves to be a suitable way of comparing the different wash processes with one another.

The question is then whether the principle of using a partial or half cycle of wash steps to gain improved differentiation, should be used for WDs - as it has already been used to validate sterilisation.

At the moment wash tests are carried out without any safety net, which means that no performance reserves are taken into account to deal with fluctuations that may occur in the practical situation, for example by drying-on of soil.

Discussion (2)

Because the clamps were contaminated in a defined way with a pipette, a standardised starting contamination could be assured. Thus it can be shown that the results of washing with the Oxivario programme without an oxidative effect are definitely inferior, and also that the statistical deviation increases.

Even at a low hydrogen peroxide concentration there was more constant washing with fewer differences in washing results. Another result of the Oxivario process with added hydrogen peroxide is the proven cleaning effectiveness, even in areas that are difficult to reach. This special deep cleaning makes the process superior in comparison to the alkaline process run without an oxidative additive.

Conclusion

The radionuclide method was used to investigate comparatively the cleaning performance of automatic washing/disinfection processes on the critical joint areas of artery clips. The defined initial soil was radioactively marked coagulable blood.

Washing using the Miele Oxivario programme with the addition of hydrogen peroxide achieves an increased cleaning performance compared to that from the alkaline detergent alone, and also attains better results in critical areas, so that the cleaning performance is standardised at high level.

Additionally, following elution of the joint areas, the direct measurements of the radionuclide method were correlated with the indirect determination of residual contamination in the eluate using the OPA method.

Further investigation

In order to implement the up and coming EN ISO 15883 in practice, we worked out the *“Guidelines of the DGKH, DGSV and AKI for validating and routinely monitoring automatic washing and disinfecting processes for thermo-stable medical devices, and principles for selecting a washer-disinfector (WD)”Part 1***.

In an inter-hospital trial conducted with 18 hospitals, the practicability and meaningfulness of the test method was investigated.

5 of 18 WD involved in the trial were over threshold.

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

Thank you for your attention

Further informations
www.smpgmbh.com