

May 2009

Prospectus: Cooperative Project
Cleaning validation according to ISO 17664
and compilation of cleaning instructions

Project 2

scheduled start: Summer 2009

Cooperative project: Cleaning validation according to DIN ISO 17664 and compilation of cleaning instructions

Background

As a service provider for medical enterprises, SMP GmbH together with the Centre of Competence for Minimally Invasive Medicine and Technology (MITT) carried out a cooperative project for the validation of cleaning processes for reusable surgical instruments according to DIN ISO EN 17664:2004 in 2007

In general, it is possible to group instruments with identical or similar attributes or features. One of the goals of that study was to validate that assumption. It was therefore the aim of this project to compile and validate appropriate reprocessing cycles for a large number of instruments from different manufacturers. The individual costs for the necessary examinations were significantly reduced by sharing them among the 29 cooperating participants.

The instruments were divided into seven groups with subcategories according to relevant attributes and parameters (such as size of a critical design feature or diameter of a tube). Additional information on the classification is found in the paper published in 2009 which is found in the annex.

Two representative cleaning processes were used in the first project, one using an alkaline detergent and the other using an enzymatic cleaning agent. These two processes are used in at least 50% of the hospitals.

Validation of the cleaning behaviour was done with the use of the Radio Nuclide Method (RNM). This method was cooperatively developed and patented by SMP GmbH, the Natural and Medical Sciences Institute (NMI), and the University of Tübingen some years ago. It uses radioactively-labelled sheep's blood to contaminate the instruments under investigation in a well-defined, repeatable manner similar to actual use contamination in a surgical setting. A measurement of the remaining radioactivity using a Gamma camera after cleaning allows a non-destructive, quantitative assessment of the effectiveness of cleaning with spatial analysis of residual soil within simple and complicated instruments. The method is well established (accepted by the ASTM as a Standard Test method for the validation of cleaning processes) and has demonstrated its practical use.

The specific cleaning procedure for each group of instruments was identified according to the design and complexity of the instruments in the group. These procedures ranged from purely automatic cleaning to processes comprised of a sequence of manual pre-cleaning, ultrasonic cleaning, and automatic cleaning.

As a response to several inquiries from enterprises which did not participate in the first project and as we have now extended the range of cleaning processes and washer/disinfectors available for this testing, we offer you the opportunity to **participate in the second cooperative project**.

Concept of the second project

The approach for the second project uses the same principles as the one used in the first project: The instruments will again be divided into seven groups using the same classification criteria. Further sub-classification of specific instruments will be informed by our experience from the first project.

In the first project, attention was focused on the use of representative cleaning processes. In the second project, we will include additional processes. The main objectives are:

- Validation of cleaning processes which avoid manual pre-cleaning,
- Simplification and/or reduction of the number of steps for the reprocessing of surgical instruments,
- Validation of new reprocessing cycles for instruments which could not be reprocessed in the first project, and
- Achievement of a higher level of assurance of achieving cleanliness.

For these purposes, the following **combined cleaning cycles** will be used:

OxiVario (Miele): This cleaning cycle uses an alkaline cleaning agent in the first cleaning step, followed by use of an oxidative agent in the second cleaning step. The oxidising effect positively influences the outcome of the cleaning process. This method may be used for metallic instruments with the exception of those containing Titanium or Aluminium. For instruments containing Titanium or Aluminium, a process called **OrthoVario (Miele)** is used, because it works in a lower range of pH-values (pH < 10) thereby avoiding changes of or damage to the materials of the instruments.

These two cleaning cycles were not included in the first project because they were only used in a small number of hospitals at the time of that study. A conversion of existing washer-disinfector machines to host these cycles is possible in a limited number of cases, as additional dosing pumps and connections especially suited for oxidising agents have to be installed. However, as these processes have become more prevalent with time, and as they are recognised as being at the leading edge of medical device cleaning efficacy, it is felt that their evaluation is important to the completeness of this study.

An additional **two-component** cleaning cycle will be used. This cycle has been developed by Borer Chemicals. It uses a near-neutral pH-value by combining Borer's detergents Twinzyme and Twinbasic. This is more easily integrated into existing machines as only a second dosing pump without special demands for compatibility with oxidising chemistry is needed. The investigations with this cycle will be made using a Miele machine.

Because of our experience in the first project (poor performance) we will not validate an enzymatic cleaning process in this second project.

Additional washer-disinfector in the project:

The first project demonstrated that the water pressure in ordinary washer disinfectors is too low for efficient cleaning of tube-shaft instruments. Since that time, SMP obtained access to a newly-developed machine (Medisafe Niagara) that provides a much higher water pressure for rinsing MIS instruments (http://www.medisafeuk.co.uk/uk/pro_niagara.html) thereby opening the way to omit manual pre-cleaning with a water-jet gun.

The final choice of **cleaning processes, instruments** and **test procedures** for the different groups of instruments will be made in close contact and agreement with the **project participants**.

Synopsis of Project and Benefits for participants:

- Comparative validation of cleaning efficacy using an alkaline process analogous to that used in the first project with omission of manual pre-cleaning steps (new washer-disinfector, Medisafe Niagara).
- Validation of cleaning efficacy using different combined cleaning processes (Miele OxiVario, Miele OrthoVario, Borer neutral chemistry) with the aim to shorten the process time and/or to simplify the process and provide a higher degree of safety (using a Miele washer/disinfector).
- Report in English.
- Recommendations for reprocessing instructions in English and German.

Additional benefits for new participants:

- Baseline validation of cleaning efficacy for instruments as done in the first project using an alkaline cleaning process.
- All of the testing discussed above for the second project.
- Report in English.
- Recommendations for reprocessing instructions in English and German.

Because of the greater amount of testing for non-participants in the first project and the integration of two new washer/disinfectors, the charge for participation is 5.000 €.

The infrastructure for the execution of the project is complete. The start of the investigations is scheduled for summer 2009. The minimum number of participants (15) has already been reached. More spaces remain at this writing. The final number of participants will be limited to not many more than 30.

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LETTER OF INTENT

Cleaning validation according to ISO 17664 and compilation of cleaning instructions - Project 2

Company: _____

Contact person: _____

Tel.: _____

Fax.: _____

E-Mail: _____

I am interested in participating in part 2 of the project at the stated price of 5.000,00 Euro

I need more information, please call me as soon as possible

date, signature

Please return this Letter of Intent before 1 July 2009 by fax to SMP GmbH