# **Original Article =**

# Performance evaluation of cleaning detergents: a proposal validation

Avaliação do desempenho de detergentes para limpeza: validação de uma proposta Evaluación del rendimiento de detergentes para limpieza: validación de una propuesta

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## Descriptores

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## Abstract

**Objective:** To develop and validate a proposal to evaluate the performance of cleaning detergents for health products.

**Methods:** A proposal was developed to evaluate the performance of detergents routinely used in Materials and Sterilization Center through an experimental study using cleaning monitors and an ultrasonic washer. Cleaning monitors were placed in the ultrasonic washer tub. The parameter adopted to evaluate the performance of detergents was the complete removal of stain from the monitors. Protein residues from tubular stainless steel and polyvinyl chloride samples were evaluated after contact with challenge organic matter and cleaning in an ultrasonic washer. Tests that showed a gradation of blue color were considered to have failed and tests that remained with a brown color were approved, as indicated in instructions for use. All tests were performed in triplicate or quintuplicate. Additionally, positive controls were performed.

**Results:** The use of the foil test with strips proved to be easy to apply and capable of differentiating cavitation at different points in the ultrasonic washer tub. The cleaning indicators impregnated with organic residues and the protein monitors used in the proposal presented varied results, making it possible to differentiate the cleaning effectiveness for each detergent used. In addition to their availability on the market, these simple tools made it possible to evaluate the detergents.

**Conclusion:** The proposal developed proved to be feasible and simple and considered products and equipment routinely found in Materials and Sterilization Centers.

## Resumo

Objetivo: Elaborar e validar uma proposta para avaliação do desempenho de detergentes na limpeza de produtos para saúde.

**Métodos:** Foi desenvolvida proposta para avaliar o desempenho de detergentes rotineiramente utilizados em Centros de Material e Esterilização por meio de um estudo experimental utilizando monitores de limpeza e lavadora ultrassônica. Monitores de limpeza foram dispostos na cuba de uma lavadora ultrassônica. O parâmetro adotado para avaliação do desempenho dos detergentes foi a remoção completa da sujidade dos monitores. Foram avaliados resíduos de proteínas de amostras tubulares de aço inoxidável e de policloreto de polivinila, após contato com carga orgânica desafio e limpeza em lavadora ultrassônica. Foram considerados reprovados os testes que apresentavam gradação da coloração azul e aprovados os testes que permaneciam com a coloração marrom, como indicado nas instruções de uso. Todos os testes foram realizados em triplicata ou quintuplicada. Adicionalmente, foram realizados controles positivos.

<sup>1</sup>Escola de Enfermagem, Universidade de São Paulo, São Paulo, SP, Brazil. Conflicts of interest: none to declare. Resultados: O uso do teste com tiras de papel alumínio, *foil test*, mostrou-se de fácil aplicação e capaz de diferenciar a cavitação em diferentes pontos da cuba da lavadora ultrassônica. Os indicadores de limpeza impregnados com resíduos orgânicos e os monitores de proteína utilizados na proposta apresentaram resultados variados, possibilitando diferenciar a eficácia da limpeza para cada detergente utilizado. Portanto, além de disponíveis no mercado, são ferramentas simples que possibilitaram a avaliação dos detergentes.

**Conclusão:** A proposta desenvolvida mostrou-se factível e simples e considerou produtos e equipamentos rotineiramente encontrados em Centros de Material e Esterilização.

## Resumen

Objetivo: Elaborar y validar una propuesta para evaluación del rendimiento de detergentes en la limpieza de productos de salud.

Métodos: Mediante un estudio experimental con el uso de monitores de limpieza y lavadora ultrasónica, se elaboró una propuesta para evaluar el rendimiento de detergentes utilizados habitualmente en centros de material y esterilización. Se colocaron monitores de limpieza en el tanque de una lavadora ultrasónica. El parámetro adoptado para evaluar el rendimiento de los detergentes fue la eliminación completa de la suciedad de los monitores. Se evaluaron residuos de proteínas de muestras tubulares de acero inoxidable y de cloruro de polivinilo, después del contacto con carga orgánica desafío y limpieza en lavadora ultrasónica. Las pruebas que presentaron una gama de coloración azul fueron reprobadas, y las que permanecían con coloración marrón fueron aprobadas, como indicado en las instrucciones de uso. Todas las pruebas fueron realizadas en triplicado o quintuplicado. Adicionalmente se realizaron controles positivos.

**Resultados:** El uso de las pruebas con tiras de papel de aluminio, *foil test*, demostró ser de fácil aplicación y con capacidad para diferenciar la cavitación en diferentes puntos del tanque de la lavadora ultrasónica. Los indicadores de limpieza impregnados de residuos orgánicos y los monitores de proteína utilizados en la propuesta presentaron resultados variados, lo que permitió diferenciar la eficacia de la limpieza en cada detergente usado. Por lo tanto, además de estar disponibles en el mercado, son herramientas simples que permiten la evaluación de los detergentes.

Conclusión: La propuesta desarrollada demostró ser factible y simple, e incluyó productos y equipos encontrados habitualmente en centros de material y esterilización.

## Introduction =

Cleaning is the fundamental step to guarantee the proper processing of health products (HP)<sup>(1,2)</sup> and health care-associated infections caused by their improper processing have already been reported.<sup>(3-5)</sup> The cleaning step can be performed manually, using brushes and pressurized water guns or in an automated way, using equipment such as jet pressure and ultrasonic washers.

The parameters that influence cleaning are summarized in the Sinner's Cycle, which is represented by a circle where the elements interfering in the process (temperature, chemical agent, time and mechanical action) interact in a compensatory way in order to guarantee adequate cleaning.<sup>(6)</sup> Therefore, the following are necessary for cleaning: water, detergent, mechanical action, temperature and time.

Detergents are sanitizers intended for cleaning products and surfaces by reducing surface tension, composed of synthetic, organic, liquid substances, or water-soluble powders containing wetting and emulsifying agents that suspend dirt and prevent the formation of insoluble compounds or foam on the instrument or the surface.<sup>(7)</sup> The use of detergents with less than desired performance can cause the organic load to settle in the processed products,<sup>(8)</sup> and inadequate cleaning can increase the organic load of these products.<sup>(9,10)</sup>

There are several options of cleaning detergents: enzymatic, which may contain one or several enzymes,<sup>(11)</sup> protease is mandatory, and others such as amylases and lipases; alkali; neutrals; acids and options with formulations that clean and disinfect simultaneously, depending on their concentration, such as those containing glucoprotamine and alkylamine, in which case the disinfectant itself has a surfactant action.

The fact that the many options available have different formulations makes it difficult to compare the products objectively. The lack of recommendations or guidelines to guide the evaluation of detergents makes the daily life of the Materials and Sterilization Center (MSC) difficult, since the choice of products is subjective. Managers of the MSC, for example, face bids to purchase detergents, and still do not have an objective tool to evaluate the product to be acquired, which makes this task difficult and can even lead to impeachment.

In addition to these complicating factors, detergent performance is a difficult variable to isolate. Although the scientific literature provides a specific instrument for evaluation of enzymatic detergents,<sup>(12)</sup> it does not present a method to objectively measure the performance of detergents in the cleaning process. To enable decision making based on objective and non-contestable factors when choosing the appropriate detergent, the aim of this study was to develop and validate a proposal for evaluating the performance of cleaning detergents for health products.

## Methods

For the performance evaluation of detergents, an experimental laboratory study was developed at the Laboratory of Microbiological Assays of the Escola de Enfermagem at Universidade de São Paulo. Devices that would challenge the cleaning action were used, which in this study were called "cleaning monitors" (Wash-Checks U, Steritec, Belgium; Valisafe CEI, Medisafe, UK; CDWA3 Chemdye, Terragene, Argentina, Assured, Getinge, Sweden). These monitors are supports impregnated with synthetic dirt that simulate organic dirt<sup>(13)</sup> or residual protein monitors. An ultrasonic washer (Sonic Reliance Benchtop, Medisafe, UK), with a 25L tub, maximum power of 700W and ultrasonic frequency of 35Khz was used to perform the cleaning cycles.

The detergents used represent a range of detergents commercially available on the national market. They were used in accordance with guidelines described on the labels.

First, it was necessary to validate the points where the cleaning monitors would be placed in the washing machines. This location must be the one considered as a critical point, that is, in ultrasonic washers, it is the region with the least action of cavitation. This point was determined using sheets of 75g aluminum foil arranged in parallel throughout the washer tub, in a test known as foil test.<sup>(14)</sup> The action of cavitation perforates the foil sheets at an intensity directly proportional to the action of cavitation.<sup>(15)</sup>

The detergents used and the respective concentrations are described in table 1. The performance of each detergent (Deter-Rio<sup>®</sup>, Rioquímica, Brazil; Tecpon Clean<sup>®</sup>, Tecpon, Brazil; Endozime<sup>™</sup> Xtreme, Ruhof, Germany; Glucosept<sup>®</sup> Power, Ecolab, United States of America; Peroxvir<sup>®</sup>, Rioquímica, Brazil; Indazyme 7 MAX<sup>®</sup>, Indalabor, Brazil; Prolystica<sup>®</sup> 2X Alcalino, Steris, Ireland; Deconex<sup>®</sup> 36 Intensiv-X, Borer Chemie, Switzerland) was evaluated separately in triplicate using five cleaning monitors (Valisafe CEI, Medsafe, United Kingdom; Wash-Cheks<sup>®</sup>, SteriTec, Belgium; Chemdye, Terragene, Argentina) arranged in the bath filled with demineralized water and heated to 50°C in 10-minute cycles. To ensure that the monitors were placed at the predetermined points, it was necessary to fix them in surgical forceps. Demineralized water was used to avoid the possible interference of water in cleaning effectiveness. For this same reason, the water from cycles was not reused and discarded after each use.

|  | Table 1. | Dilution ar | d detergents | used in | the study |
|--|----------|-------------|--------------|---------|-----------|
|--|----------|-------------|--------------|---------|-----------|

| Detergent (type)*                              | Concentration |  |  |
|--|---------------|--|--|
| Deter-Rio® (neutral without enzymes)           | 2 mL / L      |  |  |
| Tecpon Clean® (slightly alkaline)              | 2 mL / L      |  |  |
| Endozime <sup>™</sup> Xtreme Power (enzymatic) | 2 mL / L      |  |  |
| Glucosept® (25% glucoprotamine)                | 5 mL / L      |  |  |
| Peroxvir® (acid)                               | 3 mL / L      |  |  |
| Indazyme 7 MAX® (enzymatic)                    | 1 mL/L        |  |  |
| Prolystica® 2X Alcalino (alkaline)             | 4 mL / L      |  |  |
| Deconex® 36 Intensiv-X (neutral)               | 1 mL/L        |  |  |

\*information declared on the label.

The parameter adopted to evaluate the performance of detergents was the complete removal of dirt from the monitors, as indicated in instructions for use. Positive controls, in which detergents were not added to the cleaning cycles, were performed in triplicate with five monitors for each cycle. As an alternative, protein residues for different detergents were also evaluated by means of protein monitors for surface and lumen (Assured, Getinge, Sweden) in stainless steel (SST) and polyvinyl chloride (PVC) tubular samples, measuring 185 mm in length and 5 mm in internal diameter. The tubular samples were contaminated with challenge organic load (ATS Browne, Steris, United States of America) internally and externally and remained in contact with the contaminant for 4 hours, simulating the time of exposure of surgical instruments to organic dirt. A preliminary rinse was then performed to remove visible dirt for five seconds, followed by ultrasonic washing with connections for lumens (Sonic Reliance Benchtop, Medisafe, UK) for five or 15 minutes, with variation in the type of detergent and demineralized water heated to 50°C in quintuplicate. Additionally, a detergent-free group was included as a positive control group. Tests that showed any gradation of blue coloration were considered to have failed and tests that remained with a brown coloration were approved.

# **Results**

The results of monitoring the cavitation of the ultrasonic washer carried out by means of a foil test showed that the washer tub used in the study, although presenting a homogeneous distribution of cavitation, is slightly more concentrated in the upper and lower right regions, as well as in the upper central region. Table 2 summarizes the results of the cleaning monitors according to the different type of detergent used in the phase of the experiment in which cleaning monitors were used.

Table 2. Results of the cleaning monitors used in the experiment according to the type of detergent

| Detergent               | n  | Results |       |  |
|-------------------------|----|---------|-------|--|
|                         |    | S*      | I†    |  |
| Water (control)         | 15 | 0/15    | 15/15 |  |
| Indazyme® 7 MAX         | 15 | 6/15    | 9/15  |  |
| Prolystica® 2X Alkaline | 15 | 9/15    | 6/15  |  |
| Deconex® 36 Intensiv-X  | 15 | 15/15   | 0/15  |  |

\* Satisfactory (complete removal of simulated dirt from the monitor); † Insatisfactory (presence of residual dirt on the monitors)

The results referring to detergents used in the phase when protein tests were done after washing in an ultrasonic washer are summarized in table 3.

# Discussion

Decisions about purchasing and choosing products are routinely made at Health Services and in MSCs. Whether in public or private institutions, defining the best product to purchase may not be an easy task and the lack of objective parameters for choices imposes difficulties on professionals, as objective decisions tend to be more assertive than decisions made only with subjective parameters,<sup>(16)</sup> which may be based on incorrect data.

Table 3. Results of surface and lumen protein tests of PVC and stainless steel tubular samples according to the detergent used and the ultrasonic cleaning time

| Determent        | Sample          | n | Time | Protein results |      |
|------------------|-----------------|---|------|-----------------|------|
| Detergent        |                 |   |      | S*              | L†   |
| None, only water | Stainless steel | 5 | 5'   | 0/5             | 4/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
|                  | PVC             | 5 | 5'   | 0/5             | 0/5  |
|                  |                 | 5 | 15'  | 0/5             | 1/5  |
| Deter-Rio        | Stainless steel | 5 | 5'   | 0/5             | 0/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
|                  | PVC             | 5 | 5'   | 0/5             | 1/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
| Tecpon Clean     | Stainless steel | 5 | 5'   | 0/5             | 1/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
|                  | PVC             | 5 | 5'   | 1/5             | 0/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
| Endozime™ Xtreme | Stainless steel | 5 | 5'   | 1/5             | 0/5  |
| Power            |                 | 5 | 15'  | 0/5             | 1/5  |
|                  | PVC             | 5 | 5'   | 0/5             | 2/5  |
|                  |                 | 5 | 15'  | 0/5             | 1/5  |
| Glucosept        | Stainless steel | 5 | 5'   | 5/5             | 5/5  |
|                  |                 | 5 | 15'  | 3/5             | 3/5‡ |
|                  | PVC             | 5 | 5'   | 2/5             | 4/5  |
|                  |                 | 5 | 15'  | 0/5             | 5/5  |
| Peroxvir®        | Stainless steel | 5 | 5'   | 0/5             | 0/5  |
|                  |                 | 5 | 15'  | 0/5             | 0/5  |
|                  | PVC             | 5 | 5'   | 0/5             | 0/5  |
|                  |                 | 5 | 15'  | 0/5             | 1/5  |

\*Surface; †Lumen; ‡ Less intense color change in 15 minutes

The lack of a method to define the quality and effectiveness of products leaves the choice subject only to price and information from companies' marketing (often misleading). Thus, instituting objective parameters allows making choices without interference or interests and aiming only at patient safety.<sup>(17)</sup>

The validation proposal presented here describes two different options of methods to evaluate the effectiveness of cleaning with different types of detergent; using cleaning monitors for the equipment or cleaning monitors for washed surgical instruments. Both methods proved to be feasible and made use of inputs commonly used in MSC, in addition to being simple to perform and presenting the most objective results possible, thus contributing to the nursing practice in MSC.

Thus, this proposal is expected to allow that any professional in any MSC can objectively evaluate detergents, thus subsidizing the purchase of a product that meets the quality requirements to achieve effective cleaning.

Although the implementation of a specific legislation for MSC<sup>(7)</sup> is of national scope and therefore, most requirements are aimed at the minimum needs for a safe processing of HP, it also presents articles that are difficult to apply for many health institutions. Complete compliance with legislation, as well as technology parks with equipment such as thermo-disinfectors, for example, although much desired by MSC nurses, are not always a reality. <sup>(18)</sup> Therefore, the use of the ultrasonic washer was preferred in this proposal, since this equipment is commonly seen in MSCs throughout Brazil, often provided by detergent suppliers themselves under a loan for use (commodatum) agreement.

The results of the first phase of the experiment showed that in addition to being effective, the test to evaluate the cavitation of the ultrasonic washer (foil test) is simple to perform and has a low cost. It can be used in MSCs that do not have specific tests commercially available. It is recommended to perform the test in washers on a daily basis, regardless of the capacity of the tub. Note that residual pieces of aluminum are dispersed throughout the tub and they must be completely removed, including cleaning the filter after removing the water.

One limitation is related to protein testing; although well established and widely used, it cannot be considered exactly objective. There is indeed a color variation to be evaluated as a result, which in the case of the monitor used, represented the results from  $1\mu g$  to  $20\mu g$  of protein. The observed difficulty referred to determining the exact tonality, requiring a second opinion in some tests.

Although the test manufacturer recommends that 1µg is rejected (any shade of blue), international guidelines consider values ranging from 5µg of protein per side of the surgical instrument to 150µg for articulated instruments or with lumens, with values of up to 80µg considered desirable.<sup>(19,20)</sup> Currently, MSCs do not have the technology to practically and objectively quantify these values. Even in the face of this difficulty and the possibility of such disparate cutoff values, establishing realistic reference values for each service, based on constant monitoring, makes it possible to perceive flaws in the process and act accordingly.<sup>(21)</sup> Also, if all detergents evaluated effectively clean the cleaning monitors or the challenge samples, other factors that can be evaluated for tiebreakers when choosing detergents are noteworthy. Among them, we highlight the availability of reports of rinseability, corrosivity and cytotoxicity; foaming; residual odor in the product; and biodegradability, as an interesting differential.

The objective of this study was not to evaluate the effectiveness of any product, neither of detergents nor of monitors, but rather to develop a simple and objective method to evaluate the effectiveness of cleaning detergents as isolated as possible using resources available to MSCs in order to support decision-making at the MSC.

# Conclusion

The proposal developed and validated in this study has proved feasible and simple to apply, portraying differences in the quality of detergents through objective responses, such as the results of cleaning monitors. It can be widely used in MSCs to evaluate detergents for cleaning HP.

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## **Collaborations**

Bruna CQM and Graziano KU contributed to the project design, analysis and interpretation of data, article writing, relevant critical review of the intellectual content and approval of the final version to be published.

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