INDICATIONS AND LIMITATIONS OF DIFFERENT DETERGENTS USED IN THE PROCESSING OF HEALTH PRODUCTS

Indicações e limitações dos diferentes detergentes utilizados no processamento de produtos para a saúde

Indicaciones y limitaciones de los detergentes diferentes utilizados en el procesamiento para la salud

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ABSTRACT: Objective: To identify studies that address indications and limitations of different detergents used in the processing of medical devices. **Method:** Integrative review that included publications in Scientific Electronic Library Online, Science Direct, Scopus, Web of Science and PubMed, from 2000 to 2016, in English and in Portuguese. **Results:** Nine studies were identified. Alkaline detergents remove dirt well, its use is indicated for automated equipment, and they are suitable in processes that use hard water, compatible with surgical stainless steel instruments. They may damage the medical device and react with aluminum, zinc, non-ferrous metals, rubber and latex. Enzymatic detergents are compatible with various materials and, due to the presence of enzymes, remove different types of dirt from the instrument. **Conclusion:** Although alkaline and enzymatic detergents present similarities, the choice of the product requires knowledge of its action, observing the characteristics of use, compatibility with the medical device and water quality.
Keywords: Housekeeping. Equipment and supplies. Detergents.

RESUMO: Objetivo: Identificar estudos que abordem indicações e limitações dos diferentes detergentes utilizados no processamento de produtos para a saúde. **Método:** Revisão integrativa que incluiu publicações presentes nas bases de dados *Scientific Eletronic Library Online, Science Direct, Scopus, Web of Science* e *PubMed,* no período de 2000 a 2016, nos idiomas inglês e português. **Resultados:** Foram identificados nove estudos. Os detergentes alcalinos apresentam boa remoção de sujidades, são indicados para uso em equipamento automatizado, adequados em processos que utilizem água dura e compatíveis com instrumentais cirúrgicos de aço inoxidável. Podem danificar o produto para a saúde e reagir com alumínio, zinco, metais não ferrosos, borracha e látex. Detergentes enzimáticos são compatíveis com diversos materiais e, devido à presença de enzimas, removem diferentes sujidades do instrumental. **Conclusão:** Embora os detergentes alcalino e enzimático possuam similaridades, a escolha do produto exige o conhecimento da sua ação, observando as características de uso, compatibilidade com o produto para a saúde e qualidade da água.
Palavras-chave: Serviço de limpeza. Equipamentos e provisões. Detergentes.

RESUMEN: Objetivo: Identificar los estudios que abordan indicaciones y limitaciones de diferentes detergentes utilizados en el procesamiento de productos de salud. **Método:** Revisión integrada que incluye publicaciones presentes en las bases de datos Scientific Electronic Library Online, Science Direct, Scopus, Web of Science y PubMed, de 2000 a 2016, en los idiomas Inglés y Portugués. **Resultados:** Se identificaron nueve estudios. Los detergentes alcalinos tienen buena eliminación de impurezas, están indicados para su uso en equipos automatizados, los procedimientos adecuados utilizando agua dura compatibles e instrumental acero inoxidable quirúrgico. Pueden dañar la salud del producto, y reaccionar con aluminio, zinc, metales no ferrosos, caucho y látex. Detergentes enzimáticos son compatible con diversos materiales y, debido a la presencia de enzimas, eliminan diferentes suciedades de los instrumentales. **Conclusión:** Aunque detergentes alcalinos y enzimáticos presenten similitudes, la elección del producto requiere el conocimiento de su acción, observando las características de uso, compatibilidad con el producto para la salud y la calidad del agua.
Palabras clave: Servicio de limpieza. Equipos y suministros. Detergentes.

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Received: 21 Nov. 2016 – Approved: 17 Mar. 2017
DOI: 10.5327/Z1414-4425201700020008

INTRODUCTION

Health-care products (HCP) that can be processed are medical devices designed and manufactured to allow repeated cycles of cleaning, preparation and disinfection or sterilization until they are no longer effective or functional[1]. The processing of these items is indicated to maximize the benefits of products that normally present high costs for the health system, and to minimize the environmental impacts caused by the HCP, as the reuse of these devices reduces the volume of waste released into the environment[2,3].

The proper cleaning of HCP is a determinant for the effectiveness of processing. It consists of the physical removal of clinical dirt (organic and inorganic materials), accompanied by the reduction of microbial load of the internal (lumen) and external surfaces of these devices using a water and detergent solution, enzymatic products and other accessories[1,4,5].

Detergents used in the processing of HCP must be biodegradable, non-abrasive, nontoxic at manufacturer-oriented dilution, effective in dirt removal, be low foaming and have good rinsability[6-8]. Through the action of surfactants, they reduce the surface tension of the water and provide greater contact with the dirt contained in the instrument, favoring the removal of the organic and inorganic residues present in the material[1,4,6].

Currently, it is widely recommended that the detergent used in HCP cleaning have enzymatic action[9]. In Brazil, this product is regulated by the Resolution from the Collegiate Board of Directors (RDC) No. 55, November 27, 2012, from the Brazilian Health Regulatory Agency (ANVISA). It defines enzymatic detergents as products whose formulation contains, in addition to the surfactant, at least one hydrolytic enzyme in the EC 3.4 protease subclass, the purpose of which is to remove clinical dirt and prevent the formation of insoluble compounds on the surface of the devices[10-12].

Unlike common detergents, enzymatic formulations can catalyze reactions by the action of enzymes. They act selectively on organic matter, degrade specific substrates, accelerate and optimize the HCP cleaning process[4,12,13]. Thus, multi-enzyme formulations are marketed in order to increase the action spectrum of the product on the dirt, thus making cleaning more effective[4,11].

Various formulations of detergents, which not only are composed of multiple enzymes, but also have different pH levels, are still available on the market. The pH value is an important characteristic of the product, since it can interfere with the stability of the solution and, consequently, with enzymatic activity. However, in Brazil, there is no specific pH determination for these products. RDC No. 55, from November 27, 2012, from ANVISA, only determines that the pH range of the pure solution and the dilution must be reported on the detergent label.[12].

It is noted that neutral enzymatic detergents with a pH of 7 and alkaline detergents whose pH value ranges from 7 to 14 are commercially available for the processing of HCP[14]. However, in clinical practice, the predominant neutral formulation is used in the cleaning of HCP, known for its ability to preserve the instruments. And, regarding the alkaline detergent, it is observed that questions about its use for cleaning HCP have been more and more frequent. However, the lack of information on indications and limitations, not to mention the potential damage that the different ranges of pH can cause to HCP, has raised doubts that are present in the clinical practice.

Therefore, given the existence of alkaline and neutral enzymatic formulations of detergents for HCP processing and the scarce number of publications that address this issue, the following questions are asked: What are the indications and limitations of the different types of detergents used in HCP processing?

OBJECTIVE

This analysis aims to identify studies that address the indications and limitations of alkaline and neutral enzymatic detergents in order to provide base for a critical analysis by health professionals.

METHOD

The method used in this study was an integrative review of the literature, since it allows to gather and synthesize research results on a delimited topic or issue, in a systematic and orderly manner, contributing to deepen the knowledge on the subject investigated[15].

Six different steps were taken for the construction of the integrative review: choice of research question; definition of inclusion criteria and sample selection; representation of selected studies in the form of synoptic tables; analysis of the findings; interpretation of the results and presentation[15].

The following guiding question was defined: What are the indications and limitations of the different types of detergents used in HCP processing? Next, the following inclusion criteria were outlined: original articles in English or in Portuguese that addressed the indications and limitations of the different types of detergents used to clean HCP, published from 2000 to 2016. The articles analyzing enzymatic and alkaline detergents that were not related to the cleaning of HCP were excluded.

The publications were selected from the following Health Sciences Descriptors (DeCS) in Portuguese and in English: *detergentes, infecção hospitalar, saneantes*, detergents, cross infection, sanitizing products. Also, the following uncontrolled descriptors were used: *alcalino, controle de infecção, limpeza, enzima, enzimático*, alkaline, infection control, cleaning, enzyme, enzymatic. All descriptors were used in isolation, as well as associated by the connector AND on all bases cited.

The selection of articles was carried out through the Coordination Portal for the Improvement of Higher Level Personnel (CAPES) using the Scientific Electronic Library Online (SciELO), Science Direct, Scopus, Web of Science and PubMed databases.

The initial selection of publications was conducted by the exploratory reading of the title and abstract of the papers, which led to the identification of 11 studies. Of these, one was found in the SciELO database, six in Science Direct, ten in Scopus, seven in the Web of Science and eight in PubMed. Some studies have been found in more than one database. From the analytical reading of the texts, three articles were selected, in accordance with the inclusion and exclusion criteria previously defined.

Faced with the scarcity of results found in the mentioned databases, research was also conducted in electronic content provided by associations, industries and manufacturers of medical and hospital materials, laboratories, and government agencies. Thus, six publications were found. The three articles from the databases were added to these publications, totaling nine papers for evaluation. Figure 1 summarizes the search process for publications.

What followed, therefore, was the categorization of studies by the creation of a thematic framework. This was intended to outline an overview of the articles. For the composition of the thematic framework, the following information was extracted from each article: title, authors, year, type of

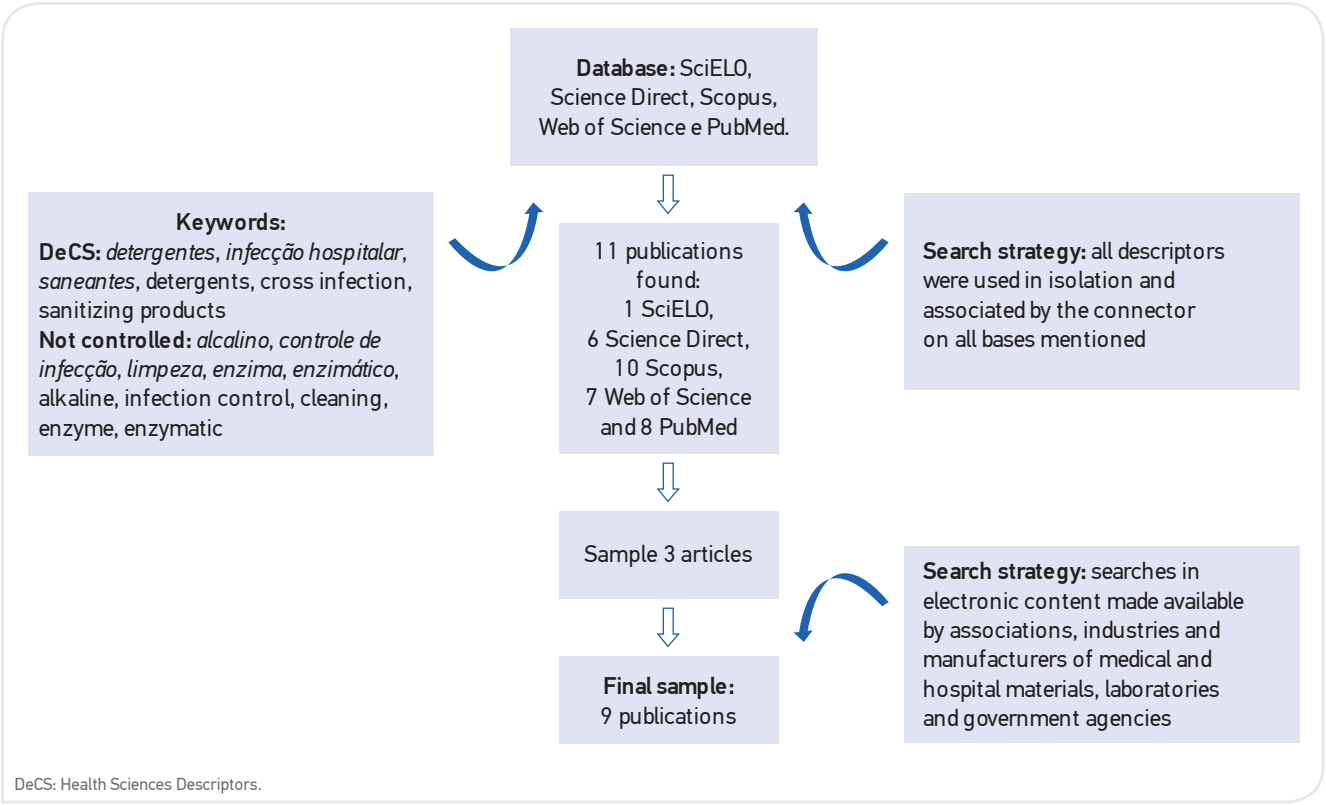


Figure 1. Search process for publications.

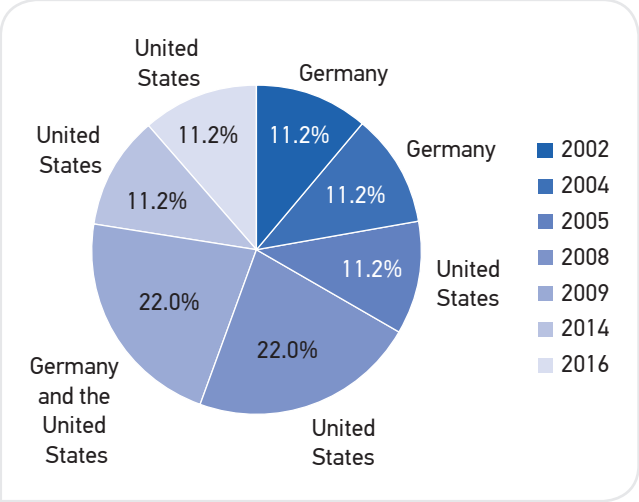
study / methodology and main results. This information was presented in Graphs 1 and 2 and Table 1.

RESULTS

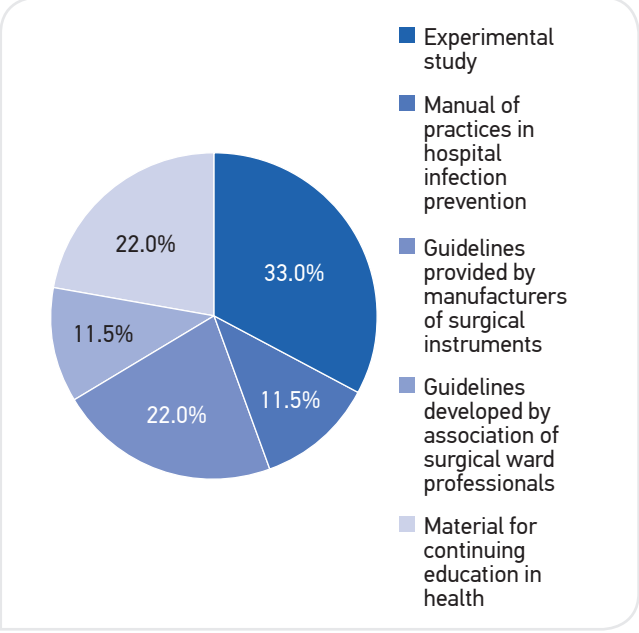
Nine publications have been identified that address the indications and limitations of alkaline and neutral enzymatic detergents. These studies were carried out in Germany (22%) and in the United States (77%). There were no studies performed in Brazil for the period analyzed. The publications were distributed as follows: 2002 (11.2%), 2004 (11.2%), 2005 (11.2%), 2008 (22%), 2009 (22%), 2014 (11.2%), 2016 (11.2%). This information is summarized in the Chart presented in Graph 1.

Regarding the studies' designs (Graph 2), three (33.0%) were experimental studies, one (11.5%) was a manual of practices on hospital infection prevention, two (22.0%) were guidelines elaborated by manufacturers of hospital medical products, one (11.5%) was elaborated by an association of professionals working in a surgical ward and two (22.0%) included materials for continuing education in health.

Indications for the application of alkaline[14,16-18] and neutral enzymatic detergents[5,10,14,17,19] used in HCP processing were pointed out in seven studies, and alkaline product



Graph 1. Percentage of publications according to year and country of origin, 2000 to 2016. Belo Horizonte, 2016.



Graph 2. Design of the selected studies during the bibliographical survey (2000-2016). Belo Horizonte, 2016.

Chart 1. Indications and limitations of the neutral and alkaline enzymatic detergents used to clean health products according to pH. Belo Horizonte, 2016.

Alkaline detergent	Indications	• Removal of organic waste[10,16-18]. • HCP cleaning in processes that use hard water[14]. • Cleaning of stainless steel surgical instruments[14]. • Cleaning in automated processes[14].
	Limitations	• Inactivation of enzymes, instrument damage and neutralizing rinse need when pH value is high[14, 20-21]. • Risk staining the instrument when not properly removed[14,20]. • Potential risk of corrosion and interference in the correct functioning of HCP[5,14,20,21]. • Risk of reacting with aluminum, zinc, non-ferrous metals, rubber and latex[14].
Neutral enzymatic detergent	Indications	• Compatible with metals and other materials used in HCP, such as aluminum, copper, plastic and rubber[5,10,14]. • Does not damage HCP[5,14,17,19].
	Limitations	• Not found.

HCP: health-care products.

limitations were cited in four publications[5,14,20,21]. No limitations were found regarding the use of neutral enzymatic detergent in the cleaning of HCP. The synopsis of these findings is shown in Chart 1.

Studies have indicated that alkaline detergents are suitable for cleaning surgical instruments made of stainless steel, and provide efficient removal of fats, proteins and other organic waste, disaggregating them from the HCP more easily when compared to the neutral detergent[14,16-18]. In cleaning processes in which hard water is used (when alkaline earth ions are present in the water), the alkaline product is the most suitable to be used[14].

Alkaline detergents can damage HCPs as they are able to stain and corrode them, interfering with their proper functioning[20,21]. These damages can occur if the detergent is not properly removed from the instruments during rinsing, if used in certain materials such as aluminum, zinc, non-ferrous metals, rubber and latex, and when the formulation has a high pH value (above 12), in which case the use of a neutralizing product is necessary to avoid more damage to the devices[14]. The neutralizing rinse takes place with the addition of an acidic solution to the water, in order to reduce the pH of the solution, leading it close to neutrality[14]. The pH higher than 12 may still impair the action of the enzymes as the functionality of these substances decreases[14].

Neutral enzyme detergents have a better profile of compatibility with different materials such as aluminum, non-ferrous metals and rubber, providing better enzyme performance, as well as not corroding surgical instruments and not damaging HCP. They are used to help the detachment of organic matter from the instrument's surface.[5,14,17,19].

DISCUSSION

The action potential of the enzymes present in the enzymatic detergent is influenced by a number of factors, including the pH of the formulation. PH value variation, higher or lower than what is necessary for the enzymatic activity to occur satisfactorily, can inactivate it and interfere with the action of these substances. This value is determined according to the nature of enzymes present in the detergent, since each of them presents with an optimal pH that allows the maximum performance of their activity[13,22]. Enzymatic detergents do not have bactericidal properties to destroy microorganisms, but to eliminate the organic matter that serves as substrate for the microorganisms to multiply[23].

According to RDC No. 55, from November 27, 2012, of ANVISA, enzymatic formulations cannot contain substances that compromise the activity of the enzymes or that damage the materials and equipment that get in contact with these products[1]. Thus, the neutral enzymatic detergent was indicated for being more compatible with the materials that compose the HCP. In the studied literature, the damage that this solution could cause to these devices was not reported[5,14,17,19].

In contrast, the alkaline product has been found to be compatible with devices made of stainless steel, but incompatible with various other materials that are present in the composition of different HCPs, including aluminum, zinc, non-ferrous metals, rubber and latex[14]. The compatibility of stainless steel with the alkaline detergent is owed to the presence of a chromium oxide (Cr2O2) layer on the surface of the material, passively formed by the reaction of oxygen with the chromium present on the surface of the material. This layer imparts extreme resistance to corrosion, protecting steel from the damage that the alkaline formulation could cause, from the action of many chemicals and physical parameters, such as temperature and pH variations[24,25].

HCPs that are not compatible with alkaline detergent may be stained, corroded, and may interfere with proper operation when in contact with the product[5,14,20,21]. These damages that occur on the devices imply higher costs for the health service, as these places will have, in addition to the budget, expenses with maintenance and replacement of instruments.

In relation to the action potential of detergents, some publications have indicated the alkaline formulation as the most effective one for the removal of organic matter[16-18]. A study developed by Smith et al.[26] corroborates this statement. The experiment consisted in evaluating the action of different chemical products, including alkaline and neutral detergents, in the removal of horse blood impregnated in stainless steel plates. The metal plates were inoculated together with the cleaning product to be tested and shaken on a shaking platform. Time of exposure and temperature were the same for all solutions tested. At the end of the procedure, the investigator found, through a bicinchoninic acid assay — protein quantification method compatible with detergents and denaturing agents[27] —, that the alkaline detergent is

more efficient for removing the proteins present on the surface of the metal plates[26].

In another study, developed by a manufacturer of products used in the processing of HCP, the performance of several detergents used for cleaning these devices was compared: alkaline detergent, alkaline with enzymes and multi -enzymatic with neutral pH. Metal plaques were prepared with different types of dirt that included: iodinated blood; clotted blood; protein-enriched lipid; polysaccharides; proteins and polysaccharide. Thereafter, they were soaked in cleaning solution and shaken in a shaker. At the end of the established contact time, the samples were removed from the solution, rinsed in cold water, dried and visually inspected. The conclusion was that neutral enzyme products presented the worst results for removing impregnated dirt from metal platelets; and alkaline formulations were the most effective ones[28].

However, a divergent result pointed out that, in terms of effectiveness, there is no significant difference between neutral and alkaline enzymatic detergents[17]. Such a finding was observed by Zuhlsdorf[17] in an experiment that consisted of inoculating blood containing *Enterococcus faecium* into teflon tubes, which were then subjected to automated cleaning with the use of different cleaning agents. The efficacy of the process was assessed visually and microbiologically by means of bacterial counting[17].

In clinical practice, professionals have noticed an apparent superiority in the performance of alkaline detergents, since the HCP, when processed with this product, acquire greater brightness and better appearance, as these formulations clean the instruments deeply, removing incrustations from their surface.

Thus, alkaline formulations have been become standard in the work routine of some health services, although the references on the subject are scarce and many professionals do not yet have the real knowledge about the product's action. The use of these formulations requires caution, since this type of detergent demands strict control of the rinse, the temperature of the solution, the pH of the water, besides not being compatible with all types of materials; otherwise, it could cause irreversible damages in HCP and impair the efficiency of device processing.

Although the marketed value of this product is generally higher than that of the enzymatic detergent, manufacturers promise better cost-effectiveness of the formulation, making it more economical. However, material wear and tear and repair, besides replacement costs, must be evaluated.

Alkaline formulations are generally indicated by manufacturers to be used in automated cleaning processes (thermodyne stricting and ultrasonic washing machines) because of low foaming. This is a necessary feature in this processing method, as it avoids damage to the equipment by decreasing the cleaning cycle time, due to the shorter rinsing time, and by causing less damage to the recirculation pump[29,30].

Although the foaming of the alkaline detergent is lower, this property should also be observed while choosing the detergent to be used for manual cleaning. Poor foaming leads to more professional safety, since it increases the visibility of sharp instruments within the solution and optimizes the cleaning process by facilitating rinsing and visualization of dirt on the instrument[14].

Being compatible with the equipment used in automated processing is an advantage of the product, since this has been considered the ideal method of cleaning. When compared to the manual method, the automated process has been shown to be more significant in terms of reducing the microbial load in HCP[31-33].

The reduction of occupational risks can also be listed as an advantage of this method, since it restricts the contact of the professional with the contaminated material; the standardization of the process, since it is expected that the equipment works equally for all different cleaning cycles; and the ability to measure and register the parameters involved in processing, such as the time and temperature of the solution.

However, other characteristics of the detergent, both neutral or alkaline, should be considered when used in the processing of HCP, regardless of the method adopted. One must be aware that bacterial contamination may be present in cleaning solutions contained in an ultrasonic washer or in manual cleaning containers, since enzymatic detergents usually have no bactericidal action[21].

The ideal action against such contamination is to dispose of the cleaning solution after each use, as recommended in the Guideline for Disinfection and Sterilization in Health Care Facilities, 2008, from the Centers for Disease Control and Prevention[5]. However, in clinical practice, enzymatic detergent solutions are reused several times, contrary to such information. In this scenario, the disposal of these products is usually determined by professionals, who use subjective methods to evaluate the quality of the solution, such as presence of visible dirt or turbidity. This practice of enzyme detergent reuse is carried out by the health services to reduce costs in the processing of the materials to

the detriment of the safety of the process, although studies indicate that the reuse of the enzymatic detergent solution can contribute with the elevation of microbial load in the HCP immersed[34].

Another important aspect to be analyzed, so that during the processing of the HCP the detergent is used correctly, refers to the characteristics of the water. In cleaning processes in which hard water is present, the alkaline detergent is the most suitable to be applied[14,35]. Hard water has a high level of alkaline earth metal salts (calcium, magnesium and strontium), which are released from the solution and settle on the surface of the HCP when the water is heated or evaporated; this impairs the action of most detergents and disinfectants. In this process, released ions interact with some chemicals and form insoluble precipitates on the surface of the instrument, causing corrosion and staining of the devices[36,37].

Water is the most widely used element throughout the HCP cleaning process and, therefore, requires attention[9]. In Brazil, the water used in the processing of HCP must meet the drinking standards defined in specific regulations, Ministerial Order No. 2914, from December 12, 2011, of the Ministry of Health[35]. When it does not meet the appropriate requirements, some processes can be used to treat it. Distillation or demineralization systems, for example, virtually remove all ionic material dissolved, turning it into soft water. It is known, therefore, that hard water is not indicated for use in health services, and its use is irregular.

CONCLUSION

Because this is a literature review, the limitations found in the results must be considered, since there is a comprehension of the strategies adopted, as well as the defined descriptors. This itself opens up a range of opportunities for investment in other studies that address the issue.

In addition to this fact, it was found that the indications and limitations of the detergents used in the HCP cleaning process were still a rather unexplored subject in the scientific literature, which contributed with the reduction of the number of articles.

The alkaline detergent is a relatively new product in the Brazilian market, and needs to have its characteristics explored and known before being implemented in health services. Although it presents prominent characteristics, such as the performance of deep cleaning in HCP, its use may cause irreversible damage to the devices. In this respect, the compatibility of the neutral enzyme detergent with different types of materials is an advantage of that formulation, as it reduces maintenance costs and acquisition of new HCP.

According to the characteristics presented, both the neutral and the alkaline enzymatic product present specific indications and limitations that must be observed by the professionals before standardizing them for cleaning the HCP.

Although literature shows records that alkaline detergents perform better in relation to the cleaning of HCP, divergent results were also verified, which highlights the need for more clinical studies on the subject.

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