

# WATER QUALITY: FACTS AND MYTHS!

*Qualidade da água: fatos e mitos!*

*Calidad del agua: hechos y mitos!*

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**ABSTRACT: Objective:** To discuss the importance of water in Central Sterile Services Department (CSSD) and the main evidence of risks, standards, related legislation, and guidelines to develop a water treatment system to rinse products. **Method:** A narrative review to investigate both facts and myths and to describe the aspects related to the need to control the quality of the water used to process medical devices. **Results:** Reports of local toxic effects and pyrogenic reactions in patients require the standardization and quality control of water to rinse products and steam generation in autoclaves. **Conclusion:** Water treatment and quality monitoring should be incorporated by health services.

**Keywords:** Surgical instruments. Sterilization. Water quality.

**RESUMO: Objetivo:** Discorrer sobre a importância da água no Centro de Material e Esterilização, sobre as principais evidências de risco, normas, legislação relacionada e orientações para a definição de um sistema de tratamento de água para enxágue de produtos. **Método:** Revisão narrativa buscando fatos, mitos e descrevendo aspectos relacionados à necessidade de controle da qualidade de água utilizada no processamento de produtos para a saúde. **Resultados:** Relatos de efeitos tóxicos locais e reações pirogênicas em pacientes demandam a padronização e o controle de qualidade da água para enxágue de produtos e geração de vapor nas autoclaves. **Conclusão:** O tratamento e o monitoramento da qualidade da água devem ser incorporados pelos serviços de saúde.

**Palavras-chave:** Instrumentos cirúrgicos. Esterilização. Qualidade da água.

**RESUMEN: Objetivo:** Analizar la importancia del agua en el Centro de Material y Esterilización, sobre las principales evidencias de riesgo, normas, legislación relacionada y orientaciones para la definición de un sistema de tratamiento de agua para enjuague de productos. **Método:** Revisión narrativa buscando hechos, mitos y describiendo aspectos relacionados a la necesidad de control de la calidad del agua utilizada en el procesamiento de productos para la salud. **Resultados:** Relatos de efectos tóxicos locales y reacciones pirógenas en pacientes demandan la estandarización y el control de la calidad del agua para enjuague de productos y generación de vapor en las autoclaves. **Conclusión:** El tratamiento y el monitoreo de la calidad del agua deben ser incorporados por los servicios de salud.

**Palabras clave:** Instrumentos quirúrgicos. Esterilización. Calidad del agua.

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## INTRODUCTION

In 2012, the ANVISA Board Resolution (RDC) No. 15, from the Brazilian Health Surveillance Agency (ANVISA)<sup>1</sup>, established that the rinsing of health products should be carried out with water that meets the potability standards specified in regulations, namely Directive No. 2,914, dated December 12, 2011<sup>2</sup>, which legislates in relation to procedures for the control and surveillance of water quality for human consumption and to its potability standards. In addition, it determined that the final rinsing of critical products for orthopedic and ophthalmic implants as well as cardiac and neurological surgeries should be performed with purified water, with water-quality monitoring and recording at set protocol intervals. Monitoring should include the measurement of water hardness, pH, chloride, copper, iron, manganese ions, and microbial load at the rinsing points in the cleaning area; however, microbiological and physicochemical acceptability standards are not determined.

These measures are not myths, noting that the literature contains several toxicity reports related to water quality in the processing of health products. Holland et al.<sup>3</sup> hypothesize about the association of diffuse lamellar keratitis in patients who underwent ocular surgery and the release of endotoxins by the biofilm present in

autoclave reservoirs. The investigation of the outbreak involving 52 patients revealed biofilm of *Burkholderia picketti* in autoclave reservoirs. The adoption of strategies for the control of biofilms in reservoirs, which included cleaning with boiling water, brushing, and application of 70% isopropyl rubbing alcohol, resulted in a significant reduction of cases.

Endotoxins may cause toxic anterior segment syndrome<sup>4,5</sup> besides inducing aseptic loosening in orthopedic implants, leading to serious consequences for patients<sup>6</sup>. Furthermore, there are reports of pyrogenic reactions in patients who had their cardiac catheters reprocessed with water without any microorganism and endotoxin control<sup>7</sup>.

In Brazil, although water microbiological and physicochemical quality control is required, there are no set acceptable parameters. Nevertheless, it is suggested that the quality standards for the water used during the final rinsing, for regulatory compliance, are guided by the *Technical Information Report 34* from 2007, published by the Association for the Advancement of Medical Instrumentation (AAMI)<sup>8</sup> (Chart 1). Although not required by the ANVISA Board Resolution (RDC) No. 15<sup>1</sup>, the standard should include the control of endotoxins and other contaminants required by manufacturers of the equipment and surgical instruments.

**Chart 1.** Water physicochemical and microbiological characterization for processing health products, in compliance with the *Technical Information Report 34*, 2007, by the Association for the Advancement of Medical Instrumentation (AAMI)\*.

Contaminants	Potable water	Soft water	Deionized water	High-purity water**
Bacteria (cfu/mL)	<200	<200	<200	≤10
Endotoxins (EU/mL)	N/A	N/A	N/A	<10
Total organic carbon (mg/L)	<1.0	<1.0	<1.0	<0.05
pH	6.5 to 8.5	6.5 to 8.5	N/A	N/A
Hardness (CaCO <sub>3</sub> in ppm)	<150	<10.0	<1.0	<1.0
Resistivity (MΩ-cm)	N/A	N/A	>1.0	>1.0
Total dissolved solids (CaCO <sub>3</sub> in mg/L)	<500	<500	<0.4	<0.4
Chloride (mg/L)	<250	<250	<1.0	<0.2
Iron (mg/L)	<0.3	<0.3	<0.2	<0.2
Copper (mg/L)	<0.1	<0.1	<0.1	<0.1
Manganese (mg/L)	<0.1	<0.1	<0.1	<0.1
Color and turbidity	Colorless, clear and without residues	Colorless, clear and without residues	Colorless, clear and without residues	Colorless, clear and without residues

\*Document updated in 2014; the 2007 edition, however, is in accordance with the parameters required by article 74 of the ANVISA Board Resolution (RDC) No. 15<sup>(1)</sup>. \*\*Recommended for final rinsing; cfu: colony-forming units; EU: endotoxin units; N/A: not applicable. Source: Translated and adapted from the AAMI, 2007<sup>8</sup>.

Aiming at a concrete estimate of the real impact of water quality on the processing safety for health products, one study assessed the cytotoxicity of hydrodissection cannulae submitted to a contamination challenge, a cleaning process based on a validated standard operating procedure (SOP) and the final rinsing in different types of water: tap, deionized, distilled, treated by reverse osmosis, and ultra-purified water<sup>9</sup>. Samples were internally and externally contaminated by a solution containing 20% of defibrinated sheep blood and 80% of 0.9% sodium chloride. Later, the lumen was filled with a viscoelastic solution, letting it remain in contact with the contaminant for 50 minutes and was then processed, in accordance with a validated SOP<sup>10</sup>. Results showed that the quality of the water used for the last rinsing, as an isolated variable, does not affect the cytotoxicity of the cannulae; however, this statement is valid only if cleaning quality is assured<sup>9</sup>. In the study, the authors did not recommend the use of water without the control of physicochemical and microbiological standards, by seasonal and geographic variation of water<sup>11</sup>, and the possibility of corrosion of instruments. They also establish that these results do not ensure the process is free from the control of vapor contaminants, in accordance with

the second part of the standards of the American National Standards Institute (ANSI), the AAMI, and the International Organization Standardization (ISO) 17665-1<sup>2</sup>.

Based on the data presented, we conclude that controlling the water quality in the processing of health products is of paramount importance, and its monitoring should be incorporated by health services.

Several technologies for water treatment are available in the market; thus, it is recommended that health services adopt a quality standard for the water used in the last rinsing and estimate treatment technologies according to Central Supply needs, considering the required volume of water and treatment system efficiency. Since water monitoring must be performed in conformity with protocol, analyses should be performed at shorter intervals after the installation of the system to assess its effectiveness. In line with the constancy in the results, monitoring may be performed with less frequency, considering that, with the history of the values obtained, it is possible to determine whether the exchange of consumables and the preventive maintenance of the treatment system are necessary, aiming at maintaining the quality standard for the treated water.

## REFERENCES

1. Brasil. Resolução da Diretoria Colegiada nº 15, de 15 de março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. Brasília: Ministério da Saúde; 2012 [citado 2015 mar 27]. Disponível em: [http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0015\\_15\\_03\\_2012.html](http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0015_15_03_2012.html)
2. Brasil. Portaria nº 2.914 de 12 de dezembro de 2011. Dispõe sobre os procedimentos de controle e de vigilância da qualidade da água para consumo humano e seu padrão de potabilidade. Brasília: Ministério da Saúde; 2011.
3. Holland SP, Mathias RG, Morck DW, Chiu J, Slade SG. Diffuse lamellar keratitis related to endotoxins released from sterilizer reservoir biofilms. *Ophthalmology*. 2000;107(7):1227-33.
4. Johnston J. Toxic anterior segment syndrome: more than sterility meets the eye. *AORN J*. 2006;84(6):969-84; quiz 985-6.
5. Mamalis N, Edelhauser HF, Dawson DG, Chew J, LeBoyer RM, Werner L. Toxic anterior segment syndrome. *J Cataract Refract Surg*. 2006;32(2):324-33.
6. Greenfield EM, Bi Y, Ragab AA, Goldberg VM, Nalepka JL, Seabold JM. Does endotoxin contribute to aseptic loosening of orthopedic implants? *J Biomed Mater Res B Appl Biomater*. 2005;72(1):179-85.
7. Ribeiro SMCP, Graziano KU, Alfa MM, Goveia VR. Reprocessamento de cateteres cardíacos: uma revisão. *Rev Bras Cir Cardiovasc*. 2006;21(3):334-42.
8. Association for the Advancement of Medical Instrumentation. Water for the reprocessing of medical devices. Arlington: AAMI; 2007. AAMI Technical Information Report 34.
9. Souza RQ, Gonçalves CR, Ikeda TI, Cruz AS, Graziano KU. O impacto do último enxágue na citotoxicidade de produtos críticos passíveis de processamento. *Rev Esc Enferm USP*. 2015;49(spe):87-92.
10. Tamashiro NS, Souza RQ, Gonçalves CR, Ikeda TI, Luz RA, Cruz AS, et al. Cytotoxicity of cannulas for ophthalmic surgery after cleaning and sterilization: evaluation of the use of enzymatic detergent to remove residual ophthalmic viscosurgical device material. *J Cataract Refract Surg*. 2013;39(6):937-41.
11. Association of Perioperative Registered Nurses. Perioperative standards and recommended practices. Denver: AORN; 2013.
12. International Organization Standardization. ANSI/AAMI/ISO 17665-1. Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1. Geneva: ISO; 2009.