

# BASES FOR SAFE USE OF THERMAL WASHER DISINFECTORS EMPHASIZING THE RELEASE FOR USE AFTER TECHNICAL INTERVENTION

*Fundamentos para uso seguro das lavadoras termodesinfetadoras com ênfase na liberação para uso após intervenção técnica*

*Bases para el uso seguro de las lavadoras termodesinfectantes colocando énfasis en la liberación para el uso después de la intervención técnica*

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**ABSTRACT:** It is seen, in the daily routine of Material and Sterilization Centers (CMEs, acronym in Portuguese), that thermal washer disinfectors submitted to technical interventions for correcting failures are released for use without evidence of operation following the required parameters for the effective performance of cleaning and thermal disinfection. Given the importance of preventing healthcare-related infections, this study presents innovated systematization of assays required for the release of thermal washers after technical interventions, as well as the necessary information to preserve such equipment in optimal operation conditions. Safe release of the equipment should include the evaluation of temperature and time parameters compared to data obtained during qualification, the conference of admitted detergent volume during cleaning, the evaluation of cleaning effectiveness with commercially available monitors, the establishment of a change control, and a protocol for directing the requalification, following the Brazilian regulations and international recommendations.

**Keywords:** Equipment maintenance. Detergents. Disinfection.

**RESUMO:** No cotidiano dos Centros de Material e Esterilização (CMEs), observa-se que as lavadoras termodesinfetadoras submetidas a intervenções técnicas para correção de falhas são liberadas para uso sem evidência de operação conforme os parâmetros requeridos para realizar limpeza e termodesinfecção eficientes. Considerando a importância da prevenção das infecções relacionadas à assistência à saúde, este estudo apresenta como inovação a sistemática dos ensaios requeridos para a liberação de termolavadoras após intervenções técnicas, assim como as informações necessárias para a conservação desses equipamentos em condições ótimas de operação. A liberação segura do equipamento deve incluir a avaliação dos parâmetros de temperatura e tempo em comparação aos dados obtidos na qualificação, a conferência do volume de detergente admitido durante a limpeza, a avaliação da eficácia da limpeza com monitores comercialmente disponíveis, o estabelecimento de um controle de mudanças e um protocolo para direcionar a requalificação, atendendo à legislação nacional e às recomendações internacionais.

**Palavras-chave:** Manutenção de equipamento. Detergentes. Desinfecção.

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**RESUMEN:** En lo cotidiano de los Centros de Material y Esterilización (CMEs), se observa que las lavadoras termodesinfectantes sometidas a intervenciones técnicas para corrección de fallas son liberadas para uso sin evidencia de operación según los parámetros requeridos para realizar limpieza y termodesinfección eficientes. Considerando la importancia de la prevención de las infecciones relacionadas a la asistencia a la salud, este estudio presenta como innovación la sistematización de los ensayos requeridos para la liberación de termolavadoras tras intervenciones técnicas, así como las informaciones necesarias para la conservación de esos equipos en condiciones excelentes de operación. La liberación segura del equipo debe incluir la evaluación de los parámetros de temperatura y tiempo en comparación a los datos obtenidos en la calificación, la conferencia del volumen de detergente admitido durante la limpieza, la evaluación de la eficacia de la limpieza con monitores comercialmente disponibles, el establecimiento de un control de cambios y un protocolo para direccionar la recalificación, atendiendo la legislación nacional y las recomendaciones internacionales.

**Palabras clave:** Mantenimiento de equipo. Detergentes. Desinfección.

## INTRODUCTION

The worldwide healthcare system has recently suffered great pressure for decreasing costs, increasing productivity, and maintaining quality and safety with the need of remaining updated following the new technologies<sup>1</sup>. With the aim of making surgical procedures less invasive and traumatic, the design of instruments has considerably evolved and has become more complex. Therefore, the cleaning process needs to be perceptive, automated, and reproducible to provide reliable results and optimization of work processes.

Hence, the thermal washer disinfectors have satisfied this demand at Material and Sterilization Centers (CMEs, acronym in Portuguese). However, like any other equipment, they require qualification, maintenance, and monitoring to meet the criteria of safety and reliability of results<sup>2,3</sup>.

In the daily routine of the CMEs, the thermal washer disinfectors submitted to technical interventions for correcting failures are released for use only based on the indicated values of temperature and time, with no evidence of their efficient performance during cleaning or thermal disinfection. Thus, since the instruments that indicate time and temperature values in the equipment panel may not be following the values obtained in qualification, the cleaning and thermal disinfection may not be effective and may compromise safety during health products processing.

The Resolution of the Joint Board of Directors No. 15 (RDC-15), from the Brazilian Health Surveillance Agency (ANVISA)<sup>2</sup>, as well as the Brazilian Association of Technical Standards (ABNT)<sup>3</sup> determine the annual qualification, gauging, maintenance, requalification, and monitoring of thermal washers in order to ensure the effectiveness of cleaning

and thermal disinfection processes. However, there are no instructions on the procedures that should be performed after a technical intervention.

Since the prevention of healthcare-related infection (IRAS, acronym in Portuguese), as well as the patient's safety, is a global issue, this review presents an innovated systematization of assays required for releasing thermal washers after technical interventions, as well as the necessary information to preserve such equipment in optimal operation conditions.

## PHASES OF WASHING AND THERMAL DISINFECTION CYCLE

In general, cleaning of health products in thermal washer disinfectors is done by means of spraying rods that use water under pressure associated with detergent effect to help the dirtiness extrication. There are specific racks adjusted to the product conformation to do such process, which aim at promoting water under pressure achievement in outer and inner surfaces.

The cleaning and thermal disinfection cycles performed in thermal washer disinfectors are presented in Figure 1, and they are described in the following text with details:

1. Pre-cleaning: in this stage, the inner and outer surfaces of the products are exposed to a spray of cold water under pressure to remove the excess of organic and inorganic residues;
2. Cleaning: performed with water at temperatures usually varying between 40 and 60°C for 5 minutes, by means of detergent that does not produce foam of neutral or alkaline pH<sup>4</sup>. In Brazil, the commonly

used enzymatic detergents should follow the determinations of the ANVISA RDC-55 from 2012<sup>5</sup>;

3. Neutralization: this stage should be conducted when the health service chooses to use alkaline detergent. In such case, neutralizing acids should be added to water for supporting the removal of detergent residues and avoiding the formation of salt storages<sup>4</sup>;
4. Rinsing: with hot or cold water and no additives<sup>4</sup>. According to ANVISA RDC-15 from 2012<sup>2</sup>, this stage requires purified water for rinsing critical products used in orthopedic and ophthalmologic implant surgeries, cardiac and neurological surgeries. Supplementary rinsing stages may be scheduled, such as for ophthalmologic and orthopedic instruments.
5. Thermal disinfection: it occurs in purified water at temperatures varying between 80 and 95°C with exposure time calculated based on the required A0 (A zero), as further described<sup>4</sup>;
6. Drying: controlled by the thermal washer disinfectant or by driers for health products<sup>4</sup>.

Water quality control is necessary in the cycle stages. The Association for the Advancement of Medical Instrumentation (AAMI) from the United States of America establishes the quality of water for processing health products, and recommends the control of bacteria, endotoxins, total organic carbon, pH, hardness, resistivity, total dissolved solids, chloride, iron, copper, manganese, color, and turbidity, because these factors may cause

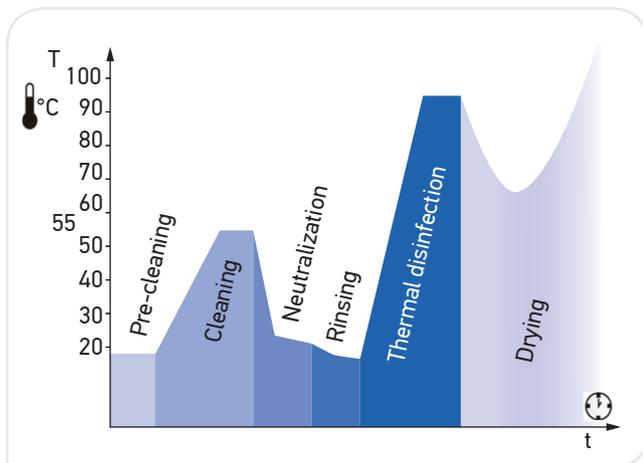
corrosion in surgical instruments, damage equipment, decrease detergent activity level, and provoke toxic reactions in patients<sup>6</sup>.

It is upon the manufacturer of health products or thermal disinfectors to establish the required water quality for the correct operation of the equipment and maintenance of product quality; however, such information has not been clearly spread and it is absent in some cases.

A daily monitoring routine of the water being supplied to the thermal washer disinfectant should be adopted in order to measure chemical purity, temperature, feeding pressure, microbiological contamination, among others, following the frequency recommended by the equipment manufacturer<sup>3</sup>. The point of collection should be as close as possible from the washer entrance so that all contamination sources could be monitored.

Manufacturers indicate the Brazilian standard (NBR) criteria from ABNT ISO 17665-2 (2013)<sup>7</sup> for the quality of the water being supplied to the equipment and for the optimal preservation and operation of the thermal washer disinfectant. Values are reproduced in Chart 1.

Some water components cannot be easily measured on a daily basis and their samples must be sent for a specialized laboratory. There are available devices that enable real-time measurement of water conductivity through increase of dissolved inorganics, whose operational limits can be determined by comparing the quality of water before and after the treatment system. Therefore, if the



**Figure 1.** Example of cycle stages of a thermal washer disinfectant. Translated and adapted from Arbeitskreis Instrumentenaufbereitung (AKI), 2012<sup>4</sup>.

**Chart 1.** Limit values recommended for contaminants in the supplied water of thermal washer disinfectants, adapted of the NBR ISO 17.665-2:2013<sup>7</sup>.

Component	Value
Silicate (SiO <sub>2</sub> )	≤ 0.1 mg/L
Iron	≤ 0.1 mg/L
Cadmium	≤ 0.005 mg/L
Lead	≤ 0.05 mg/L
Other heavy metals, except iron, cadmium, and lead	≤ 0.1 mg/L
Chloride	≤ 0.1 mg/L
Phosphate (P <sub>2</sub> O <sub>5</sub> )	≤ 0.1 mg/L
Conductivity	≤ 3 µS/cm
pH	5 to 7
Appearance	Clean, dull, without Hsediments
Hardness	≤ 0.02 mmol/L

water conductivity exceeds the established limit, it is clear that the physical chemical characteristic of such water had been altered and it should not be used until the identification of the altered component<sup>8</sup>.

There are also commercially available tests that enable to monitor the water pH and hardness (amount of CaCO<sub>3</sub> and manganese in parts per million), by using tapes that chemically react with the presence of these components, thus changing the color according to its level, or electronic systems with digital indication of the values found<sup>8</sup>.

## ASSAY ROUTINES FOR EVALUATING THE THERMAL WASHER DISINFECTOR OPERATION

Professionals in charge of the CME operationalization should implement actions to ensure proper functioning of the department's technological equipment, ensuring the quality of processed products, and avoiding interruptions owing to technical failures. Equipment failures result in delays and increase the risks of errors caused by emergent actions and contingent plans. Thus, a routine of daily, quarterly, and

annual assays is suggested to evaluate the operation of thermal washer disinfectors<sup>9</sup>, which should be a supplement to the manufacturer's recommendations. Routine assays are presented in Chart 2.

## ROUTINE FOR RELEASING THERMAL WASHER DISINFECTORS AFTER TECHNICAL INTERVENTION

The safe release of thermal washer disinfectors after intervention comprises not only the evaluation of cycle temperature and time, but also the volume conference of the detergent admitted during cleaning and evaluation of cleaning efficacy with the commercially available monitors in association with guidelines to elaborate an evaluation and maintenance plan of the operation, as previously described.

A graduated cylinder is used for checking whether the detergent dilution remains with the scheduled amount. It should be positioned in the dosage exit inside the washer. The dosage command is operated subsequently; the volume obtained inside the cylinder represents the amount

**Chart 2.** Guidelines to elaborate an evaluation and maintenance plan of thermal washer disinfectors operation based on periodicity.

Item to be evaluated	Periodicity		
	Daily	Quarterly	Annual
Water conductivity**	X		
Detergent volume	X		
Cleaning and fixation of water storage grate inside the chamber	X		
Movement of spraying rods	X		
Printer paper	X		
Printer ink cartridge	X		
Water leaks	X		
Cleaning visual inspection of all loads	X		
Indication of low detergent volume*		X	
Dosage system of detergent volume*		X	
Cleaning efficacy using dirtiness simulators*		X	
Temperature of a cycle with load, with outer instrument*		X	
Door locking system*		X	
Qualification (minimal)**			X
Gauging (minimal)**			X
Requalification	Based on the events stabilized during change control		

\*NBR ISO 15.883-13; \*\*RDC-15 from ANVISA, of 2012<sup>2</sup>.

of admitted product in each cycle. The result of this action should be compared to predetermined parameters of the equipment and to the detergent manufacturer’s recommendations, thereby proving if the detergent volume admitted in each washing cycle is correct.

Then, a cleaning cycle should be scheduled and the thermal disinfection and drying phases may be excluded, thus challenging cleaning with tests that simulate dirtiness based on the recommendations of the ISO 15.883-5:2005<sup>10</sup>. Several monitors with different markers, like proteins, blood, and adenosine triphosphate (ATP)<sup>10-13</sup>, are available for cleaning monitoring. Interpretation of the results obtained with these products may be performed following the manufacturer’s guidance; nevertheless, it is worth noting that there are no fast tests to detect the residues of fat, biofilms, and prion proteins for use during the CME routine.

After the equipment has been approved during the cleaning phase, one need to check whether the thermal disinfection is being achieved by using a commercially available indicator during a standardized cycle that will show if the scheduled time and temperature were actually being achieved<sup>3</sup>. Exposure time and temperature parameters are challenged in the thermal qualification process, which should be conducted at least once a year<sup>2</sup>, in compliance with the frequency and procedures indicated by the manufacturer, or if any component of this measurement chain has been replaced.

The thermal disinfection phase has its efficiency determined by means of the statistical calculation identified by A0 (A zero). This concept is established in ISO 15.883-1:2013<sup>3</sup>, in which, based on the disinfection process and for a specific time at a certain temperature, predictable lethality occurs on a population of standardized microorganisms.

The formula used for calculating A0 in Figure 2 is the same as that used for calculating F0 (F zero) in sterilization processes through saturated vapor, in which F indicates the reference temperature of 121°C and A indicates reference temperature of 80°C in the thermal disinfection case. The Z value represents the temperature variation that will determine the decrease of 1 log for each instant and is fixed at 10°C. Therefore, the formula will provide the total time requested to obtain the desired level of disinfection.

This formula was idealized with reference temperature of 80°C, assuming that the temperature raise would decrease exposure time, and not the contrary. Thus, the use of this formula is not recommended for temperatures below 80°C<sup>3</sup>. For such temperatures, the A0 formula can only be applied

until the 70°C limit, and at least 75°C are suggested so that inactivation of thermal-resistant bacteria and virus occur comparable to the A0<sup>14</sup> integration. Since inactivation of bacteria like *Enterococcus*, *Legionella*, and some kinds of protozoans is generally effective at temperatures above 65°C, the A0 formula integration should be carried out with this temperature henceforth<sup>14</sup>.

The A0 value is calculated in seconds. The NBR ISO 15.883-1<sup>3</sup> standard establishes the minimum value of 600 seconds for products that will be sterilized and 3,000 seconds for those that will not<sup>15</sup>. The exposure times for each temperature are shown in Chart 3.

There is neither an indicator available in the Brazilian market that can be used as reference to determine A0, nor a monitoring device of the thermal disinfection phase with microbial load reduction proof. The only commercially available devices are chemical indicators that report whether the temperature has been achieved during a certain period of exposure.

Brazilian CMEs still have difficulties in understanding and implementing thermal disinfection parameters based on A0, according to Rosenberg<sup>15</sup> and ABNT<sup>3</sup>, owing to many reasons, including thermal sensitivity of the products.

The A0 calculation formula is not recommended for temperatures below 80°C in thermal disinfection. If the calculation was for 70°C – such temperature is usually adopted in our area for thermal disinfection of inhalotherapy and

$$A0 = \sum 10^{\frac{(T-T_{ref})}{Z}} \times \Delta t$$

Source: ABNT NBR ISO 15883-1:2013<sup>3</sup>

Figure 2. A0 formula.

Chart 3. Minimum time of exposure for each temperature of the requested A0, according to NBR ISO 15.883-1:2013<sup>3</sup> and Rosenberg (2003)<sup>15</sup>.

A0 (seconds)	Temperature (°C)	Time (minutes)
600	80	10
	90	1
	93	0.5
3,000	80	50
	90	5
	93	2.5

ventilator support products – the required time, according to the formula, would be 500 minutes at 70°C for A0 from 3,000 and 100 minutes for A0 of 600.

Hepatitis B virus requires 20 minutes at 80°C to be inactivated and for 70°C temperature, almost 200 minutes would be necessary to reach the same reduction<sup>16</sup>.

In 2000, an investigation evaluated the efficacy of 77°C parameters for 30 minutes applied through a pasteurizer machine (a “bain-marie” with temperature control) to disinfect the ventilator support and anesthesia devices. A high number of testing microorganisms ( $10^4$  to  $10^6$  colony-forming units) were inoculated against plastic and metallic tubes (3 mm of diameter and 40 cm of length), and submitted to thermal disinfection cycle. *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Candida albicans*, and *Mycobacterium terrae* were removed; however, *Bacillus subtilis* spores were not. In this study, the authors concluded that such equipment is effective for ventilator support and anesthesia devices and pasteurization was focused as an alternative for disinfection using chemical disinfectants<sup>17</sup>. Therefore, release and monitoring of thermal disinfection phase for temperatures below 80°C, based on A0 integration, should have theoretical and scientific basis proving that the adopted time and temperature are appropriate for reaching the necessary efficacy for the process.

Every equipment can fail, we therefore recommend the elaboration of a change evaluation protocol to establish the impact of interventions on the equipment performance, thus indicating the qualification stages that should be repeated in order to determine the operation continuity in the work range that had been challenged in the annual qualification. The ABNT NBR ISO 17.665-1<sup>18</sup> provides guidelines for sterilization process validation that may help to develop a protocol and may also be adjusted to thermal disinfection.

This document, as well as this investigation, should help professionals working at CMEs to determine when the piece of equipment needs to be requalified after technical intervention, following the requirements of article 41 from RDC-15 of ANVISA, in 2012<sup>2</sup>.

Since NBR ISO 17.665-1<sup>18</sup> is directed to vapor sterilization equipment, we recommend the development of a specific standard for elaborating a change evaluation protocol with qualification stages that require repetition after technical interventions in thermal washer disinfectors. Results obtained with such procedures have to be confronted with tests performed during qualification, including comparison with physical records and, if they are in compliance, the thermal washer disinfectant should be released for use.

## CONCLUSION

The adoption of a continuous procedure of assays to evaluate the operation of thermal washer disinfectors enables early diagnosis of failures, providing more control and quality to the cleaning and thermal disinfection automated process.

Equipment submitted to intervention need more attention before their routine use, because only data provided in the panel do not certify the safety of the cleaning and thermal disinfection process. Safe release of the equipment should include the evaluation of temperature and time parameters compared to data obtained during qualification, checking of admitted detergent volume during cleaning, evaluation of cleaning effectiveness with commercially available monitors, and establishment of a change control and of a protocol for directing the requalification following the Brazilian regulations and international recommendations.

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