UNIVERSITÀ DEGLI STUDI DI PADOVA

—

DIPARTIMENTO DI INGEGNERIA DELL'INFORMAZIONE

—

CORSO DI LAUREA MAGISTRALE IN BIOINGEGNERIA

ANALYSIS AND IMPLEMENTATION OF EN ISO 15883 TECHNICAL STANDARD: EXECUTION OF TYPE TESTS ON MEDICAL DEVICES FOR THERMAL-DISINFECTION AND DEVELOPMENT OF A PROTOTYPE

RELATORE: CH.MO PROF. ING. GIULIO ROSATI

CORRELATORE: CHRISTIAN ARTUSO

LAUREANDO: ALESSANDRO MARIGO

MATRICOLA: 2026961

ANNO ACCADEMICO 2021-2022

ai miei genitori...

“ Faber est suae quisque fortunae ”

Appius Claudius Caecus

Epistulae ad Caesarem senem de re publica

Contents

Abstract

Contact between contaminated or non properly reprocessed medical devices and patient sterile tissues during any healthcare procedure is a major risk that may cause an unwanted infection to a healthy individual.
These infections not only have a negative impact on patient's quality of life, but also on other aspects such as the average length of hospital stay and healthcare costs/expenditure. For these reasons it is important to reduce the risk as much as possible, for example by correctly reprocessing medical items.

This graduation thesis describes part of a six months work experience in Steelco, a company that manufactures medical devices intended for the reprocessing of reusable medical items.

The first two chapters are focused on the distinction among medical devices and their relative correct reprocessing principles and procedures, as well as the place where these procedures are carried on, the central sterile service department.
The third one describes the ISO 15883 technical standard, that regulates the design, principles and functioning of any medical device that performs the washing and disinfection stages of the reprocessing, and is directly linked to the chapter four. This part represents an extended work that was carried out during the working experience, aimed at establishing that one of the most popular Steelco device is compliant with ISO 15883 through the study of the same technical standard and extensive testing activity.
Finally the last chapter is about the final development stages of a new device, both hardware and software-wise, as well as some testing activity that improved

the compliance with the technical standard.

Introduction

All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection. Failure to properly disinfect or sterilise equipment may lead to transmission via contaminated medical and surgical devices.[1]
This risk is known as *biohazard*: the potential that the exposure or contact with contaminated materials may cause an infection to a healthy individual.
These infections belong to the so-called *nosocomial* infections, a subset of infectious diseases acquired in a healthcare facility. These develop at least 48 hours after admission and can lead to serious problems like sepsis and even death. Surgical site infections are the second most common type that can develop after surgery, and length of operation, surgical technique and sterility are all factors that can affect the incidence of surgical site nosocomial infections.

Across Europe, it is estimated that every year these hospital acquired infections cause:[2]

- 16 million extra days of hospital stay;
- $7 billion in healthcare cost alone;
- 37.000 deaths, whilst contributing to a further 110.000 deaths.

In May 2003, a prevalence study of nosocomial infections was carried out in 21 hospitals, representing 63% of all hospital beds for acute patients of the Veneto region. Overall, 6.352 patients were surveyed: the prevalence of nosocomial infections was 7.6% (range 2.6%-17.7%). The most frequent infections affected the

following: urinary tract (28.4%), surgical site (20.3%), blood stream (19.3%), pulmonary and lower respiratory tract (17.6%). This study showed that nosocomial infections are frequent and they make up for a huge public expense.[2]

This data alone suggests that medical devices, and in particular reusable medical devices, should be treated appropriately to maximize patients and medical staff safety and minimize medical expenditure.

Chapter 1

Medical devices and organization

This chapter describes the partition among medical devices established in 1957 by Earle Spaulding, that is still a reference point among clinical practice. Moreover, it provides a brief description of Steelco Spa and a focus on Central Sterile Services Departments (CSSDs).

1.1 Medical equipment

In order to reduce the incidence of hospital-acquired infections, in 1957 Earle Spaulding devised a rational approach to disinfection and sterilisation of patient care items or equipment, called Spaulding criteria.[3] This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals when planning methods for disinfection or sterilisation.

Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories based on the degree of risk of infection involved in the use of the items.

The three categories he described were critical (enters sterile tissue and must be sterile), semi-critical (contacts mucous membranes or non intact skin and requires high-level disinfection), and non-critical (comes in contact with intact skin and requires low-level disinfection). The Spaulding criteria clearly refers to both reusable and disposable medical devices.

1.1.1 Critical items

Critical items are critical because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Therefore, it is critical that objects that enter sterile tissue or the vascular system are sterile because any microbial contamination could result in disease transmission.
This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. The items in this category should be purchased as sterile or be sterilised by steam sterilisation if possible. Otherwise if heat-sensitive, the object may be treated with ethylene oxide, hydrogen peroxide gas plasma, vaporised hydrogen peroxide, hydrogen peroxide vapour and ozone, or liquid chemical sterilants if other methods are unsuitable. With the exception of 0.2% peracetic acid (12 minutes at 50°C-56°C), the indicated exposure times for liquid chemical sterilants range from 3-12 hours. Liquid chemical sterilants, as well as the other sterilisation methods, can be relied on to produce sterility only if cleaning, which eliminates organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met.
Another limitation to sterilisation of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in a liquid chemical sterilant; therefore, it is impossible to maintain sterility after processing and during storage. Furthermore, devices may require rinsing after exposure to the liquid chemical sterilant with water that, in general, is not sterile. Therefore, because of the inherent limitations of using liquid chemical sterilants in a non automated (or automated) reprocessor, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilisation methods.

1.1.2 Semi-critical items

Semi-critical items are items that come in contact with mucous membranes or non intact skin.
Respiratory therapy and anaesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes are examples of items included in this category.
These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, bacteria); however, small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semi-critical items require at least high-level disinfection using chemical disinfectants. The exposure time for most high-level disinfectants varies from 8-45 minutes at 20°C-25°C.
Because semi-critical equipment has been associated with reprocessing errors that result in patient lookback and notifications, it is essential that control measures be instituted to prevent patient exposures. Before new equipment is used for patient care on more than one patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested.

1.1.3 Non-critical items

Non-critical items are items that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is not critical. Examples of noncritical items are bedpans, bed rails, bedside tables, patient furniture, and floors. In contrast with critical and the vast majority of semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area.
There is virtually no documented risk of transmitting infectious agents to patients via noncritical items when they are used as noncritical items and do not contact

non-intact skin or mucous membranes. However, these items (e.g. bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of health care personnel or by contact with medical equipment that will subsequently come in contact with patients.[4]

1.2 Steelco

Steelco Spa is a company located in the region of Treviso, that is devoted to the development of cutting-edge technologies used for the reprocessing of critical, semi-critical, and non critical items. In the past, these items were cleaned manually, but in recent years this process was gradually replaced with automatic and advanced solutions to meet specific demands of safety, time and traceability: in this way it was possible to be sure about the cleanliness of the reprocessed items.

Steelco first started its business in April 2001, with the development of medium-small devices for the reprocessing of non critical and semi-critical items. It started growing really fast after launching the production of bigger devices with a PLC and a touch screen on board, and eventually it started branching towards the reprocessing of new kind of specific healthcare items, such as surgical tools, anaesthesia tubes, surgical boards and hospital beds.

During the years Steelco continued growing and split into a few departments: the Medical department, that today is responsible for the 50% of the total revenue, followed by Pharma, Life science, and Lab. Each one is responsible for specific lines of devices, that work using similar principles but are equipped with different components, and some of them are even custom built for customers using their specifications.
In June 2017 Steelco was acquired by Mièle Group: it was an opportunity that enabled Steelco to grow even more, hire new people, make connections with new markets, broaden their device selection and invest time and money into Research and Development.

Today Steelco devices operate in more than 100 countries, thanks to 10 company branches located around the world. It is one of the world biggest manufacturers for washing, disinfection and sterilisation systems, and stands out among the others because it still offers custom made planning, systems and installations.

1.3 Central Sterile Services Department (CSSD)

The delicate stages of disinfection and sterilisation that are carried on inside any health care facility need dedicated rooms with specific structural and technological requirements. Those stages are not just limited to the reprocessing of surgical items, but they include every item used in patient care.

The Central Sterile Services Department, also called CSSD, is an integrated place in hospitals and other health care facilities, and it is responsible for preparing medical/surgical supplies and equipment so that they can be sterile (or at least disinfected) and ready for use in patient care. As the number and variety of surgical procedures and the types of medical devices are consistently growing, an optimised processing is very important for efficiency, economy and patient safety.[5]

According to DPR 14th January 1997, no.37, the CSSDs structure and organisation shall be dependent on the hospital size. Simpler facilities such as dental clinics, still need to follow some directions in order to make sure that the items and medical devices are still sterile.

Every healthcare facility defined in DPR 14th January 1997, no.37 (hospital, clinic etc) has to have their own CSSD, subject to the following requirements:

- The CSSD shall be distinctly divided into specific portions; one of those is intended for the arrival and the pre-processing of contaminated items, another one is intended for the visual inspection of decontaminated items

and their packaging and finally the last one is assigned to storage and distribution of sterile items. Those three areas shall be arranged in such a way that the sterile portion cannot be accessed directly from the contaminated portion.

- The CSSD portions shall be properly ventilated and have a controlled atmosphere, that has to be checked periodically as specified in UNI EN ISO 14644.
- The walls, flooring and ceiling shall be built with a material and a finish that is easy to clean.
- It shall not be possible to open the windows, if any.
- Prior to the washing and disinfection stages, it is suggested to pre-process the items using a specific ultrasound decontamination workstation: that way it's possible to obtain better results in terms of cleaning efficacy.
- Washing and disinfection stages shall be carried out using automatic devices, in order to obtain better results in terms of cleaning efficacy.
- The devices responsible for washing and disinfection stages shall be placed between the contaminated and the decontaminated areas, and the devices responsible for the sterilisation stage shall be placed between the decontaminated and the contaminated areas.
- A traceability system shall be implemented to support the entire process.

Steelco offers a wide selection of devices that are specific for these CSSDs, and each device is appropriate for one of the three main parts of any CSSD: furniture, instruments washer-disinfectors, trolley washer-disinfectors, ultrasonic washers and tunnel washers shall be installed between the contaminated and the decontaminated areas, while steam sterilisers autoclaves and low temperature vaporised H2O2 sterilisers shall be placed between the decontaminated and the sterile areas. For reference, the following picture represents a typical CSSD found in a medium sized hospital.

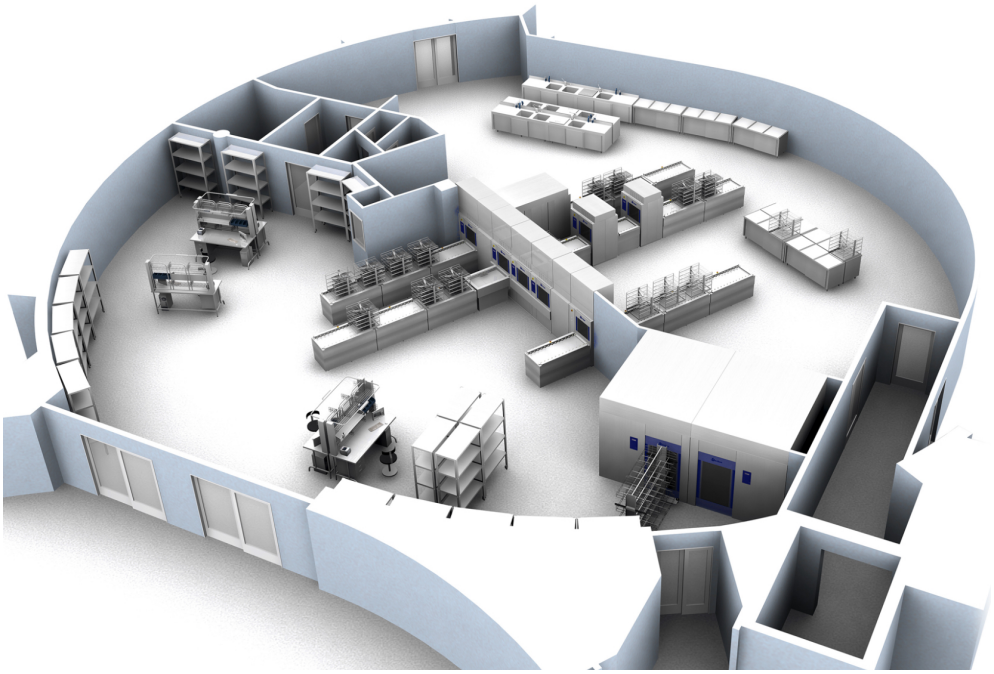


Figure 1.1: Medium sized CSSD

1.4 Purpose of this thesis

This thesis reflects part of a 6 months working experience carried out in Steelco Spa, and in particular puts the study of ISO 15883 technical standard into practice through type tests performed on an existing device, as well as an attentive and considerate development of a prototype and its components.

The so-called type test can be expressed with the concept of "testing for conformity": It is a series of experimental tests and checks specified by a representative technical standard, that has to be carried out (together with mechanical and process checks) on a device in order to be able to state that the same device is compliant with the technical standard.
Initially the goal of my work was to write a pre-filled form that consisted of a protocol of tests that would be used by the RD team for the type tests and would be appropriate for any device manufactured by Steelco. Then this testing activity was carried out on a popular washer-disinfector: the DS 1000.

This theme will be introduced in chapter 3 and further explained in chapter 4.

The development part of this thesis refers to a new model of bedpan washer, called BP 100 HP. During early pre-market stages, it is important to follow the instruction of the reference technical standard.
This included activities such as the refinement of cleaning spray nozzles, improvement of cleaning efficacy and improvement of washing cycles (both time and consumption wise).
This topic will be discussed in chapter 5.

Chapter 2

Reprocessing of reusable medical devices

Reusable medical devices (RMDs) are used for diagnostic (e.g. endoscopes) and/or treatment purposes (e.g. surgical forceps) for multiple patients and are intended by the device manufacturer for reprocessing and reuse.
Reprocessing refers to the activities required to ensure that a RMD is safe for its intended use, so the activities clearly depend on the risk associated to that same device.[6] When the labelling instructions for reprocessing are completely and correctly followed after each use of the device, reprocessing results in a medical device that can be safely used more than once in the same patient or in more than one patient.

It is a multistep process that is performed by trained staff at every healthcare facility, regardless of its dimensions, that includes:

- collection and transfer;
- preprocessing, that sometimes is performed at the point of use (e.g. operating theatre), also known as decontamination;
- cleaning and disinfection stages;
- inspection and assembly;

- functional testing and procedures to restore its safety (if applicable);
- packaging and labelling;
- sterilization (if applicable);
- storage.

These stages represent the path that any instrument goes through after its use, until it is ready to be used again.[7]

2.1 Collection and transfer

It is the first step of the reprocessing process, it may require the healthcare staff to take apart the soiled items and to place them in designated containers. For this reason the staff is exposed to potentially dangerous biological agents from the very first step, and suitable safety measures have to be taken.
The transport of the (pre-treated) items from the examination room or the operating room to the reprocessing area should be undertaken in a sealed basket or container, that will go through the entire reprocessing as the reusable medical devices that they carry. This eliminates the risk of microbial transmission to the environment or health care personnel.

2.2 Decontamination

It is one of the tasks defined in D.Lgs 81/2008, it's a community safety measure and has to be performed prior to any washing/cleaning stage through the immersion in a solution containing a specific agent. This safety measure contributes to the safety of the medical staff, specially those who are in charge of the collection and transfer of the soiled devices.[8]
This procedure can be performed by means of either a manual or an automatic process assisted by specific devices, that shall be compliant to their relative technical standard (proven by the certificate of conformity). The soiled items are

loaded inside the cleaning device and the appropriate cleaning program is selected and launched: the program shall comply with the instructions given by the manufacturer of the item to be decontaminated.

A good decontamination process shall include the following steps:

- Choice of an appropriate detergent. It shall be effective against biological agents and at the same time it shall not damage the item during the process.
- The items shall be submerged in the solution containing a good amount of detergent.
- Choice of an appropriate time interval. It has to follow the directions given by the detergent manufacturer.

At the end of the decontamination process, the solution shall be correctly disposed of.

2.3 Washing stage

It is the removal of foreign material (e.g. soil) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilisation because organic and inorganic materials that remain on the surfaces of instruments interfere with the effectiveness of the process.
Surgical instruments should be pre-soaked or rinsed to prevent drying of blood and to soften blood from the instruments, hinged instruments should be opened fully to allow adequate contact with the detergent solution, and stacking of instruments should be avoided.[9]

Cleaning is done manually for fragile or difficult to clean instruments, but it is quite uncommon: this is a key stage of the reprocessing, and for this reason it shall be performed by an automatic cleaning device, such as the automatic

washer-disinfectors or the ultrasonic cleaners sold by Steelco. Moreover, automatic cleaning reduces the risks for the medical staff related to contaminated instruments.

The most common types of automatic cleaning devices are:

- Ultrasonic cleaners: ultrasonic cleaning removes soil by cavitation and implosion, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold soil to surfaces.

- Washer-decontaminators and washer-disinfectors: these devices remove soil using a combination of water circulation and detergents. They may perform a cycle that subjects the instruments to a substantial heat or one that exposes the items to aggressive chemical agents (both alkaline and acid chemical agents). They are generally computer controlled and can clean a broad variety of instruments, even if they have hollow or difficult-to-reach parts.

- Washers-sterilisers: these are modified steam-sterilisers, that clean by filling the chamber to the brim with water and detergents through which steam passes to provide agitation. Instruments are then rinsed and they undergo a short steam sterilisation cycle.

These cleaning devices should undergo preventive ordinary maintenance, as recommended by the device manufacturer and more importantly by the technical standard UNI EN ISO 15883.

The following recommendations are useful for the success of the cleaning stage:

- High water quality (the technical standard UNI EN ISO 15883 reports the acceptable values).

- Regular maintenance of the hydraulic system, in particular regular checks should be carried out on that parts that are responsible for the mechanical action.

- Precise commands and control on the temperature reached by the automatic cleaning device.
- Good chemical agents quality and appropriate dosage.
- Proper loading of the items.
- Hinged instruments should be fully opened to allow contact with the detergent solution.
- Cart, baskets and din baskets should not be overloaded, otherwise some instruments may remain covered by the other ones.
- The smaller items should not be placed below the bigger ones.
- The items that exhibit cavities and holes shall be cleaned with the help of additional accessories that are specific for these instruments.

Common detergent solutions are characterised by slightly alkaline or neutral pH because such solutions provide a good compromise between material compatibility and good soil removal. Enzymes sometimes are added to neutral pH solutions to assist in removing organic material: these enzymes attack proteins that make up for a large portion of soil, but they are not disinfectants.

As with all chemicals, enzymes must be rinsed from the equipment too otherwise the patients could show symptoms of adverse reaction: the cleaning stage always ends with a rinsing phase, that takes advantage of running water and then demineralized water, in order to remove the chemical agent residual and to take the pH value back to normal.

2.4 Disinfection

It is the most important stage of the entire reprocessing process. It can be performed either by exposing the items to high temperatures (thermal disinfection) or by exposing their surface to chemical agents (chemical disinfection), and this

partition is necessary because not every medical device can go through extreme heat or vice versa through strong chemical agents.

2.4.1 Thermal disinfection

It is a procedure that is carried out on every medical device or item that is not thermolabile, such as surgical instruments, dishes, bedpans etc. This method requires to keep the items in contact with a high temperature, this way the fungicidal and bactericidal effect is guaranteed.
The disinfection efficacy is deeply bound to the temperature that is maintained during this process and its duration, and for this reason it can be described using a specific index called A_0, that depends exponentially on temperature and linearly on time:

$$A_0 = \tau \cdot 10^{(T-80)/10} \tag{2.1}$$

τ is the *holding time* of the disinfection temperature, measured in seconds.

T is the disinfection temperature, measured in °C.

For this reason the A_0 index states the deadliness of this procedure, and a big value suggests that the bacterial load was greatly reduced.

Here are reported the values for the A_0 index that are generally considered acceptable for the reprocessing of different kind of items:

- The non-critical items should be treated at least until $A_0 = 60$ is reached.
- The semi-critical ones should be treated at least until $A_0 = 600$ is reached.
- The critical ones should be treated at least until $A_0 = 3000$ is reached.

Given that this index depends both on the time and temperature, it is logical to think that the same value is obtainable just by raising the temperature, or by extending the duration, or both at the same time, that is usually the best option. The following tables represent different combination of time and temperature values that allow to obtain the same disinfection level ($A_0 = 60$, $A_0 = 600$, $A_0 = 3000$):

Temperature	Holding time
°C	s
80	60
90	6
91	5
92	4
93	3

Table 2.1: $A_0 = 60$

Temperature	Holding time
°C	s
80	600
90	60
91	48
92	38
93	30

Table 2.2: $A_0 = 600$

Temperature	Holding time
°C	s
80	3000
90	300
91	238
92	189
93	150

Table 2.3: $A_0 = 3000$

The following picture represents a typical washer-disinfector cycle: A short prewash stage with cold (< 30°C) water, followed by a wash whose duration may vary and usually employs an alkaline detergent as well as warm (> 50°C and $<$ 60°C) water, a neutralisation stage with an acid chemical agent and a rinse stage, together they create the cleaning stage. This is followed by a thermal disinfection and a prolonged drying stage.

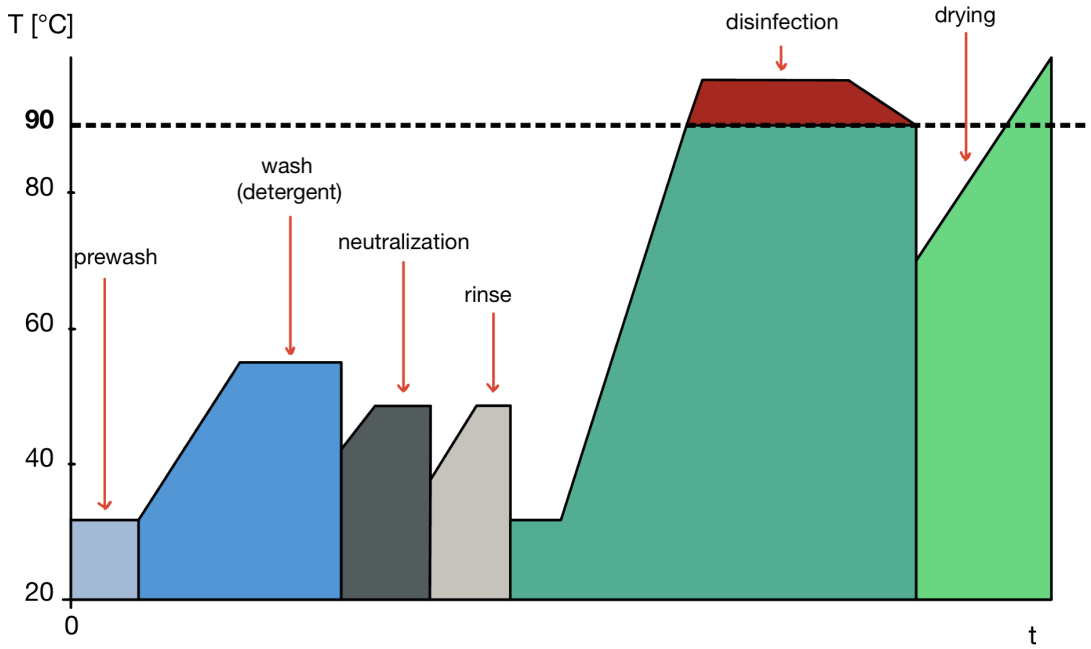


Figure 2.1: Typical WD cycle

2.4.2 Chemical disinfection

It is generally carried out on devices that are thermolabile and can not stand the temperatures that are reached during thermal disinfection, such as flexible endoscopes that are usually submerged in an effective detergent solution at less than 50°C.
The chemical disinfection is performed to preserve the most fragile medical devices, whose structure is very delicate, like the endoscopes. Since it is less precise than the thermal procedure, the washing devices that are responsible for the chemical disinfection go through specific self-disinfections cycles.
An example of chemical agent that is used frequently nowadays is peracetic acid. Glutaraldehyde was employed too until it was banned in some European countries a few years ago, considered poisonous for ingestion and dangerous to the touch.
At the end of this stage, the items are usually dried and then they are ready for the packaging and the sterilisation stage.

2.5 Inspection and assembly

These are two steps that are always performed manually by the CSSD operators. First of all the staff inspects visually each item in search of any trace of biological material (usually blood clots) with the help of specific magnifying glasses. Great attention goes to complex instrument points like hinges, that are the most difficult to treat and are the ones where the soil gathers.
Since it is a visual inspection it is important that the room is properly lighted.
An improper placement of the items and instruments in the washer-disinfector basket, or their involuntary movement as a result of an impact, for example the overlapping of instruments, may lead to soil sticking to those points that were not accessible to water during the washing stage: for this reason the inspection is as important as the washing or disinfection, because if done wrong could lead to contaminated instruments being used again on another patient.
Another operation that is performed by the CSSD workers is (where applicable)

the assembly of items at the end of the disinfection as specified by the item manufacturer, in order to restore its original performance.

The other stages following the assembly (in particular the sterilisation) are just as important but won't be covered in this report.

Chapter 3

UNI EN ISO 15883

Almost every CSSD is distinguished by a set of reprocessing devices placed between the contaminated and the decontaminated part, and they usually belong to the category of washer-disinfectors.
The design, principles, and functioning of any of the medical device that perform the washing and the disinfection are regulated by a dedicated technical standard: ISO 15883.
Given that there is a certain diversity in the field of washer-disinfectors (because of the variety of items to be reprocessed), ISO 15883 is divided into 7 parts, and each one relates to every or to just certain devices.

3.0.1 Overview on the technical standard - Part 1

ISO 15883-1:2006 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.[10]

When processed in the WDs, the medical devices might be intended for immediate

use or might be intended for packing and sterilisation. In both cases, the efficacy of cleaning and disinfection is of major importance. In either case, this is for the well being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilisation process is not unduly challenged by residual soil.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of ISO 15883. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.
ISO 15883-1:2006 does not specify requirements intended for machines for use for laundry or general catering purposes and does not include requirements for machines which are intended to sterilize the load, or which are designated as "sterilizers", these are specified in other standards e.g. EN 285.
The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

3.0.2 Overview on the technical standard - Part 2

ISO 15883-2:2009 specifies requirements and tests for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of reusable medical devices.[11]

This part is the second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to devices that reprocess medical instruments that are meant to be reused, such as:

- Surgical instruments;
- powered devices;

- instrument trays;
- instruments for minimally invasive surgery;
- lumen devices and tubing;
- rigid endoscopes;
- anaesthetic and respiratory equipment;
- bowls, dishes and receivers;
- glassware;
- containers for transit.

The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.
It is recommended that this part is read in conjunction with ISO 15883-1:2006.

3.0.3 Overview on the technical standard - Part 3

ISO 15883-3:2009 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bedpan washer-disinfectors.[12] The requirements given in this part apply to devices that are used for emptying, flushing, cleaning and thermally disinfecting human waste containers intended for re-use, such as:

- Portable sanitary pans;
- support for single-use bedpans;
- hospital bowls;
- urine bottles;
- suction bottles;

- products similar to the above and used for similar purposes.

It is recommended that this part is read in conjunction with ISO 15883-1:2006.

3.0.4 Overview on the technical standard - Part 4

ISO 15883-4:2009 is the fourth of a series of standards specifying the performance of washer-disinfectors and specifies the particular requirements and performance criteria for devices that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes. This part also specifies the performance requirements for the accessories that are needed in order to fulfill the necessary criteria.
The methods, instrumentation and instruction required for type testing, works testing, validation, routine control and monitoring, and re-qualification of WD periodically and after essential repairs, are also specified.[13]

WD complying with this document can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended and validated this method of disinfection.
WD complying with the requirements of this document are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilised by thermal methods.
The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.
It is recommended that this part is read in conjunction with ISO 15883-1:2006.

3.0.5 Overview on the technical standard - Part 5

ISO 15883-5:2009 is the fifth of a series of standards specifying the procedures and test methods used to demonstrate the cleaning efficacy of washer-disinfectors and their accessories intended to be used for cleaning of reusable medical devices.

Testing of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. This testing includes type testing under simulated use conditions. In addition to type testing, performance qualification testing is performed under clinical use conditions.[14]

The cleaning efficacy of washer-disinfectors has historically been demonstrated by referring to different test soils and methods that have been used in several different countries. This document gives requirements for standardized methods for demonstration of cleaning efficacy, including examples of test soils. The individual requirements for the various types of washer-disinfectors and processing procedures can vary, but this document provides the basis for the demonstration of cleaning efficacy. Cleaning efficacy testing is performed in the WD and with associated accessories in two phases:

- type testing, under simulated use conditions, with defined test soils and their analytes, soiling methods and test surfaces/medical devices/product representative of design and intended applications;
- performance qualification testing under clinical conditions with load(s) that are soiled with the most challenging soil from clinical use.

This document excludes the verification of cleaning of product that could have been exposed to prions, the causative agent in transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD).

3.0.6 Overview on the technical standard - Part 6

ISO 15883-6:2015 is the sixth of a series specifying the performance of washer-disinfectors and specifies the particular requirements for performance applicable to general-purpose washer-disinfectors.[15] Its requirements apply to WD used for cleaning and disinfection of non-invasive and non-critical reusable medical devices (i.e. not penetrating skin or contacting mucosal surfaces) and for other items for use without further treatment in healthcare settings. Such reusable items need to

be cleaned and disinfected, but their processing in a WD for surgical instruments, human waste containers, or endoscopes is inappropriate and/or impractical.
Some examples are:

- Non-invasive medical devices;
- washbowls;
- cleaning equipment (buckets);
- footwear;
- container systems used to transport medical devices, including trolleys and transport carts;
- bedsteads, wheelchairs, aid for the disabled.

It is recommended that this part is read in conjunction with ISO 15883-1:2006.

3.0.7 Overview on the technical standard - Part 7

ISO 15883-7:2016 is the seventh of a series specifying the performance of washer-disinfectors.[16] It specifies the particular requirements for performance applicable to washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment, such as:

- Bedframes;
- bedside tables;
- transport carts;
- containers;
- surgical tables;
- sterilization containers;
- surgical clogs;

- wheelchairs, aids for the disabled.

Its requirements apply to WD used for cleaning and disinfection of thermolabile equipment for use without further treatment in healthcare settings. Such reusable items need to be cleaned and disinfected, but their processing in a WD for surgical instruments, human waste containers, endoscopes, or for non-invasive, non-critical medical devices, and healthcare equipment employing thermal disinfection is inappropriate and/or impractical.

Each one of these seven parts follows the same structure, in particular the chapters no. 6 were the most important ones for this thesis, as they reviewed the testing procedures required for validity of the WD and will be discussed later on.

3.1 Steelco washer-disinfectors

The devices that are intended for washing and disinfection that Steelco manufactures and are currently on the market can be divided into the following types:

- Decontamination stations and devices: they can be further divided into DC series and US series and should comply with ISO 15883-1 and ISO 15883-5.
- Bedpan washers: they are represented by the BP series and should comply with ISO 15883-1, ISO 15883-3 and ISO 15883-5.
- Instrument washer-disinfectors: they can be further divided into DS series and EW series and should comply with ISO 15883-1, ISO 15883-2 and ISO 15883-5.
- Trolley washer-disinfectors: they are represented by the LC series and should comply with ISO 15883-1, ISO 15883-2, ISO 15883-5, ISO 15883-6 and ISO 15883-7.
- Tunnel washers: they are represented by the TW series and should comply with ISO 15883-1, ISO 15883-3 and ISO 15883-5.

3.1.1 US Series

This set of devices is usually employed prior to the washing stage, exploiting the ultrasonic cavitation method to remove dried soil on the surface of the items, such as blood clots. The load is submerged inside a chamber that is then filled with water to the brim, and at that point the ultrasound generators emit vibration with a standard frequency of 38kHz.

For reference, cavitation is a phenomenon in which the static pressure of a liquid reduces to below the liquid's vapour pressure, leading to the formation of small vapour-filled gaps in the liquid. When exposed to a higher pressure, this gaps (also called bubbles) collapse and can generate shock waves, that are very strong close to the collapsing bubble but rapidly weaken. In particular the US series exploits the non-intertial cavitation method, that is a process in which a bubble located inside a fluid is forced to oscillate in size and shape due to an acoustic field.
This device is able to remove the smallest and hidden dried organic residue, and can be considered a good alternative to a normal washing stage where the mechanical action is given by the spray arms. However the US line is normally followed by a standard washing cycle with another Steelco device, like for example one from the DS series.

3.1.2 BP Series

This represent the simplest devices that Steelco manufactures nowadays, that are used for the reprocessing (in particular the wash and disinfection stages) of reusable items such as bedpans, bed urinals and bowls.

The washing stage is carried on using specific types of water nozzles, that make sure that every spot of the chamber, even the corners, is reached by an appropriate quantity of water with an equally appropriate pressure to obtain the best result. There are at least 2 to 3 types of nozzles inside the chamber of any device

of the BP series, some of them are fixed while others rotate. During this stage it is possible to use some kind of detergent and the water temperature, as well as the chamber one is kept low.
The thermal disinfection stage is performed after the wash and a quick rinse to reduce the chance of residues remaining on the items. It is accomplished by means of a boiler that heats a certain amount of water to produce steam, and as soon as its temperature reaches 100°C the steam is emitted inside the chamber through the water nozzles. In this way the entire hydraulic circuit, the items and the chamber go through a thermal disinfection cycle.

Every BP series model works in a similar fashion, in particular during the aforementioned stages, and the main differences apply to the presence/absence of two doors or automatic door/s, to the presence/absence of a drying circuit and a fan, and to the overall dimensions. The BP series (in particular the BP 100 HP) will be further explained in the last chapter.

3.1.3 DS Series

This line include some of the most complete devices on the market, developed for the washing, disinfection and drying stage of medical devices. The DS series in particular deals with small and medium-sized heat-resistant items.

The washing process is accomplished by means of a set of tanks, spray arms, peristaltic pumps and a main hydraulic system that all together ensure great water flow rates as well as great pressure values. The procedure can be very different compared to that in BP models, especially its duration, the temperature values and the complexity of the entire cycle, and usually each load goes through a different washing process.
The thermal disinfection stage is performed after the wash and a quick rinse to reduce the chance of residues remaining on the items. It is quite similar to the wash, both visually and conceptually, but this time the temperature inside the chamber is raised to a specific set point (e.g. 93°C) and then maintained above

that value for an appropriate time (called holding time). An appropriate value for these two parameters lead to a good disinfection efficacy, that is quantified by the A_0 index. Usually, the desired A_0 value for this product line has to be at least equal to 3000, because of the nature of the items to reprocess.
The final step is the drying stage, that dries the items before the next steps but most importantly before sterilisation. Every device that belongs to the DS series is equipped with a dedicated drying hydraulic circuit, a fan and a heating element, and the stage follows the same principle of the previous ones: the device maintains the temperature above a certain target for a set holding time.

The units that belong to this series can be equipped with endless optional accessories, for example they can be configured with up to 3 pre-heating tanks, a steam condenser, a conductivity meter, a pH-meter, control flow meters, HEPA filters, up to 4 peristaltic pump, an automatic loading system and so on. Besides, the customer can choose the unit heating systems (electrical or steam heating).
The DS series (in particular the DS 1000) will be further explained in the next chapter.

3.1.4 EW Series

This line include some of the most complete devices on the market, developed for the washing and disinfection of medical devices. The EW series in particular deals with flexible and rigid endoscopes, and is complementary to the DS series. This product line is unique and stands out from the others: as a matter of fact the endoscope is a thermolabile medical device, and for this reason it can't withstand a thermal disinfection cycle. These devices go through a chemical disinfection cycle, and particular attention is brought to the chemical agent of choice.
For the sake of safety these units perform one cycle of auto-thermal-disinfection every day after use, in order to remove process or soil residuals that may be harmful. Due to its radical differences from the other devices, the EW series won't be covered anymore in this report.

3.1.5 LC Series

It is a limited series that is specific for the reprocessing of containers, instrument baskets and boxes, carts, hospital beds and tables, equipment that is not strictly considered a medical device but still needs to be cleaned and disinfected for the sake of safety. It is not just a safety measure for the patients, but instead also for the facility staff.
Its functioning is similar to that of DS series, the hydraulic system is almost the same but bigger, but the spray arms are replaced by a big number of spray nozzles, that are connected with each other and they move simultaneously to make sure that the load gets the appropriate quantity of water at the appropriate pressure.

3.2 Mechanical and process requirements

As previously discussed, every Steelco device that is currently on the market complies with the technical standard ISO 15883, and in particular each product line refers to one or more parts. In order to demonstrate this statement it is important to conduct a series of checks and experimental activities on the devices (most of them were carried out by myself during the six months stay in Steelco), that are reported in the following pages.

Materials, design and manufacture/construction: The materials used in the WD and its accessories, including load carriers, shall tolerate the chemical, mechanical and thermal strains encountered during normal use as specified by the manufacturer.
The parts of the WD which come into contact with the load should be manufactured from materials which have corrosion and abrasion resistance properties.
The combination of materials used in the construction of the WD should be compatible with each other and with the parameters of the process.
The chamber shall be designated to withstand no less than 10000 operational cycles without suffering failure when operated and maintained in accordance with

the WD manufacturer's instructions.

Safety: The WD shall comply with the requirements of IEC 61010-2-045.

Calorifiers and tanks: The WD shall be designed and constructed so that during the disinfection and subsequent stages of the operating cycle there shall be no re-contamination and/or transfer of micro-organisms from the WD to the load, to an extent which is unacceptable for the intended use of the load.
Tanks for storing process water within the WD shall be free-draining, located such that that they are cleanable without dismantling any part of the machine other than normally removable panels, either drained down automatically when the machine is switched off or fitted with a manual drain system accessible to the user, fitted with a warning pipe to indicate to the operator that a tank is overflowing.
In order to ensure freedom from microbial contamination, rinse water used in the final stage after disinfection should be of potable quality and kept constantly in the tank at a minimum of 65°C.

Loading and unloading doors and their control: Machines can be fitted with either one door, which serves for both loading and unloading, or two doors, being of the pass-through type in which one door is used for loading and the other for unloading.
The door seal shall prevent fluid passing the seal interface during an operating cycle, and the door design shall ensure that any residual water present when the door(s) is/are opened will be discharged to drain.
When the loading door is closed and locked at the beginning of a cycle, it shall not be possible to open the unloading door until the WD has completed a successful (without any fault) operating cycle, and if a fault develops, it shall only be possible to open the loading door.
It shall not be possible for an operator at one end of the WD to open or close a door at the opposite end. In addition to that, it shall not be possible for the two doors of a WD to be opened simultaneously to permit free passage of air.

Pipework and fittings: The pipework, pumps, valves and fittings shall be constructed, installed and/or operated so that any residual liquid will flow towards a drain discharge point.
The pipework should be so constructed that the dead volume is minimized, and that quantity has to be stated by the manufacturer.

Spray systems: Spray nozzles shall be positioned to ensure complete contact of the spray with all parts of the load together with the appropriate load carrier when loaded in accordance with the manufacturer's instructions.
Nozzles shall be protected from blockage by the passage of particles by means of specific filters, and moreover they should be designed to minimise the possibility of blockage.
It shall be possible to check whether spray nozzles and fixed nozzles are blocked.

Dosing systems: The WD shall be fitted with dosing systems for controlling the admission of all necessary process chemicals. Each system shall be provided with means to adjust the volume admitted.
The stage(s) in the operating cycle at which each dosing system admits chemical to the WD shall be under direct control of the automatic controller.
Finally the WD shall be fitted with a system that will indicate when there is insufficient process chemical available for the next cycle.

Load temperature protection: WDs intended to process items, which may be damaged if the pre-set temperatures are exceeded, shall be provided with one or more temperature cut-outs to protect the load from exposure to excessive temperature, and those cut-outs shall be capable of being manually reset.
When used to limit the temperature of any medium coming into contact with the load, temperature cut-outs shall operate at a temperature not more than 5°C higher than the highest temperature provided by any temperature control or temperature-limiting device.

Process temperature control limits: The process shall meet the following requirements:

- the temperatures recorded on the surface of the load and load carrier are within - 0 °C and + 5 °C of the disinfection temperature throughout the holding period for the disinfection stage;
- the temperatures recorded on the surface of the load and load carrier are within 5 °C of the set temperature for the relevant stage throughout the holding period for each of the other stages;
- the temperature profile obtained for the temperature controlled stages of the operating cycle shall be consistent within 2,5 °C for the last three of four test cycles;
- the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the disinfection stage (or the specified A0 value has been obtained);
- during the holding time the measured temperatures on the surface of the load and load carriers are within the disinfection temperature band specified for the operating cycle (or the specified A_0 value has been obtained);
- the temperatures shown on the chamber temperature indicator and/or recorder are within + 2 °C of the temperature measured at the automatic control sensor;
- the temperature measured on the surface of each load item does not fluctuate by more than 2 °C and does not differ from that in other load items by more than 4 °C;
- at the end of the cycle the temperature sensors are found to have remained in position.

Switches, gauges and indicating devices: The operating cycle shall be started by means of a single switch. Each switch, gauge, or indicating device shall be marked with an appropriate symbol.

Process verification: The WD shall be fitted with means to verify and record the attainment of the specified process conditions. The choice of process verification system shall be based on a documented risk analysis in accordance with ISO 14971 which shall include considerations of the intended use of the WD and the nature of the WD control system.
One of the following three levels of process verification shall be used:

- verification by the operator of the attainment of thermal disinfection;
- verification by process record, independent from the controller, of the attainment of thermal disinfection conditions;
- verification by process record, independent from the controller, of the attainment of those process variables affecting both the cleaning and disinfection processes.

Instrumentation and controls: Instruments and controls shall be designed, positioned and protected so that their performance is maintained when operating in an ambient temperature range of 5°C to 40°C and with a relative humidity not exceeding 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C.
For calibration purposes, each instrument shall be provided with a means of adjustment without removing it from its position.
At least one temperature sensor shall be located in a position which was previously determined as being representative of the lowest temperature achieved within the load.
Failure of any sensor in a system controlling disinfection time or temperature shall cause a fault to be indicated.

Temperature indicating systems: Temperature sensors shall be either platinum resistance types complying with class B of IEC 60751 of thermocouples complying with one of the international tables specified in tolerance class 2 of IEC 60584.
The WD chamber temperature indicating systems shall:

- be either digital or analog;
- be graduated in Celsius degrees;
- have a scale that includes the range 5°C to 99°C;
- have an accuracy of at least 1°C over the scale range 10°C to 99°C;
- for analog instruments, be graduated in divisions not greater than 1°C, for digital instruments have a resolution of at least 1°C.

Pressure indicating systems: Pressure indicating systems, when fitted shall:

- be either digital or analog;
- be graduated in kPa or bar;
- have an accuracy of at least 5 kPa (0.05 bar);
- have a scale range such that the maximum intended operating pressure does not exceed 80% of full scale;
- for analog instruments, be graduated in divisions not greater than 20 kPa, for digital instruments have a resolution of at least 1 kPa.

Timing equipment: Process control timers shall have an accuracy and repeatability at least an order of magnitude better than the time intervals which they are intended to measure.

Operating cycle indicating equipment: There shall be a visual indication of the stage reached in the operating cycle.

Recording instruments: The sensors connected to the process verification recorder shall be independent of the sensors used for process control functions.

Control systems: The WD shall be provided with an automatic controller, that shall check the attainment or otherwise of the pre-set cycle variables, within pre-determined limits, essential to the efficacy of the operating cycle.

Override of automatic control: The override control accessible to the operator from the control panel shall remain inoperative unless a fault has occurred, allow the manual control of the doors, and only be activated by the use of a key, code or tool.

Microprocessor control system: If a microprocessor control is used, the following shall apply:

- Access shall be restricted by a code;
- it shall be provided with means to monitor the voltage or current present at each output and the condition of each output;
- it shall not be possible to change process parameters without use of codes or keys;
- it shall be provided with batteries for maintaining programme data memory;
- it shall be provided with an indications system for displaying faults and errors (by means of a code or in plain language).

Fault indication systems: If the values of the cycle variables are outside the limits specified by the manufacturer or a failure of a service occurs sufficient to prevent the attainment of these variables, the automatic controller shall cause a visual indication that a fault has occurred and another visual indication of the stage of the washing/disinfection cycle at which the fault occurred, or the nature of the fault.
In that case, any load which has not been satisfactorily processed, shall be discharged on the loading side of the WD.

Venting and drainage systems: The WD shall be vented wither directly to the atmosphere external ti the building, or indirectly into the drainage system via a condenser, or into the working area. Where a vent discharges into the working area, a condenser or a microbiological filter may be required.

Means shall be provided to ensure that any condensate draining from the ductwork will not contact the load.

Load handling and supports for use within the WD: When the WD is supplied with a system for supporting the load or for transferring the load, the force required by the operator, either directly or by the application of a mechanical device, to remove the load from the chamber does not exceed 250 N when fully loaded.

This series of checks is usually really helpful during the development stage. Prior to the mass production and the sale it is important to carry on a set of experimental activities too, the so-called "testing for conformity".

3.3 Testing for conformity

One of the activities that took most of the time and resources during my 6 months stay in Steelco is related to the testing for conformity. It all started with an attentive study of the technical standard ISO 15883, and in particular the chapters 6 of each one of the 7 parts, as they are closely related to the experimental activities that have to be performed on WDs.
The goal of my work was to write a pre-filled form that would be used by the RD team and would be appropriate for any device manufactured by Steelco, that consists of a protocol of tests that have to be carried out on every model in order to state that the unit is compliant with ISO 15883, also called "Type tests".
This form reports all the tests that are requested in every part of ISO 15883, and the idea is that whenever someone is doing a type test of a specific product line that is subject to just some parts of the technical standard (for example ISO 15883-1, ISO 15883-2, ISO 15883-5), he/she will fill only the fields that are related to those parts and will delete the other tests that are related to the complementary parts of ISO 15883 (in this case tests from ISO 15883-3, ISO 15883-4, ISO 15883-6, ISO 15883-7).

This form is shown in the next chapter, as it was used in order to state that one of the most popular WD device, called DS 1000, is compliant with the technical standard ISO 15883.

Another formal document that was written is the so called "Working Instructions", a guideline that is meant to help those who perform type tests on Steelco devices, by giving them information such as conditions, instruments, probes, load and soil necessary in order to carry out the tests according to what is reported on ISO 15883.

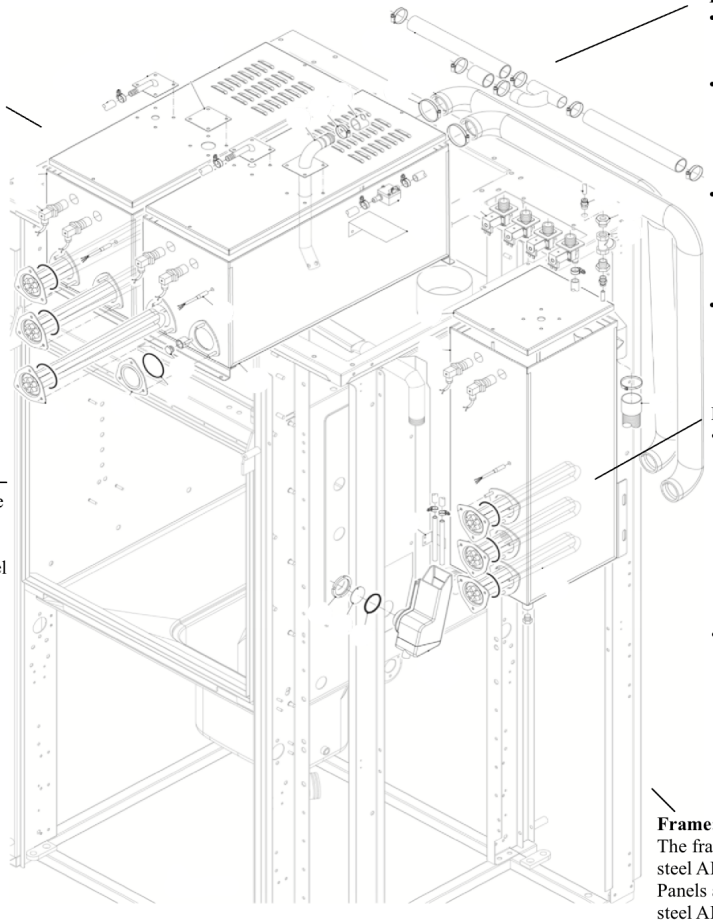
Chapter 4

DS 1000 Type test

The DS Series include some of the most complete and popular devices on the market, that deal with small and medium-sized heat-resistant items, like surgical instruments, MIS instruments, anaesthesia instruments, ophthalmology instruments, containers, OP rubber shoes and baby bottles.
This range of devices offers a complete washing and thermal disinfection treatment and are equipped with an efficient hot air drying system, which ensures a perfect drying of all instruments and tubes thanks to the accurate distribution of the air on all the chamber zones and on the washing loading racks level.
Fast cycle models (like the DS 1000) can perform a complete cycle within 30 minutes only including pre-wash, main wash, rinse, thermal disinfection and drying, with a great improvement in working efficiency and a consequent reduction of energy consumption.

In this report we will focus on the DS 1000, as it is the subject of the type tests. Here are reported a few pictures/drawings of the DS 1000 with particular attention at some parts/features that are object of the testing for conformity:

Figure 4.1: DS 1000 and some of its features



Doors:
The doors are made of double HST tempered glass with inside frame made of stainless steel AISI 304.
A silicone foam gasket ensures a perfect sealing.
Both the doors are motorized and slide down, and they are equipped with a safety lock system.
Doors are interlocked to avoid simultaneous opening.

Washing chamber:
Every component inside the chamber (spray arms, filters and so on) is made of stainless steel or materials resistant to aggressive chemical agents.
The chamber itself is manufactured without edges, therefore removing breeding ground for germs.
The central sump, with rounded edges, allows for a very fast drainage and improves water recirculation during cycle.
3 levels water filtering system.

Pre-heating tanks:
- Power consumption is 13.5 kW / 6 kW / 12 kW.
- Tanks are directly connected to the chamber allowing for a reduction of the loading time.
- Functions and temperatures of the 3 tanks can be modified to best suit the customer needs.
- The volume is equal to 40 L for each tank.

Heating elements:
- On the standard unit the water heating system (24 kW) is placed into a heat exchanger connected to the washing chamber. It is used for both water and air.
- On the reduced width units the heating elements (18 kW) are placed in the sump at the bottom of the chamber.

Frame:
The frame is made of stainless steel AISI 304 (DIN 1.4301).
Panels are made of stainless steel AISI 304 (DIN 1.4301) brush finishing.

Figure 4.2: DS 1000 and some of its features

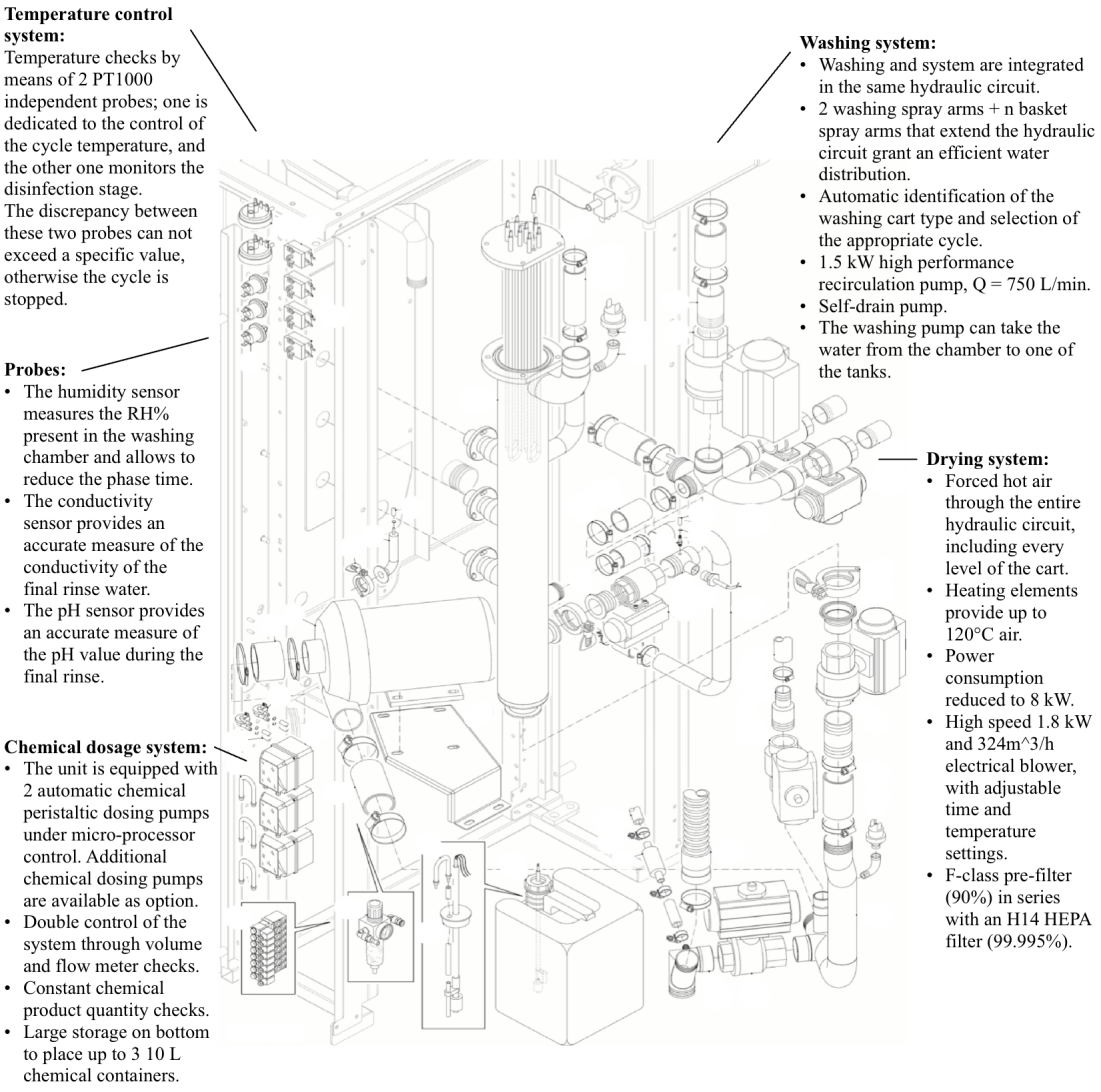


Figure 4.3: DS 1000 and some of its features

The testing for conformity (if not specified) was performed using the standard cycle, that consist of the following stages:

1. Drain;
2. pre-wash, 38 L, softened cold water, holding time 120";
3. drain;
4. wash, 38 L, pre-heated water, set point 60°C, holding time 120", 3‰ alkaline detergent;

5. drain;
6. neutralization, 38 L, pre-heated water, set point 55°C, holding time 60", 2‰ acid detergent;
7. drain;
8. rinse, 38 L, softened warm water, set point 60°C, holding time 60";
9. drain;
10. disinfection, 38 L, demineralized water, set point 90°C, holding time 60-300", 0.5‰ rinse aid;
11. drain;
12. drying, min speed for 60", max speed for 1200", set point 120°C.

4.1 Type test

The following document is the official DS 1000 type test (testing for conformity): the pre-compiled form was created from scratch after an attentive study of ISO 15883 technical standard. This report, together with the mechanical and process requirements, states that the device is compliant with ISO 15883.

DS1000 TYPE TEST

Machine Type	Washer-disinfector		
Machine Model	DS1000	Serial Number (s/n)	2003010LW222
Manufacturer	Steelco S.p.A.		
Test	The following tests shall demonstrate compliance with performance requirements of ISO 15883 about: • Cleaning; • Disinfecting; • Rinsing; • Drying (when applicable).		
Test Type	☐ Safety ☒ Performance ☐ Usability/Ergonomy ☐ Other:		
Standard Reference	EN ISO 15883-1, EN ISO 15883-5, EN ISO 15883-2, EN ISO 15883-3, EN ISO 15883-4, EN ISO 15883-6, EN ISO 15883-7.		
Test Location	Steelco S.p.a | Via Balegante 27 – 31039 Riese Pio X (TV) – Italy		
Test Initial Date	26-Aug-22		
Test Closure Date	10-Nov-22		
Result of Test	☒ **PASS** ☐ **FAIL** ☐ **N/A**		

Approval

	Name	Function	Date
Issued by	A. Marigo & A. Gardano	Validation Specialist	10-Nov-22
Reviewed by	C. Artuso	TPM	11-Nov-22
Approved by	M. Zanatta	R&D Director	14-Nov-22

Change Log

Revision	Date	Change
00	10-Nov-22	First version

Index

1. Scope

Machine Type	Washer-disinfector		
Machine Model	DS1000 G2	Serial Number (s/n)	2003010LW222
Optional Components	Two pre-heating tanks, steam condenser, automatic load carrier detection system.		

1.1 Other Models Covered by this Report

Model	Difference from the Main Model	Additional Test Performed
TW3000/2	Separate chambers (one for cleaning and disinfection, the other for the drying stage)	N.A.
DS900	It has only one door, used for both loading and unloading the WD chamber.	N.A.

2. Test Conditions

	Required	Measured
Ambient Temperature	N.A.	18-35 °C
Ambient Humidity	N.A.	42-59 RH%
Pressure	N.A.	1006-1017 mbar
Voltage	400V ± 10%	400 V

3. Equipment and Instruments for Test

Equipment / Instruments ID	Type of Equipment / Instruments	Calibration Date	Calibration Due Date
S05-029	EBRO datalogger (temperature/pressure probes)	22-Nov-21	22-Nov-22
S12-003	FG-5100 Force gauge	04-Mar-22	04-Mar-23
N.A.	Toledo conducimeter	16-Jun-22	16-Jun-23
N.A.	Piusi K 24 flowmeter (± 1 mL)	08-Feb-22	08-Feb-23
N.A.	Stabila spirit level	N.A.	N.A.
N.A.	Graduated vessel (± 1 mL)	N.A.	N.A.

4. Tests

4.1 Test on doors, interlocks and fault indication (6.3)

Test	**Cycle start interlock (6.3.1)**
Method	Check for compliance establishing whether it was possible to initiate a cycle with one or more doors open.
Measuring Uncertainty	N.A.
Acceptance Criteria	It shall not be possible for the operator to start the process if the doors are not blocked.

Test Execution

Make an attempt to initiate an operating cycle both with the door(s) open and then with the door(s) closed but unlocked.

For machines with double doors make the attempt to initiate a cycle with each door left unlocked in turn and with both doors unlocked.

On machines in which the door locking mechanism is automatically activated after the door is closed and an operating cycle is initiated, the door locking mechanism shall be disabled for the purposes of this test.

For machines not fitted with doors, any guard or interlock intended to have similar effect to a door shall be tested in a similar manner.

Test Results

The WD being tested is a double door model, one door is placed on the loading side, and the other one on the unloading side.

The door on the loading side was opened, a cycle (standard cycle) was selected, but when the WD was about to start the cycle, the warning message “open door” appeared and the WD could not start the cycle.

The test was repeated two more times with the unloading door and then both doors opened, and the result was the same: the WD could not start the cycle.

Executed by	A. Marigo & A. Gardano	Date	26-Aug-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

None.

Test	**Door locking during cycle (6.3.2)**
Method	Check for compliance establishing whether it was possible to unlock the door during the operating cycle.
Measuring Uncertainty	N.A.
Acceptance Criteria	After initiation of an operating cycle the doors for loading and unloading shall be unlocked and opened only after completion of the operating cycle.

Test Execution

Close and lock the door(s) and start the operating cycle. While the operating cycle is in progress, make an attempt to unlock each of the doors.

Report whether it was possible to unlock any of the doors. When practicable, the interlocks should be visually inspected to verify engagement before attempting to open the door.

Test Results

During the cycle it was not possible to unlock and open any door.

At the end of a completed cycle a message appeared on the display to report that the cycle ended correctly. The unloading door opened automatically.

Executed by	A. Marigo & A. Gardano	Date	26-Aug-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

If any phase of an operating cycle is skipped, at the end of the cycle the WD shows the warning message “completed cycle non ok” and as a result it is not possible to open the unloading door.

Test	**Door interlocks on double ended WDs (6.3.3)**
Method	During a cycle make an attempt to open both the loading door and unloading door of the double ended WD. Between cycles make an attempt to open both loading and unloading doors simultaneously.
Measuring Uncertainty	N.A.
Acceptance Criteria	When the loading door is closed and locked it shall not be possible to open the unloading door until the WD has completed a successful operating cycle. It shall not be possible for an operator at one end of the WD to open or close a door at the opposite end. It shall not be possible for the doors of a WD to be opened simultaneously to permit free passage of air through the WD under normal operation. The indication “cycle complete” or an equivalent indication shall be cancelled when the unloading door is unlocked, and the loading door shall remain locked until the unloading door has been locked again.

Test Execution

Inspect the operator controls to establish whether either the loading or unloading door can be operated from the opposite end of the WD. After a satisfactory operating cycle:

- during unloading observe whether the loading door remains locked when the unloading door is unlocked;
- during unloading and loading observe when the indication “cycle complete” is cancelled.

Report:

a) whether it was possible:

- to open either the unloading door after initiation of a cycle before the cycle had been completed satisfactorily;
- for both doors to be open simultaneously;
- for an operator at one end to operate the door at the other end;

b) whether the loading door remains locked until the unloading door was locked;

c) whether the indication “cycle complete” was cancelled when the unloading door was opened.

Test Results

During the cycle it is not possible to unlock and open any of the two doors.

As soon as the loading door is locked, it is not possible to open the unloading door unless a cycle is launched and completes successfully. At the end of a cycle the message “cycle completed ok” pops up on the display while the unloading door automatically opens up.

After the completion of the cycle, it wasn’t possible to open both doors simultaneously. Moreover, it was not possible to open/close the door placed on the opposite side of the WD.

Executed by	A. Marigo & A. Gardano	Date	26-Aug-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

Test	**Cycle complete door interlocks (6.3.4)**
Method	Report whether it is possible to open the door(s) before the operating cycle is completed.
Measuring Uncertainty	N.A.
Acceptance Criteria	After initiation of an operating cycle the doors for loading and unloading shall be capable of being unlocked and opened only after completion of the operating cycle. The control initiating the automatic cycle shall be at the loading side of the WD only. When the loading door is closed and locked, it shall not be possible to open the unloading door until the WD has completed a successful operating cycle i.e., without showing a fault. The indication “cycle complete”, or an equivalent indication, shall be cancelled when the unloading door is unlocked, and the loading door shall remain locked until the unloading door has been locked again.

Test Execution

During an operating cycle, make an attempt to open the door(s). Report whether the cycle complete indication was cancelled when the unloading door was opened.

Test Results

During the cycle it is not possible to open the WD doors. They can be unlocked only after completion of the cycle.

When a cycle completes successfully, the message “cycle completed ok” appears on the display, and the unloading door automatically opens up. Then the loading door can be opened only when the unloading one is closed. At that point it is not possible to open the unloading door anymore, until another cycle completes successfully.

Executed by	A. Marigo & A. Gardano	Date	26-Aug-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

None.

Test	**Fault indication on sensor failure (6.3.5)**
Method	Each sensor providing information to the automatic controller is disabled in turn to establish that a fault is indicated.
Measuring Uncertainty	N.A.
Acceptance Criteria	Report whether a fault was indicated during or at the end of the cycle (5.4.1.5). Report whether it was possible to open the door on a single-ended WD or the unloading door of a double-ended WD.

Test Execution

Carry out the testing of each sensor as follows:

- start an operating cycle;

-during, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle, disable the sensor. Test each sensor in both “open circuit” and “short circuit” failure modes.

Test Results

In case of disconnection (short circuit or open circuit), each sensor provides the user with an alarm and the doors remain locked. The alarm message appears in both the loading and unloading side displays.

A set of alarms (shown in the table below) was tested to ensure that the requirements are fulfilled.

00 PLC CONTROLLO IN BLOCCO	These alarms cannot be tested.
01 PROBLEMI PLC CONTROLLO (XOB8)	
02 PROBLEMI PLC CONTROLLO (XOB10)	
03 PROBLEMI PLC CONTROLLO (XOB12)	
04 PROBLEMI PLC CONTROLLO (TEST)	
05 PROBLEMI PLC REGISTRAZIONE	We run a WD cycle and disconnected the MJ2 ethernet cable between the HMI (human-machine interface) and the recording device. This alarm was generated.
06 MANCANZA AUSILIARI O EMERG.	We run a WD cycle. Pressing the emergency button, this alarm was generated.
07 THERMAL SAFETY	We run a WD cycle. We opened the circuit of one thermal safety device (in particular the one related with the air heating element). This alarm was generated.
08 PHASES SEQUENCE UNCORRECT	We switched off two of the three phases cables of the main power supply. This alarm was generated.
09 ALL DOORS OPENED	We run a WD cycle. Opening both the loading and unloading doors using their respective contactors, this alarm was generated. This alarm was correctly generated also off cycle (during the machine rest time).
10 FAILURE LOADING DOOR (TIME)	We disconnected the loading door motor from its contactor and then we pressed the open door button. After 15 seconds this alarm was correctly generated.
11 FAILURE UNLOADING (TIME)	We disconnected the unloading door motor from its contactor and then we pressed the open door button. After 15 seconds this alarm was correctly generated.
12 LOADING DOOR OPEN	We run a WD cycle. Opening the loading door using its contactor, this alarm was generated.
13 UNLOADING DOOR OPEN	We run a WD cycle. Opening the unloading door using its contactor, this alarm was generated.
14 FAILURE ON BASKET LOCK.	We disconnected the basket lock piston compressed air valve. We tried to start a WD cycle, but this alarm was correctly generated, and the cycle stopped. We reset the alarm, but the cycle did not continue: after a few seconds the alarm appeared correctly again.
15 VENT STACK FAILURE	N.A.

16 HAKKO TOUCH SCREEN NOT ACTIVE	We disconnected the ethernet cable between PLC and the Hakko touch screen. As soon as we reconnected that cable, this alarm was generated. It works both during an operating cycle and during a rest phase.
17 CHAMBER PROBE FAILURE	We disconnected the 15.0 cable of the chamber control probe from the PLC, as soon as the WD was turned on the alarm was correctly generated.
18 DRYER PROBE FAILURE	We disconnected the 15.1 cable of the drying probe from the PLC. After switching on the WD, the alarm was correctly generated.
19 pH TRANSDUCER PROBLEMS !!!	N.A.
20 RECORD TANK PROBE	We disconnected the 8.1 cable of the record tank probe from the 8AP4 electronic board. This alarm was correctly generated.
21 TANK PROBE DISPARITY	We set the maximum difference between the two probes to 0.1°C. We set the minimum temperature at which the difference between the two probes was calculated at 1°C. Then, during an operating cycle the alarm was correctly generated.
22 FAILURE WATER CONNECTION 1	N.A.
23 FAILURE WATER CONNECTION 2	N.A.
24 FAILURE WATER CONNECTION 3	We created a cycle made of only a drain and a prewash stage which used cold water (3). We closed the water tap. We started the cycle and after few seconds this alarm was correctly generated. We disconnected 25PC3 water 3 flowmeter and we run a WD short cycle. This alarm was correctly generated again.
25 FAILURE WATER CONNECTION 4	We created a cycle made of only one drain and one prewash stage which used demi water (4). We closed the water tap. We started the cycle and after few seconds this alarm was correctly generated.
26 FAILURE ON CHEMICALS 1	We disconnected the chemical 1 flowmeter and we run a WD cycle. This alarm was correctly generated.
27 FAILURE ON CHEMICALS 2	We disconnected the chemical 2 flowmeter and we run a WD cycle. This alarm was correctly generated.
28 FAILURE ON CHEMICALS 3	N.A.
29 FAILURE ON CHEMICALS 4	N.A.
30 CHEM.FLOW.READ.FAIL	N.A.
31 WASH.PUMP PRESS.SWITCH 1	We disconnected 12SP29 (washing pump pressure switch) and we run a WD cycle. This alarm was correctly generated during the pump activation.
32 CHAMB.HEATING FAILURE (TIME)	We disconnected the chamber heating element by removing 4.6, 4.7, 4.8 cable from the 19KM92 contactor.

	We run a WD cycle and the alarm was correctly generated after few seconds (default).
33 DRYER HEATING FAILURE (TIME)	We disconnected the drying heating element by removing 4.6, 4.7, 4.8 cable from the 19KM92 contactor. We run an only drying cycle and the alarm was correctly generated after few seconds (default).
34 WASH PUMP PRESS. SWITCH 2	We disconnected the pressure switch cable (14.45) from the electronic board and we run a WD cycle. This alarm was correctly generated.
35 DRAIN FAILURE (TIME)	We set max drain time to 5". During an operating cycle the alarm was correctly generated.
36 DRYER PRESSURE SWITCHES 1	We disconnected 12SP30 pressure switch and we run an only drying cycle. This alarm was correctly generated.
37 SUMP PROBE FAILURE	We disconnected the cable 15.7 of the sump probe from the PLC, then this alarm was correctly generated.
38 CHEMICAL NOT DOSABLE FOR TEMPERATURE	We set the minimum temperature for the injection of chemical agent 1 to 90°C (instead of 38°C). We run a cycle which used detergent 1 and this alarm was correctly generated.
39 COMPRESSED AIR LACK	We closed the compressed air tap and we run a cycle. This alarm was correctly generated.
40 EMERGENCY + DRYING TEMP.	We set the maximum drying temperature at 10°C and we run an only drying cycle. This alarm was correctly generated.
41 DRYER PRESSURE SWITCHES 2	We disconnected the pressure switch 2 14ST43 and we run an only drying cycle. This alarm was correctly generated.
42 NOT PRESENT	N.A.
43 FAILURE ON SOL.WATER 1 !!!	There is the pre-heating tank 1. We created a short circuit with a small external cable to the 9SQ0 level switch when the tank 1 was full of water. Then we open this level switch and the alarm was correctly generated.
44 FAILURE ON SOL.WATER 2 !!!	That is related to the pre-heating tank 2. We misbehaved (short circuit with a small external cable) the 9SQ1 and the 12SL24 level switches and this alarm was correctly generated. In particular, even if the tank was not full, we closed the maximum level and then we opened it, without opening any outlet valve.
45 FAILURE ON SOL.WATER 3 !!!	We disconnected the 25PC3 flow meter switch from its original position and we connected it with a single flow meter. We blew some air into the flowmeter keeping the 18YV86 closed and this alarm was correctly generated.
46 FAILURE ON SOL.WATER 4 !!!	We disconnected the 25PC4 flow meter switch from its original position and we connected it with a single flow

	meter. We blew some air into the flowmeter keeping the 18YV87 closed and this alarm was correctly generated.
47 FAILURE ON SOL.PRODUCT 1 !!	We disconnected the 9PC5 flow meter from its original position. We connected it to another flow meter and we run it using compressed air. This alarm was correctly generated.
48 FAILURE ON SOL.PRODUCT 2 !!	We disconnected the 9PC6 flow meter from its original position. We connected it to another flow meter and we run it using compressed air. This alarm was correctly generated.
49 FAILURE ON SOL.PRODUCT 3 !!	N.A.
50 FAILURE ON SOL.PRODUCT 4 !!	N.A.
51 FAST AN.INPUT FAILURE	N.A.
52 TANK 1 MAX LEVEL FAILURE	We emptied the tank 1. We disconnected its 11SL20 level switch and we started to refill the tank. This alarm was correctly generated. After that, we emptied the tank 1. We disconnected its 9SQ0 level switch and we started to refill the tank. This alarm was correctly generated.
53 TANK 2 MAX LEVEL FAILURE	We disconnected the 12SL24 level switch of the tank 2 and we run a short cycle. This alarm was correctly generated. After that, we disconnected the 9SQ1 maximum level switch of the tank 2 and we run a WD short cycle. This alarm was correctly generated one more time.
54 TANK 3 MAX LEVEL FAILURE	N.A.
55 LOADING DOOR LS DISPARITY	When the loading door was completely closed, we manually pressed the opening micro switch and this alarm was correctly generated.
56 UNLOADING DOOR LS DISPARITY	When the unloading door was completely closed, we manually pressed the opening micro switch and this alarm was correctly generated.
57 MAX.PREW.TEMP.	We set the maximum prewash temperature at the value of 1°C (instead of 90°C) and we run an only drain and prewash cycle. This alarm was correctly generated as soon as the drain stage ended and the prewash stage started.
58 WATER LEAK-OVERFLOW	We inverted the 12SP26 pressure switch electric cables with the 19SP95 cables and then we run a short cycle. This alarm was correctly generated.
59 CONDUCT.TRANSD.PUMP PRESSURE	15BP4 pressure transmitter missing on the machine (15.4 cable missing on PLC).
60 CONDUCT.TRANSD.FAILURE	N.A.
61 CONDUC.TOO HIGH	N.A.

62 CHECKSUM PLC !!!	This alarm cannot be tested without the help a software engineer.
63 ENERGY LACK !!!	We started a short cycle and then we switched off the WD. As soon as we switched on the WD again, this alarm was correctly generated.
64 HYGROMETER FAILURE	N.A.
65 pH OUT OF LIMITS !!!	N.A.
66 WASHARMS SPEED READING FAILURE	N.A.
67 FAILURE ON MACHINE TOP WASHARM	We set the maximum and minimum speed of the washarms to 5 rev/min and 2 rev/min. We launched a short cycle and during the pre-wash phase the alarm was correctly generated.
68 FAIL. ON M.BOTTOM.WASHARM	We set the maximum and minimum speed of the washarms to 5 rev/min and 2 rev/min. We launched a short cycle and during the pre-wash phase the alarm was correctly generated.
69 FAIL. ON ‘A’ BASK. WASHARM	N.A.
70 FAIL. ON ‘B’ BASK. WASHARM	N.A.
71 FAIL. ON ‘C’ BASK. WASHARM	N.A.
72 FAIL. ON ‘D’ BASK. WASHARM	N.A.
73 FAIL. ON ‘E’ BASK. WASHARM	N.A.
74 LOAD/UNLOAD TIME	N.A.
75 LOW SET POINT ON THE TANK 3	N.A.
76 DRAIN SV FAILURE	We disconnected the drain EV 19YV95 and we run a WD cycle. This alarm was correctly generated.
77 FAIL. DRAIN TANK 3	N.A.
78 NOT PRESENT	N.A.
79 FAIL. WATER FILLING TANK 3	N.A.
80 OUT OF RANGE PT100 TANK 1	We set the minimum and the maximum temperature of the tank 1 to 25°C, with tolerance value equal to 0. We run a WD cycle and this alarm was correctly generated during the prewash stage.
81 OUT OF RANGE PT100 TANK 2	We set the minimum and the maximum temperature of the tank 2 to 25°C, with tolerance value equal to 0. We run a WD cycle and this alarm was correctly generated during the prewash stage.
82 OUT OF RANGE PT100 TANK 3	N.A.
83 FAIL. HEATING TANK 1	We disconnected 4A.31, 4A.32, 4A.33 and then we set the Tank 1 temperature in stand-by to 90°C and the max

	1°C tank heating time to 5''. We run a WD cycle and this alarm was correctly generated.
84 FAIL. HEATING TANK 2	We disconnected 4A.28, 4A.29, 4A.30 and then we set the Tank 2 temperature in stand-by to 90°C and the max 1°C tank heating time to 5''. We run a WD cycle and this alarm was correctly generated.
85 FAIL. HEATING TANK 3	N.A.
86 FAIL. TANK 1 WATER FILLING	We closed the tank 1 water tap. Then we tried to fill up the tank 1 in manual mode and the alarm was correctly generated.
87 FAIL. TANK 2 WATER FILLING	We closed the tank 2 water tap. Then we tried to fill up the tank 2 in manual mode and the alarm was correctly generated.
88 FAIL. WATER 1 FILLING	We disconnected the 18YV84 pneumatic valve and then we run a cycle with the use of demi water (water 1) in it. This alarm was correctly generated.
89 FAIL. WATER 2 FILLING	We disconnected the 18YV85 pneumatic valve and then we run a cycle with the use of water 2 in it. This alarm was correctly generated.
90 TANK/SV LEAKAGE ON CHAMBER (+)	We disconnected the 12SP26 pressure switch and we run a WD cycle. This alarm was correctly generated.
91 NOT PRESENT	N.A.
92 NOT PRESENT	N.A.
93 NOT PRESENT	N.A.
94 LOW SET POINT ON TANK 1	We set the quantity of water (tank 1) to be used in a single phase of a WD cycle to 50 L, then immediately after running the cycle this alarm was correctly generated.
95 LOW SET POINT ON TANK 2	We set the quantity of water (tank 2) to be used in a single phase of a WD cycle to 50 L, then immediately after running the cycle this alarm was correctly generated.
96 CHAMBER TEMPERATURE EMERGENCY	N.A.
97 TANK 1 TEMPERATURE EMERGENCY	We set the maximum limit temperature of the chamber to the value of 50°C and we run a cycle which used tank 1 water at the temperature of 60°C. This alarm was correctly generated.
98 TANK 2 TEMPERATURE EMERGENCY	N.A.
99 TANK 3 TEMPERATURE EMERGENCY	N.A.
100 EXCESSIVE TEMPERATURE ON TANK/CYCLE	N.A.
101 TANK EXCESSIVE TEMPERATURE	N.A.

102 CHEMICAL 1 DISPARITY	N.A. (no control flow meters)
103 CHEMICAL 2 DISPARITY	N.A.
104 CHEMICAL 3 DISPARITY	N.A.
105 CHEMICAL 4 DISPARITY	N.A.
106 LOW TEMP FOR 'A0' LIMIT	We set the minimum temperature for A0 estimate to 99°C, while the maximum temperature reached during the WD cycle was lower than that. We run a cycle and the alarm was correctly generated.

Executed by A. Marigo & A. Gardano Date 13-Sep-22

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

None.

Test	**Fault indication on service failure (6.3.6)**
Method	The aim of this test is to verify alarms related to service supply (air steam, electricity, water and drainage).
Measuring Uncertainty	N.A.
Acceptance Criteria	Report whether a fault was indicated.

Test Execution

Start an operating cycle. During, or before, the stage of the operating cycle at which the service is required, interrupt the service supply. Carry out the test for each service required by the WD.

Test Results

Faults are indicated as soon as the service supply (air, electricity, water etc) is interrupted. For the complete list of alarms refer to the previous test (Faut indication on sensor failure).

Executed by A. Marigo & A. Gardano Date 13-Sep-22

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

None.

Test	**Failed cycle interlock (6.3.7)**
Method	This test is intended to verify that the interlock provided to prevent an operator from removing a load in the normal manner at the end of a cycle that failed is functioning.
Measuring Uncertainty	N.A.
Acceptance Criteria	If a fault occurs during an operating cycle, it shall be displayed and access to the load shall be restricted.

	For machines in which access to the load is restricted by means of locked doors this shall require the use of a special key, code or tool to release the door lock and gain access to the load. For a continuous process machine, it might not be necessary to open a door to gain access to the load. If a fault develops, it shall only be possible to open the loading door.

Test Execution

During an operating cycle impair the operation of the WD sufficiently to cause a cycle failure.

Report whether a “fault” was indicated. Report whether it was possible to open the unloading door (if fitted), and if it was possible to open the loading and/or unloading door only by means of a special key, code or tool.

Test Results

During any fault, the doors remain locked until the reset of the alarm. At the end of a faulty cycle the loading door opens automatically, while the unloading door cannot be opened anymore until an operating cycle is performed correctly.

Executed by	A. Marigo & A. Gardano	Date	13-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

Test	Blocked drain protection (6.3.8)
Method	This test is intended to verify that the interlock provided to prevent the door being opened if on completion of an operating cycle the water level within the chamber remains above the lowest point of the chamber door seal is functioning. Blocked drain protection is intended to prevent spillage and minimize the risk of (cross) infection. NOTE: This test might not be required if the design of the WD prevents the fluid level within the WD chamber reaching the level of the door.
Measuring Uncertainty	N.A.
Acceptance Criteria	If after completion of an operating cycle the water level within the chamber remains above the lowest point of the chamber door seal the control system shall cause a fault to be indicated. A fault shall be indicated once the water level is above the lowest point of the door seal at the end of the cycle and it shall not be possible to open the door without the use of a special key, code or tool.

Test Execution

Block the drain to prevent discharge of water from the chamber of the WD. Close the door and start the operating cycle. On completion of the operating cycle, attempt to open the door using the normal door release procedure. If the door opens and the level of the retained water is below the door seal close the door and start another operating cycle. Repeat the operating cycle as many times as necessary for either the water level at the end of the cycle to be above the level of the door seal or for a fault to be indicated. For WDs without sealed doors, the operating cycles should be repeated until either water has spilled from the machine or a fault has been indicated.

Test Results

A custom WD cycle was created, it was made of two consecutive treatment stages without a draining stage between them. That cycle was launched, and the draining valve was manually locked in its closed position. The water started flowing in the chamber but as soon as it reached a specific level (below the loading door lowest seal) the alarm n.58: Water leak – overflow was generated and it was not possible to open any of the two doors nor to force quit the cycle.

As soon as the draining valve was unlocked, a safety system opened that valve to drain some of the excess water.

Executed by	A. Marigo & A. Gardano	Date	13-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

4.2 Test on water quality and water volume (6.4)

Test	Quality of final rinse water (6.4.2)
Method	The sample shall be taken from the supply line as close as practicable to the WD. When the rinse water is stored in a tank within the WD, heated in a calorifier in the WD or otherwise treated within the WD, samples shall also be taken from the discharge point into the chamber.
Measuring Uncertainty	N.A.
Acceptance Criteria	The acceptable values/ranges shall be specified by the manufacturer.

Test Execution

Tests for chemical purity

Tests for chemical purity shall include tests for those determinants known to influence the efficacy of the process.

NOTE This can include, but is not limited to, tests to determine the value of the following:

- conductivity;
- pH;
- oxidizable substances [determined by the European Pharmacopoeia (EP) method or as redox potential determined by the United States Pharmacopoeia (USP) method];
- total hardness (salts of Ca2, Mg2, Sr2 expressed as mmol CaCO3);
- total dissolved solids (TDS) determined as evaporative residue;
- inorganic phosphate [Pi] and inorganic silicate [SiO2], determined as the molybdate reactive species;
- chloride [Cl^-].

Tests for bacterial endotoxins

If a requirement for the level of bacterial endotoxins in the final rinse water is given in other parts of ISO 15883, determine the level by the limulus amoebocyte lysate (LAL) test with a sensitivity of 0,25 U/ml, or better, using the method given in the European Pharmacopeia (EP) or United States Pharmacopeia (USP).

Tests for microbial quality

Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R2A-medium in accordance with Annex D, or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophilic viable count. Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used.

Test Results

These are the water requirement reported by Steelco in the user manual:

2.4.1 Qualità dell'acqua in ingresso alla macchina

La qualità dell'acqua utilizzata in tutte le fasi di pulizia è importante per ottenere buoni risultati.

L'acqua utilizzata in ogni fase deve essere compatibile con:

- Il materiale con cui è costruita la macchina.
- I prodotti chimici utilizzati nel processo.
- Requisiti per le varie fasi del processo.

I fattori principali per una buona qualità dell'acqua in ingresso in relazione all'efficacia di lavaggio sono:

DUREZZA	L'elevata durezza dell'acqua genera una inattivazione del detergente riducendo la sua efficacia. Inoltre, può causare depositi di calcare nella macchina pregiudicando la pulizia sia degli strumenti che della macchina stessa, in particolar modo sulle parti calde.
CONTAMINANTI IONICI	L'alta concentrazione di contaminanti ionici può causare la corrosione degli strumenti realizzati in acciaio, manganese o rame.
CONTAMINANTI MICROBICI	I contaminanti microbici possono aumentare la contaminazione microbica degli strumenti alla fine del lavaggio.

Il costruttore raccomanda che:

- l'acqua utilizzata nelle fasi di prelavaggio e lavaggio sia potabile e di qualità conforme con la "Linea guida per l'acqua potabile 3° Edizione" pubblicata dall'Organizzazione mondiale della sanità.
- per le fasi di risciacquo utilizzare acqua demineralizzata.
  Le specifiche tipiche dell'acqua demineralizzata sono:

Concentrazione ioni H+	4.5…7 pH
Conducibilità	< 30 µs.cm^{-1}
Residuo fisso 180 °C (TDS)	< 40 mg/l
Durezza massima ($CaCO_3$)	< 10 mg/l
Cloro	< 10 mg/l
Metalli pesanti	< 10 mg/l
Fosfati	< 0.2 mg/l come P_2O_5
Silicati	< 0.2 mg/l come SiO_2
Endotossine	< 0.25 EU/ml
Numero totale di colonie di micro-organismi (UFC)	< 100 per 100 ml (*)

(*) per risciacqui successivi al trattamento di disinfezione, il limite massimo passa a 0.

Ulteriori informazioni posso ottenute anche dai produttori di prodotti chimici e di attrezzature mediche.
Dove sono presenti normative locali più severe rispetto a quelle fornite, il costruttore raccomanda di seguirle.
N.B.: è responsabilità dell'utilizzatore equipaggiare la macchina con acqua idonea.

Executed by	A. Marigo & A. Gardano	Date	13-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

Test	**Quality of water used during testing (6.4.3)**
Method	Prior to carrying out operational qualification and performance qualification testing, determine the quality of water used at each stage of the operating cycle other than the final rinse. Tests for chemical purity shall include tests for those determinants known to influence the efficacy of the process
Measuring Uncertainty	N.A.
Acceptance Criteria	The acceptable values/ranges shall be specified by the manufacturer.

Test Execution

Tests for chemical purity

Tests for chemical purity shall include tests for those determinants known to influence the efficacy of the process.

NOTE This can include, but is not limited to, tests to determine the value of the following:

- conductivity;
- pH;

- oxidizable substances [determined by the European Pharmacopoeia (EP) method or as redox potential determined by the United States Pharmacopoeia (USP) method];
- total hardness (salts of Ca2, Mg2, Sr2 expressed as mmol CaCO3);
- total dissolved solids (TDS) determined as evaporative residue;
- inorganic phosphate [Pi] and inorganic silicate [SiO2], determined as the molybdate reactive species;
- chloride [Cl^-].

Tests for bacterial endotoxins

If a requirement for the level of bacterial endotoxins in the final rinse water is given in other parts of ISO 5883, determine the level by the limulus amoebocyte lysate (LAL) test with a sensitivity of 0,25 U/ml, or better, using the method given in the European Pharmacopeia (EP) or United States Pharmacopeia (USP).

Tests for microbial quality

Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R2A-medium in accordance with Annex D, or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophilic viable count. Other methods, including rapid methods such as ATP bioluminescence, that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used.

Test Results

RISULTATI ANALITICI

	Valore/ Incertezza	U.M.	Valori di riferimento	Riferimenti
COLORE (dil. 1/10, spess. 10 cm) Met.: APAT IRSA-CNR 2020 29/03	non percettibile		non percettibile	DM 30/07/99
ODORE Met.: APAT-IRSA 2050 29/03	non causa molestie		non causa molestie	DM 30/07/99
MATERIALI IN SOSPENSIONE Met.: APAT CNR IRSA 2090 B Man 29 2003	< RL	mg/l	<35	DM 30/07/99
MATERIALI GROSSOLANI Met.: L-319/76	assenti		assenti	DM 30/07/99
pH Met.: APAT CNR IRSA 2060 Man 29 2003	7,94±0,70		[6,0-9,0]	DM 30/07/99
ANIONI Met.: EPA 9056 A 2007				
Cloruri	2,35±0,53	mg/l (come Cl)	<300	DM 30/07/99
Fluoruri	< RL	mg/l	<6	DM 30/07/99
Solfati	11,4±2,3	mg/l (come SO3)	<500	DM 30/07/99
SOLVENTI ORGANICI AZOTATI Met.: EPA 5021A 2014 + EPA 8260 D 2018				
Composti organici azotati	<0,022	mg/l	<0,1	DM 30/07/99
CONTA ESCHERICHIA COLI Met.: APAT CNR IRSA 7030 F Man 29 2003	0	UFC/100 ml	<5000	DM 30/07/99

Executed by A. Marigo & A. Gardano Date 13-Sep-22

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

If necessary, the complete certificate of analysis of the water emitted by an independent laboratory is available.

Test	**Volume of water used per stage (6.4.4)**
Method	Measure the volume of water used at each stage of the operating cycle using suitable volumetric measuring vessels.
Measuring Uncertainty	± 1 mL (both for the graduated vessel and the flowmeters)
Acceptance Criteria	The measured water volume shall be consistent with the value specified by the manufacturer.

Test Execution

The accuracy of the vessels shall be equal to, or better than, 1 % of the volume to be measured, as specified by the manufacturer.

Alternatively, the volume may be measured by interposing a total volume flow meter(s) in the pipe(s) supplying the WD and determining the volume used from readings taken immediately before and after each stage of the operating cycle. The meter should be in a known state of calibration, suitable for the operating pressure range of the WD and designed for connection within a supply pipe of the diameter used on the WD. The meter shall be located on a straight section of pipe with no less than 20 pipe internal diameters from the nearest bend or obstruction on either side of the meter. Volume/time flow meters should not be used since the calculation of the total volume from measurements of time and varying flow are unlikely to be sufficiently accurate.

Test Results

The cycle tested is the Standard cycle, that is installed by default on the WD. Its settings are reported in the table below.

STANDARD CYCLE									
Nr.	Phase name	Water				Chemical agent		Temperature	Time
		Cold water	Demi water	V 1	V 2	Dos. 1	Dos. 2		
1	Drain								
2	Pre-wash	38 L							120''
3	Drain								
4	Treatment				38 L	~114 mL		60°C	120''
5	Drain								
6	Treatment				38 L		~76 mL	55°C	60''
7	Drain								
8	Treatment		38 L					60°C	60''
9	Drain								
10	Treatment			38 L				90°C	60''
11	Drain								
12	Drying							120°C	1260''

The water volume values related to this cycle were collected three times, with the help of two flowmeters (Piusi K24) and a graduated vessel (for the chemical agents). The flowmeters were installed in series to all the water supply connections mentioned in the cycle. Each cycle was launched with both the tanks at their full level.

The following results were obtained:

STANDARD CYCLE					
Nr.		Water	Chemical agent	Temperature	Time

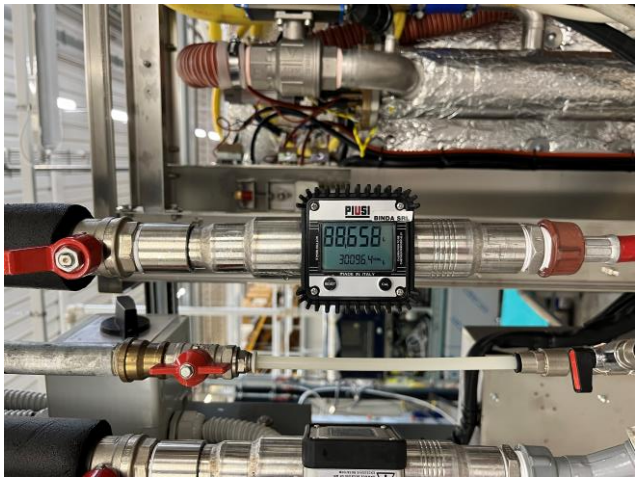
	Phase name	Cold water	Demi water	V 1	V 2	Dos. 1	Dos. 2		
1	Drain								
2	Pre-wash	35.582 L							120''
3	Drain								
4	Treatment				42.958 L	~114 mL		60°C	120''
5	Drain								
6	Treatment				41.231 L		~76 mL	55°C	60''
7	Drain								
8	Treatment		35.928 L					60°C	60''
9	Drain								
10	Treatment			37.440 L				90°C	60''
11	Drain								
12	Drying							120°C	1260''

Executed by A. Marigo & A. Gardano Date 14-Sep-22

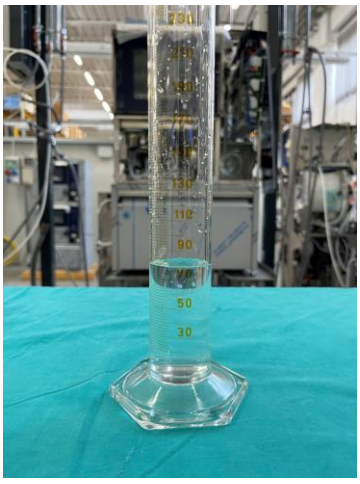
Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes



Piusi K24 flowmeter


Graduated vessel

4.3 Test on pipeworks (6.5)

Test	**Free draining (tanks, chamber, load corries) (6.5.4)**
Method	Visual inspection.
Measuring Uncertainty	N.A.
Acceptance Criteria	Verify that, as designed, built and installed, the washer disinfector will effectively discharge all the water from the system.

Test Execution

Free draining of chamber and load carriers

At the end of an operating cycle, aborted before the commencement of any drying stage, visually inspect the chamber and load carriers for pools of retained water. Droplets on vertical and sloping surfaces that slowly coalesce and drain away are not considered to be retained water.

Free draining of tanks

Fill all tanks and reservoirs for water and aqueous solutions with water to the maximum level required for normal operation and then allow them to drain. Inspect the tanks for evidence of pools of retained water.

Test Results

Both the tanks, the chamber (precisely the sump) and the load carrier were visually examined at the end of a cycle without a drying stage. There was not any evidence of relevant pools of retained water.

Executed by	A. Marigo & A. Gardano	Date	15-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

Bottom of a tank at the end of a cycle

Test	Estimation of dead volume of pipework (6.5.1)
Method	This test is intended to verify the volume stated by the manufacturer. This test should be carried out after the successful checks for free drainage specified above (6.5.4). The equipment required in order to carry out this test are volumetric measuring vessels of appropriate size.
Measuring Uncertainty	± 1 mL
Acceptance Criteria	The volume of retained water has to be equal to or less than the maximum retained volume stated by the manufacturer.

Test Execution

Flush the pipework of the WD which is known to be dry (either following disassembly and re-assembly or purging with compressed air for no less than 30 minutes) with a known volume of water (simulating the flow that would occur in normal use).

The volume of water flushed through the system should be twice that determined as the volume used per operating cycle. Measure the volume of water discharged and the dead volume, estimated as the volume retained, calculated from the difference between the two values. When the WD has two or more pipework systems which are entirely separated (e.g. for flushing water, wash water, rinse water, chemical disinfectant solution), each system may be tested separately.

This test can also be useful to investigate problems such as carry over of detergents or microbial contamination occurring in a WD.

Test Results

A standard cycle (without drying) was launched. At the end of it, a flowmeter (Piusi K24) was installed on the drain flexible pipe and all the pneumatic valves were opened, then all the hydraulic circuits were flushed with compressed air in order to remove all the retained water.

This resulted in a dead water volume of 1.130 L.

Executed by	A. Marigo & A. Gardano	Date	15-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

Flow meter installed on the draining pipe.

Test	Free draining of chamber and load carriers (6.5.2)
Method	The test is intended to verify if in the chamber and load carriers there is evidence of pools of retained water. Visual inspection.
Measuring Uncertainty	N.A.
Acceptance Criteria	At visual inspection there should not be any evidence of pools of retained water.

Test Execution

At the end of a normal operating cycle, inspect the chamber and load carriers for evidence of pools of retained water.

Test Results

Both the tanks, the chamber (precisely the sump) and the load carrier were visually examined at the end of a cycle without a drying stage. There was not any evidence of relevant pools of retained water.

Executed by	A. Marigo & A. Gardano	Date	15-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

Test	Chamber leak tightness (6.5.3)
Method	The test is intended to verify the chamber leak tightness by visual inspection.
Measuring Uncertainty	N.A.
Acceptance Criteria	At visual inspection there should not be any evidence of leakage.

Test Execution
After loading a carrier with a test load equal to the maximum volume accommodated, fill the chamber with the volume of water equivalent to the maximum volume of water used for any stage of the cycle. Inspect the WD for possible leakage.
Test Results
During and after a Standard cycle the unit was inspected. There was no evidence of leakage.
Executed by A. Marigo & A. Gardano Date 19-Sep-22
Test Evaluation
☒ **PASS** ☐ **FAIL** ☐ **N/A**
Notes
None.

Test	**Pipework flow to discharge point (6.5.5)**
Method	The test is intended to determine whether the slope is such that any contained liquid will tend to drain towards the discharge point. Visual inspection. If necessary, use a spirit level to determine whether the slope is in the required direction.
Measuring Uncertainty	N.A.
Acceptance Criteria	Any contained liquid must drain towards the discharge point.
Test Execution	
Visually inspect all pipework to determine whether the slope (the angle made with the horizontal) is such that any contained liquid will tend to drain towards the discharge point.	
Test Results	
The entire pipework was inspected visually and with the help of a spirit bubble, and it was determined that every slope is such that any contained liquid tend to drain from top to bottom towards the discharge point.	
Executed by A. Marigo & A. Gardano Date 15-Sep-22	
Test Evaluation	
☒ **PASS** ☐ **FAIL** ☐ **N/A**	
Notes	
None.	

Test	**Venting (6.5.6)**
Method	This test is intended to verify, with the help of a pressure gauge, the pressure inside of the chamber and the venting system.
Measuring Uncertainty	N.A.
Acceptance Criteria	For WDs in which the load is heated and/or thermally disinfected by steam heating, the chamber shall be protected against a rise in pressure above the designed working pressure of the chamber. A chamber designed to work at atmospheric pressure shall not exceed atmospheric pressure by more than 200 hPa (200 mbar). The design of the venting system shall ensure that the pressure within the chamber is discharged solely through the vent.
Test Execution	

Close and seal the chamber of the WD in the manner specified by the manufacturer and start an operating cycle.
Override the automatic controller to allow the continuous emission of steam to the chamber.
Observe where steam is vented, and note the maximum value obtained on the pressure gauge.

Test Results

A smoke machine (1200W) was installed inside the WD chamber. The doors were closed so that the only hole connecting the chamber with the external environment was the machine chimney (The smoke machine power cord was inserted in the chimney). Then we activated the smoke machine and we ensured that no smoke was coming out from the chamber (doors etc) except for the chimney. The test was successful.

Executed by	A. Marigo & A. Gardano	Date	19-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

Pictures showing that the smoke was coming out only from the chimney.

Test	**Load contamination from ductwork of the WD (6.5.7)**
Method	This test is intended to verify whether there is any visible water on load or on load carriers. The equipment consists of: - vessel of no less than 500 ml capacity, having a discharge port at its base connected to a flexible tube, fitted with an on/off valve and a flow control valve; - stopwatch; - load carrier (baskets or trolleys) and full load appropriate for the WD; - paper towels.
Measuring Uncertainty	N.A.
Acceptance Criteria	Ensure that any condensate draining from the ductwork will not contact the load.

Test Execution

Disconnect the external ducting to the WD 1 m above the chamber. (If it is not possible to disconnect the ducting at this position, the ducting should be disconnected at the chamber and a spare 1 m length of ducting should be connected to the chamber.)

Position the vessel approximately 1 m above the level of the chamber discharge to the vent. With the on/off valve closed, fill the vessel with (200±20) ml of cold water. Open the valve and adjust the flow control valve so that the contents of the vessel are discharged in (60±5) s. Refill the vessel with (200±20) ml of cold water. Feed the flexible tube into the ducting so that the open end of the flexible tube is 600 mm to 800 mm above the top of the chamber.

Load the chamber with a full load of dry load items in accordance with the manufacturer's instructions. Close the chamber door and then open the on/off valve. Record the time required for the vessel to empty. Within 1 min of the vessel emptying, open the chamber door and remove the load and any removable load containers. Place all the removed items on absorbent paper and examine all surfaces of the load and the absorbent paper for traces of water. Repeat the above procedure for the full range of load carriers which the WD is designed to process.

Test Results

First of all a device made of a plastic bottle, a valve and a flow regulator was made and calibrated. This device discharged 200 mL of water per 60 seconds, that way it was possible to perform the test consistently with the given description. This device was then raised to a given height over the WD exhaust and kept in a way such that the flow sticked to the exhaust walls.

There was no evidence of water coming from the exhaust contacting the load, nor the chamber.

Executed by	A. Marigo & A. Gardano	Date	19-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

Pictures of the device used to perfrom this test.

4.4 Tests on instrumentation fitted on WD (6.6)

Test	Verification of calibration (6.6.1)
Method	Verify the calibration of all measuring equipment fitted to the automatic controller or process verification system by comparison with test instruments. The test instrument shall be in a known state of calibration in accordance with the WI.
Measuring Uncertainty	N.A.

Acceptance Criteria	The readings obtained from the WD system should be coherent with those obtained from the test instrument.

Test Execution

Carry out the verification of calibration with the sensor of both the WD system and the test instrument maintained under steady state conditions.

The steady state condition shall be at the value at which readings will be made during an operational cycle, or at two or more values in the range of values over which readings will be made during an operational cycle, as specified by the manufacturer.

Compare the readings obtained from the test instrument and the WD system.

Test Results

A cycle made of a 30°C stage, a 60°C stage and a 90°C one (holding time = 5 min) was created for this test. A temperature probe (Ebro datalogger) was placed inside the chamber next to the WD recording and control probes.

During the cycle, the temperature values of the three probes were recorded (see table below). Using linear regression those values were necessary to adjust the two WD temperature probes sensitivity and offset.

First measurement				
Temperature REFERENCE probe	**Temperature CONTROL probe**	**control probe error measured**	**Temperature RECORDING probe**	**recording probe error measured**
[°C]	[°C]	[°C]	[°C]	[°C]
34,6	32,8	1,8	34,4	0,2
63,5	61,7	1,8	63,4	0,1
92,5	90,6	1,9	92,5	0,0
		MAX DEVIATION		MAX DEVIATION
		1,9		0,2

Adjustment					
	ZERO=	1,7 °C		ZERO=	0,3 °C	
	SPAN=	0,2 °C		SPAN=	- 0,3 °C	

Check				
Temperature REFERENCE probe	**Temperature CONTROL probe**	**control probe error measured**	**Temperature RECORDING probe**	**recording probe error measured**
[°C]	[°C]	[°C]	[°C]	[°C]
32,6	32,4	0,2	32,4	0,2
61,8	61,8	0,0	62,0	-0,2
90,7	90,7	0,0	90,6	0,1
		MAX DEVIATION		MAX DEVIATION
		1,9		0,2

Max deviation allowed:	± 1 °C

Executed by A. Marigo & A. Gardano Date 22-Sep-22

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

Steelco Miele Group Member | Code FORM-0047 | Revision 01 | Status VALID
Title Probes Calibration Report | Date 14-Mar-2022

PROBES CALIBRATION REPORT / *RAPPORTO DI CALIBRAZIONE SONDE* / PROGRAMM-TESTBERICHT / *RAPPORT DE CALIBRAGE SONDES*

CALIBRATION CENTER:
CENTRO DI CALIBRAZIONE:
KALIBRIERSTELLE:
CENTRE DE CALIBRAGE:
STEELCO-01
Via Balegante, 27
I-31039 RESE PIO X (TV)
ITALY

Referring to the machine model:
Modello e n° serie macchina di rif.:
Modell und Seriennummer der Maschine:
Modèle et n° serié machine de référence:
DS 1000

Serial number:
Numero di serie:
Seriennummer:
Numéro de série:
2203010CO016

Calibrated reference instrument:
Strumento tarato di riferimento:
Kalibriergerät:
Instrument calibré de référence:
S05-029 44690 - 45054

Certificate of calibration:
Certificato di taratura:
Bestätigung der Kalibrierung:
Certificat de calibrage:
22-05-56598

Issued at:
Emesso il:
Ausgestellt am:
Emis le
9-May-2022

The measurement results reported in this report were obtained following the procedure:
I risultati di misura riportati nel presente rapporto sono stati ottenuti applicando la procedura:
Die im vorliegenden Bericht angeführten Messergebnisse wurden mittels angewendeter Prozedur erhalten:
Les résultats de mesure reportés dans le présent rapport ont été obtenus en appliquant la procédure
WI-0016 Rev.00

Calibration results / *Risultati della calibrazione* / Kalibrierungsergebnisse / *Résultats de calibrage*

No	Calibrated Reference Instrument Temperature - Temperatura strumento campione - Temperatur des Testinstrumentes - *Température instrument échantillon* Value displayed [°C]	Control Temperature - *Temperatura di controllo* - Kontrolltemperatur - *Température de controle* Value displayed [°C]	Δ	Recording Temperature - *Temperatura di registrazione* - Registrierungstemperatur - *Température d'enregistrement* Value displayed [°C]	Δ	Measure uncertainty - *Incertezza di misura* - Differenz auf Mass - *Incertitude de mesure* [°C]
1	34,6	34,6	0,2	34,6	1,0	0,3
2	63,5	63,5	0	63,5	2,0	0,3
3	92,5	92,5	0	92,5	3,0	0,3

Adjustment done:
Correzione eseguita:
Erfolgte Korrektur:
Correction effectuée:

ZERO =	1,7 °C	ZERO =	0,3 °C
SPAN =	0,2 °C	SPAN =	-0,3 °C
Max deviation / *Deviazione max* / Hoechstabweichung / *Déviance max*	0,2 [°C]		0,2 [°C]

Notes:
Note:
Anmerkung:
Note:

Sign of the Operator:
Firma dell'Operatore:
Unterschrift des Bedieners:
Signature Opérateur:

Date:
Data:
Datum:
Date:
22-Sep-2022

Page 1 of

Test	**Legibility (6.6.2)**
Method	The test is intended to verify the legibility of all indicators by visual inspection (normal sighted operator).
Measuring Uncertainty	N.A.
Acceptance Criteria	The readings must be legible as specified below.

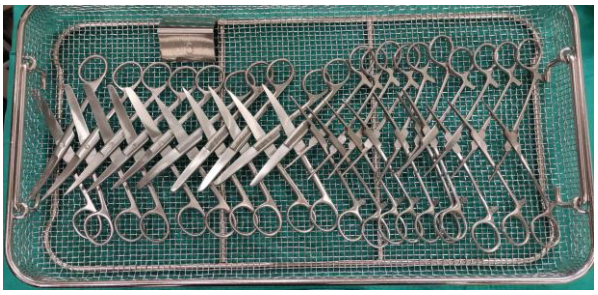
Test Execution
Determine the legibility of all indicators and gauges fitted to the WD by visual observation. The observer shall view the indicator or gauge under diffuse illumination of 300 ± 100 lx at a distance of 0.25 (or +0.05 m) m and at a distance of 1.0 (or -0.05 m) m to determine whether the reading is legible.
Test Results
Both the HMIs of the machine (loading side Hakko display and unloading side Mitsubishi display) can be correctly viewed by a normal sighted operator at a distance of the range specified above.
Executed by: A. Marigo & A. Gardano — Date: 22-Sep-22
Test Evaluation
☒ **PASS** ☐ **FAIL** ☐ **N/A**
Notes
None.

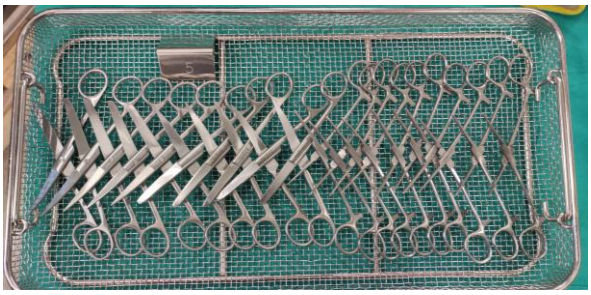
4.5 Tests on load carriers (6.7)

Test	**Load carriers used within the chamber (6.7.1)**
Method	Verify the load carriers used within the chamber. This test makes use of a spring balance calibrated in kilograms with a range including 0 kg to 30 kg and with an accuracy of ±1 kg over the range 0 kg to 30 kg attached to the load carrier with a non-extensible means of attachment.
Measuring Uncertainty	± 0,1 N
Acceptance Criteria	a) It must be established that: - the load remained wholly supported and retained within the usable chamber space for the duration of the operating cycle; - the load carrier was retained in the chamber by a mechanism which was only released when the transfer system was in place; - the load carrier remained stable when withdrawn for a distance specified by the manufacturer, and was fitted with a retaining device, which had to be released if the load was to be withdrawn further; - the load carrier could not be mis-positioned in a manner which would prevent the free drainage of water and penetration of water and/or steam into the load by connection to service supplies within the chamber in the manner intended by the manufacturer. b) The force required to remove the full load in the basket/trolley shall be lower than 250 N.

Test Execution
This test can be carried out as follows: a. Fully load the system for supporting the load within the chamber and/or transferring the load into and/or out of the chamber and operate it in the manner specify by the manufacturer. During loading and after cycle completion carry out an inspection to see if the requirements of the acceptance criteria are met . b. Measure the force required to remove the load from the chamber using the spring balance.
Test Results
C100W load carrier with 5 levels was used for this test and a standard WD cycle was started. All the requirements of 5.27 were met. In fact, the load remained supported and retained as shown in the pictures below. Moreover, the load carrier was also retained during the cycle, it remained stable and could not be mis-positioned. The force required to remove the load carrier from the chamber, as shown in the pictures below, was measured. The force during this action reached the value of 60,0 N and the acceptance criteria were met.
Executed by: A. Marigo & A. Gardano — Date: 23-Sep-22
Test Evaluation
☒ **PASS** ☐ **FAIL** ☐ **N/A**

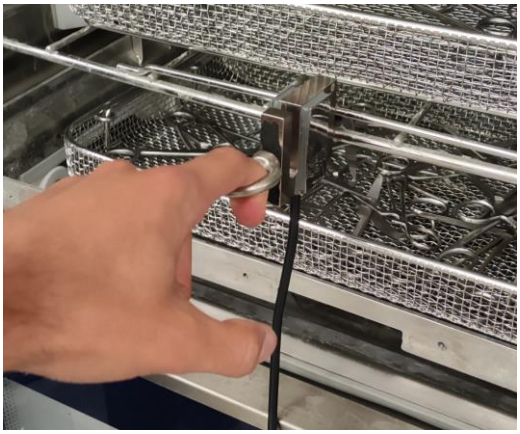
Notes

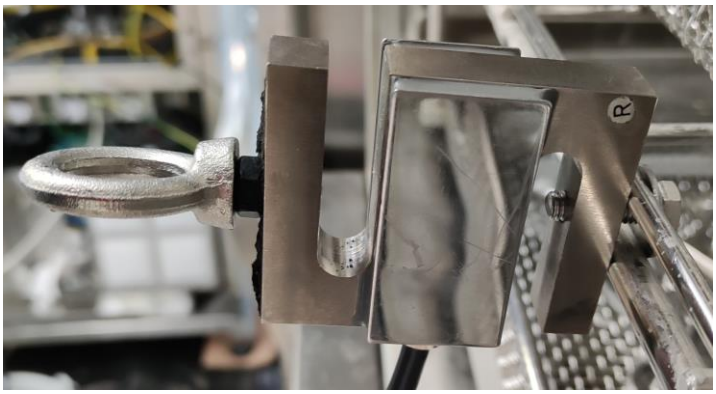




The two pictures represent the load basket number 5, that is shown also in the picture above (it's the third from the top of the picture). The load before the WD cycle is shown in the picture on the left; the same load after the cycle is on the right.

C100 load carrier in the WD chamber and a picture of the same model empty carrier.





The force gauge fixed on the C100W load carrier.

Test	**Trolleys (6.7.2)**
Method	This test makes use of a spring balance calibrated in kilograms with a range including 0 kg to 30 kg and with an accuracy of ±1 kg over the range 0 kg to 30 kg attached to the load carrier with a non-extensible means of attachment.
Measuring Uncertainty	± 0,1 N
Acceptance Criteria	1. The trolley shall remain stable when subjected to a force not exceeding 250 N applied horizontally in any direction to the trolley whilst it is supporting its maximum design load. 2. The trolley shall allow the operator easily to align the trolley with the WD for loading and unloading. 3. The trolley shall be provided with means to collect liquid residues from the load to prevent these from dripping onto the floor. The means provided shall be detachable for cleaning. 4. The trolley shall be provided with swivel wheels or equivalent means to facilitate maneuvering. 5. The trolley shall be designed to secure the load carriers on the trolley during loading and unloading and while traversing a gradient at a slope of up to 1 in 20. 6. The trolley shall be fitted with a parking brake capable of retaining the fully loaded trolley on a slope with a gradient of 1 in 20.

Test Execution

When the WD is supplied with a trolley for handling the load outside the chamber, carry out the following inspections and tests.

1. Stability: fully load the trolley in accordance with the manufacturer's instructions. Apply a force of 250 N horizontally to the highest point of the load or accessory using the balance according to 6.7.2.1. Apply the force successively in at least eight directions at 45° intervals.
2. Alignment: visually inspect the trolley for vertical and horizontal alignment with the WD during loading and unloading.
3. Collection of liquid residues: by inspection and operation verify that the trolley is provided with means, which are detachable for cleaning, to collect liquid residues from the load and that liquid from the load cannot drip onto the floor.
4. Maneuverability: check by inspection.
5. Retention of load carriers: fully load the trolley with load carriers each filled to maximum capacity in accordance with the manufacturer's instructions. By visual inspection determine whether the load carriers were securely retained: - during loading and unloading; - while traversing a gradient at a slope of 1 in 20.
6. Parking brake: fully load the trolley in accordance with the manufacturer's instructions. Position the trolley on a gradient at a slope of 1 in 20 so that it is free to roll down the slope. Apply the parking brake. Observe whether the trolley remains stationary

Test Results

The trolley remained stable when subjected to the horizontal maximum force of 250 N, blocked and supporting the maximum designed load. The stability requirement is fulfilled. Moreover, the trolley was easy to align to the WD and its maneuverability was satisfactory. As shown in the picture below, the trolley structure guaranteed that any liquid residues from the load was collected on it and there was no possibility of dripping on the floor.

The trolley is provided with a locking system (as shown in the figure below), which secured the load carrier to the trolley structure. Even on a slope greater than the one requested, the locking system worked correctly. Also the parking brake worked successfully.

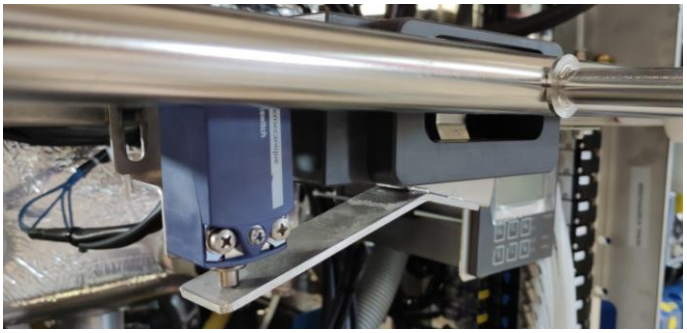
Executed by	A. Marigo & A. Gardano	Date	23-Sep-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

Trolley with carrier on the WD loading side.



The load side trolley inlet (the same component is placed on the unloading side).

The swivel wheels of the trolley with their lock system.

The trolley locking system for the load carrier.

4.6 Thermometric Tests (6.8)

Test	**Chamber wall temperature test (6.8.3)**
Method	This test aims at recording temperatures at chamber corners and walls, using a temperature recorder complying with the requirements specified in WI.
Measuring Uncertainty	0,01 °C
Acceptance Criteria	The test shall be considered satisfactory if the following requirements are met: a) the temperatures recorded on the surface of the chamber throughout the holding period for the disinfection stage are within - 0 °C and + 5 °C of the disinfection temperature; b) the temperatures recorded on the surface of the chamber throughout the holding period for each of the stages, other than the disinfection stage (see above) are within ± 5 °C of the set temperature for the relevant stage; c) the temperature indicated/recorded by the WD instruments are within ± 2 °C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage; d) the temperature profile obtained for the temperature controlled stages of the operating cycle are consistent within ±2,5 °C for the last three of four test cycles.

Test Execution

Locate the temperature sensors as follows:

a) one in each corner of the chamber;
b) one in the center of the two side walls;
c) one in the center of the roof of the chamber;
d) one adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Use additional locations for sensors on sequential cycles, when there is reason to believe that other locations can give lower temperatures e.g. when parts of the outer surface of the chamber are not insulated.

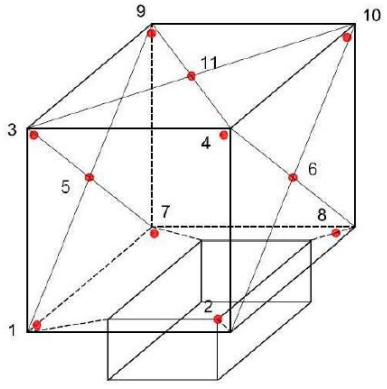
Measure the temperature attained throughout four operating cycles, the first of which should be at least 60 min since the machine was last used (a “cold start") and the final three with not more than 15 min intervals between cycles (a “hot start").

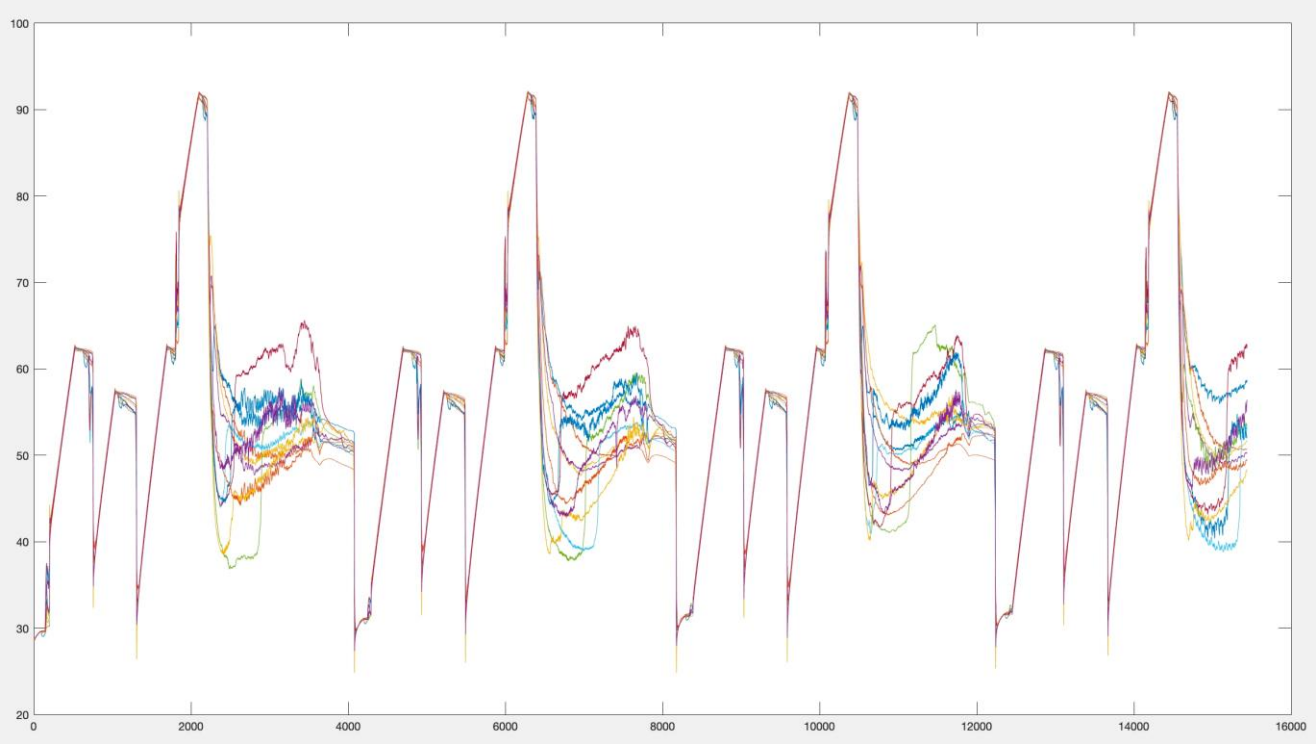
Operate the WD with a load consisting of a reference load (see subsequent parts of ISO 15883).

Multi-chamber WDs can be tested with each chamber tested consecutively or concurrently. In the latter case, 12 sensors will be required for each chamber.

Test Results

EBRO dataloggers EBI10 were used as temperature probes and they were placed as shown in the following picture. Temperature probe number 4 is one of the probes placed on the angles, but also the probe adjacent to the temperature sensor used as the reference for chamber temperature.





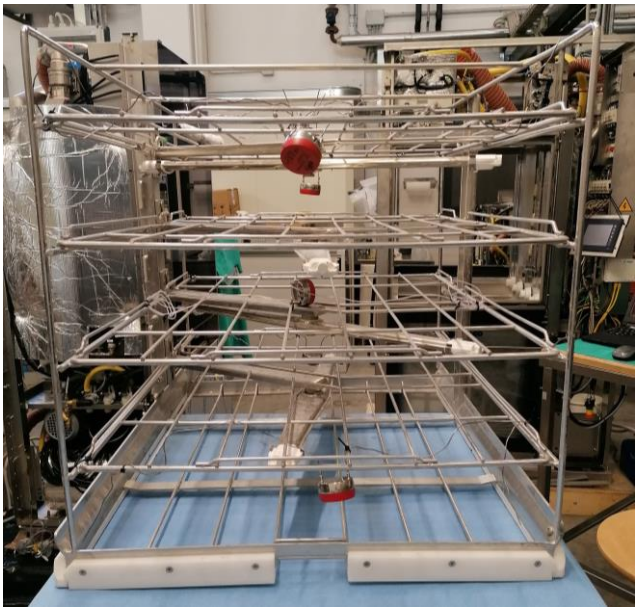
Four operating cycle were launched, the first one with a “cold start”. The temperatures values recorded by EBRO probes, the control temperature values and the recording temperature values of the WD chamber are all represented in this MATLAB plot. The values of all the four cycles fulfil the acceptance requirements: in the temperature-controlled stages (except drying), they are aligned with each other.

Executed by	A. Marigo & A. Gardano	Date	26-Sep-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes



C100 carrier with EBRO temperature probe placed on it to measure the chamber temperature in the different positions specified above.

Test	Temperature tests on tanks (6.8.4)
Method	This test aims at recording temperatures inside of WD tanks, using a temperature recorder complying with the requirements specified in WI.
Measuring Uncertainty	0,01 °C
Acceptance Criteria	The water in the tank is kept constantly at a minimum of 65 °C, (NOTE In order to maintain a minimum temperature of 65 °C the tank would have to be maintained at a higher temperature, e.g. 75 °C, so that when the supply is replenished by incoming cold water the temperature remains above 65 °C).

Test Execution

Locate the temperature sensors at two diagonally opposite corners of the tank, in the approximate geometric center of the tank and adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Measure the temperature attained throughout three operating cycles, the first of which shall be at least 60 min since the machine was last used (a “cold start") and the final two with not more than a 15 min interval between cycles (a “hot start").

Operate the WD empty except for chamber furniture (e.g. load carriers).

WDs with more than one tank may be tested with each tank tested consecutively.

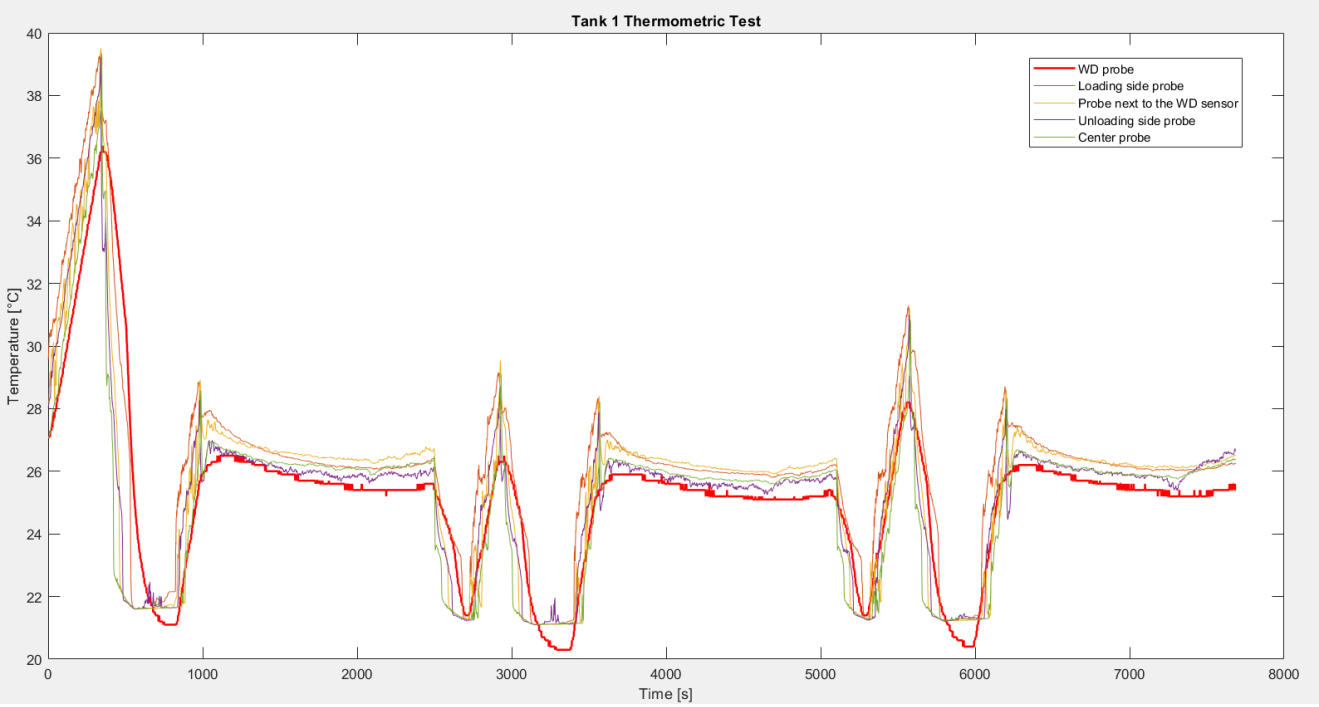
Test Results

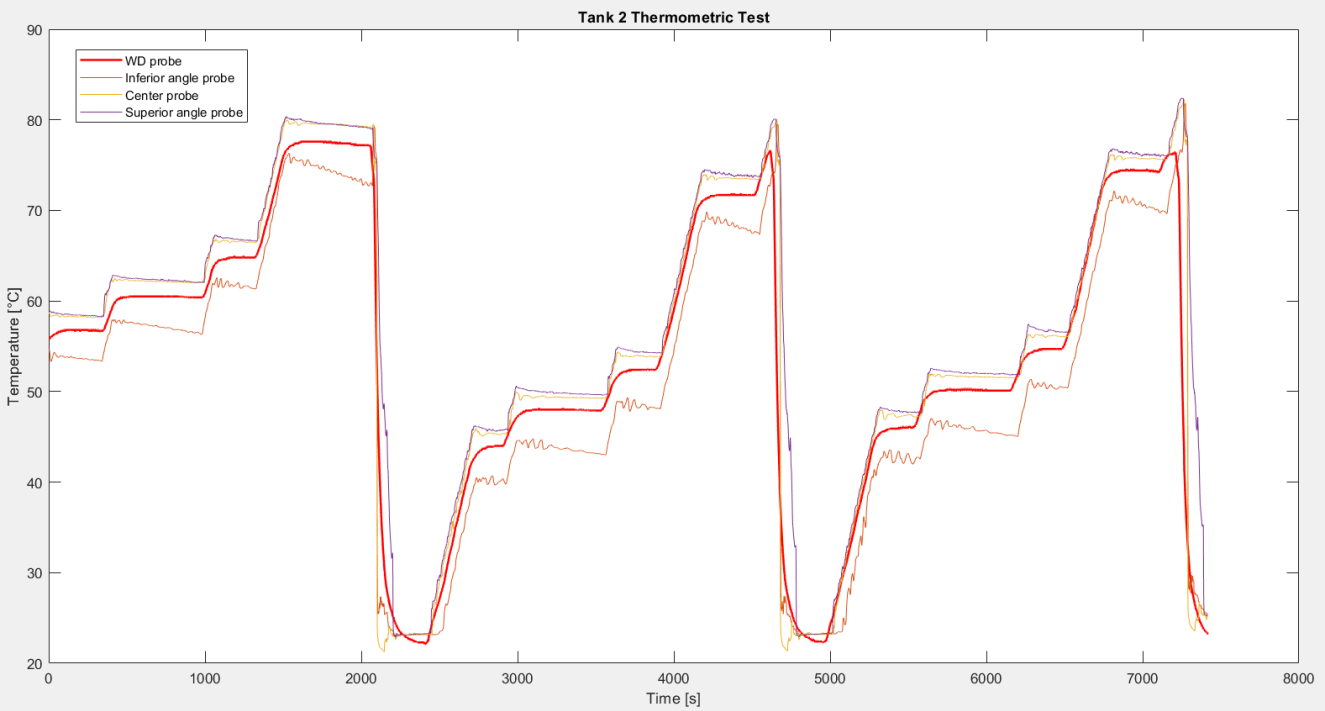
The test was performed with the help of 3 Ebro temperature probes (3 channels and 2 channels) and a brand new software developed for this kind of tests that reads the measurements coming from the WD probes and writes them on an Excel file.

The Ebro temperature probes were placed inside the tanks as described in the test execution.

The WD chamber was loaded with an empty C100W load carrier and a standard cycle was launched (cold start).

Two consecutive standard cycles followed the first one and the two plots below show the obtained results, both for the tank 1 and the tank 2:





Executed by	A. Marigo & A. Gardano	Date	26-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

Test	**Load temperature protection (6.8.5)**
Method	The aim of this test is to ensure that, in the event of the automatic control failing to control the temperature in the WD, the temperature will not rise to a level which would damage the load in the WD. The test instrument shall be a temperature recorder complying with the requirements specified in WI or as an alternative three independent data loggers and a temperature recorder, having at least one sensor.
Measuring Uncertainty	N.A.
Acceptance Criteria	The test shall be considered satisfactory if the following requirement is met: when used to limit the temperature of any medium coming into contact with the load, temperature cut-outs shall operate at a temperature not more than 5 °C higher than the highest temperature provided by any temperature control or temperature-limiting device. This requirement shall apply to both non-adjustable and adjustable temperature cut-outs, when set at their minimum temperature, and pre-set temperature cut-outs.

Test Execution

Locate the temperature sensors at two diagonally opposite corners of the load carrier, in the approximate geometric center of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature. Operate the WD empty, except for the load carrier, on a normal operating cycle.

For multi-cycle machines, test the two cycles having the highest and lowest operating temperatures.

During the stage of the cycle when the maximum temperature is attained, disable the temperature control system in the manner specified by the manufacturer, e.g. by removing the temperature sensor connected to the automatic controller.

Test Results

First of all, the temperature probes (that are responsible for the heating elements activation/deactivation) located inside the washing/drying circuit and the chamber were removed and exposed to the environmental temperature. Then, after placing three independent temperature probes in the chamber as described above, a drying cycle (Tref = 120°C) was created and launched.

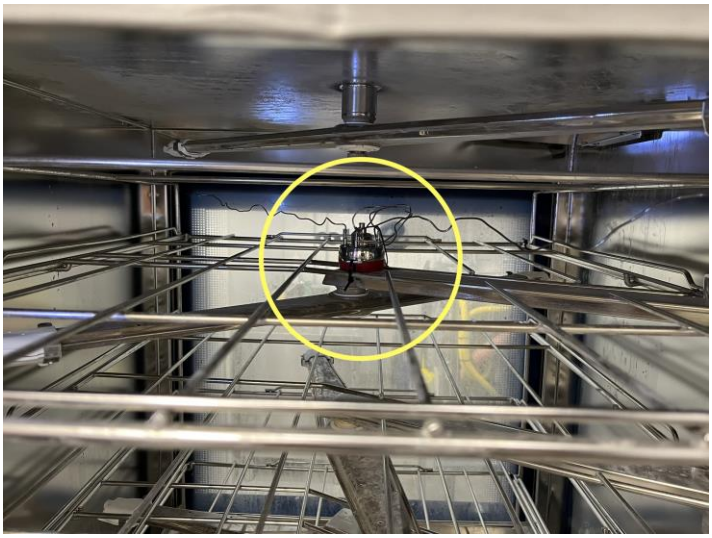
Our unit is equipped with an independent automatic control system, that generated an alarm and stopped the running cycle once the temperature exceeded a temperature set point (specific for the thermal circuit breaker). The set point was reached next to the heating elements, while inside the chamber the temperature was much lower.

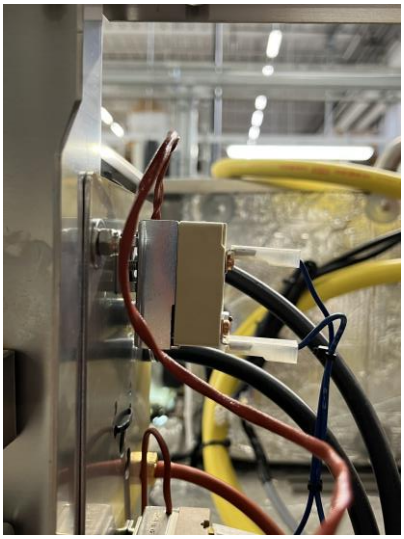
Executed by	A. Marigo & A. Gardano	Date	27-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes





Pictures of the independent Ebro temperature probes and the thermal circuit breaker equipped in our unit.

4.7 Chemical Dosing Tests (6.9)

Test	Ejected volume (6.9.1)
Method	Apply the test method specified by the manufacturer (5.7.4) or, if not specified, apply the Volumetric method or otherwise the Concentration method (both specified below).
Measuring Uncertainty	± 1 mL
Acceptance Criteria	The test shall be considered satisfactory if the requirements of 5.7.4 and 5.7.5 are met.

Test Execution

1. Volumetric method: Fill up a graduated test tube (of appropriate size) with a chemical agent until two-thirds of the vessel are reached. Place a suction pipe into the test tube and start a normal operating cycle. At the end of the cycle, carefully fill up the test tube until the maximum level is reached, and start another normal operating cycle. Carefully fill up to the maximum level another test tube with the same chemical agent. At the end of the operating cycle, fill up the first test tube to the maximum level with the chemical agent contained in the second one. Register the chemical agent volume poured from the second test tube into the first one. Then also record the quantity of chemical agent used in the second operating cycle and compare it with the delivered volume. Start one more operating cycle and measure the ejected volume again.
2. Concentration method: This is recommended for those WD that need a specific chemical agent concentration inside of the chamber. Take a sample of the water used in a specific phase of the operating cycle and determine the volume of chemical agent needed for each water litre, in the chamber with a direct measuring method (e.g. using an electrode, trough spectrophotometric method). After that, the nominal volume can be calculated multiplying the

volume obtained with the one as in 6.6.4, or separately measuring of the volume retained out of the holding tank of the WD.

The volumetric method is the one usually performed in Steelco.

Test Results

Our unit is equipped with two peristaltic pumps and two flowmeters (they have to be calibrated each time a new chemical agent is used) that are assigned to two separate chemical agents: one is a detergent and the other one is slightly acid and used to balance the detergent. For this test we used Dr.Weigert's Mediclean Forte and Steelco Acid.

After the calibration of the two flowmeters we launched four standard WD cycles, and the quantities of chemical agent used in each one were measured using two appropriate graduated vessels. These are reported in the following table:

CHEMICAL AGENTS QUANTITY CHECK (mL per cycle)				
	PUMP 1 (REAL)	PUMP 2 (REAL)	PUMP 1 (IDEAL)	PUMP 2 (IDEAL)
CYCLE 1	115	76	114	76
CYCLE 2	114	77	114	76
CYCLE 3	116	76	114	76
CYCLE 4	115	76	114	76

The maximum error has to be lower or equal to ± 5%, and our results fulfil this requirement.

Executed by A. Marigo & A. Gardano Date 28-Sep-22

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

Pictures related to the calibration stage and the two chemical agents used.

Test	**Insufficient chemical agent warning (6.9.2)**
Method	Apply the test method specified in the text execution below to determine if the WD warns the operator when there is not a sufficient amount of chemical agent loaded.
Measuring Uncertainty	N.A.

Acceptance Criteria	The test result shall be considered satisfactory if the WD warns the operator when there is not enough chemical agent to complete an operating cycle.

Test Execution

Fill up a vessel with enough chemical agent to carry out more than three operating cycles but less than five. Start the WD for five consecutive cycles. Estimate the remaining volume at the end of each cycle (pre-marked vessel, dipstick or mass).

Test Results

A custom cycle was created: it was made of a single treatment stage, with 40 L of water inside the chamber and a quantity of chemical agent = 10 ‰.

Then the vessel that contained the float of the sucking inlet was filled with detergent until the float was in its closed position and again filled with another 1.4 L of water.

1.4 L was chosen because it was enough to complete 3 of these cycles, but not enough to complete 5 of them.

A series of 4 cycles was then launched and this is the overall chemical agent consumption:

CHEMICAL AGENT CONSUMPTION CHECK		
CYCLE	PUMPED QUANTITY [mL]	QUANTITY REMAINING [mL]
		1400
1	400	1000
2	400	600
3	400	200

The WD was not able to complete the 4th cycle because the detergent was not enough, and the alarm no.26 “FAILURE ON CHEMICAL 1” was generated. Moreover it was not possible to launch the 5th cycle without a refill.

Executed by	A. Marigo & A. Gardano	Date	28-Sep-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

None.

4.8 Cleaning efficacy tests (6.10)

Test	**Cleaning efficacy test (6.10.2)**
Method	During tests of cleaning efficacy, the cycle shall be run without a disinfection stage. The drying stage may also be omitted if this is necessary to facilitate the detection of residual contamination or test soil. This test shall be carried out using the appropriate test method(s) and test soil(s) as described in ISO/TS 15883-5 by taking into consideration the corresponding category of load. The attention of users is drawn to local regulations that can require the use of particular test soils and test methods. The attention of manufacturers is drawn to the user’s choice of test soil(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied. The test soil used for the load, chamber wall and load carriers may not be the same. Where different test soils are used the rationale for the choice of test soil should be documented.
Measuring Uncertainty	N.A.
Acceptance Criteria	At least 95% of the load in each DIN basket shall be clean to consider the result satisfactory.

Test Execution

Contaminate the test load, chamber walls and load carrier with the test soil as described in the relevant test method of ISO/TS 15883-5. Operate a normal wash cycle for the load type under test. After completion of the wash cycle, examine the test load,

chamber walls and load carrier for the presence of residual test soil using the method described in the relevant test method of ISO/TS 15883-5.

Test Results

The following program cycle was created:

- Drain;
- Prewash: using cold water for 180'';
- Drain;
- Wash: using warm water (from tank 2 at 40 °C) for 300'', set point at 55 °C, detergent (chemical agent 1) 7 ‰ dosed at 45 °C;
- Drain;
- Rinse: using warm water (from tank 2 at 40 °C) for 60'', set point at 55 °C, neutralizer (chemical agent 2) 2 ‰ immediately dosed;
- Drain;
- Final rinse: using demi water (from tank 1 at 60°C) for 60'';
- Final drain;

After that the test was performed according to the following instructions:

- The solution of blood and protamine must be prepared mixing 20 mL of blood with 300 µL of protamine sulphate;
- The test instrument shall already be disinfected: 10 scissors and 10 clamps inside each DIN basket;
- For each type of instrument, 5 units must be placed upwards and 5 downwards;
- When coagulation starts, the blood cannot be used in the test anymore;
- The dirty brush must be passed on both side of each instrument, opened at 90° if applicable;
- The dirty instruments must be placed as shown in the figure below;
- When all the instruments have been soiled, wait 30 minutes;
- Remove the excess blood clot and wait 30 more minutes;
- Place the DIN baskets in the WD chamber and start the cycle.
- The instrument control must be performed under a 1000 lux light at 50 cm from the working table.

GKE and Tosi biological markers were also placed on the DIN baskets containing dirty instruments.

The WD carrier (C100W model) was placed in the chamber completely full (3 baskets for each level, 15 baskets in the camber): one dirty DIN basket and two clean ones on each level of the WD carrier, as shown in the figure below.

The chamber walls were also soiled with blood, to verify the complete cleaning of all the WD chamber.

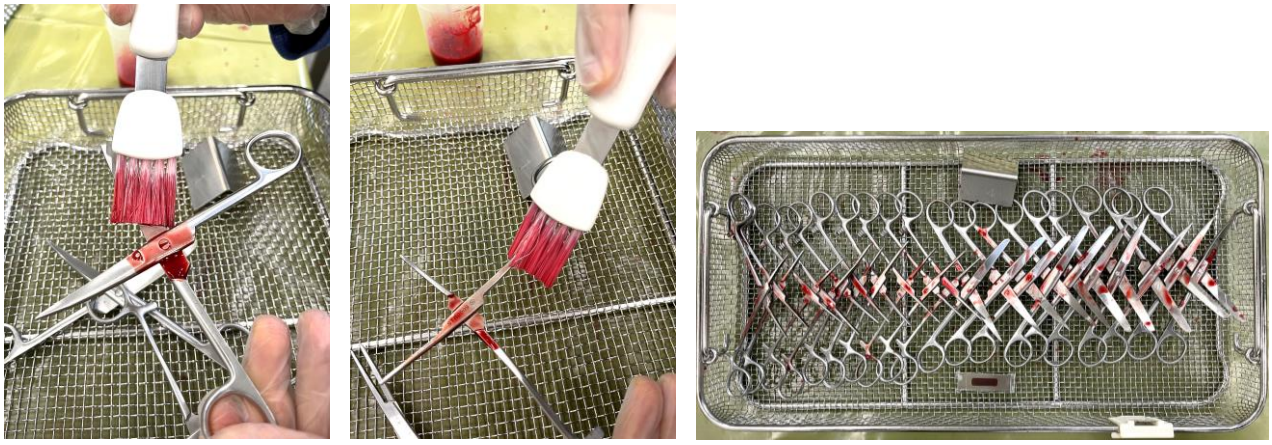
After the cycle the load and the chamber were carefully studied to find any residual soil on the instruments and on the chamber walls (as shown in the pictures below). The result was that less than the 5% of the instruments (maximum tolerance) showed some residual soil: the test result is satisfactory.

Executed by	A. Marigo & A. Gardano	Date	11-Oct-22

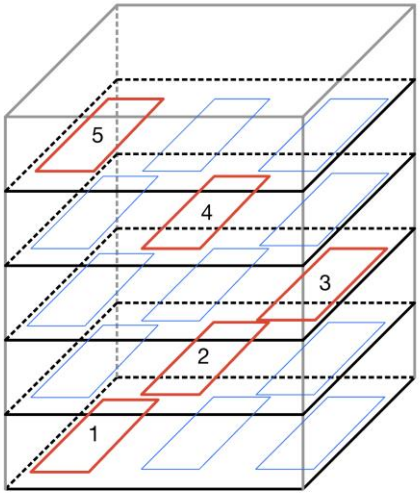
Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

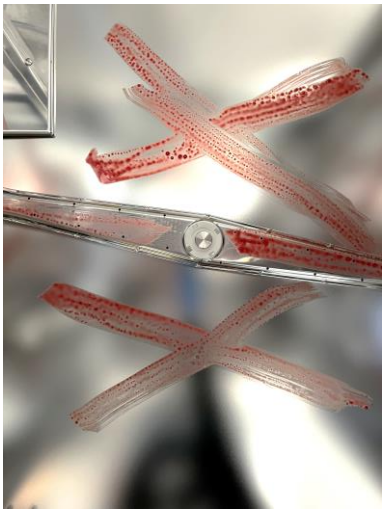
Notes

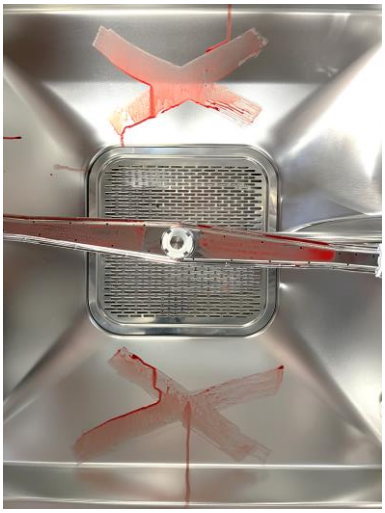


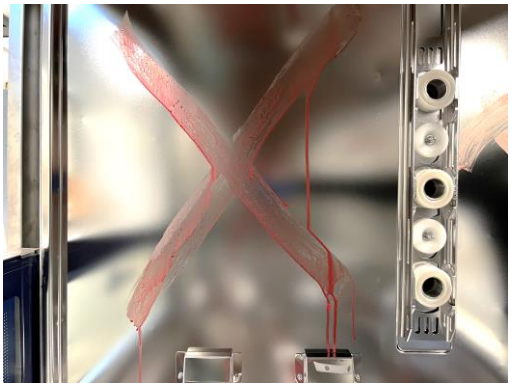
The application of blood soil on scissors and clamps on the left. A full DIN basket with 10 dirty scissors and 10 dirty clamps on the right, with the small plate showing the level number and the biological markers fixed on the wall of the basket.



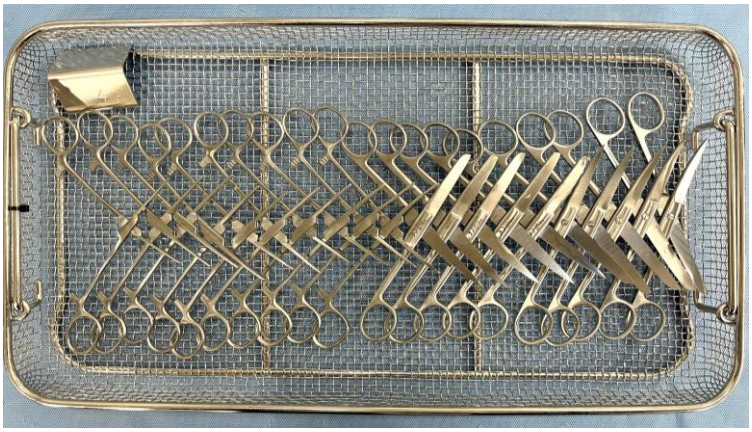
These pictures represent the full loaded C100W carrier: in the drawing on the left, the red boxes represent the soiled instruments baskets, while the blue boxes represent the clean ones; on the right is the full carrier inside the WD chamber.



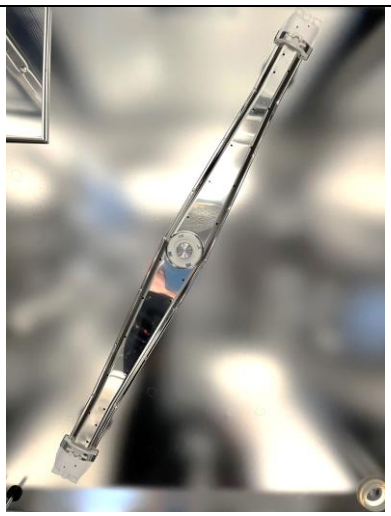
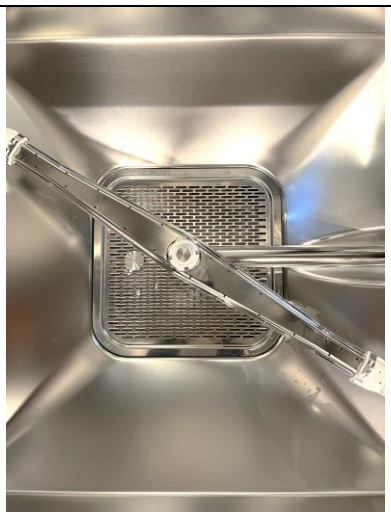
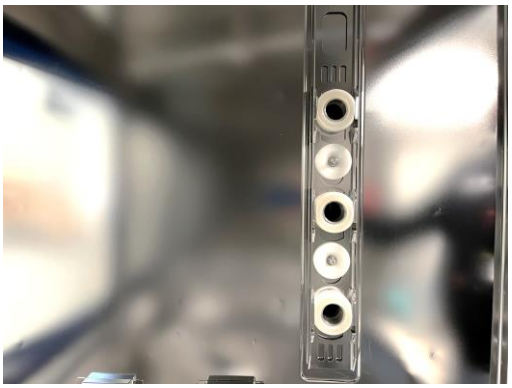




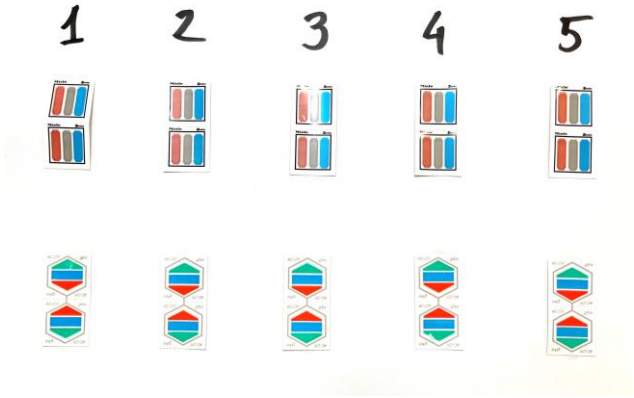
The chamber walls were also soiled with blood. From left to right: the upper wall and its spray arm, the lower part of the chamber with its spray arm, and one side wall.

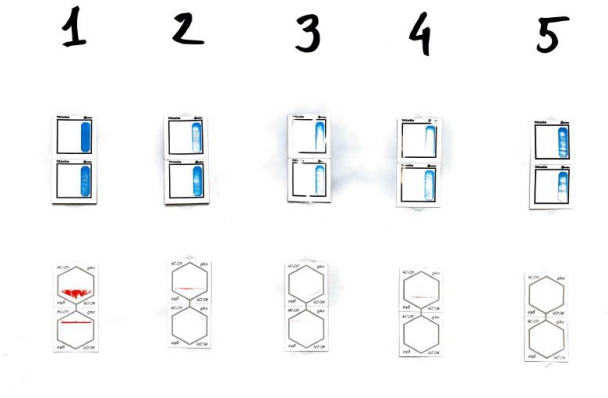


The clean DIN basket number 4 after the cleaning efficacy test WD cycle.

The clean chamber walls after the WD cycle.





The biological markers involved in this test are shown in this figure: before the WD cycle on the left, after the cleaning cycle on the right. The numbers on the top refer to the DIN baskets and their levels in the carrier. The reference markers are the GKE, reported on the second row. As shown in the picture, the results were satisfactory: except for the DIN basket on the level 1 (where the marker is still partially red), all the other GKE markers placed on the other four levels resulted satisfactory. The first row reports the results of Steelco-Mièle markers, which are not completely developed yet, but are reported for internal interest.

Test	**Tests for process residuals (6.10.4)**
Method	The nature of the residues and their level which can be of concern depend on the process chemical agents used during the process and the intended use of the washed and disinfected product. The chemical agents used during the process (e.g. detergents, rinse aids) may not be completely removed by the rinsing process. The sampling method and analytical method shall be capable of determining the presence of the chemical agent at concentrations below that specified as potentially harmful, i.e. as the maximum acceptable level.
Measuring Uncertainty	0.1 µS/cm
Acceptance Criteria	Check for compliance with 4.4.1 and 4.4.2 and report whether the concentration on the simulated product is lower than the specified maximum acceptable level. When residual limits are not specified and/or no analytical method is available, biocompatibility testing to ISO 10993 can be used to meet the requirements of this test.
	Test Execution
Test the efficacy of the rinse process by using the upper limit of the normal dose of the process chemical on a normal operating cycle using a test load of simulated product. Carry out an analysis by the method recommended by the manufacturer	

on the final rinse water and on the simulated product. If the cycle includes a neutralizer for the process chemical under study, the volume of neutralizer used shall be the lower limit of the normal dose.

Test Results

In order to study the process residuals we decided to evaluate the purity of water from cations and anions, that have a strong correlation with the chemical agents being used. As for the other tests, two chemical agents were employed during a standard cycle: Dr.Weigert's Mediclean Forte (3 ‰) and Steelco Acid (2 ‰). Besides, demi water was supplied by a deionizer (Evoqua water technologies).

Here is reported the standard cycle for reference:

STANDARD CYCLE									
Nr.	Phase name	Water				Chemical agent		Temperature	Time
		Cold water	Demi water	V 1 Demi	V 2 Rec	Dos. 1	Dos. 2		
1	Drain								
2	Pre-wash	38 L							120''
3	Drain								
4	Treatment				38 L	~114 mL		60°C	120''
5	Drain								
6	Treatment				38 L		~76 mL	55°C	60''
7	Drain								
8	Treatment		38 L					60°C	60''
9	Drain								
10	Treatment			38 L				90°C	60''
11	Drain								
12	Drying							120°C	1260''

Three samples of the water coming from stages no. 7-9-11 were collected in order to measure their conductivity, using a Mettler-Toledo conductivity meter, and here are reported the recorded values:

STANDARD CYCLE (MEDICLEAN FORTE and STEELCO ACID)								
Nr.	Phase name	Water				Chemical agent		Conductivity [µS/cm]
		Cold water	Demi water	V 1 Demi	V 2 Rec	Dos. 1	Dos. 2	
1	Drain							
2	Pre-wash	38 L						
3	Drain							
4	Treatment				38 L	~114 mL		
5	Drain							
6	Treatment				38 L		~76 mL	
7	Drain							681.7
8	Treatment		38 L					
9	Drain							584.7
10	Treatment			38 L				
11	Drain							28.7
12	Drying							

The result fulfils the requirements: the final conductivity value means that the previous two phases are very effective.

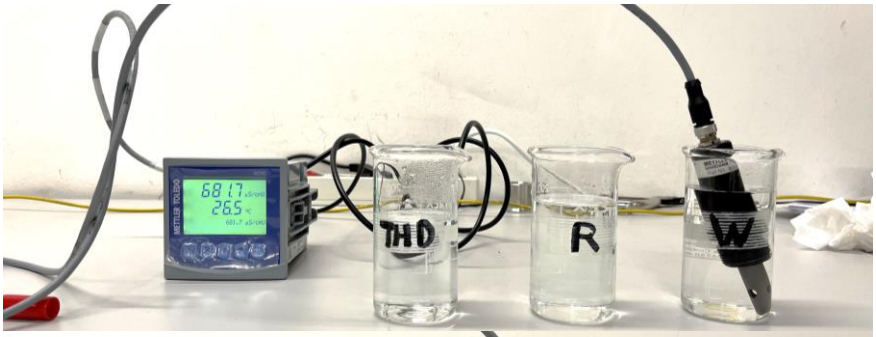
Executed by	A. Marigo & A. Gardano	Date	29-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

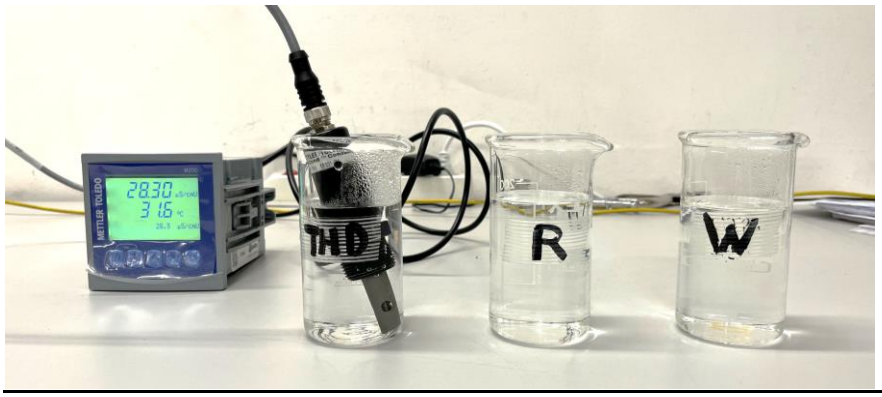
Notes

Pictures showing a full load before the cycle and the deionizer used to obtain Demi water.



Conductivity value of the water obtained after the washing stage, prior to any rinse. It is pretty high, due to the chemical agents used.

Conductivity value of the water obtained after the rinsing stage.



Conductivity value of the water obtained after the disinfection stage. This can be considered as a second rinsing stage, and it is really efficient.

4.9 Air quality tests (6.11)

Test	**Air quality test (6.11)**
Method	Test the complete installation using the method described in ISO 14644-3.
Measuring Uncertainty	N.A.
Acceptance Criteria	The test shall be considered satisfactory if the reading on the photometer is steady and repeatable and does not exceed 0,01 % of the upstream reading.

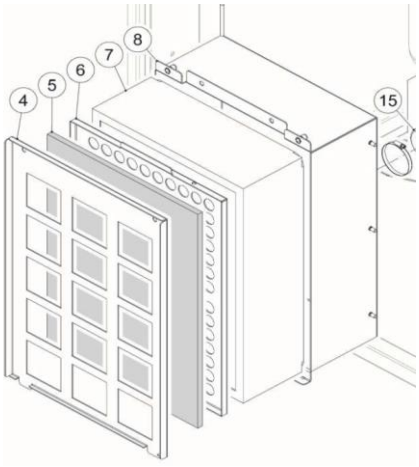
Test Execution

Introduce a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator into the air upstream of the filter. Scan the downstream face of the filter and its housing for leakage using a photometer.

Test Results

Our unit is equipped with an HEPA filter. Specifically, there is an air filter (that filters out 90.8% of particles) and behind that, an HEPA H14 filter (that filters out 99.995% of particles). For this reason, it fulfils the requirements.

This is a drawing of the filter installed on our unit:



No. 5 is the 90.8% air filter, while no. 7 is the HEPA H14 99.995% filter.

Executed by	A. Marigo & A. Gardano	Date	30-Sep-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

None.

4.10 Load dryness test (6.12)

Test	**Load dryness test (6.12)**
Method	This test shall be performed if the operating cycle includes a load drying stage.
Measuring Uncertainty	N.A.
Acceptance Criteria	Report whether or not any residual water was found. If not, the test result shall be considered satisfactory.

Test Execution

Fully load the WD with a test load as specified in the relevant subsequent part of ISO 15883. Carry out a normal operating cycle from a cold start (i.e. the WD shall not have been used within the previous hour). Within 5 min of the end of the operating cycle, place a sheet of colored (e.g. blue or green) crepe paper on a flat surface and place the load on it. When removing the load from the WD, and as the individual load items are placed onto the crepe paper, observe and record any water being discharged. Examine the crepe paper for dampness shown by dark spots on the paper which shall be regarded as evidence of residual water. When the test load includes items with a lumen these items shall be examined for internal retained moisture by blowing through with dry compressed air and aiming the discharge at a mirror. Misting of the mirror or the expulsion of visible drops of moisture shall be regarded as evidence of residual water.

Test Results

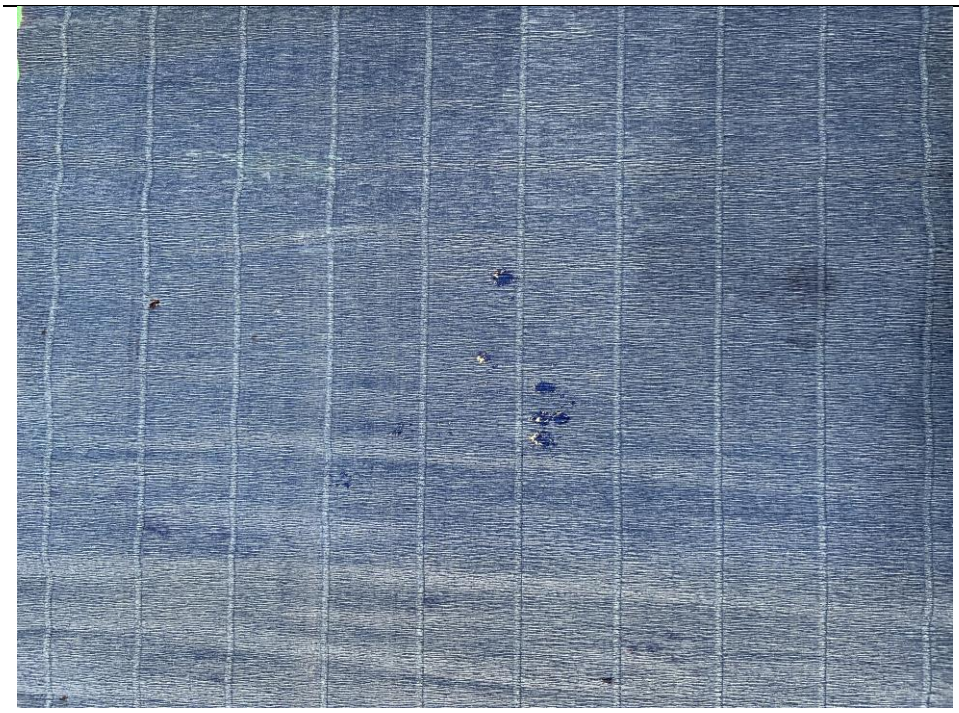
The load dryness was studied following a standard operating cycle. The test load (full load) was made of 15 din baskets, and each one contained 10 surgical scissors and 10 surgical pliers.

The drying stage was 21 minutes long with a temperature of 120°C.

Each din basket was examined visually on top of a sheet of blue crepe paper, shaking each instrument to drop the remaining water. The results show that the drying efficiency is correct for the intended use, but the pliers are harder to dry compared to the scissors.

The light residues of water (shown in the picture below) found on the surface of the paper are acceptable, considering the load. The result fulfils the requirements.

Pictures of the load used in this test.



Picture related to the quantity of water that was found on a din basket.

Executed by	A. Marigo & A. Gardano	Date	30-Sep-22

Test Evaluation

☒ PASS	☐ FAIL	☐ N/A

Notes

None.

4.11 Automatic control test (6.13)

Test	**Automatic control test (6.13)**
Method	This test is designed to demonstrate that the operating cycle correctly functions as shown by the values of the cycle variables, shown and recorded by the instruments fitted to the WD. During this test, the temperature sensors for thermometric testing shall be connected to the chamber. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments, the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.
Measuring Uncertainty	N.A.
Acceptance Criteria	The test result shall be considered satisfactory if the following aspects are assured: a) a visual display indicating “cycle complete” occurs; b) during the whole operational cycle, the values of the cycle variables as indicated by the instruments on the WD or shown on the batch process record are within the limits specified; c) during the disinfection stage: 1. the recorded chamber temperatures are within the range specified; 2. the time for which the disinfection temperature was maintained was not less than that specified; d) the door(s) cannot be opened until the cycle completes; e) the person conducting the test does not detect any anomaly. Repeat the test three times to ensure that the automatic control system consistently produces operating cycles controlled within the limits specified by the manufacturer.

Test Execution
Place the test load in the chamber. The test load shall be appropriate to the specific model of WD and shall be kept within the load carrier. For WDs equipped with multiple cycle capability, select the operating cycle to be tested. Start the cycle. Ensure that a process record is made by the recording instrument fitted to the WD. If the WD does not have a recorder, observe and note the elapsed time, indicated chamber temperatures and pressures at all significant points of the operating cycle (e.g. the beginning and ending of each stage or sub-stage), and the maximum values during the holding time. At the approximate mid-point of the disinfection holding time, take note of the elapsed time and the indicated chamber temperature.
Test Results
The automatic control systems equipped in our unit work appropriately: they can stop the WD functioning at any time if a fault is detected (as shown by the test “Fault indication on sensor failure (6.3.5)“) and they fulfil all the acceptance criteria. The temperature probes equipped in this unit were calibrated as shown in the previous test “Verification of calibration (§6.6.1)”.
Executed by A. Marigo & A. Gardano Date 12-Oct-22
Test Evaluation
☒ **PASS** ☐ **FAIL** ☐ **N/A**
Notes
None.

5. Results Evaluation

The DS1000 G2 washer-disinfector successfully fulfilled all the requirements and for this reason Steelco states that it is compliant with UNI EN ISO 15883 technical standard.

Chapter 5

Bedpan washer BP 100

The BP series represent the simplest devices that Steelco manufactures nowadays, that are used for the reprocessing (in particular the washing and disinfection stages) of specific reusable non critical items such as bedpans, bed urinals and bowls.

Every BP series model works in a similar fashion, in particular during the aforementioned stages, and the main differences apply to the presence/absence of two doors or automatic door/s, to the presence/absence of a drying circuit and a fan, and to the overall dimensions.

The washing stage is carried on using specific types of water nozzles, that make sure that every spot of the chamber, even the corners, is reached by an appropriate quantity of water with an equally appropriate pressure to obtain the best result. There are at least 2 to 3 types of nozzles inside the chamber of any BP device, some of them are fixed while others rotate. During this stage it is possible to use some kind of detergent.

The thermal disinfection stage is performed after the wash and a quick rinse to reduce the chance of residues remaining on the items: it is accomplished by means of a boiler that heats a certain amount of water to produce steam, and as soon as its temperature reaches 100°C the steam is emitted inside the chamber through the water nozzles. In this way the entire hydraulic circuit, the items and the chamber go through a thermal disinfection cycle. As with the DS devices, this stage is controlled by the A_0 index: given that these devices reprocess non-critical

items, the A_0 index value has to be greater or equal to 600.

5.1 BP 100 HE

Until today, the BP 100 HE is the most popular device for the reprocessing of non-critical items, and for reference here is reported its picture as well as the most important information:

Figure 5.1: BP 100 HE 1000 and some of its features

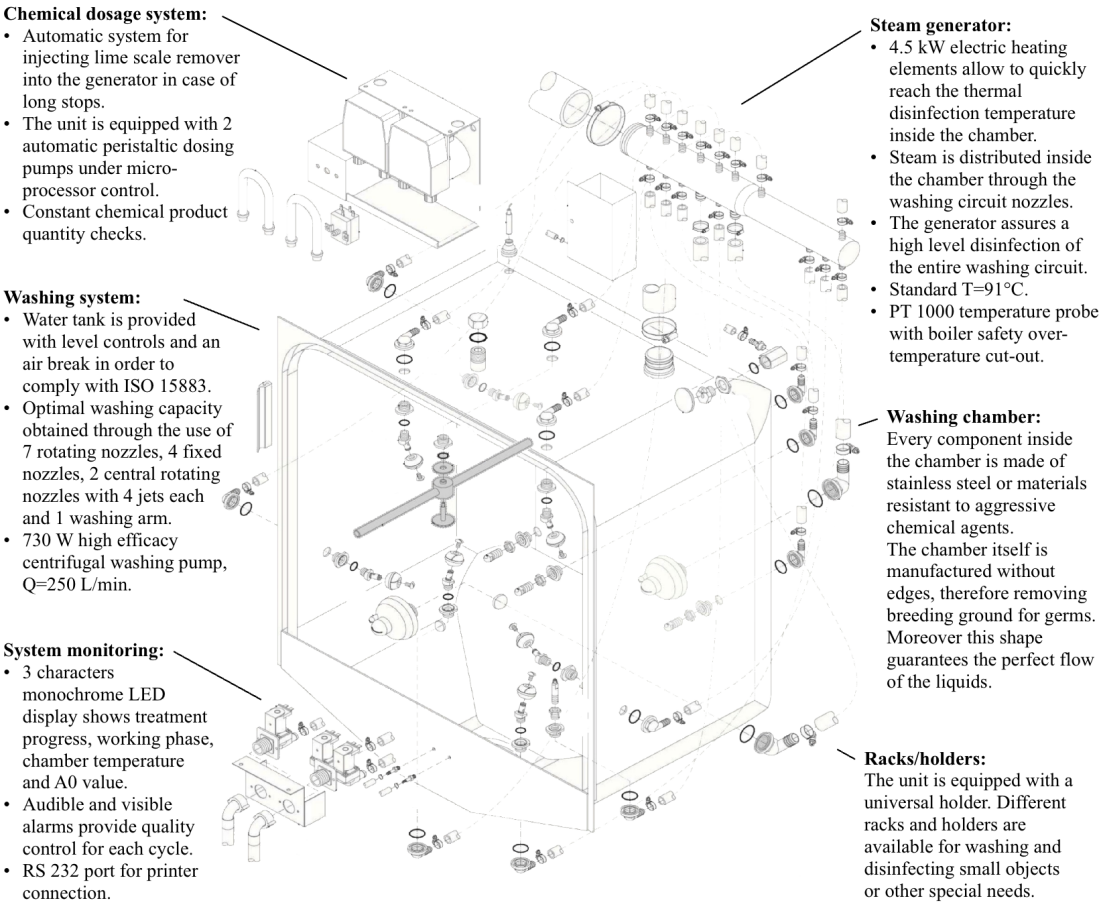


Figure 5.2: BP 100 HE and some of its features

This device is excellent for the reprocessing of non-critical items, but it needs too much water and the cycles duration is pretty extended. For this reason at the very beginning of 2022, Steelco RD team started the development of a new generation of bedpan washers: the BP 100 HP.

This new device promises to reduce water and energy consumption as well as cycles duration, while maintaining the top notch performance in terms of cleaning and disinfection efficacy that made the BP 100 HE stand out among the other devices on the market.

The development of BP 100 HP, hardware and software wise, is one of the main activities that was carried out by myself and other colleagues during this six months stage at Steelco.

5.2 BP 100 HP

At the beginning of 2022, Steelco R&D team started the development of a new generation of bedpan washers, the BP 100 HP, a project that changed almost every aspect of its previous generation, like basic components such as the water tank, functional components such as its washing nozzles, and the cycles implementation and working principles.
Hardware-wise, the following main changes distinguish this device from the previous one:

- a new water tank, that is bigger, constantly monitored by two level switches and directly connected to the chamber and the washing pump;
- a new steam generator system, that is used during the disinfection stage and is protected via software to avoid critical conditions where it could remain half-empty, therefore exposing electrical heating elements;
- distinct washing circuits for each type of nozzle (three main circuits + one more for an additional cooling phase) controlled by solenoid valves;
- redesigned rotating and fixed nozzles that enable to obtain greater water pressure and more accurate sprays;
- new cooling system on the back of the washing chamber that avoids wetting the load after the disinfection stage;
- new ECS electric boards.

I contributed to two of these hardware main changes:

- study of the best place and height to install the two level switches inside the tank, that was strongly correlated with the optimisation of operating cycles via software changes;

- testing of rotating nozzles prototypes aimed at obtaining greater water pressure and overall better performance. The cleaning tests were carried out as specified in ISO 15883-3.

The following document reports an official test performed on three new Steelco rotating nozzles in order to study water pressure changes and to compare them with the older nozzle.

BP 100 HE – Pressure test on three new versions of rotating nozzle

Machine Type	Flusher-disinfector		
Machine Model	BP 100 HE	Serial Number (s/n)	2203E10H3310
Manufacturer	Steelco S.p.A.		
Test	**Pressure test on three new versions of rotating nozzle**		
Test Type	☐ Safety ☒ Performance ☐ Usability/Ergonomy ☐ Other: (specify)		
Standard Reference	N.A.		
Test Location	Steelco S.p.a | Via Balegante 27 – 31039 Riese Pio X (TV) – Italy		
Test Initial Date	27-Jul-2022		
Test Closure Date	27-Jul-2022		
Result of Test	☒ **PASS** ☐ **FAIL** ☐ **N/A**		

Approval

	Name	**Function**	**Date**
Issued by	A. Marigo & A. Gardano	Validation Specialist	27-Jul-2022
Reviewed by	Christian Artuso	Validation Specialist	27-Jul-2022
Approved by	Maurizio Zanatta	R&D Director	10-Nov-2022

Index

1. Scope

Machine Type	Flusher-Disinfector		
Machine Model	BP 100 HE	Serial Number (s/n)	2203E10H3310
Optional Components	N.A.		

1.1 Tested Components/Parts

Component / Part Code	Manufacturer	Batch / s/n	Technical Data	Required Marks & Certificates of Conformity
N.A.	Steelco s.p.a.	N.A.	Ugello rotante economico G2	N.A.
N.A.	Steelco s.p.a.	N.A.	Ugello rotante economico G2 modified version no.1	N.A.
N.A.	Steelco s.p.a.	N.A.	Ugello rotante economico G2 modified version no.2	N.A.

2. Test Conditions

	Required	Measured
Ambient Temperature	N.A.	29°C
Ambient Humidity	N.A.	49 %RH
Pressure	N.A.	N.A.
Voltage	N.A.	400 V

3. Equipment and Instruments for Test

Equipment / Instruments ID	Type of Equipment / Instruments	Calibration Date	Calibration Due Date
S05-029	Temperature/pressure dataloggers (Ebro)	11-Nov-2021	11-Nov-2022

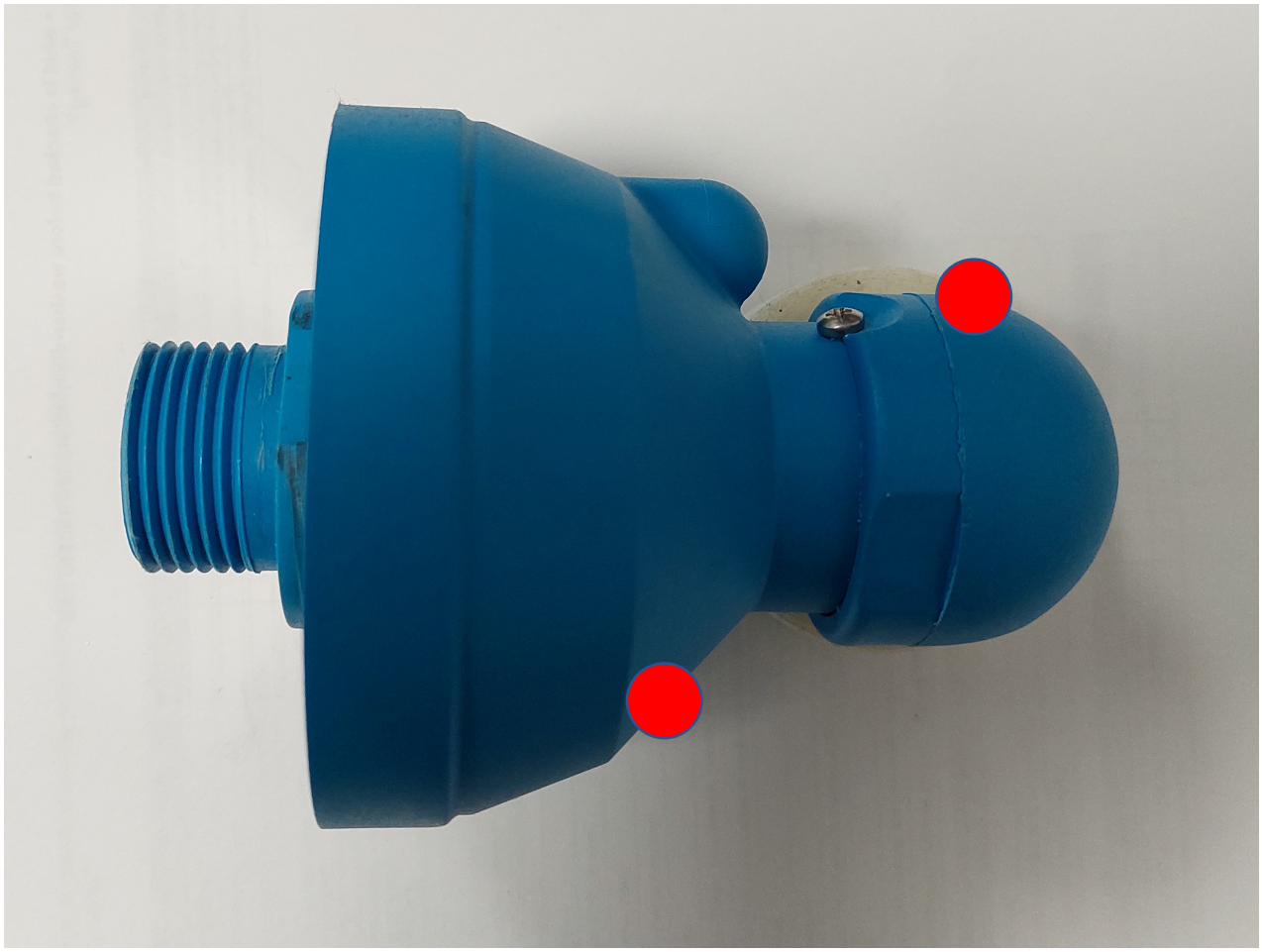
4. Test

4.1 Test No.1

Test	**Pressure test on new rotating nozzle no.1**
Method	Pressure values inside the original rotating nozzle and the first modified version were measured in order to compare them. Moreover, it is a good method to indirectly evaluate the cleaning efficacy.
Measuring Uncertainty	N.A.
Acceptance Criteria	N.A.

Test Execution

First of all the two rotating nozzles were pierced in two different places: one hole on the upper chamber and one on the lower chamber of the nozzle (see figure). That was useful to install two Ebro dataloggers and record pressure values inside of the two chambers.



The values were recorded for each cycle and then were further processed using MATLAB 2021.

We were mainly interested in pressure values coming from the washing phases, since those are truly responsible for an efficient cleaning.

Test Results

Below are reported the most relevant values obtained during the washing phases, on both the upper and the lower chamber of each nozzle. This kind of pressure is constant but lasts for a few seconds only due to the nature of the washing cycles.

Short cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	550	461
2	524	462
3	520	442
4	540	481
Average pressure	534	462

Standard cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	517	462
2	526	459
3	530	479
4	542	479
Average pressure	529	470

Intensive cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	523	475
2	541	465
3	550	467
4	536	487
5	554	474
6	536	450
Average pressure	540	470

Short cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]) :

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	275	95
2	258	96
3	253	96
4	253	94
Average pressure	260	95

Standard cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]) :

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	262	96
2	254	95
3	261	95
4	251	97
Average pressure	257	96

Intensive cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]) :

Washing stages	Current rotating nozzle	New rotating nozzle no.1
1	233	96
2	246	94
3	237	94
4	237	95
5	266	97
6	231	93
Average pressure	242	95

Executed by A. Marigo & A. Gardano Date 27-Jul-2022

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

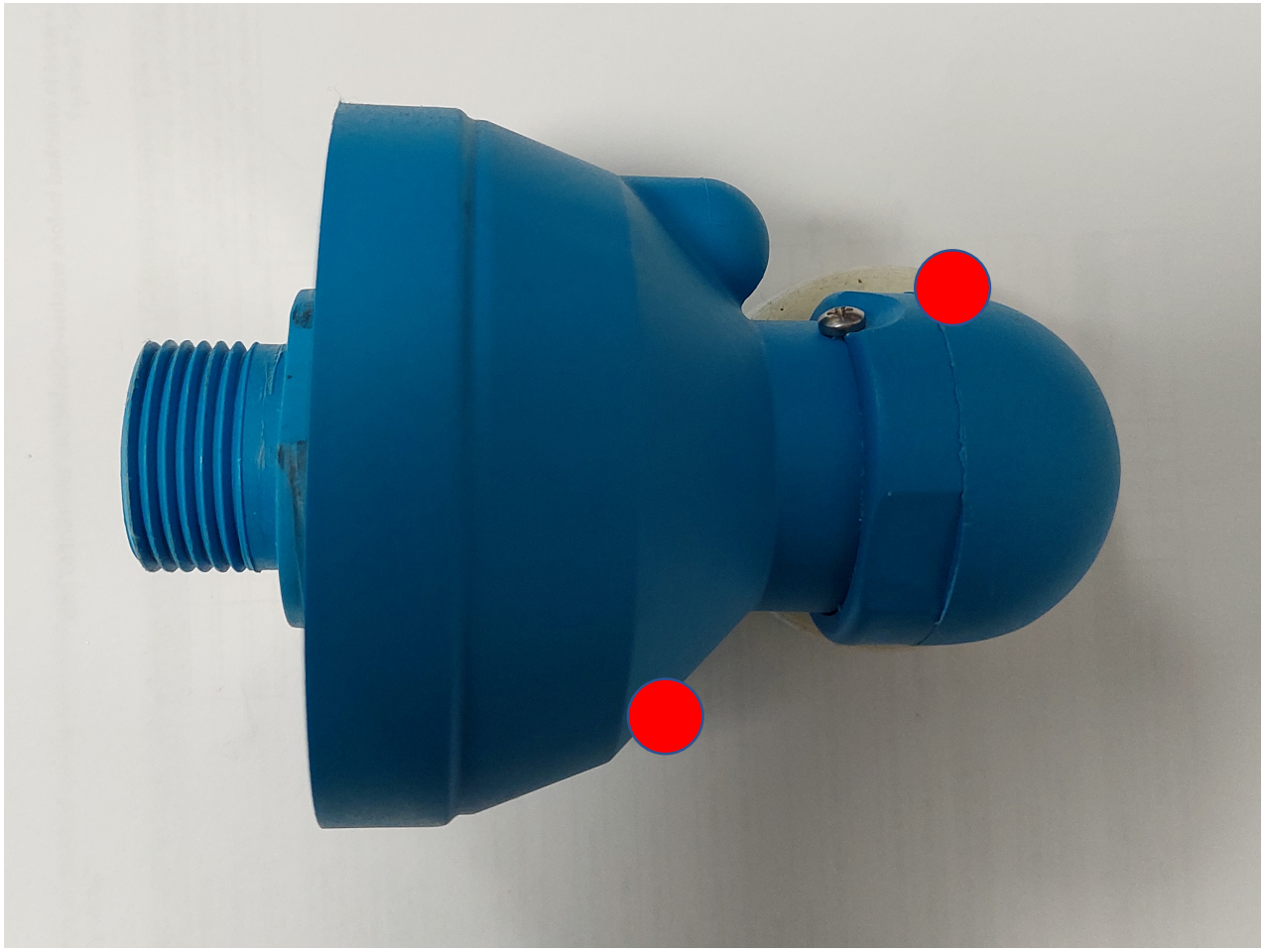
N.A.

4.2 Test No.2

Test	**Pressure test on new rotating nozzle no.2**
Method	Pressure values inside the original rotating nozzle and the second modified version were measured in order to compare them. Moreover, it is a good method to indirectly evaluate the cleaning efficacy.
Measuring Uncertainty	N.A.
Acceptance Criteria	N.A.

Test Execution

First of all the two rotating nozzles were pierced in two different places: one hole on the upper chamber and one on the lower chamber of the nozzle (see figure). That was useful to install two Ebro dataloggers and record pressure values inside of the two nozzles.



The values were recorded for each cycle and then were further processed using MATLAB 2021.

We were mainly interested in pressure values coming from the washing phases, since those are truly responsible for an efficient cleaning.

Test Results

Below are reported the most relevant values obtained during the washing phases, on both the upper and the lower chamber of each nozzle. This kind of pressure is constant but lasts for a few seconds only due to the nature of the washing cycles.

Short cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	550	525
2	524	564
3	520	525
4	540	511
Average pressure	534	531

Standard cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	517	533
2	526	528
3	530	544
4	542	554
Average pressure	529	540

Intensive cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	523	527
2	541	521
3	550	522
4	536	516
5	554	525
6	536	521
Average pressure	540	522

Short cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	275	160
2	258	168
3	253	165
4	253	152
Average pressure	260	161

Standard cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	262	161
2	254	158
3	261	160
4	251	164
Average pressure	257	161

Intensive cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.2
1	233	161
2	246	161
3	237	166
4	237	160
5	266	166
6	231	166
Average pressure	242	163

Executed by A. Marigo & A. Gardano Date 27-Jul-2022

Test Evaluation

☒ **PASS** ☐ **FAIL** ☐ **N/A**

Notes

N.A.

4.3 Test No.3

Test	**Pressure test on new rotating nozzle no.3**
Method	Pressure values inside a new version of rotating nozzle were measured in order to compare them with the previous obtained values.
Measuring Uncertainty	N.A.
Acceptance Criteria	N.A.

Test Execution

First of all the two rotating nozzles (new and current one) were pierced in two different places: one hole on the upper chamber and one on the lower chamber of the nozzle. That was useful to install two Ebro dataloggers and record pressure values inside of the two nozzles.

The values were recorded for each cycle and then were further processed using MATLAB 2021.

We were mainly interested in pressure values coming from the washing phases, since those are truly responsible for an efficient cleaning.

Test Results

Below are reported the most relevant values obtained during the washing phases, on both the upper and the lower chamber of each nozzle. This kind of pressure is constant but lasts for a few seconds only due to the nature of the washing cycles.

Short cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	550	560
2	524	603
3	520	640
4	540	630
Average pressure	534	610

Standard cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	517	639
2	526	650
3	530	608
4	542	538
Average pressure	529	619

Intensive cycle, pressure measured in the **higher** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	523	572
2	541	570
3	550	649
4	536	637
5	554	614
6	536	635
Average pressure	540	613

Short cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	275	216
2	258	204
3	253	201
4	253	227
Average pressure	260	209

Standard cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	262	200
2	254	206
3	261	193
4	251	169
Average pressure	257	194

Intensive cycle, pressure measured in the **lower** part of the rotating nozzle (maximum pressure values [mbar]):

Washing stages	Current rotating nozzle	New rotating nozzle no.3
1	233	202
2	246	167
3	237	166
4	237	181
5	266	200
6	231	202
Average pressure	242	183

Executed by	A. Marigo & A. Gardano	Date	09-09-22

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

N.A.

5. Results Evaluation

The pressure values inside the chambers of the two modified nozzles are lower than the ones inside of the original nozzle. In particular the values recorded on the upper chamber and on the first modified version are really low, and for this reason the washing phase might be ineffective.

Considering the third nozzle, the pressure values are higher than for the previous new model. We recorded higher values than the original nozzle for the higher chamber, but lower values considering the lower chamber.

The following document reports an official test performed on two rotating nozzles, that differ for the dimension of their shafts, that evaluates cleaning performance of the two nozzles. The testing procedure is the exact one specified in ISO 15883-3.

Comparison of cleaning efficacy: standard and new rotating nozzles

Machine Type	Flusher disinfector		
Machine Model	BP 100 HE	Serial Number (s/n)	N.A.
Manufacturer	Steelco S.p.A.		
Test	**Comparison of cleaning efficacy using standard and new rotating nozzles**		
Test Type	☐ Safety ☒ Performance ☐ Usability/Ergonomy ☐ Other: (specify)		
Standard Reference	EN ISO 15883-5		
Test Location	Steelco S.p.a | Via Balegante 27 – 31039 Riese Pio X (TV) – Italy		
Test Initial Date	28/10/2022		
Test Closure Date	28/10/2022		
Result of Test	☒ **PASS** ☐ **FAIL** ☐ **N/A**		

Approval

	Name	Function	Date
Issued by	A. Marigo, A. Gardano, F. Slaviero	Validation Specialist	28-Oct-2022
Reviewed by	Christian Artuso	Validation Specialist	28-Oct-2022
Approved by	Maurizio Zanatta	R&D Director	12-Nov-2022

Index

1. Scope

Machine Type	Flusher disinfector		
Machine Model	BP 100 HE	Serial Number (s/n)	N.A.
Optional Components	N.A.		

1.1 Tested Components/Parts

Component / Part Code	Manufacturer	Batch / s/n	Technical Data	Required Marks & Certificates of Conformity
223554 v.1	Steelco S.p.a.	N.A.	Current rotating nozzle	N.A.
223554 v.2	Steelco S.p.a.	N.A.	Updated rotating nozzle	N.A.

1.2 Other Models Covered by this Report

Model	Difference from the Main Model	Additional Test Performed
HSE	N.A.	N.A.
HAE	N.A.	N.A.

2. Test Conditions

	Required	Measured
Ambient Temperature	20 °C	20°C

3. Equipment and Instruments for Test

Equipment / Instruments ID	Type of Equipment / Instruments	Calibration Date	Calibration Due Date
N.A.	N.A.	N.A.	N.A.

4. Test

4.1 Test No. 1

Test	**Cleaning efficacy test with standard rotating nozzles**
Method	Evaluation of the cleaning efficacy according to EN ISO 15883-5
Measuring Uncertainty	N.A.
Acceptance Criteria	The bedpan shall be visually clean.

Test Execution

The KMNE test soil has been prepared according to the instructions of the EN ISO 15883-5. We soiled a bedpan following the procedure indicated by the technical standard. We started a standard cycle and we stopped it directly after the cleaning step (before the disinfection phase). The cleaning performance has been checked by visual inspection.

Figure 1. Test soil preparation

Figure 2. Soiling procedure

Test Results

In the pictures below it is possible to see results of the cleaning with standard rotating nozzles: there were some residues.

Figure 3. Cleaning results with standard rotating nozzles.

Executed by	A. Marigo, A. Gardano, F. Slaviero	Date	28/10/2022

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

None.

4.2 Test No. 2

Test	**Cleaning efficacy test with new rotating nozzles**
Method	Evaluation of the cleaning efficacy according to EN ISO 15883
Measuring Uncertainty	N.A.
Acceptance Criteria	The bedpan shall be visually clean.

Test Execution

The soiling procedure described in the previous test (4.1) has been repeated after the replacement of standard rotating nozzles with the new ones.

Test Results

In the pictures below it is possible to see results of the cleaning with new rotating nozzles: there were still some residues inside the pocket of the bedpan, which is notoriously the most difficult area to clean, but the cleaning efficacy was improved.

Figure 4. Cleaning results with new rotating nozzles.

Executed by	C. Artuso, A. Gardano, A. Marigo, F. Slaviero	Date	28/10/2022

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

Just for reference, this is the main part of the rotating nozzles that was updated: on the left it's the current shaft while on the right the updated one.

5. Results Evaluation

The installation of the new rotating nozzles improved the cleaning performance of the flusher disinfector.

The hardware changes lead to software changes: they enabled Steelco to create new washing cycles that can reprocess the same non-critical items as before and at the same time avoid excessive water consumption. The older generation (BP 100 HE) washing cycles were similar to each other, and they relied on consecutive filling/emptying of the water tank.
This procedure was performed four to five times during the cycles, and this lead to water consumption of approximately 80 L per cycles and long waiting times during the filling phases (approx. 15 minutes per cycle).

The creation of distinct washing circuits allowed us to divide the washing stage into three sub-stages:

- Activation of solenoid valve no.1 (central rotating nozzle), specific to clean the internal part of the bedpan;
- activation of solenoid valve no.2 (fixed bottom nozzles), specific to clean the interior of the two urine bottles;
- activation of solenoid valve no.3 (rotating nozzles all around the chamber), specific to clean the external parts of both the bedpan and the urine bottles.

The duration of the three sub-stages depends on the selected cycle (short, standard or intensive), and we established that the following values are enough to ensure a good result:

	S.V.1 activation [s]	S.V.2 activation [s]	S.V.3 activation [s]
Short cycle	10	10	10
Standard cycle	20	10	20
Intensive cycle	40	10	40

Table 5.1: Solenoid valves activation time

At this point the quantity of water used per cycle was already half as the one used by the previous BP generation, but we managed to reduce it even more by

introducing several parameters that controlled the functioning of the device. Here is reported a description of each washing cycle:

- **Short cycle:** first of all the water tank is filled with cold+warm water until the so called "medium" level (that corresponds to the higher level switch) is reached, with no extra-fill time (parameter P115=0). If P54=1 the tank is already filled to the medium level at the beginning of any cycle. During the three washing sub-stages the pump is constantly kept turned on and the device cannot execute any refill. The water level inside the tank goes down the so called "minimum" level (that corresponds to the lower level switch) + P3 seconds, and the washing stage ends. The water tank is now completely empty and the washing stage is completed.

- **Standard cycle:** first of all the water tank is filled with cold+warm water until the so called "medium" level (that corresponds to the higher level switch) is reached, plus an extra-fill time of 3 seconds (parameter P116=3). If P54=1 the tank is already filled to the medium level at the beginning of any cycle and the unit fills the tank for P116 seconds only. During the three washing sub-stages the pump is constantly kept turned on and the device refills the tank only during the second sub-stage. The water level inside the tank goes down the so called "minimum" level (that corresponds to the lower level switch) + P3 seconds, and the washing stage ends. The water tank is now completely empty and the washing stage is completed.

- **Intensive cycle:** first of all the water tank is filled with cold+warm water until the so called "medium" level (that corresponds to the higher level switch) is reached plus an extra-fill time of 6 seconds (parameter P117=6). If P54=1 the tank is already filled to the medium level at the beginning of any cycle and the unit fills the tank for P117 seconds only. During the first two washing sub-stages the pump is constantly kept turned on, while the third one requires to turn off the pump for a few seconds in order to refill the tank until minimum + P121 (15 seconds) level is reached. Finally, the water level inside the tank goes down the so called "minimum" level (that corresponds to the lower level switch) + P3 seconds, and the washing stage

ends. The water tank is now completely empty and the washing stage is completed.

An appropriate testing protocol revealed that there could be chemical agent residues on top of the items after each washing cycle, and for this reason we introduced a new simple but effective rinse stage (easily adjustable by means of three parameters), that is carried out just before the disinfection:

- The tank is filled with cold + warm water until the minimum level + P124 (2) seconds is reached;
- activation of solenoid valve no.1 (central rotating nozzle) and solenoid valve no.3 (rotating nozzles all around the chamber) for P125 (3) seconds;
- activation of solenoid valve no.2 (fixed bottom nozzles) for P126 (3) seconds;

Repeated tests on the WD underlined a problem with the steam generator system. At installation this system is empty and when a cycle is launched for the first time it does not have enough time to fill up completely, thus leaving half of the heating elements exposed: this is an issue that can cause the heating elements to overheat.
A simple solution was to implement an automatic short filling cycle that starts as soon as the WD is turned on for the first time or after a few consecutive days, that effectively solves this issue.

These software changes lead to a great improvement in cycle duration and water consumption. The following document is an official test that quantifies water and energy consumption, both for the 5.05 kW and the 3.05 kW steam generator configuration.

BP 100 HP Water and energy consumption test

Machine Type	Washer-disinfector		
Machine Model	BP 100 HE G2	Serial Number (s/n)	11883070
Manufacturer	Steelco S.p.A.		
Test	**Water and energy consumption test**		
Test Type	☐ Safety ☒ Performance ☐ Usability/Ergonomy ☐ Other: (specify)		
Standard Reference	N.A.		
Test Location	Steelco S.p.a | Via Balegante 27 – 31039 Riese Pio X (TV) – Italy		
Test Initial Date	28-Jun-2022		
Test Closure Date	29-Jun-2022		
Result of Test	☒ **PASS** ☐ **FAIL** ☐ **N/A**		

Approval

	Name	**Function**	**Date**
Issued by	A. Marigo & A. Gardano	Validation Specialist	29-Jun-2022
Reviewed by	Christian Artuso	Validation Specialist	29-Jun-2022
Approved by	Maurizio Zanatta	R&D Director	11-Jul-2022

Index

1. Scope

Machine Type	Washer-disinfector		
Machine Model	BP 100 HE G2	Serial Number (s/n)	11883070
Optional Components	N.A.		

2. Test Conditions

	Required	**Measured**
Ambient Temperature	N.A.	30°C
Ambient Humidity	N.A.	47 RH%
Pressure	N.A.	N.A.
Voltage	N.A.	400 V

3. Equipment and Instruments for Test

Equipment / Instruments ID	**Type of Equipment / Instruments**	**Calibration Date**	**Calibration Due Date**
S04-001	Thermo-Hygrometer	05-Jul-2021	05-Jul-2022
S04-002	Thermo-Hygrometer probe	25-Oct-2021	25-Oct-2022
S05-053	Power quality and energy analyzer	21-Sep-2021	22-Sep-2022
S15-001	Stopwatch	16-Nov-2021	16-Nov-2022
S05-029	Temperature/pressure datalogger	11-Nov-2021	11-Nov-2022
F0040710A	Piusi s.p.a. flow meter	N.A.	N.A.

4. Test

4.1 Test No. 1

Test	**Water consumption, total time spent and chamber temperature during Short, Standard and Intensive programs, with the water boiler set to its 5kW configuration.**
Method	Cold and warm water consumption, duration and chamber temperature was measured for each program (short P1, standard P2 and intensive P3) of a BP washer-disinfector. The measurements were acquired 3/4 times for each program, in order to obtain some statistically relevant data and remove outliers. The collected data was then evaluated using the proprietary datalogger software, as well as using MATLAB 2020. The aim of this test is to define some robust quantities that customers can rely on.
Measuring Uncertainty	Humidity: 0.1 RH% Water volume: 0.01 L Temperature: 0.01 °C Time: 1 s
Acceptance Criteria	N.A.

Test Execution

First of all, the water boiler was set to its 5kW energy consumption configuration.

The test was carried out as follows:

- The temperature probe was properly placed inside of the chamber, and the flowmeters were reset to 0 L.
- An operating cycle (e.g. short) was launched. It always consisted of a washing phase, a disinfection phase and a cooling phase.
- The temperature values were automatically retrieved by the probe every 2 seconds, while the duration of each phase and the water volume used were manually collected and put in a spreadsheet.
- The operating cycle stopped and then data could be assessed.

This procedure was carried out 3/4 times for each program so that the measures obtained were statistically relevant.

Test Results

The following results of duration and water volume for each phase for operating cycle P1 were obtained:

	Cycle 1			Cycle 2			Cycle 3		
P1	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	1'26''	5.472	5.154	1'17''	5.698	5.322	1'19''	5.754	5.445
Disinfection	5'57''	5.472	5.154	6'11''	5.698	5.322	5'51''	5.754	5.445
Cooling	1'	8.152	5.154	1'	8.378	5.322	1'	8.434	5.445
Refill		17.021	11.135		17.021	11.291		17.337	11.425
TOT	8'23''	28.156		8'28''	28.312		8'10''	28.762	

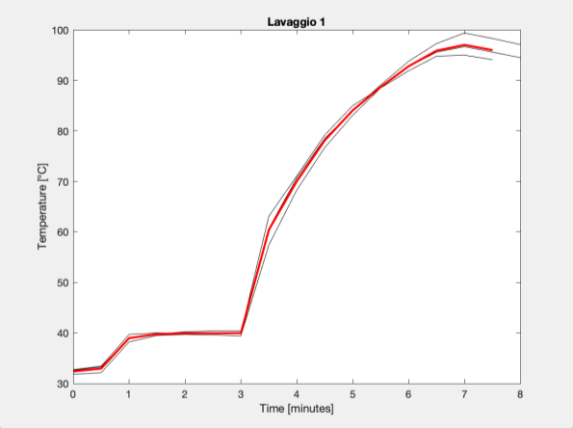
The same was done for the operating cycle P2, and these are the obtained results:

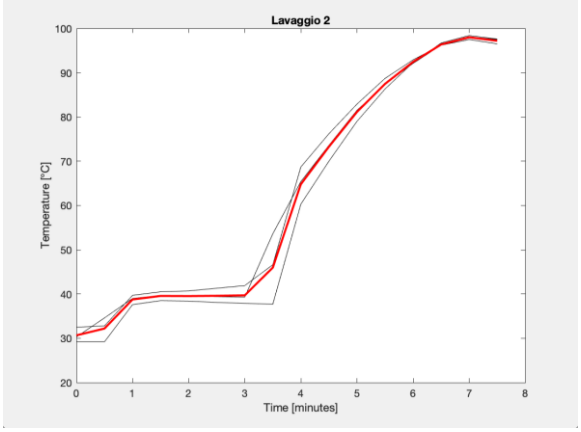
	Cycle 1			Cycle 2			Cycle 3		
P2	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	1'30''	6.375	6.003	1'27''	5.822	5.500	1'27''	6.544	6.103
Disinfection	5'53''	6.375	6.003	5'58''	5.822	5.500	5'56''	6.544	6.103
Cooling	1'	9.055	6.003	1'	8.502	5.500	1'	9.224	6.103
Refill		18.060	12.798		18.037	12.318		17.845	12.061
TOT	8'23''	30.858		8'25''	30.355		8'23''	29.906	

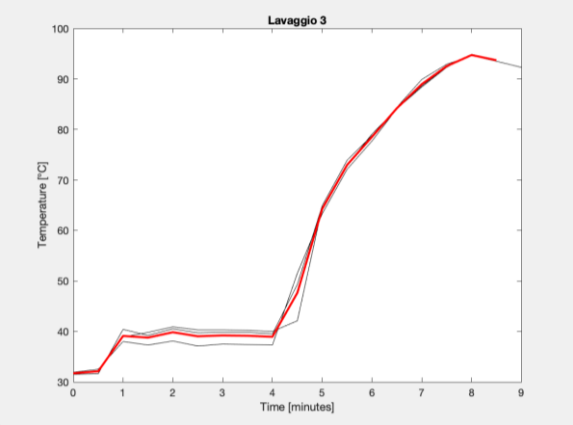
Finally, here are reported the results of the third operating cycle P3:

	Cycle 1			Cycle 2			Cycle 3		
P3	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	2'31''	11.927	11.135	2'31''	11.306	10.700	2'27''	12.107	11.414
Disinfection	6'6''	11.927	11.135	6'1''	11.306	10.700	5'57''	12.107	11.414
Cooling	1'	14.607	11.135	1'	13.986	10.700	1'	14.787	11.414
Refill		22.878	17.105		22.855	16.658		22.887	16.854
TOT	9'37''	39.983		9'32''	39.513		9'24''	39.741	

Moreover, using a temperature probe and MATLAB 2020 the following graphs were obtained:







The black lines represent temperatures during single cycles, while the red ones represent the average temperature for each program.

Executed by	A. Marigo & A. Gardano	Date	28-Jun-2022

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

N.A.

4.2 Test No. 2

Test	**Water consumption, total time spent and chamber temperature during Short, Standard and Intensive programs, with the water boiler set to its 3kW configuration.**
Method	Cold and warm water consumption, duration and chamber temperature was measured for each program (short P1, standard P2 and intensive P3) of a BP washer-disinfector. The measurements were acquired 3/4 times for each program, in order to obtain some statistically relevant data and remove outliers. The collected data was then evaluated using the proprietary datalogger software, as well as using MATLAB 2020. The aim of this test is to define some robust quantities that customers can rely on.
Measuring Uncertainty	Humidity: 0.1 RH% Water volume: 0.01 L Temperature: 0.01 °C Time: 1 s
Acceptance Criteria	N.A.

Test Execution

First of all, the water boiler was set to its 3kW energy consumption configuration.

The test was carried out as follows:

- The temperature probe was properly placed inside of the chamber, and the flowmeters were reset to 0 L.
- An operating cycle (e.g. short) was launched. It always consisted of a washing phase, a disinfection phase and a cooling phase.
- The temperature values were automatically retrieved by the probe every 2 seconds, while the duration of each phase and the water volume used were manually collected and put in a spreadsheet.
- The operating cycle stopped and then data could be assessed.

This procedure was carried out 3/4 times for each program so that the measures obtained were statistically relevant.

Test Results

The following results of duration and water volume for each phase for operating cycle P1 were obtained:

	Cycle 1			Cycle 2			Cycle 3		
P1	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	1'5''	5.472	5.154	1'10''	5.698	5.322	1'2''	5.754	5.445
Disinfection	9'18''	5.472	5.154	9'19''	5.698	5.322	9'10''	5.754	5.445
Cooling	1'	8.152	5.154	1'	8.378	5.322	1'	8.434	5.445
Refill		17.021	11.135		17.021	11.291		17.337	11.425
TOT	11'23''	28.156		11'29''	28.312		11'12''	28.762	

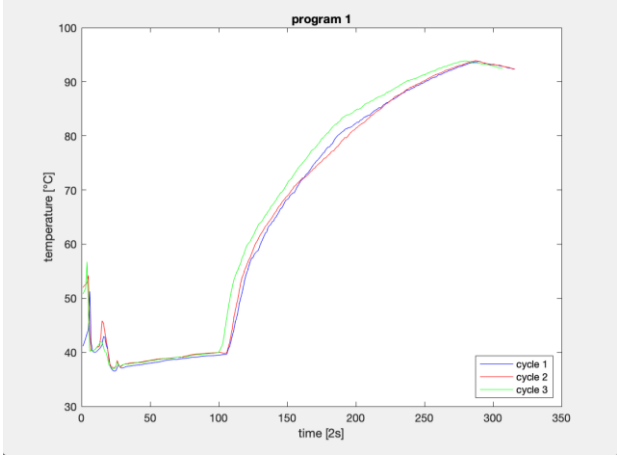
The same was done for the operating cycle P2, and these are the obtained results:

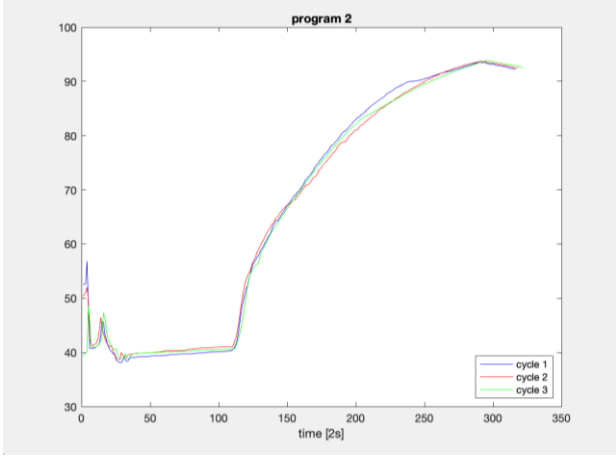
	Cycle 1			Cycle 2			Cycle 3		
P2	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	1'20''	6.375	6.003	1'16''	5.822	5.500	1'16''	6.544	6.103
Disinfection	9'10''	6.375	6.003	9'18''	5.822	5.500	9'26''	6.544	6.103
Cooling	1'	9.055	6.003	1'	8.502	5.500	1'	9.224	6.103
Refill		18.060	12.798		18.037	12.318		17.845	12.061
TOT	11'30''	30.858		11'34''	30.355		11'42''	29.906	

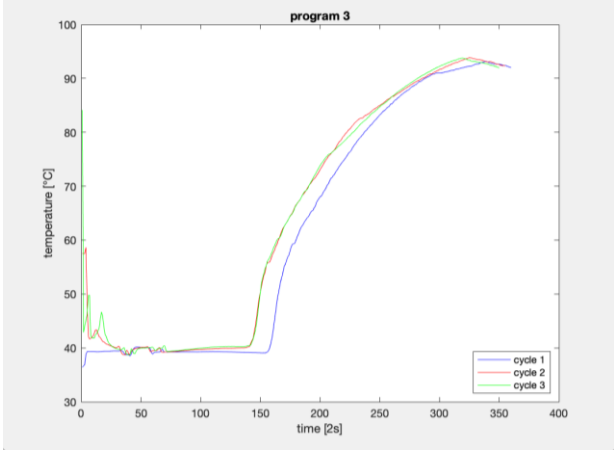
Finally, here are reported the results of the third operating cycle P3:

	Cycle 1			Cycle 2			Cycle 3		
P3	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]	Time	CW [L]	WW [L]
Wash	2'18''	11.927	11.135	2'15''	11.306	10.700	2'16''	12.107	11.414
Disinfection	9'40''	11.927	11.135	9'33''	11.306	10.700	9'19''	12.107	11.414
Cooling	1'	14.607	11.135	1'	13.986	10.700	1'	14.787	11.414
Refill		22.878	17.105		22.855	16.658		22.887	16.854
TOT	12'58''	39.983		12'48''	39.513		12'35''	39.741	

Moreover, using a temperature probe and MATLAB 2020 the following graphs were obtained:







Executed by	A. Marigo & A. Gardano	Date	28-Jun-2022

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

N.A.

4.3 Test No. 3

Test	**Power consumption during P1, P2, and P3 cycles, with the water boiler set to its 3kW and 5kW configurations**
Method	Energy consumption was measured for each program (short P1, standard P2 and intensive P3) of a BP washer-disinfector. The measurements were acquired at the end of each program. The aim of this test is to define some robust quantities that customers can rely on.
Measuring Uncertainty	Energy consumption: 0.001 kWh
Acceptance Criteria	N.A.

Test Execution

The test was carried on as follows:

- The power and energy analyser was set up and properly connected to the washing device.
- An operating cycle (e.g. short) was launched. It always consisted of a washing phase, a disinfection phase and a cooling phase.
- After the cooling phase, measurements about power consumption (kWh) were acquired.

This procedure was repeated once for each program, for both the 3kW and 5kW water boiler configurations, to compare the power consumption.

Test Results

The following measurements of power consumption were collected:

	3kW config. consumption [kWh]	5kW config. consumption [kWh]
Program 1	0.307	0.265
Program 2	0.300	0.272
Program 3	0.317	0.278

The avg 5kW configuration power consumption is 0.272 kWh, 12% less than the avg 3kW configuration power consumption, that is 0.308 kWh.

Executed by	A. Marigo & A. Gardano	Date	28-Jun-2022

Test Evaluation

☒ **PASS**	☐ **FAIL**	☐ **N/A**

Notes

N.A.

5. Results Evaluation

The results are very robust, P1 and P2 programs looks quite similar to each other in terms of water consumption and duration, and very different when compared to P3.

Different cycles of a single program return similar measurements too.

Conclusions

This report aimed at providing an overview on the reprocessing of medical items, in particular the washing and disinfection stages and highlighting the importance of this process in order to avoid potentially fatal consequences.
It started with the basics of medical items, and then shifted towards fundamental knowledge on each reprocessing step as well as the central sterile services department.
Given the risk involved in reusing medical items on different patients, in particular those that are used during surgery, an entire chapter of this thesis reviewed an important technical standard, ISO 15883. These guidelines protect both patients and the healthcare staff from contamination and infections.
Every part of this standard reports the mechanical and process requirements, as well as the testing for conformity that have to be fulfilled in order to state that a reprocessing device is compliant with said standard.
The last two chapters are all about work activities that were carried out with a fellow intern. These involved a deep knowledge of Steelco devices, the use of laboratory instruments such as temperature and pressure probes, power quality and energy analyzer, conducimeter, anemometer, thermohygrometer and so on, but the common thread remained ISO 15883.

The content of this thesis portrays just part of the activities that were carried out during my six months apprenticeship in Steelco, other tasks dealt with some other Steelco devices already on the market, new replacement components in order to make up for the lack of parts, and a product of the competition.
During the first month I was trained and I spent a few days at testing stations,

production lines and at Steelco Academy, and that gave me enough knowledge to plan and execute the first basic tests on new components.
The following months I had the opportunity to work together with professionals from other departments, such as RD, quality, sales and production: this was a key aspect that lead to the writing and refinement of the pre-filled form for the type tests (testing for conformity).

This internship in Steelco showed me the importance of critical and analytical thinking when approaching delicate topics, and the relevance of working as a team to reach a specific target. I had the opportunity to learn from professionals and at the same time I had the chance to take advantage of the skills I learned during the five years at university: this experience marked the end of my academic path and the beginning of my career as an engineer.

Bibliography

[1] Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT, "High-level disinfection, sterilization and antisepsis: Current issues in reprocessing medical and surgical instruments," *Journal of Infection Control*, vol. 41, 2013.

[2] A. Lizioli, G. Privitera, E. Alliata, E.M. Antonietta Banfi, L. Boselli, M.L. Panceri, M.C. Perna, A.D. Porretta, M.G. Santini, V. Carreri, "Prevalence of nosocomial infections in italy: Result from the lombardy survey in 2000," *The Journal of hospital infections*, 2003.

[3] William A. Rutala PhD, MPH, David J. Weber MD, MPH, "Disinfection and sterilization: An overview," *American Journal of Infection Control*, vol. 41, 2013.

[4] David J. Weber MD, MPH, William A. Rutala PhD, MPH,, "Disinfection and sterilization in health care facilities: an overview and current issues," *Elsevier Inc.*, 2016.

[5] Centers for disease control and prevention, "Guideline for disinfection and sterilization in healthcare facilities," 2016.

[6] European Commission, "Reprocessing of medical devices," https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices_en.

[7] Clinical Excellence Commission, "Reprocessing of reusable medical devices," https://www.cec.health.nsw.gov.au/keep-patients-safe/infection-prevention-and-control/Reprocessing-of-Reusable-Medical-Devices.

[8] "Decreto legislativo 81/2008 - testo unico sulla sicurezza," http://www.lavoro.gov.it/NR/rdonlyres/0D78BF49-8227-45BA-854F-064DE686809A/0/ 20080409 Dlgs 81.pdf.

[9] Report from the commission to the European Parliament and the Council, "Report on the issue of the reprocessing of medical devices in the european union, in accordance with article 12a of directive 93/42/eec," Brussels, August 2010.

[10] UNI EN ISO 15883-1, 2006.

[11] UNI EN ISO 15883-2, 2009.

[12] UNI EN ISO 15883-3, 2009.

[13] UNI EN ISO 15883-4, 2009.

[14] UNI EN ISO 15883-5, 2009.

[15] UNI EN ISO 15883-6, 2015.

[16] UNI EN ISO 15883-7, 2016.