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SCUOLA DI INGEGNERIA INDUSTRIALE
E DELL'INFORMAZIONE

EVALUATION OF THE TECHNOLOGICAL IMPACT OF NEW EQUIPMENT AND IMPLEMENTATION OF A PRODUCTIVITY DASHBOARD FOR THE CENTRAL STERILE SERVICES DEPARTMENT AT HUMANITAS RESEARCH HOSPITAL

TESI DI LAUREA MAGISTRALE IN
CLINICAL ENGINEERING
INGEGNERIA CLINICA

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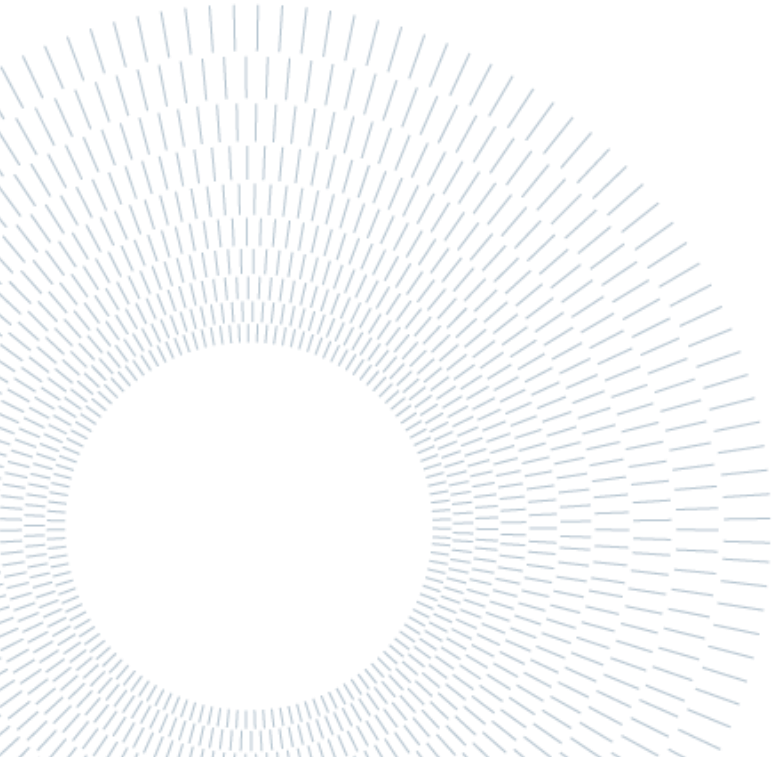
Academic Year: 2022-23



Abstract

Purpose: Effective sterilization processes are critical for preventing hospital-acquired infections and ensuring patient safety during surgical procedures. This thesis investigates the modernization of the Sterile Services Department (SSD) within the Humanitas Research Hospital, focusing on the integration of new technologies, the implementation of a productivity dashboard and the introduction of further traceability measures. The study aims to validate three hypotheses: firstly, that the adoption of new technologies reduces process times; secondly, that a tailored productivity dashboard aids operators in monitoring production; and thirdly, that operating room traceability reduces packaging times.

Methodology: The process analysis was based a database provided by *Sixster*, the traceability software, spanning from February 2022 to July 2023. To mitigate the effects of seasonality and isolate the impact of the new equipment, corresponding months from February to July were compared across the two years. The analysis was conducted using *Splunk* software, wherein various parameters (such as Output Volumes Produced, Number of Partially Processed Kits, Process Durations, Equipment Operability) were computed and juxtaposed between the two years. The productivity dashboard was created utilizing the software Microsoft Power BI; the potential impact of its adoption was assessed via a questionnaire administered to personnel engaged in the process. Following comprehensive training for both operating room and SSD personnel, the implementation of traceability measures within the operating room was examined through timed pilot tests, conducted in the cardiothoracic surgery block under the supervision of the head nurse.

Results: The process analysis reveals that the integration of new equipment led to significant reductions in process times and increase in productivity in equipment-intensive phases, namely washing and sterilization. This is not true for human-dependent phases, especially the packaging which shows to be the real bottleneck of the entire process. The productivity dashboard provided operators with a centralized platform for production monitoring, simplifying their tasks and allowing them to make more informed decisions. Finally, while the potential benefits of operating room traceability on packaging times are recognized, challenges in consistent implementation were observed, warranting further investigation.

Key-words: central sterile services department, efficiency, CSSD, productivity dashboard, hospital.

Abstract in Italiano

Scopo: Un processo di sterilizzazione efficace risulta cruciale per prevenire le infezioni ospedaliere e garantire la sicurezza dei pazienti durante gli interventi chirurgici. Questa tesi indaga sulla modernizzazione della Centrale di Sterilizzazione dell'Istituto Clinico Humanitas, concentrandosi sull'adozione di nuove tecnologie, sull'implementazione di un cruscotto di produttività e sull'introduzione di ulteriori misure di tracciabilità. Lo studio mira a convalidare tre ipotesi: innanzitutto, che l'adozione di nuove tecnologie riduca i tempi di processo; in secondo luogo, che un cruscotto di produttività personalizzato aiuti gli operatori nel monitoraggio della produzione; infine, che la tracciabilità in sala operatoria riduca i tempi di confezionamento.

Metodologia: L'analisi del processo si è basata su un database fornito da *Sixster*, il software di tracciabilità, che copre il periodo da febbraio 2022 a luglio 2023. Al fine di isolare l'impatto delle nuove apparecchiature, sono stati confrontati per i due anni i mesi da febbraio a luglio. Grazie al software *Splunk* è stato possibile calcolare e mettere a confronto vari parametri, quali i volumi prodotti, i kit parzialmente processati, i tempi processi e l'operatività delle attrezzature. La dashboard di produttività è stata creata utilizzando Microsoft Power BI; il potenziale impatto della sua adozione è stato valutato con un questionario somministrato al personale coinvolto. Dopo una formazione completa sia per il personale in sala operatoria che per quello della centrale di sterilizzazione, è stata esaminata l'implementazione delle misure di tracciabilità in sala operatoria attraverso test pilota cronometrati, condotti nel blocco di cardiochirurgia.

Risultati: L'analisi rivela che l'integrazione delle nuove apparecchiature ha portato ad una riduzione dei tempi di processo e ad un aumento di produttività nelle fasi di utilizzo intensivo delle apparecchiature, quali il lavaggio e la sterilizzazione. Differenti sono i risultati per le fasi maggiormente condizionate dall'azione umana, in particolar modo il confezionamento, che si rivela il punto critico dell'intero processo. Il cruscotto di produttività ha fornito agli operatori una piattaforma centralizzata per il monitoraggio della produzione, semplificando le loro attività e consentendo loro di prendere decisioni più informate. Infine, sebbene siano riconosciuti i potenziali benefici della tracciabilità in sala operatoria sui tempi di confezionamento, sono stati osservati ostacoli nell'implementazione sistematica, che richiedono ulteriori indagini.

Parole chiave: centrale di sterilizzazione, efficienza, CSSD, cruscotto di produttività, ospedale.

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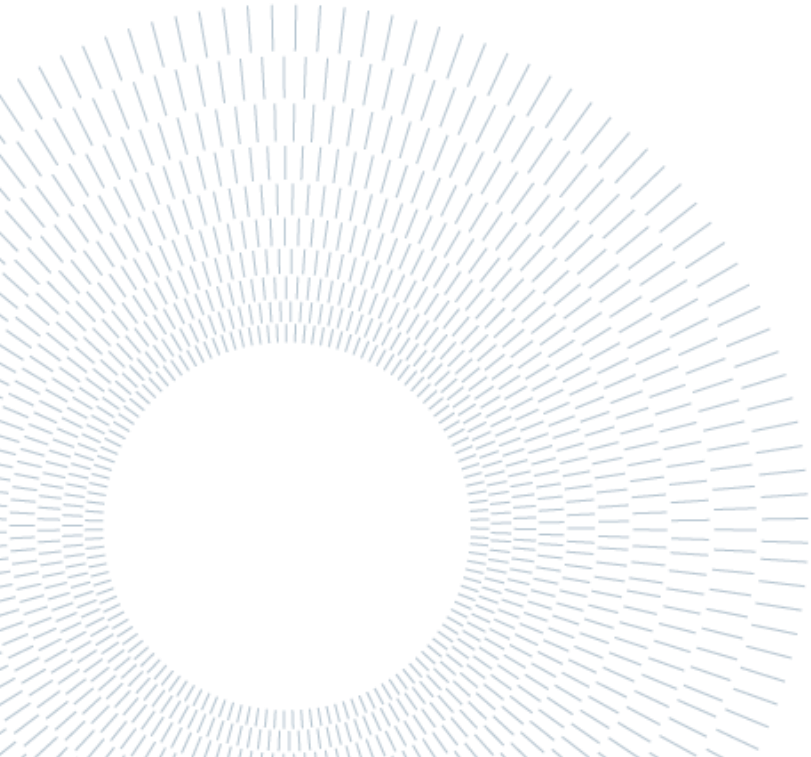


Introduction

Sterilization plays a pivotal role in preventing hospital-acquired infections, ensuring patient safety, and facilitating seamless surgical operations. Despite its critical significance, a comprehensive assessment of the productivity of the sterilization process has been lacking within the sterilization department of the Humanitas Research Hospital.

In this context, the sterilization service is split between two central facilities: CSSD 1 and CSSD 2. The process is meticulously tracked from the acceptance of soiled instruments to the dispatch of sterilized kits to operating blocks. However, a comprehensive system for tracking the hospital-wide flow of instruments remains absent.

In the period spanning 2021 to 2023, a series of activities were undertaken to comprehensively revamp the Sterile Services Department, ensuring compliance with UNI EN ISO 13485. These initiatives encompassed both technical and structural aspects, including the acquisition of new equipment and a refunctionalization of CSSD 1's physical and infrastructure layout. The structural and infrastructural updates were successfully completed by August 2022.

This thesis delves into two critical aspects of the Central Sterilization modernization effort: the integration of new equipment and the establishment of traceability measures. Both endeavours are oriented towards enhancing efficiency, safety, and the overall quality of services provided within the hospital context. Furthermore, a segment of this work is dedicated to the implementation of a productivity dashboard and to the assessment of the impact associated with its deployment.

The study Investigates three key hypotheses:

1. The adoption of new technologies reduces process times: this hypothesis suggests that the integration of new technologies within the sterilization department could enhance efficiency and streamline workflow.

2. The productivity dashboard aids operators in monitoring production, thereby facilitating nursing staff operations: this hypothesis proposes that utilizing a productivity monitoring dashboard can benefit operators and nursing personnel by providing them with a centralized platform to monitor production metrics.
3. Operating room traceability reduces packaging times: this hypothesis proposes that implementing a traceability system in the operating room could streamline the packaging process. Personnel would be able to swiftly identify the specific instruments used and efficiently package them.

This research effort seeks to validate these hypotheses through comprehensive analysis, culminating in insights that contribute to the advancement of sterilization processes and healthcare operational excellence.

1 State of art

1.1. Hospital sterilization

Until the 1940s, medical/surgical supplies were, for the most part, processed and maintained in the departments and patient care areas in which they were to be used. Under this system, there was considerable duplication of effort and equipment, and it was difficult to maintain consistently high standards for sterilization technique and product quality throughout the health care facility. As the number and variety of surgical procedures grew and the types of medical devices, equipment, and supplies proliferated, it became apparent that a centralized processing was needed for efficiency, economy, and patient safety. The **Sterile Processing Department (SPD)**, also known as the Central Sterile Services Department (CSSD), is the area in a hospital where cleaning and sterilization of devices used in medical procedures takes place. The processes an instrument goes through in the CSSD depend on its use, material construction, and other factors. In any case, the result of these processes is sterility. Once sterilized, the instrument can either be sent back to a procedure room to be used again, or into sterile storage until it is needed again for a procedure.

1.1.1. Classification of patient care items

More than 50 years ago, Earle H. Spaulding provided a classification of patient care items [1] to develop a rational approach to disinfection and sterilization. These items can be divided into three categories: noncritical, semi critical and critical items. Noncritical items come in contact only with undamaged skin which behaves as an efficient barrier to most microorganisms; therefore, the sterility of items encountering intact skin is "not critical." Examples of this type of devices are bedpans, blood pressure cuffs, crutches, bed rails, bedside tables, patient furniture, portable equipment (e.g., wheel chairs, infusion pumps, pulse oximeters, and medication carts) and floors. In patient environment, the five most touched noncritical items have been quantitatively shown to be bed rails, bed surface, supply cart, overbed table, and intravenous (IV) pump.

Semi critical items touch intact mucous membranes or injured skin; these medical devices should not show microorganisms, although some bacterial spores may be present. This category includes respiratory therapy and anaesthesia equipment, some endoscopes, laryngoscope blades and handles, esopha geal manometry probes, endocavitary probes, nasopharyngoscopies, prostate biopsy probes, infrared

coagulation device, anorectal manometry catheters, cystoscopes, and diaphragm fitting rings. [2]

Critical items enter tissues or the vascular system; they are at high risk of infection since any microbial contamination could result in disease transmission. Healthcare professionals strive to reduce nosocomial infections and patient contamination risks, hazards that are particularly relevant in the operating rooms.[3] This category, indeed, includes surgical instruments, cardiac and urinary catheters, implants, arthroscopes, laparoscopes, and ultrasound probes used in sterile body cavities.

1.1.2. Reusable medical devices (RMDs)

Critical items can be divided in single-use devices, that must be purchased sterile, or reusable medical devices.[4] Reusable medical devices (RMDs), such as surgical instruments, are used in surgeries, sterilized, and then reused in other surgeries. During every procedure, the surgeon uses one or more RMDs' sets, which contain different numbers and types of instruments due to surgery characteristics and needs. Therefore, they may have different sizes (or volumes). Once used, the sets are sent to the sterilization service; this can happen at fixed times or at different times during the day since each surgery may have a diverse starting and ending time.[5]

1.1.3. Centralized, distributed or outsourced sterilization service

By tradition, sterilization and operating theatre support services (SOTS) have been performed internally as their purposes are strictly connected with the governance of the surgical practices and with patients' health outcomes. These services entail competences and technologies that are often considered not strategic for the hospital core business while having a significant impact on costs; for these reasons, year by year, the outsourcing of SOTS services has been progressively considered as a reasonable approach for health organizations.[6] Outsourcing implies placing the sterilization unit at a larger distance, introducing a longer logistic loop that may result in lower instrument availability and higher cost. However, the effects of outsourcing SOTS services on hospital efficiency and on the productivity of the surgical services have not been deeply investigated.

Hospital networking represents an organizational choice that can provide remarkable opportunities to cope with cost and quality issues: indeed, pooling the available resources should improve efficiency and effectiveness due to synergies and cost savings. Within a hospital network, two major alternatives could be considered:

1. each hospital performs in-house its sterilization activities independently from other hospitals;
2. all hospitals of the network group the resources requested by sterilization services by sharing only one Central Sterilization Service (CSS).

The first configuration is referred to as ''distributed sterilization service'', the second one as ''centralized sterilization service''. The centralization could lead to better resource deployment and significant cost savings through the advantage of economy of scale. Nevertheless, this alternative can be considered only if the different hospitals are placed in the same region as well as the sterilization centre. Moreover, sterilization service centralization raises the risk of sterile item unavailability; for this reason, it requires a high level of management to guarantee the coordination and the satisfaction of all the network actors. The centralization could be total or partial; the latter option implies that some products are processed in the hospital while others are sent to the centralized sterilization service and can be another interesting alternative to study.

1.1.4. Sterilization's steps

A typical sterilization service consists of the steps in Fig.1.

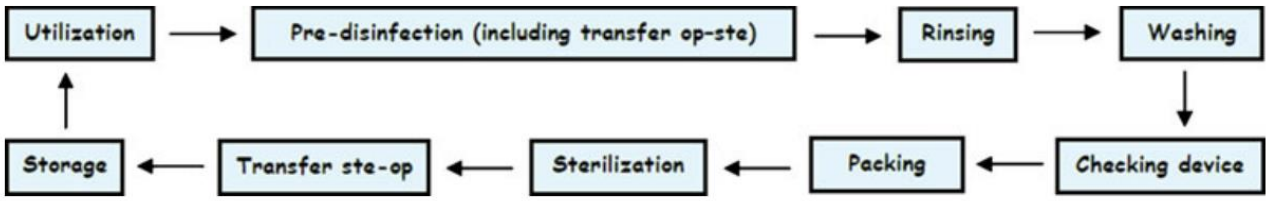


Fig. 1: steps of a typical sterilization service

During the utilization step, the RMDs' sets are opened in the operating room and the instruments utilized for the procedure. The pre-disinfection is a manual step where RMDs are submerged in a chemical substance to reduce the population of micro-organisms on the soiled equipment. The aim of this phase is to protect the staff when handling medical devices and to facilitate washing. The rinsing step can be carried out manually or in washers. Washing seeks at removing stains to obtain a clean device; surgical instruments are typically washed in automatic washers. More than one set can be washed in an automatic washer at the same as long as the machine capacity is not exceeded; sets washed all at once represent a single batch. Depending on the organization between operating rooms and the sterilization service, arrivals of Reusable Medical Devices' sets can be known in advance (for example, the CSSD may accept RMD arrivals only at specific times during the day).

After washing, the device is examined to ensure that no deterioration is expected to affect its security, integrity, or function. Packing represents a barrier to micro-organisms and must be carried out as soon as possible. The arrangement of instruments into bags or containers must allow good penetration of the sterilizing agent and aseptic extraction of each sterile device. [7]

The following step is sterilization. Surgical instruments are typically made of heat stable materials and can be treated with steam in autoclaves; however, since 1950, there

has been a rise in medical devices and instruments constituted by materials (e.g. plastics) that need low-temperature sterilization. ETO gas was the first technique used for heat-sensitive and moisture-sensitive medical devices although in the last decades, several new, low-temperature sterilization systems (eg, HPGP, VHP, and hydrogen peroxide plus ozone) have been developed and put in practice. Steam sterilization is the most effective and has the largest margin of safety, followed by ETO and HPGP and, lastly, VHP. Data demonstrate how sterilization technologies appear to be reliable only if the treatment is preceded by cleaning to reduce or remove the organic and inorganic material as well as microbial load.[2] Major advantages and disadvantages of the different sterilization's techniques are shown in Table 1.

Method	Advantages	Disadvantages
Steam	▪ Nontoxic to patient, staff, environment ▪ Cycle easy to control and monitor ▪ Rapidly microbicidal ▪ Least affected by organic/inorganic soils among sterilization processes listed ▪ Rapid cycle time ▪ Penetrates medical packing, device lumens	▪ Deleterious for heat-sensitive instruments ▪ Microsurgical instruments damaged by repeated exposure ▪ May leave instruments wet, causing them to rust ▪ Potential for burns
HPGP	▪ Safe for the environment and HCP ▪ Leaves no toxic residuals ▪ Cycle time is 28-38 min and no aeration necessary ▪ Used for heat-sensitive and moisture-sensitive items because process temperature <50°C ▪ Simple to operate, install (208-V outlet), and monitor ▪ Compatible with most medical devices ▪ Requires only electrical outlet ▪ Microbicidal efficacy data	▪ Cellulose (paper), linens, and liquids cannot be pro ▪ Endoscope or medical device restrictions based on internal diameter and length (see manufacturer's recommendations) ▪ (eg, single-channel and dual-channel device with stainless steel lumen that is >1.0 mm internal diameter and <150 mm in length) ▪ Requires synthetic packaging (polypropylene wraps and polyolefin pouches) and special container tray ▪ Hydrogen peroxide may be toxic at levels >1 pm TWA ▪ Organic matter reduces microbicidal activity
100% ETO (gas blends phased out in 2015)	▪ Penetrates packaging materials, device lumens ▪ Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure ▪ Simple to operate and monitor ▪ Compatible with most medical materials	▪ Requires aeration time to remove TO residue ▪ ETO is toxic, a probable carcinogen, and flammable ▪ ETO emission regulated by states/countries. Catalytic converters and acid water scrubbers reduce TO emissions. ▪ ETO cartridges should be stored in flammable liquid storage cabinet ▪ Lengthy cycle/aeration time ▪ Organic matter reduces microbicidal activity
VHP	▪ Safe for the environment and HCP ▪ It leaves no toxic residue; no aeration necessary ▪ Cycle time, 28-55 min ▪ Used for heat-sensitive and moisture-sensitive items (metal and nonmetal devices)	▪ Medical devices restrictions based on lumen internal diameter and length--see manufacturer's recommendations, (eg, single-channel device with stainless steel lumen that is >0.7 mm internal diameter and <500 mm in length) ▪ Not used for liquid, linens, powders, or any cellulose materials ▪ Requires synthetic packaging (polypropylene) ▪ Limited materials compatibility data ▪ Limited clinical use data ▪ Limited comparative microbicidal efficacy data

		▪ Organic matter reduces microbicidal activity
Hydrogen peroxide and ozone	▪ Safe for the environment and HCP ▪ Uses dual sterilant, hydrogen peroxide, and ozone ▪ No aeration needed due to no toxic byproducts ▪ Compatible with common medical devices ▪ Cycle time, 46-70 min ▪ FDA cleared for general instruments and multichannel flexible endoscopes (see manufacturer's instructions)	▪ Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer's recommendations) ▪ (eg, single-channel and dual-channel device with stainless steel lumen that is 20.7 mm internal diameter and $500 mm in length) ▪ Limited clinical use data ▪ Limited materials compatibility data ▪ Limited microbicidal efficacy data ▪ Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray ▪ Organic matter reduces microbicidal activity

Table 1: sterilization's techinques.

The transfer op-ste, carried out during the pre-disinfection step, consists in moving soiled MDs from operating rooms to the sterilization service; the transfer ste-op corresponds to transferring sterile MDs from the CSSD to the storage area near the operating rooms.

1.1.5. CSSD staff

As shown in Fig.2, CSSD staff in hospital consists of at least one nurse with coordinating function and highly specialized operators and technicians; clinicians are not required. The personnel wears protective clothing, which includes a scrub uniform covered by a moisture-resistant barrier, shoe covers, rubber or plastic gloves, and a hair covering.

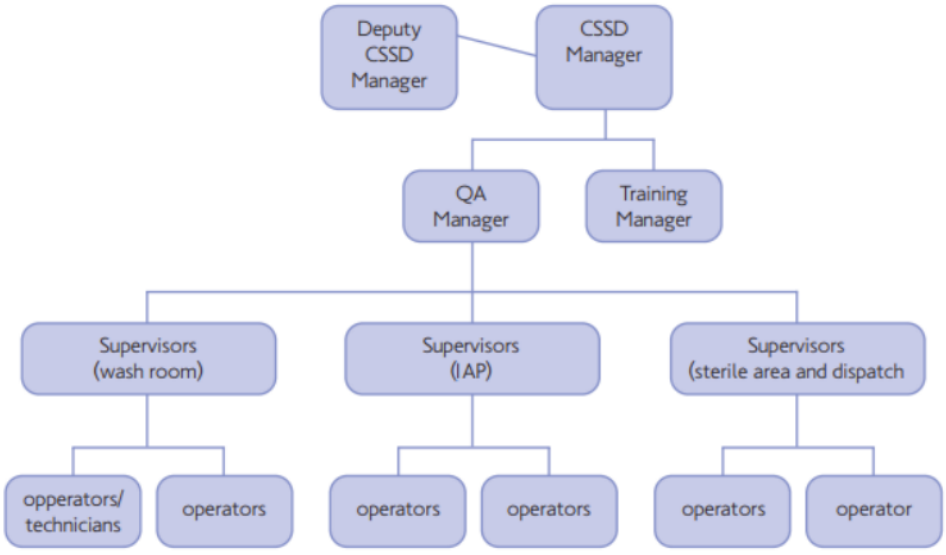


Fig. 2: CSSD staff organizational chart

1.1.6. CSSD plants

CSSD plants must guarantee water quality for cleaning and sterilization and air quality for drying.

In the Central Sterile Services Department, the water used for cleaning, disinfection, and sterilization purposes should have low surface tension and should be free from minerals (i.e., low total dissolved solids, hardness, and conductivity) and microbes. Mineral free water is required to prevent salt build-up on surgical instruments and electrical elements, in order for this equipment to work properly for a long time. Moreover, water should be free from microorganisms to avoid the formation of pyrogens after disinfection and sterilization.

Therefore, it is crucial to identify and test the source of water and the purification system to achieve a high-quality water supply. Regular chemical tests, including chlorine levels between 0.2-0.5 ppm and pH levels around 8, as well as microbiological tests for bacteria such as Pseudomonas and coliforms, are necessary for water quality monitoring. Water can be softened by different methods, namely filtration to remove minerals and salts and reverse osmosis to remove chlorides.

To prepare and preserve sterile materials, it is essential to have air that is purified and free of moisture. The international standard for a Central Sterile Services Department (CSSD), which includes sterile storage, specifies that the temperature should be maintained between 20-22 °C and relative humidity should be between 30-60%. Airflow should always be directed from the sterile zone to the dirty zone to prevent cross-contamination. To ensure that the air in the sterile zone is free from particles, air filters with pore sizes ranging from 0.05 μm to a maximum of ≤10 μm should be used. Additionally, tests for differential air pressure (minimum, 2.5 Pascals), air velocity (minimum, 2,500 cfm), air exchange rate (≥10 per hour), and air microbiology (measuring bacterial and fungal colonies) must be conducted to minimize impurities in the sterile zone.[8]

1.1.7. Layout and room functions

To accomplish the functions of cleaning, disinfection, packaging and sterilization, the CSSD is divided into three major areas with two pass-through barriers (Fig.3):

- the soiled zone, where used supplies and equipment from operating rooms are collected;
- the double-door washer-disinfectors, the first barrier where heat-tolerant items are disinfected;
- the clean zone, where already disinfected surgical instruments are sorted and packed;
- the double-door sterilizer, the second barrier where supplies and equipment are sterilized;

- the sterile zone, where items are transferred until it's time for them to be issued.

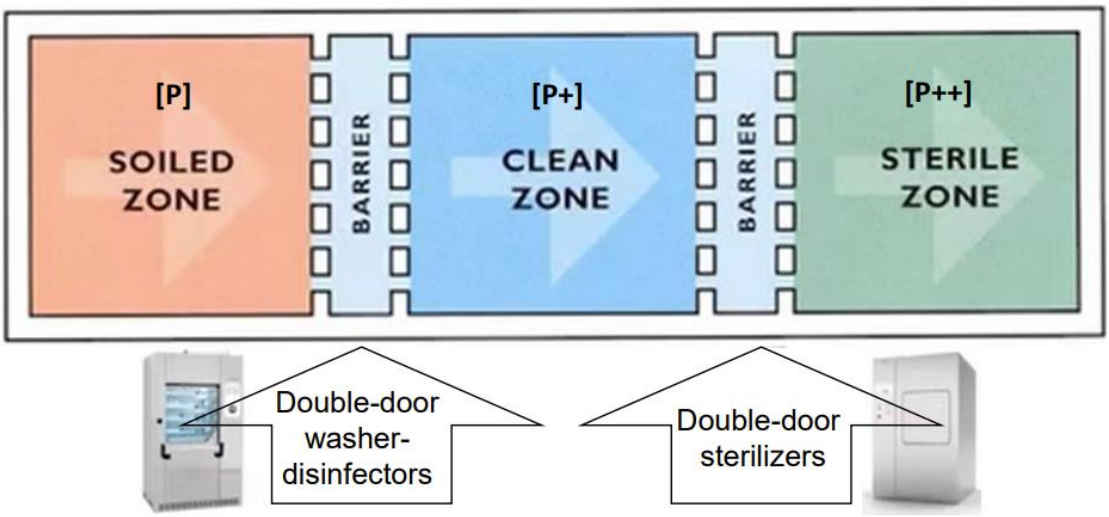


Fig. 3: general CSSD plant.

1.1.8. Equipment

Decontamination sinks

Decontamination sinks are commonly used for manual cleaning of surgical instruments and medical devices. Staff using these sinks must follow a multi-step process, which involves immersing the device in a cleaning solution and using a physical action to wipe, brush, and/or flush the device. This manual cleaning process is typically the first step for reprocessing devices in the SPD. Delicate or complex instruments such as drills, endoscopes, or microsurgical instruments require disassembly and specific manual cleaning steps, as stated in the device manufacturer's instructions for use (IFU).

For manual cleaning in a decontamination sink, a three-bay configuration is recommended. The first sink bay is used for pre-rinsing instruments with cold water to remove any pre-treatment product or blood. The second bay is used for pre-soaking instruments in an enzymatic or neutral detergent solution, followed by manual brushing using instrument cleaning brushes. When cleaning lumened or cannulated medical devices, staff should use the appropriate size brush and bristle type and material, followed by flushing the device. The third sink bay is used for the final treated rinse, which should be of a certain quality to help reduce any risk to patients. The final rinse may include controlled levels of water hardness, chloride, and microorganisms, as per the manufacturer's recommended practices or a facility's standards.

Ultrasonic cleaners

Ultrasonic cleaners are commonly used to provide automated cleaning for delicate surgical instruments that cannot withstand a washer disinfector or have hard-to-reach areas. These machines are especially useful for critical devices such as minimally invasive surgical instruments, laparoscopic devices, robotic surgical attachments, microsurgical, and ophthalmology devices.

The working mechanism is based on three parameters: cavitation, flow/sonic irrigation, and cleaning chemistry. Cavitation forms microscopic air bubbles that can reach small crevices and hard-to-reach areas on a device such as fine serrations or box lock joints, imploding on the instrument's surface. Traditionally, ultrasonic cleaning systems have a frequency of 40kHz. However, higher frequency or even dual frequency systems can provide greater cleaning efficacy for the exposure time.

To ensure effective use of ultrasonic cleaners, it is recommended to remove gross soil from instruments before placing them in the cleaner and to use low foaming cleaning agents. It is also essential to manually rinse the device following ultrasonic cleaning and to change the cleaning solution frequently. Instrument sets should not be stacked, and the unit needs to be emptied, cleaned, rinsed, and dried daily. Additionally, the water in the unit needs to be degassed each time it is changed by running a cycle with just the metal basket (no instruments) inside.

Washer disinfectors

Washer disinfectors are used for automated cleaning of surgical instruments and work by combining impingement, water temperature, and detergent to clean heat-resistant devices. These devices offer several advantages, including consistency, productivity, and control over essential parameters such as temperature and chemistry.

The decontamination phase of processing medical devices is a multi-step process. After manual cleaning, most devices are then cleaned and disinfected through an automated washer disinfector process. Users should only use pre-programmed cycles validated by the equipment's manufacturer, and custom cycles should be re-validated before use. Washer disinfector cycles usually consist of pre-wash, washing with specific cleaning agents under controlled conditions, rinsing one or several times depending on the cleaning chemistry used and thermal rinse to provide disinfection.

Modern washer disinfectors have features that improve efficiency and safety, such as independent process monitoring, documentation and traceability, HEPA filtration, and water and energy usage efficiency.

Hospital cart washers

Hospital cart washers are machines used in SPDs to automate the cleaning process and disinfect surgical instrument case carts, containers, utensils, and other reusable non-

critical items at a low to intermediate level. Some cart washers have an instrument cycle and are validated to wash and disinfect specific surgical instruments. It is recommended to test the instrument cycle program of the washer at least weekly, preferably daily, if available.

Cart washers utilize different cleaning phases such as washing, rinsing, thermal rinse, and drying to provide low to intermediate-level thermal disinfection. They can use low or high impingement with chemical solutions to loosen soils from the surfaces of these items. [9]

Steam sterilizer

Steam sterilizers, also known as autoclaves, are crucial in the decontamination and sterilization process carried out by sterile processing departments (SPD) in healthcare facilities.

The basic principle of steam sterilization is to expose each item to direct steam contact at the required temperature and pressure for the specified time, with four parameters: steam, pressure, temperature, and time. Dry saturated steam and entrained water with a dryness fraction of at least 97% is ideal for sterilization, with pressure used to achieve high temperatures necessary to quickly kill microorganisms. The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F), with recognized minimum exposure periods of 30 minutes at 121°C (250°F) in a gravity displacement sterilizer or 4 minutes at 132°C (270°F) in a prevacuum sterilizer for wrapped healthcare supplies.

The two basic types of steam sterilizers (autoclaves) are the gravity displacement autoclave and the high-speed prevacuum sterilizer. In the former, steam is admitted at the top or the sides of the sterilizing chamber and, because the steam is lighter than air, forces air out the bottom of the chamber through the drain vent. For gravity displacement sterilizers the penetration time into porous items is prolonged because of incomplete air elimination. The high-speed prevacuum sterilizers are fitted with a vacuum pump (or ejector) to ensure air removal from the sterilizing chamber and load before the steam is admitted. The advantage of using a vacuum pump is that there is nearly instantaneous steam penetration even into porous loads.

Steam sterilizers usually are monitored using a printout by measuring temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biological indicator containing spores of Geobacillus stearothermophilus (formerly Bacillus stearothermophilus). Positive spore test results are a relatively rare event and can be attributed to operator error, inadequate steam delivery, or equipment malfunction.[10]

Hydrogen Peroxide Gas Plasma sterilizer

Hydrogen peroxide gas plasma is an effective method for sterilizing materials and devices that cannot withstand high temperatures and humidity, such as certain plastics, electrical devices, and corrosion-susceptible metal alloys.

Gas plasma has been referred to as the fourth state of matter and it is generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. The proposed mechanism of action consists in the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. The type of seed gas used and the depth of the vacuum are two important variables that can determine the effectiveness of the process.

The technology involves evacuating the sterilization chamber and injecting and vaporizing the hydrogen peroxide solution. The hydrogen peroxide vapor diffuses through the chamber (50 minutes), exposes all surfaces of the load to the sterilant, and initiates the inactivation of microorganisms. An electrical field created by a radio frequency is applied to the chamber to create a gas plasma. Microbicidal free radicals (e.g., hydroxyl and hydroperoxyl) are generated in the plasma. The by-products of the cycle (e.g., water vapor, oxygen) are nontoxic and eliminate the need for aeration. Thus, the sterilized materials can be handled safely, either for immediate use or storage. The process operates in the range of 37-44°C and has a cycle time of 75 minutes. If any moisture is present on the objects, the vacuum will not be achieved and the cycle aborts.

The sterilizer efficacy is improved by using two cycles a hydrogen peroxide diffusion stage and a plasma stage per sterilization cycle. [11]

1.2. Humanitas Clinical Institute

Humanitas is a highly specialised hospital, besides a research centre and a university teaching site.

The polyclinic, which is accredited by the National Health Service, includes specialised centres for the treatment of cancer, cardiovascular, neurological and orthopaedic diseases. In addition, the Institute is equipped with an Eye Centre, a Fertility Centre and a highly specialised EAS Emergency Room. Acknowledged by the Ministry as a Scientific Institute for Research and Treatment (Istituto di Ricovero e Cura a Carattere Scientifico, or IRCCS), it is a world reference point for research into diseases linked to the immune system, from tumours to rheumatoid arthritis.

The Humanitas Clinical Institute is the main of a group of 9 hospitals and 13 diagnostic centers (Humanitas Medical Care) on the national territory in Milan, Bergamo,

Castellanza, Arese, Turin, and Catania. It is considered one of the most technologically advanced hospitals in Europe. Among the most cutting-edge technologies available to patients, there are the latest-generation linear accelerators for radiotherapy for tumours treatment, robots in the operating theatre for increasingly less invasive surgery, latest-generation lasers in Ophthalmology, systems (such as Dose Watch) to reduce radiation in Radiology, and 3 CT scans in the operating theatres used during Neurosurgery.

1.2.1. History

The origins of Humanitas date back to the second half of the 1980s when the meeting between Professor Nicola Dioguardi and Pier Carlo Romagnoli with Gianfelice Rocca and a group of entrepreneurs gave rise to the idea of creating "a modern, well-organised, efficient hospital, with the doctor-patient duo at the centre of everything". After some years, the construction of the hospital was completed and on 4th March 1996 Humanitas opened its doors and welcomed its first patient. Another important milestone was the agreement with the National Health Service (i.e., Servizio Sanitario Nazionale or SSN) for hospitalization services in 1997. In 2000, Humanitas became the teaching center of the University of Milan for the degree course in Nursing, later followed by Medicine and Biotechnology; in 2002, first among the Italian hospitals, it obtained the accreditation of excellence from Joint Commission International, one of the world's leading hospital quality certification bodies, and became a case study for the master's in Business Administration at Harvard University. In 2005, Humanitas was recognized by the Ministry of Health as a Scientific Institute for Research, Hospitalization and Healthcare (IRCCS). A few years later, the constant growth of the Impact Factor score placed the hospital among the top Italian IRCCS for scientific production.

Humanitas University, a university dedicated to medical sciences, was founded in 2014. At that time, it included three degree courses: single-cycle international master's degree courses in Medicine and Surgery, three-year degree course in Nursing Sciences and three-year degree course in Physiotherapy. In 2019 in collaboration with the Milan Polytechnic, the MEDTEC School opened: it consists in a degree course that enhances medical skills with technological engineering approaches.

In 2020, following the health emergency caused by the SARS Covid-19 pandemic, the Emergency Hospital 19 was built. It is an autonomous facility dedicated to the treatment of infectious diseases, with its own emergency room, diagnostics, intensive and sub-intensive care departments, two operating theatres and twenty-five hospitalization rooms.

Facilities and activities

The hospital has expanded its activities through the construction of new buildings. Building 2 is the main building and houses high-intensity clinical departments, including general surgery operating wards, day-hospital operating wards, cardiac surgery, minimally invasive interventional cardiology, intensive care units for general and heart surgery, the coronary unit, diagnostic imaging services such as radiology, nuclear medicine, and ultrasound, day-hospital wards for oncology, multidisciplinary wards, multi-specialty clinics, endoscopy, accident and emergency (A&E), and radiotherapy.

The SSN, Ophthalmic Center, Fertility Center, Women's Center (mammography and breast ultrasounds), and Blood Collection Center are located in external buildings 4 and 5.

Cascina Perseghetto Center (CCP, Building 8) is a recently built facility that houses a convention hall, the Ortho Center day-hospital operating ward for orthopedics, and four rehabilitation wards. The new University Campus houses didactic activities and research laboratories, including the Simulation Center, which promotes scientific research and technological development.

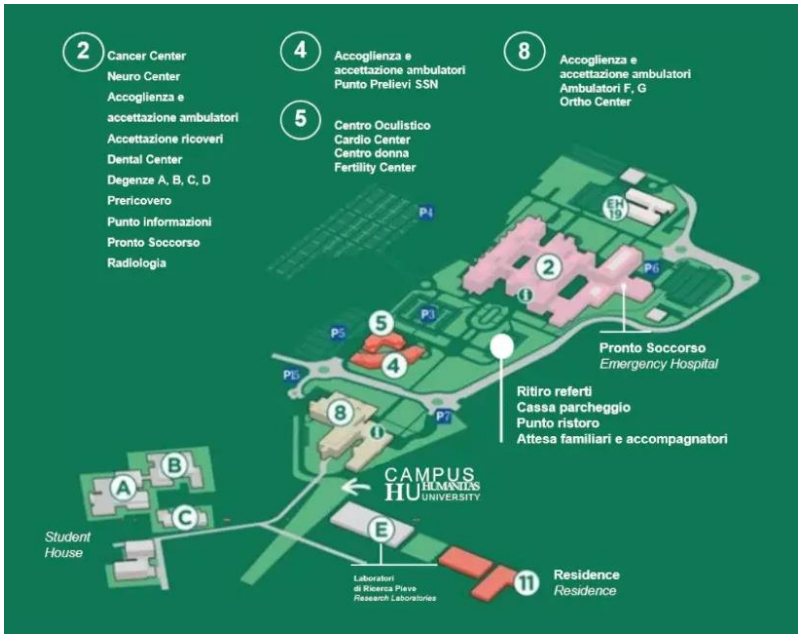


Fig. 4: Humanitas hospital complex.

The hospital complex (Fig.4) spans over 90,000 m², with 75,000 m² dedicated to clinical activity, 6,000 m² to scientific activity, 4,000 m² for teaching, and 5,000 m² for patient and family reception facilities. The hospital has 747 beds, including 73 for medical, surgical, and oncological day-hospital, 31 for intensive care, and 154 for cardio-pulmonary, orthopedic, and neuromotor rehabilitation. The hospital also has 42 operating theatres and over 200 medical clinics.

Humanitas is known for being one of the most technologically advanced hospitals in Europe, with a focus on technological innovation as a central aspect of its corporate strategy. The hospital utilizes high-tech radiotherapy devices, robotic surgery systems, innovative lasers for ophthalmological surgery, and an inventory of CTs and angiographs. To fully leverage the potential of this equipment, the hospital has established a Clinical Engineering Service (Servizio di Ingegneria Clinica, or SIC) that plays a strategic role in ensuring the effective and efficient management of the hospital's technology. The SIC is responsible for selecting appropriate technologies in terms of cost and quality of performance, ensuring the safe use of devices for patients and operators, monitoring service quality, and optimizing costs.

In the last years, the Clinical Engineering Service has acquired the management of the surgical instrumentation in the entirety of its flow, from the purchase to the maintenance and disposal, in the context of a project of renovation of the Central Sterile Services Department.

1.3. Humanitas CSSD

1.3.1. Regulatory framework

The concept of Quality in Healthcare was introduced in Italy with Legislative Decree 502 of 30 December 1992 "reorganisation of the discipline in health matters" and reinforced with the introduction of the Presidential Decree of 14/01/1997 and the subsequent Legislative Decree 229, the 2010 Ispesl guideline on sterilisation activities as collective protection from, the new European Medical Device Regulation 2017/745, and the 2017 Gelli decree on the criminal liability of the practicing healthcare profession.

The sterilization process in hospital settings is defined as a "special" process. It represents one of the most important methods for the prevention and control of hospital infections. A public or private hospital is obliged to comply with the legislative framework by complying with and applying national and international standards and pertinent guidelines (Fig.5) in order to safeguard and protect the well-being of healthcare personnel, patients and community.

In the context of hospital sterilization, the application of ISO 13485 is crucial to ensure that sterilization processes are reliable, safe, and effective. ISO 13485:2016 outlines the prerequisites for a quality management system, where an entity must demonstrate its capacity to consistently deliver medical devices and associated services that meet the expectations of customers and relevant regulatory standards. These entities may be engaged in various stages of the product life cycle, encompassing design and development, manufacturing, warehousing, distribution, installation, servicing of medical devices, and the design, development, or provision of related activities (e.g.,

technical support). ISO 13485:2016 is also applicable to suppliers or external entities offering products and services related to quality management systems for these organizations. [12]

The stipulations of ISO 13485:2016 are relevant to organizations of all sizes and types, unless explicitly stated otherwise. Whenever requirements are specified in the context of medical devices, they equally pertain to any associated services provided by the organization.

The adoption of ISO 13485 requires a series of measures, including:

- Accurate documentation: Hospitals must develop documented procedures for sterilization, including detailed instructions for instrument preparation, sterilization cycles, monitoring, and record-keeping.
- Process monitoring: Hospitals must establish systems for monitoring sterilization processes, including sterilization control tests, biological tests, and monitoring of sterilization cycles.
- Staff training: Personnel involved in sterilization processes must receive adequate training and demonstrate competence in using equipment and following correct sterilization procedures.
- Verification and validation: Hospitals must regularly perform verifications and validations of sterilization processes to ensure they conform to standards and produce consistent results.
- Risk management: ISO 13485 requires a comprehensive assessment of risks associated with sterilization processes and the implementation of measures to mitigate them.

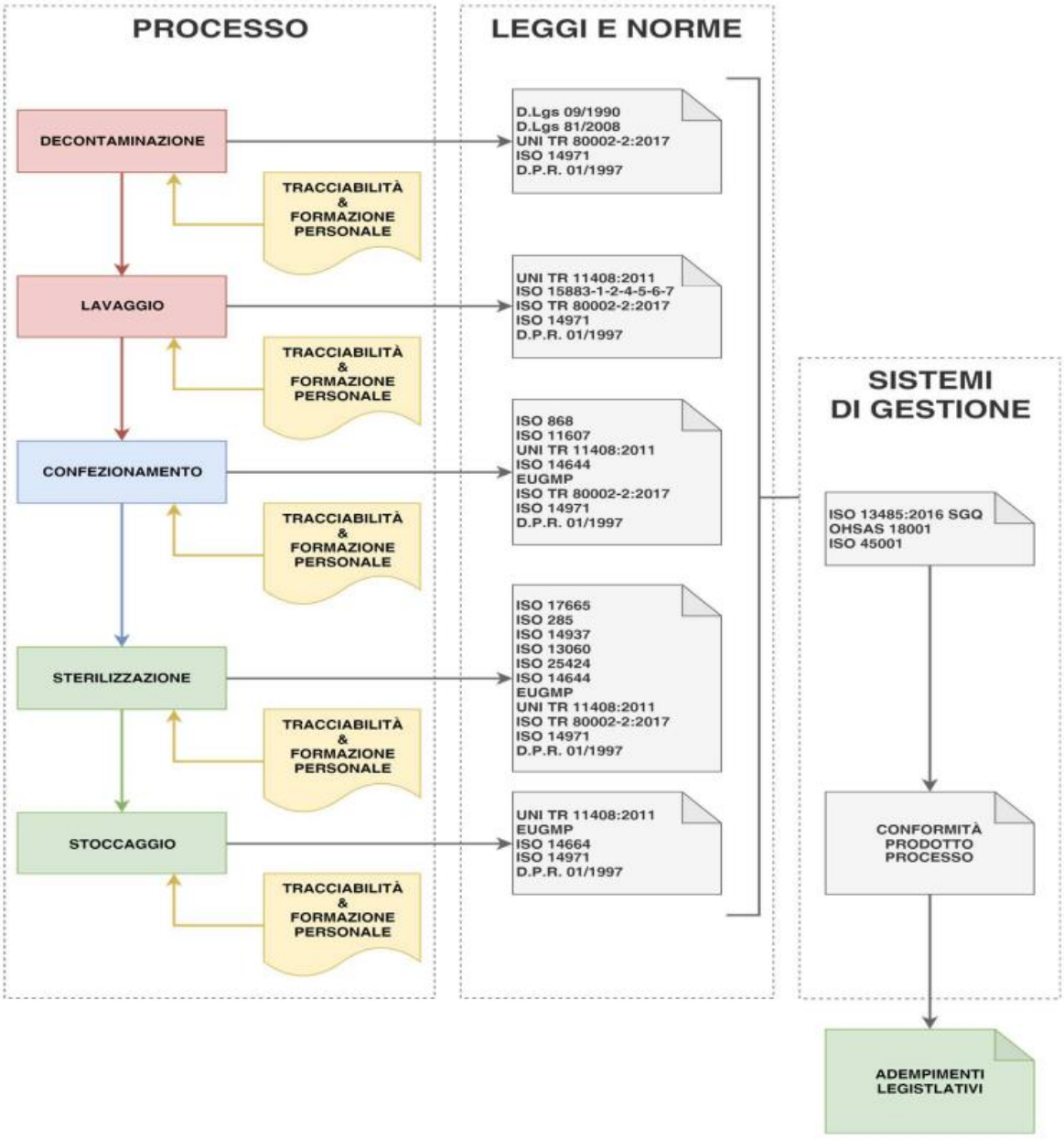


Fig. 5: norms of reference for each step of the sterilization process in hospital

1.3.2. Buildings mapping and operatory wards

The surgical activity at Humanitas Clinical Institute is carried out in two different buildings: Building 2 and Building 8. The two Central Sterilisation Units are both in Building 2 (Fig.6). The first unit, CSSD1, is on ground floor, in a central position, close to operatory ward E (BOE) and directly connected with two dedicated lifts to the operatory wards A and D (BOA and BOD). The second unit, CSSD2, is located as well on the ground floor, in a prefabricated building connected to Building 2 via two corridors, one of which is the same as the entrance to CSSD1. The access to the outside is provided by two dedicated entrances, one on the dirty side and one on the sterile side, which allow logistics towards the operatory ward G (BOG).

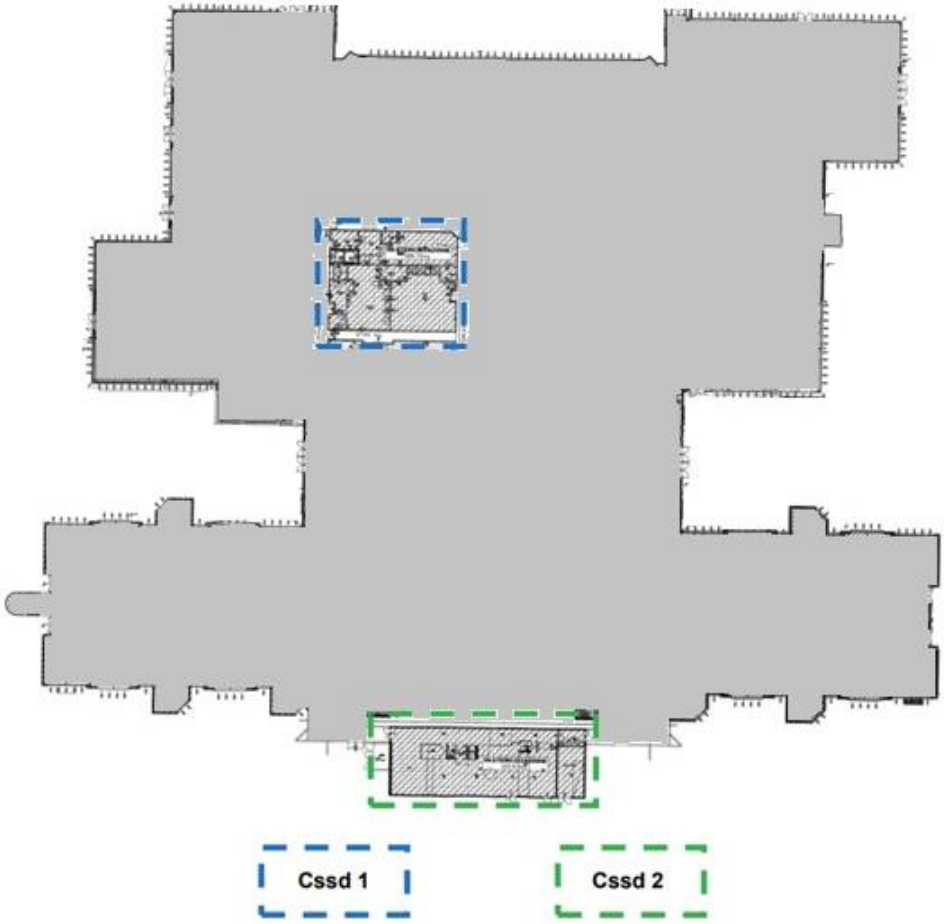


Fig. 6: CSSD 1 and CSSD 2 locations inside Building 2

All the Operating Units (Table 2) in Building 2, which account for most of the Institute, are managed by CSSD1. BOE's orthopaedic material and surgical instrumentation from BOG, instead, are taken and managed by CSSD2.

Building	Floor	Operating ward	Specialty	N° operating rooms	Time
2	2	BOA	Neurosurgery, urology, thoracic surgery	6	07-20
2	2	BOD	General surgery, traumatology, emergency	6	07-20
2	0	BOE	Orthopedics, ophthalmology, gynecology	5	07-20
2	1	BOF	General surgery/bariatric, plastic, senology, otolaryngology	5	07-20
2	2	PMA	General surgery	2	07-20
2	2	BOC	Cardiac surgery, vascular surgery	2	07-20
2	2	BOB	Haemodynamics, electrophysiology	4	07-20
2	0	ANGIO	Interventional radiology	1	08-19

Table 2: operating wards organization (specialties, number of operating rooms and time)

1.3.3. Equipment

Starting from the soiled area towards the sterile zone, the CSSD 1 is equipped with the devices in Fig.7:

- Three AMSCO 7053 HP washer disinfectors from Steris;
- One benchtop US 80 ultrasonic cleaning system from SteelCo;
- One ID 300 instrument Drying Cabinet from SteelCo;
- One Vision 1300 cart and utensil Washer Disinfector from Steris;
- Six electrified worktables for packing AISI 304 from Bawer Spa;
- Two MINIRO' H-LAN TOUCH heat sealers;
- Three AMSCO 600 Medium Steam Sterilizers;
- One V-PRO maX 2 Low Temperature Sterilizer.

a) 

b) 

c) 

d) 

e) 

f) 

g) 

Fig. 7: CSSD 1's equipment: a) AMSCO 7053 HP washer disinfectors; b) US 80 ultrasonic cleaning system; c) ID 300 instrument Drying Cabinet; d) Vision 1300 cart and utensil Washer Disinfector; e) MINIRO' H-LAN TOUCH heat sealers; f) AMSCO 600 Medium Steam Sterilizers; g) V-PRO maX 2 Low Temperature Sterilizer

Starting from the soiled area towards the sterile zone, the CSSD 2 is equipped with the devices in Fig.8:

- Three DS 1000 2S washer disinfectors from SteelCo;
- One LC 20/2 containers washer disinfector;
- One LC 80/3 cart washer disinfector;
- One Heratherm OMS 180 instrument Drying Cabinet from Heraeus Instruments GMBH;
- One MINIRO' H-LAN TOUCH heat sealers;
- Three VS 8/2 E Steam Sterilizers;
- One STERRAD 100 NX Sterilizer.

a) 

b) 

c) 

Fig. 8: CSSD 2's equipment: a) DS 1000 2S washer disinfector; b) LC 20/2 containers washer disinfector; c) LC 80/3 cart washer disinfector; d) Heratherm OMS 180 instrument Drying Cabinet; e) MINIRO' H-LAN TOUCH heat sealers; f) VS 8/2 E Steam Sterilizer; g) STERRAD 100 NX Sterilizer

1.3.4. Staff

The two sterilisation units are controlled by the same coordination team consisting of one head nurse and three nurses who alternate during the day. The presence of at least one coordinator is guaranteed from 7 a.m. until 9 p.m., while during the night shift there isn't a coordination figure.

CSSD 1 is opened 24 hours a day from Monday to Friday and on Saturday mornings. The organisation includes three main shifts, morning, evening, night. The maximum concentration of staff is guaranteed between 1 p.m. and 9 p.m. All shifts last between 7 and 8 hours, apart from the night shift which consists of 10 hours of work, from 9 p.m. to 7 a.m. of the following morning.

CSSD 2 is opened from 7 a.m. to 9 p.m. during weekdays. The organisation includes three shifts (opening, intermediate, evening) and the maximum concentration of staff occurs from 2 p.m. to 6 p.m.

1.3.5. Traceability

In the two CSSDs, the traceability system currently in use is Sixster. The basic logic of the system provides a series of checkpoints that each instrument or kit of must pass before continuing its journey through the central sterilisation of sterilisation.

The main operational steps are:

- ACCEPTANCE: it consists in the identification of incoming soiled instruments. In this phase only kits are accepted since they are 'physically' identified by a label with its unique barcode. Everything identified with a barcode label is considered a Kit, starting from a single instrument up to complex sets consisting of more than 100 instruments.
- WASHING: in this step, sets are assigned to a specific washing trolley, which in turn is associated with an instrument washer. In this way, it is possible to trace at any time the position and process stage in which the kit is located.
- PACKAGING: all the material is packed according to the specifications defined in the inventory. In this phase, also bagged items are registered with a generic name where only the operating block to which they belong is specified.
- STERILISATION: kit and bagged material are assigned to the destination autoclave for execution of the sterilisation process; subsequently, upon successful completion of the process, the sterilisation certificate is printed.
- SHIPMENT: delivery notes are automatically printed with the indication of the sterilisation lot. This step is never performed in CSSD 1 while is sometimes done in CSSD 2.

1.3.6. Process' steps

Transfer op-ste

In all the operating wards, immediately after the surgery, used materials are placed in a storage box called "proteo" with the grids containing the instruments inside; the instruments are decontaminated with a spray of Aniosyme Prime. Unused instrumentation is left in its container/sterilisation kit. The operation is carried out by the nursing staff "instrumentalist" that can take up to 45 minutes if several specialist kits are used (e.g. multi-speciality VLS). The proteo and the containers with the unused instruments are placed in an open trolley with a sheet attached for each operation where the following data: operating ward, date, preparation time, room, name of instrumentalist.

Once the trolley has been placed in the dirty aisle, Integral Service personnel are called to transport it to the agreed sterilisation station. In order to reach BOA and BOC, Integral Service staff use a dedicated lift that starts in the dirty area of the central sterilisation facility and arrives directly in the dirty aisle on floor 2 next to the operating

wards. The soiled materials are moved in a closed trolley and transferred to the CSSD1. In the same corridor, there is a shelving unit where the personnel of the operating ward B (BOB) store the dirty materials that has to be collected.

For BOD and PMA ("Procreazione Medicalmente Assistita", medically assisted procreation), the route involves crossing a corridor that is not dedicated but is open to the public, located between BOA/BOC dirty hallway and BOD.

BOE is next to CSSD1. It can be accessed through the unrestrained hallway passage and the dedicated dirt corridor where the materials ready for collection are placed in open trolleys. The sets are transferred to a closed cupboard to be shipped to CSSD1.

The route to the BOF involves passing through the unrestrained corridor to a dedicated lift which arrives in the dirt aisle of the block on floor 1. Here, the materials are prepared in open trolleys which are transferred into closed trolleys for subsequent handling.

BOG is located in Bulding 8 on floor -1; it is staffed by Integral Service personnel dedicated to the collection and decontamination of RMD and warehouse management. Logistics is entrusted to Integral Service and is managed through a van equipped with a tail lift. After use, the materials are placed in open trolleys in the dirt corridor next to the operating theatres. The devices are transferred into a closed trolley which is transported outside by a dedicated lift. There are two dedicated dirty/clean aisles with dedicated lifts to manage the flows correctly.

Washing

The surgical instruments from BOA, BOB, BOC, BOD, BOE (except the orthopaedics ones, which flow into CSSD 2) BOF, PMA, inpatient, outpatient and intensive care are reconditioned in CSSD 1; CSSD 2 is dedicated to BOG instrumentation. Used instrumentation is shipped to the two CSSD through carts (Fig.9) by Integral Service operators.

Fig. 9: cart with soiled materials shipped from the operating wards to CSSD.

The activity in the washing area is managed by two CSSD operators. One takes care of the acceptance phase of the incoming kits on Sixster; these come from the operating wards with a paper form (Fig.10), placed on top of the metal container and filled in by the instrumentalists. This paper shows the operating ward, the operating room number, the CdC ("Centro di Costo", cost center), the time when the instruments are ready to be collected, and the signature of the instrumentalist.

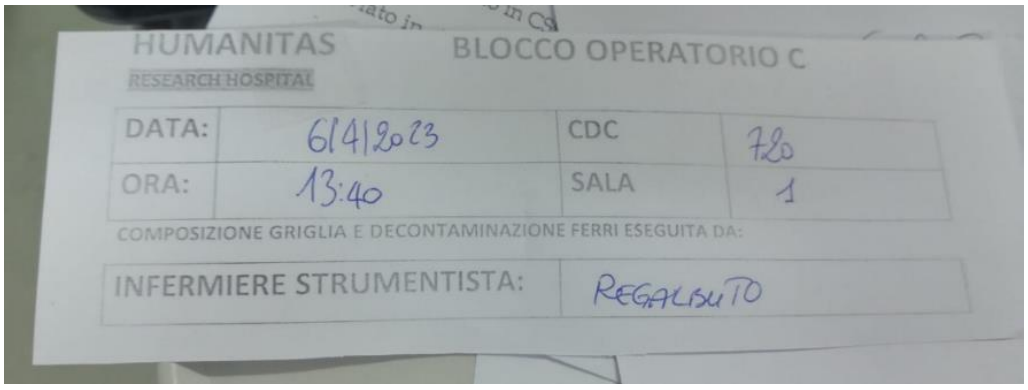
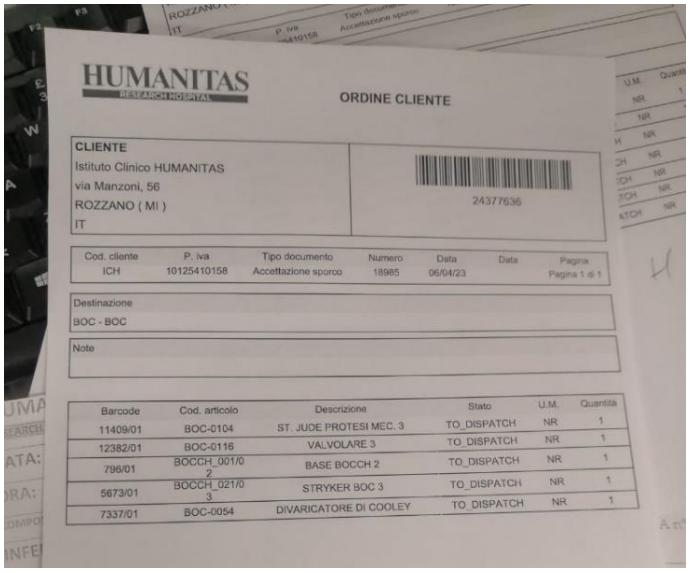


Fig. 10: paper form that comes with the soiled kit from the operating room to the CSSD; it contains the information regarding the date and hour of usage, the operating ward and room, the cost center and the instrumentalist nurse

The operator prints the Sixster acceptance form (Fig.11) for each set of kits dropped off in the CSSD.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Destinazione
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Note
Barcode	Cod. articolo	Descrizione	Stato	U.M.	Quantità
11409/01	BOC-0104	ST. JUDE PROTESI MEC. 3	TO_DISPATCH	NR	1
12382/01	BOC-0116	VALVOLARE 3	TO_DISPATCH	NR	1
796/01	BOCCH_001/02	BASE BOCCH 2	TO_DISPATCH	NR	1
5673/01	BOCCH_021/03	STRYKER BOC 3	TO_DISPATCH	NR	1
7337/01	BOC-0054	DIVARICATORE DI COOLEY	TO_DISPATCH	NR	1

Fig. 11: acceptance form of the soiled kits dropped off in the CSSD

The other operator removes the grids with the instruments that have to be reprocessed from the tanks called "proteo", dividing the instruments that can be thermodisinfected from those that can only be only manually washed. The manual pre-washing phase (Fig. 12) concerns only some devices such as the tips of the laparoscopic forceps and clot clamps, which are pre-treated with the steamer/brass brush.

Fig. 12: manual pre-washing phase for specific surgical instrumentation

The grids with the instruments are placed on the washer cart, identified with coloured “cavalieri” with a marked number on them (Fig.13). The colour identifies the operating ward while the number is the one of the specific OR. Urgent kits are identified with a red rider is added; these sets are usually accompanied by the urgent request form.

a) b)

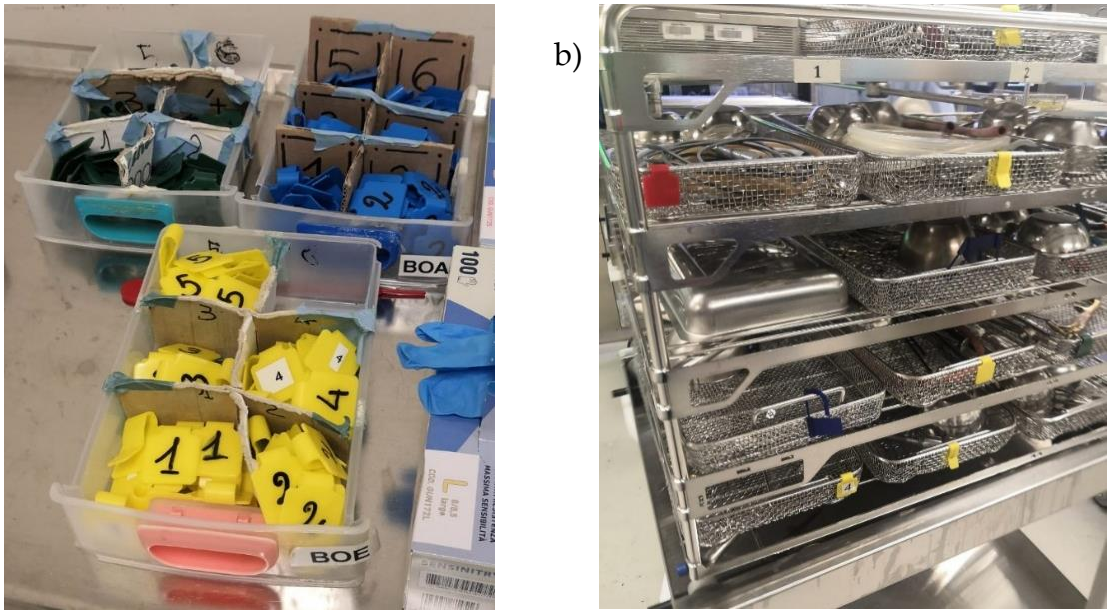


Fig. 13: a) coloured "cavalieri" for sets identification: the colour identifies the operating ward while the number the operating room; b) grids identified with coloured "cavalieri" placed on the cart, ready to be washed

An association is made via Sixster between the loaded kits and the instrument washer cart. The washer is started with the associated material (Fig.14); the characteristics of the washing cycle depends on the specific equipment.

Fig. 14: loading of the washer disinfectors at the beginning of the washing phase

Usually, there are different pre-programmed washing cycles (standard, rapid, intensive etc.) that are chosen according to the needs; some parameters are fixed

while other can be changed. The standard cycle is reported in Fig.15.The detergents drained during the cycle are:

- Prolystica Ultra Concentrated Enzyme Cleaner
- Alkaline cleaner Prolystica ultra concentrated
- Neutral cleaner Prolystica ultra concentrated

Standard Cycle

Nr	Phase name	Water					Chemical			Temperature	Time	
		Cold water	Demi water	V2 Rec. water	TANK 2 STATUS	V1 Demi water	Dos. 1	Dos. 2	Dos. 3		LS	HS
1	Drain											
2	Prewashing	38 lt									120"	
3	Drain											
4	Washing			38 lt	Full		3 ‰			60 °C	120"	
5	Drain											
6	Neutralisation			38 lt	Full			2 ‰		55 °C	60"	
7	Drain											
8	Rinse			38 lt	Empty					60 °C	60"	
9	Drain											
10	Th.disinfection					38 lt			0.5 ‰	91 °C	60"	
11	Drain (SPECIAL)											
12	Drying									140 °C	60"	1200"

Ao value = 600

Fig. 15: washing cycle example

Instruments that cannot be thermodisinfected (motors, cameras, battery holders etc.) are treated manually with the chemical Sekusept Plus, rinsed, pre-dried with compressed air and finally placed inside the dryer shown in Fig.16.

Fig. 16: instrument Drying Cabinet to dry instruments that cannot be thermodisinfected

Packing

The urgent request form is taken to the packaging area (Fig.17).

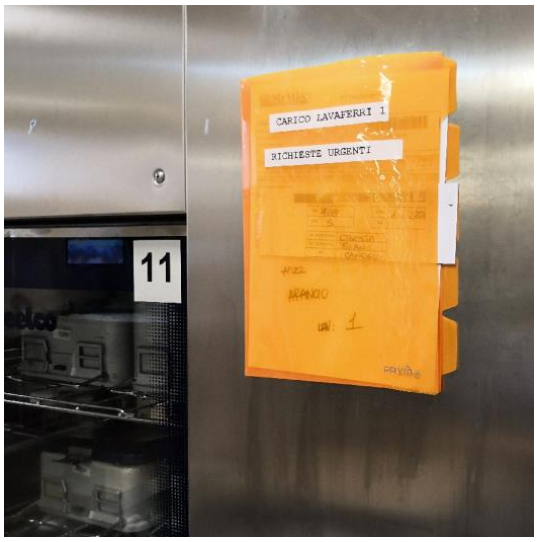


Fig. 17: urgent request form moved from the soiled zone to the clean area

Once the washing cycle has ended, the washers are opened on the clean side and the instruments taken to be repacked (Fig.18).

Fig. 18: end of the washing cycle (clean side of the CSSD)

Faulty instrumentation is brought to clinical engineering, and once it has been repaired or replaced, it is returned to the CSSD. The instrumentation to be repaired comes with a paper summary form and tracked by the nurses on Sixster.

During the reassembly phase, the CSSD operator places the instruments on the bench (Fig.19), repositions the instruments inside the container grid and performs an overall check of the content using the check list on Sixster. The most delicate instruments are protected with special tip protectors or placed inside packaging bags.

Fig. 19: packing workstation

If any instruments are missing from the check list, the following steps are taken:

- it is checked whether the instrument is present in the previous days' inventories, for which there is a dedicated tank;
- if the instrument is not present in the stock tank, the operating block is notified to make sure that it has not been left in the operating room and ask whether the set can be used without that piece;
- if the piece is not available from the instruments stock in the CSSD, the absence is marked by an adhesive labels placed on the outside of the container;
- The sterilisation nurses make the purchase request.
- Once the checklist is entirely verified, three traceability labels are printed:
- two labels are placed on the outside of the kit;
- one label is used to create the steriliser load sheet.

Suitable packaging seals are applied to each container or packaging is carried out by means of Non-Tissue Fabric (N.T.) shown in Fig.20. The assured sterility period for containers and packs is 30 days; sets that are more likely to expire, are packed with a special double layer Non-Tissue Fabric that guarantees a longer sterility period (90 days).

Fig. 20: Non-Tissue fabric used for the packaging of washed kits

The individually bagged instruments are identified by Sixster with the words General Medical Device.

The thermolabile instruments are packed and labelled in a dedicated location.

Sterilization

Once the sterilizer is ready to be started, an operator traces the instruments, physically loaded on the trolley, on the traceability system. The procedure consists in:

- Selecting the steriliser, the type of cycle, and the cycle reference
- Reading with the barcode reader the third printed traceability label for the sets and the general label for the individually bagged items
- A Helix test indicator is placed on each steam sterilisation cycle.
- The sterilization cycle is always composed of three different phases:
- Preconditioning phase: in this phase, air from the chamber is removed before the exposure phase. After removing the air, the chamber heats up to the defined exposure temperature.
- Exposure phase: the standard process involves a timed exposure. The stopwatch is activated only when the chamber reaches and maintains the pre-selected exposure temperature.
- Post-conditioning drying phase: vacuum is used to evaporate the moisture in the chamber and load.

The operator can choose between two different type of pre-programmed cycles, as showed in Table 3. The one at 134 °C is used for sets with metallic instrumentation while the one at 121 °C is used for more delicate and "rubbery" pieces.

Types of cycles	Temperature	Sterilization time (minutes)	Drying time (minutes)
Prevacuum	121 *C	16,5	25
Prevacuum	134 °C	3,5	25
Passer	Returns the loading trolley to double-door sterilizers for which separate pass-through doors are not available.		

Table 3: sterilization cycles

The instruments that were previously treated manually and put in the air drier are sterilized at low temperature in the hydrogen peroxide sterilizer.

Once the sterilisation cycle is complete, the autoclave unloads the trolley automatically. The operator removes the parametric release of the cycle in question from the steriliser printer and attaches it to the sterilisation load summary sheet, taken before from the clean area to the sterile area. For steam steriliser cycles he also attaches helix tests. He confirms the sterilisation cycle on the traceability system and places the sterile instruments in the trolleys/shelves dedicated to temporary storage.

Transfer ste-op

At 7.00 am, the dedicated personnel for each operating ward goes to CSSD 1 and collect the sterile material of its competence, which is stored in closed cabinets.

During the rest of the day, the operating ward staff goes to CSSD 1 to collect the urgencies required, as well as the available sterile kits. The only block that regularly goes to CSSD 1 to retrieve sterile kits is BOA/BOD, which makes two further rounds at 11.00 and 20.30 in addition to the one at 7.00 am.

For BOG, all the logistics is managed by Integral Service personnel, as described before.

The handling of the emergency request is completed differently from the standard procedure. The operating block that requested the urgency is informed when the instrument is ready for collection; the CSSD operator transcribes on the urgency form the time they informed the operating ward that the emergency is ready for collection; once the sterile instrumentation is collected by the instrumentalist, the latter signs the urgency form for successful collection.

2 Materials and methods

Sterilisation plays a fundamental role in the prevention of hospital infections, patients' safety, and the proper operation of surgical theatres. However, despite the importance of this critical phase, the evaluation of the productivity of the sterilisation process has never been analysed in depth within the Humanitas Clinical Institute.

The purpose of this chapter is to provide a detailed overview of the materials and methods used in the study to evaluate the technological impact of new technologies in the hospital's sterilisation department and in the realisation of a productivity dashboard to monitor and evaluate sterilisation performance.

The chapter begins with a description of the current practices and technologies used in the hospital's central sterilisation unit. Current gaps and challenges in monitoring and evaluating process performance will be identified.

The chapter will then proceed with a detailed explanation of the analysis methods: evaluation criteria and measurable parameters to assess the effectiveness of the technologies implemented will be outlined.

Lastly, the focus will be shifted towards the productivity dashboard and on the methodology used to evaluate the impact of its adoption.

Through the detailed analysis of materials and methods, the aim is to fill the existing gap in the evaluation of sterilisation process productivity at the Humanitas Clinical Institute, providing a complete and objective picture of the impact of new technologies and offering a monitoring dashboard to support decision-making and continuous improvement of sterilisation department performance.

2.1. Evaluation of the technological impact of new equipment

The sterilisation process within the Humanitas Clinical Institute is divided between CSSD 1 and CSSD 2, respectively the old sterilization centre, conceived since the hospital’s opening, and the newer one, opened more recently.

In the three-year period 2021-2023, a series of activities have been planned to significantly revise and modernise the Central Sterilisation department to ensure that the entire process complies with UNI EN ISO 13485. The macro-areas affected by the renovation process are the surgical instrumentation, the CSSD team and the technical-structural part.

In June 2021, the management of the surgical instrumentation was handed over to the clinical engineering office, which set up structured procedures for acquisition and in/out flows. The instrumentation was then inventoried in November 2021 and in January 2022, the SIXSTER programme for traceability underwent a major upgrade.

The CSSD team joined a training programme held by STERIS specialists, divided into five modules: decontamination, washing and thermodisinfection, assembly and disassembly of specialised instrumentation, routine instrument maintenance activities, and sterile instrument release checks.

From a technical-structural point of view, starting from the end of 2020, the department faced major changes:

- In December 2020, the lighting system in CSSD 1, the old central Sterilisation Centre, was replaced.
- In March 2021, the sterilisation activity in the BOC sub central was suspended in order to provide more control and uniformity on sterilisation activity, concentrating it entirely in CSSD1 and CSSD2.
- In April 2021, new counters were introduced in the old central Sterilisation Centre.
- In August 2022, a structural and plant reorganisation of CSSD 1 was implemented. New equipment was provided and introduced in the unit.

In this thesis, the focus will be on CSSD 1 and the improvements introduced with the recent renovation. It will be important to assess the impact of these changes on the overall productivity of the sterilisation process and the efficiency with which surgical kits are processed and made available for hospital procedures.

2.1.1. Process analysis

In the CSSDs, one working day is considered starting at 7 a.m. of one day and ending at 7 a.m. of the following day. In the morning, at the beginning of the first shift, the head nurse fills an excel sheet (Fig.21) containing different information:

- the number of active workers;
- the number of accepted kits;
- the number of urgent kits for CSSD1 and CSSD2 (as explained in the previous chapter, some sets are sent to the CSSDs signed as “urgent”, which guarantees that they are processed within a few hours);
- the number of sets to recompose and pack at 7 a.m. in CSSD 1 and CSSD 2 (“remains to package”);
- the number of sets to sterilize at 7 a.m. in CSSD 1 and CSSD 2 (“remains to sterilize”);

- the number of non-functioning washers;
- the number of non-functioning sterilizers.

Currently, all these data are registered only manually, taking with them all the flaws that this collection procedure takes with it: mistakes, incompleteness, inaccuracy.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	data giorno calcolato dalle 7.01 -alle 7.00	persone in servizio attivo	KIT ricevuti	imbust.	di cui dalle 16 alle 18	di cui dalle 18,01 alle 24,00	set creati nuovi	urgenze CSSD1	urgenze CSSD2	kit da ricomporre alle ore 7 CSSD1	kit da ricomporre alle ore 7 CSSD2	set solo da sterilizzare alle 7 CSSD1	set solo da sterilizzare alle 7 CSSD2	invalidati	LAVAFERRI GUASTE	AUTOCLAVI GUASTE	STERRAD GUASTE
2	1-gen-21																
3	2-gen-21																
4	3-gen-22	10	139		15	31	0	1	/	0	/	0	/	15	0	0	0
5	4-gen-22	12	128		25	27	0	9	/	3	/	0	/	23	0	0	0
6	5-gen-22	10	183		38	22	7	0	/	0	/	0	/	49	0	0	0
7	6-gen-22																
8	7-gen-22	13	134		15	21	2	0	/	0	/	0	/	32	0	0	0
9	8-gen-22																
10	9-gen-22																
11	10-gen-22	22	478		92	39	0	15	0	0	0	0	0	16	0	0	0
12	11-gen-22	22	418		50	57	0	11	3	0	0	0	0	12	0	0	0
13	12-gen-22	20	423		45	65	4	6	3	0	0	0	0	11	0	0	0
14	13-gen-22	21	517		80	67	4	19	2	0	0	0	0	26	0	1	0
15	14-gen-22	23	405		50	60	6	22	2	15	0	0	0	2	0	1	0
16	15-gen-22																
17	16-gen-22																
18	17-gen-22	24	422		65	26	2	3	3	0	0	0	0	58	0	1	0
19	18-gen-22	24	430		48	35	4	11	6	0	0	0	0	94	0	1	0
20	19-gen-22	22	523		75	68	0	14	1	0	0	0	0	54	0	1	0
21	20-gen-22	24	466		89	46	1	16	3	10	0	0	0	81	0	1	0
22	21-gen-22	24	510		93	67	0	16	0	21	0	0	0	31	0	0	0

Fig. 21: Excel file used for process monitoring in the two CSSDSs. It is manually filled by the nurses and contains information regarding the number of workers, the sets received and the non-functioning equipment.

The sterilisation process is divided into five phases. The first phase is acceptance, in which soiled kits arrive in the sterilization department and are registered by reading a unique barcode. This is followed by the washing phase, in which the kits are subjected to different cleaning methods depending on their type and characteristics. A further step is the clean acceptance, where expired sets can enter in the process without being washed again. The following step is packaging, in which the kits are reassembled and packaged appropriately to ensure integrity and safety during the sterilisation process. The next stage is sterilisation, during which surgical instruments are sterilized. Finally, there is the shipping stage, where it is recorded that the sterilised kits are sent to the operating wards.

All the kits accepted during the day are washed: nothing is left in the soiled side of the CSSD. On the contrary, it is not sure that what is washed will be packed in the same day or that what is packaged will be sterilized in the same day. The sets that are washed but not packed and sterilized during the same day are called “remains to package” (“avanzi da confezionare”); the sets that are washed and packed but not sterilized are named “remains to sterilize” (“avanzi da sterilizzare”).

The traceability of the process is not complete. First of all, single bagged items are not identified by unique barcodes but go under the generic name of “medical devices”: this means that it is not possible to identify the specific item that results to be untraceable during the entire process. These items can only be manually counted to verify that the total number of processed items corresponds to the total shown by the

traceability programme. Moreover, the shipping of sterilized surgical sets appears to be lacking (rarely done in CSSD 1 and never done in CSSD 2).

While the traceability flow in CSSD is fundamentally complete, the hospital traceability implementation (Fig.22) is totally absent. Currently, clean instrumentation is delivered to the hospital wards; during surgeries, multiple sets and single bagged items are used. At the end of each procedure, used items are casually placed inside grids and shipped back to the sterilization department.

Fig. 22: CSSD and hospital traceability flows

The hospital flow for traceability would include four phases:

1. Delivery of clean surgical instrumentation.
2. Check-in: in the operating room, sets that need to be used are registered by reading their barcodes.
3. Check-out: at the end of the surgery, used sets are checked out and associated with the grids in which they are contained.
4. Shipping of soiled instrumentation.

Currently, there is no established system to monitor or record when these sterilized sets are put to use during surgical procedures. The absence of traceability severely hampers the ability to plan the sterilization process effectively, leading to potential delays and operational challenges. Without a reliable tracking system for surgical instruments, it becomes challenging to coordinate the availability of sterilized equipment precisely when needed. As a result, surgical teams may face unexpected delays while waiting for the required instruments, disrupting the surgical schedule and overall workflow.

Moreover, the lack of traceability also complicates the packaging phase of the sterilization process: indeed, once the surgical sets exit the washers, there is no reliable method to determine their specific placement within the grids. Consequently, it becomes challenging to ascertain which items belong to each set or whether they might be inadvertently mixed with components from other sets or individually packaged items. The recomposition of the sets fully relies on the knowledge and attention of the operators.

2.1.2. Dataset

The analysis is founded on a comprehensive dataset provided by Sixster, the software used for traceability in the sterilization department. This dataset spans from February 2022 to July 2023, and it includes multiple Excel files organized according to the distinct phases of the sterilization process.

The exploratory analysis was performed using Splunk.

- The time frame was reparametrized to align with the working hours of the central sterilization facility. Each day was defined as starting from 7:00 AM and ending at 7:00 AM the following day, considering the hours after midnight as part of the previous day.
- Single bagged items were excluded from the evaluation.
- Since CSSD 1 functions only on Saturday mornings while CSSD 2 is completely closed both on Saturdays and on Sundays, weekend days were eliminated from the dataset. In this way, it was possible to ensure that the analysis was representative of typical working days and to avoid any potential biases.

2.1.3. Acceptance

tipo_articolo	barcode_inventariale	timestamp_accettato	cycle_code	prod_code	prod_desc
KIT	1413/01	2023/01/02 07:05:35	230000002	URO_032/02	PCNL 2
KIT	7679/01	2023/01/02 07:05:40	230000003	BOA URO-0068	OTTICA 12° URO 2
KIT	9808/01	2023/01/02 07:06:04	230000005	BOD TRA-0408	DESOUTTER GRANDE C/D 3
KIT	9352/01	2023/01/02 07:06:05	230000006	BOD TRA-0353	BATTERIA DESOUTTER GRANDE C/D 1
KIT	1994/01	2023/01/02 07:06:06	230000008	ORT_092/01	STELO C2 NUOVO 1
KIT	2360/01	2023/01/02 07:06:07	230000009	TRA_060/02	ACC. ANCA TRAUMA 2
KIT	3762/01	2023/01/02 07:06:09	230000010	TRA_065/03	SET TRAUMA NUOVO 3
KIT	6797/01	2023/01/02 07:09:40	230000012	BOF-0030	PINZA BIP. GEN 1
KIT	9875/01	2023/01/02 07:09:41	230000014	BOD TRA-0413	TFNA C/D 2
KIT	9876/01	2023/01/02 07:09:42	230000015	BOD TRA-0414	TFNA C/D 3
KIT	10198/01	2023/01/02 07:09:43	230000016	BOD TRA-0434	TFNA C/D 1A
KIT	3763/01	2023/01/02 07:09:44	230000017	TRA_065/04	SET TRAUMA NUOVO 4

Fig. 23: extract of the acceptance dataset

For the acceptance phase, the data provided by the software (Fig.23) are the following:

- **tipo_articolo**: it indicates if the item is a kit (KIT) or a single bagged item (IMB).

- **barcode_inventariale**: it is the unique barcode defined for each set.
- **timestamp_accettato**: it indicates the date and time at which the soiled set was accepted in the sterilization department.
- **cycle_code**: it is a unique barcode, generated during the acceptance phase, that identifies the kit during the entire process.
- **prod_code**: it is a more extensive code defined for each kit.
- **prod_desc**: it is the description of the set. In case of single bagged items, the product description is always the same and contains the wording "DISPOSITIVO MEDICO" (the Italian for medical device).

The dataset provided by Sixster reveals instances where certain kits have been accepted twice within a relatively short timeframe. This duplicate acceptance of kits could occur due to various reasons, such as miscommunication, processing errors, or oversight during the initial acceptance phase. To avoid the presence of duplicates, kits identified with the same barcode accepted twice within four hours were counted as one.

2.1.4. Clean acceptance

tipo_articolo	barcode_inventariale	cycle_code	timestamp_accettato_pulito	prod_code	prod_desc	codice_causale	desc_causale
KIT	7015/01	230130761	20/07/2023 09:11	BOG-0324	HOMANN 5		
KIT	395/01	230130759	20/07/2023 08:48	ORT_011/02	ACCESSORI ANCA 2		
KIT	3476/01	230130757	20/07/2023 08:15	ORT_292/01	LPS STRUMENTI BALDINI 1		
IMB	202300168222		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168235		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168234		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168233		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168232		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168231		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168230		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168224		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		
IMB	202300168225		20/07/2023 07:59	DEGENZA_29	D.M. P.S. BUSTA SINGOLA		

Fig. 24: extract of the clean acceptance dataset

In the sterilization process, sets that have expired, meaning they are not used before their sterilization validity date, are not subject to full reprocessing. Instead, these expired sets are accepted as clean and undergo a specific procedure: they are repackaged, and then subjected to another round of sterilization without going through the entire washing process again.

For the clean acceptance phase, the data provided by the software (Fig.24) are the following:

- **tipo_articolo**
- **barcode_inventariale**
- **cycle_code**
- **timestamp_accettato_pulito**: it indicates the date and time at which the set was accepted in the sterilization department.

- **prod_code**
- **prod_desc**
- **codice_causale**: it is a code to indicate the reason of the clean acceptance.
- **desc_causale**: it is the description of the reason of the clean acceptance.

The last two fields can show the code EXP1 and the description "scaduto" (expired) but they are usually empty.

2.1.5. Washing

a)

tipo_articolo	barcode_inventariale	cycle_code	prod_code	prod_desc	stato1
KIT	8639/01	230130712	BOD 743-0007	ULTRACISION BOD 8	CONTAINER_WASH
KIT	10960/01	230130711	BOD-0251	CAVO SINGOLO PINPOINT	CONTAINER_WASH
KIT	13018/01	230130705	BOD-0301	CAVO CASTORO OLYMPUS C/V 1	CONTAINER_WASH
KIT	9882/01	230130706	BOD-0199	OTTICA CASTORO C/D 2	CONTAINER_WASH
KIT	9881/01	230130702	BOD-0198	ESOFAGO CASTORO	CONTAINER_WASH
KIT	9701/01	230130714	BOD-0177	OTTICA 4K 30° 10MM 3	CONTAINER_WASH
KIT	8968/01	230130704	BOD-0142	PINZE VLS CASTORO 1	CONTAINER_WASH
KIT	300/01	230130710	CHG_001/02	GRANDI INTERVENTI 2	CONTAINER_WASH
KIT	138/01	230130709	CHMIN_001/02	SET VLS PLUS 2	CONTAINER_WASH
KIT	1303/01	230130703	CHMIN_001/06	SET VLS PLUS 6	CONTAINER_WASH
KIT	11688/01	230130708	BOD-0274	SET VLS SPINELLI 4	CONTAINER_WASH
KIT	10177/01	230130713	BOD-0210	CALIBRATORI DOTT. SPINELLI 2	CONTAINER_WASH

b)

timestamp_carrello	stato2	timestamp_lavastrumenti	stato3	timestamp_lavato	codice_lav	desc_lav
2023/07/20 00:10:16	ASSOCIATED_WASH	2023/07/20 00:10:16	WASHED	2023/07/20 00:10:16	LAVM	LAVAGGIO A MANO
2023/07/20 00:10:14	ASSOCIATED_WASH	2023/07/20 00:10:14	WASHED	2023/07/20 00:10:14	LAVM	LAVAGGIO A MANO
2023/07/19 23:02:05	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:05	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:05	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:04	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:04	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:04	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:04	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:04	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:03	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1
2023/07/19 23:02:03	ASSOCIATED_WASH	2023/07/19 23:02:13	WASHED	2023/07/20 00:05:45	LAV1	Lavastrumenti 1

Fig. 25: extract of the washing dataset; a) first set of variables, from the type of article to state 1; b) second set of variables, from the timestamp of the cart (which identifies the beginning of the washing) to the description of the washing modality

For the washing phase, the data provided by the software (Fig.25) are the following:

- **tipo_articolo**
- **barcode_inventariale**
- **cycle_code**
- **prod_code**
- **prod_desc**

- **stato 1**: it is the first state of the washing phase and it indicates that the soiled set has been placed on the chart to be washed.
- **timestamp_carrello**: it indicates the date and time at which the soiled set has been placed on the chart to be washed.
- **stato 2**: it is the second state of the washing phase and it indicates that the washer disinfector cycle has started.
- **timestamp_lavastrumenti**: it indicates the date and time of the start of the washer disinfector cycle.
- **stato 3**: it is the third state of the washing phase and it indicates that the washer disinfector cycle has ended.
- **timestamp_lavato**: it indicates the date and time of the end of the washer disinfector cycle.
- **codice_lav**: it is a code that identifies the type of wash, or the washer used.
- **desc_lav**: it is the description of the type of wash or washer used. It includes:
    - the washer disinfectors of CSSD 1 (*Lavastrumenti 1, Lavastrumenti 2 and Lavastrumenti 3*)
    - the old washer disinfectors of CSSD 1 (*STERIS HAMO T21/1, STERIS HAMO T21/2, STERIS HAMO T21/3, LAVAFERRI GETINGE*)
    - the washer disinfectors of CSSD 2 (*LAVAFERRI STEELCO 1, LAVAFERRI STEELCO 2B and LAVAFERRI STEELCO 3*)
    - hand washing (*LAVAGGIO A MANO*)
    - the containers washer of CSSD 1 (*LAVACONTAINER*).

2.1.6. Packaging

tipo_articolo	barcode_inventariale	barcode_processo	cycle_code	timestamp_confezionato	prod_code	prod_desc
KIT	6878/01	202300168264	230129983	2023/07/20 09:00:55	BOG-0259	SPARA K.GRANDE 2
KIT	12872/01	202300168263	230130193	2023/07/20 08:57:30	BOG-2946	SPARA K. GRANDE BOE 2
KIT	3455/01	202300168259	230130623	2023/07/20 08:52:47	ORT_253/04	OTTICA 30° HD S&N 4
KIT	6088/01	202300168255	230130052	2023/07/20 08:48:52	ORT_254/21	TELECAMERA HD S&N 21+CAVO LUCE
KIT	6087/01	202300168253	230130282	2023/07/20 08:47:39	ORT_254/20	TELECAMERA HD S&N 20+CAVO LUCE
KIT	3517/01	202300168252	230130506	2023/07/20 08:45:18	ORT_254/09	TELECAMERA HD S&N 9+CAVO LUCE
KIT	6025/01	202300168250	230130505	2023/07/20 08:43:00	ORT_253/21	OTTICA 30° HD S&N 21
KIT	3734/01	202300168248	230130407	2023/07/20 08:42:11	ORT_253/11	OTTICA 30° HD S&N 11
KIT	2268/01	202300168245	230130367	2023/07/20 08:38:51	ORT_063/03	GINOCCHIO BASE 3
KIT	4546/01	202300168244	230130379	2023/07/20 08:38:18	ORT_335/01	ALESATORI DI LORD MIS.7/14
IMB	202300168241	202300168241		2023/07/20 08:28:16	ST00001	DISPOSITIVO MEDICO
KIT	3476/01	202300168239	230130757	2023/07/20 08:15:47	ORT_292/01	LPS STRUMENTI BALDINI 1

Fig. 26: extract of the packaging dataset

For the packaging phase, the data provided by the software (Fig.26) are the following:

- **tipo_articolo**: in this phase, not only kits but also single bagged items are registered.
- **barcode_inventariale**

- **barcode_processo:** it is a unique barcode generated in the packaging phase and also present during the sterilization.
- **cycle_code**
- **timestamp_confezionato**: it indicates the date and time of the end of the packaging.
- **prod_code**
- **prod_desc**

2.1.7. Sterilization

a)

tipo_articolo	barcode_inventariale	prod_code	prod_desc	barcode_processo	cycle_code
IMB	202300168204	ST00008	D.M. OCULISTICA	202300168204	230130753-202300168204
IMB	202300168205	ST00008	D.M. OCULISTICA	202300168205	230130753-202300168205
IMB	202300168206	ST00008	D.M. OCULISTICA	202300168206	230130753-202300168206
KIT	10716/01	BOF-0291	SET COLLO ORL 6	202300168128	230130584
KIT	7675/01	BOA NCH-0159	SOLERA 5.5/6.0 SCHORTS 2	202300168123	230130654
KIT	12999/01	BOE-0962	SPECILLO MIS.3 CHR BOE 2	202300168129	230130743
KIT	12818/01	BOF_ORL-0055	BIPO. ORECCHIO ORL 2	202300168135	230130581
KIT	7674/01	BOA NCH-0158	SOLERA 5.5/6.0 MAS 2	202300168127	230130651
KIT	241/01	CHG_003/14	PICCOLI INTERVENTI 14	202300168136	230130583
KIT	229/01	CHG_003/02	PICCOLI INTERVENTI 2	202300168134	230130579
IMB	202300168159	ST00001	DISPOSITIVO MEDICO	202300168159	230130750-202300168159
IMB	202300168160	ST00001	DISPOSITIVO MEDICO	202300168160	230130750-202300168160

b)

stato1	timestamp_carrello	stato2	timestamp_autoclave	stato3	timestamp_sterilizzato	codice_auto	desc_auto
CONTAINER_AUTO	2023/07/20 07:32:49	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:49	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:49	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:27	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:23	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:25	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:30	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:22	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:35	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:32:32	ASSOCIATED_AUTO	2023/07/20 07:33:55	STERILIZED	2023/07/20 08:34:55	GRETA	GRETA
CONTAINER_AUTO	2023/07/20 07:34:07	ASSOCIATED_AUTO	2023/07/20 07:39:20	STERILIZED	2023/07/20 08:31:25	SOFIA	SOFIA
CONTAINER_AUTO	2023/07/20 07:34:07	ASSOCIATED_AUTO	2023/07/20 07:39:20	STERILIZED	2023/07/20 08:31:25	SOFIA	SOFIA

Fig. 27: extract of the sterilization dataset; ; a) first set of variables, from the type of article to cycle code; b) second set of variables, from state 1 to the description of the sterilization equipment

For the sterilization phase, the data provided by the software (Fig.27) are the following:

- **tipo_articolo**
- **barcode_inventariale**
- **prod_code**
- **prod_desc**
- **barcode_processo**
- **cycle_code**
- **stato 1**: it is the first state of the sterilization stage, and it indicates that the set has been placed on the chart to be sterilized.

- **timestamp_carrello**: it indicates the date and time at which the set has been placed on the chart to be sterilized.
- **stato 2**: it is the second state of the sterilization stage, and it indicates that the set has been associated to the autoclave.
- **timestamp_autoclave**: it indicates the date and time of the start of the sterilizer cycle.
- **stato 3**: it is the third state of the sterilization stage, and it indicates that the sterilizer cycle has ended.
- **timestamp_sterilizzato**: it indicates the date and time of the end of the sterilizer cycle.
- **codice_auto**: it is a code that identifies the type of steriliser used.
- **desc_auto**: it is the description of the steriliser used. It includes:
    - the steam sterilizers of CSSD 1 (*DALILA, GRETA and SOFIA*);
    - the old steam sterilizers of CSSD 1 (*GIADA, AMETISTA and CORALLO*);
    - the Hydrogen Peroxide Gas Plasma sterilizer of CSSD 1 (*CSSD: DIAMANTE*);
    - the steam sterilizers of CSSD 2 (*CSSD2: Africa, CSSD2: America, CSSD2: Europa*);
    - the Hydrogen Peroxide Gas Plasma sterilizer of CSSD 2 (*CSSD2: ONICE*).

2.1.8. Shipping

tipo_articolo	barcode_inventariale	timestamp_spedito	prod_code	prod_desc	code	description
IMB	202200257879	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202200257878	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202200257877	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202200257876	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
KIT	2876/01	2023/01/23 20:57:47	ORT_249/02	SAGITTAL SAW DESOUTTER 2	BOG	Blocco operatorio G
KIT	2862/01	2023/01/23 20:57:47	ORT_151/04	DRILL STRYKER 4 ORT NEW	BOG	Blocco operatorio G
KIT	6666/01	2023/01/23 20:57:47	BOE-0170	MICROPLASTY GRIGIO 2	BOG	Blocco operatorio G
IMB	202300010174	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010173	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010172	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010171	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010170	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010169	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G
IMB	202300010168	2023/01/23 20:57:47	ST01464	PROVETTE 744	BOG	Blocco operatorio G

Fig. 28: extract of the shipping dataset

For the shipping phase, the data provided by the software (Fig.28) are the following:

- **tipo_articolo**
- **barcode_inventariale**
- **timestemp_spedito**: it indicates the date and time at which the item is shipped.
- **prod_code**

- **prod_desc**
- **code**: it is a code to identify the operating ward to which the item is shipped.
- **description**: it contains the description of the operating ward to which the item is shipped.

The amount of data available for the shipping is significantly lower than the amount of data available for the other stages, due to the fact that it is almost never performed in the sterilization department.

2.1.9. Parameters

Various parameters were calculated to evaluate the process's productivity. These parameters included the volumes of output produced, the presence of remains (partially processed surgical kits), processing times, hourly ratings, and some Key Performance Indicators (KPIs).

The research was divided into two distinct time frames: pre-August and post-August 2022. This significant milestone marked the introduction of new state-of-the-art sterilization equipment within the hospital's facilities.

The parameters and KPIs used to evaluate the sterilization process included:

- Volumes of Output Produced: this parameter assessed the quantities of kits successfully sterilized within specific time periods, indicating the efficiency of the sterilization process.
- Remains: the presence of remains was carefully monitored to understand the process's effectiveness in completing sterilization procedures within a single day.
- Processing Times: The duration taken to complete sterilization procedures was analyzed to identify the process's efficiency and effectiveness.
- Hourly Ratings: This parameter evaluated the performance of the sterilization process and its staff within each hour of operation, allowing the identification of peak productivity periods and potential inefficiencies.
- KPIs:
    - Equipment operativity: Measures the hours per day in which the equipment is operational.
    - Daily cycles: Measures the number of completed equipment cycles per day.

2.2. Productivity dashboard

Healthcare is a critical sector that plays a significant role in impacting a country's economy. Effectively measuring, monitoring, and responding to health-related metrics has become indispensable for modern healthcare organizations to enhance their performance. Data-driven decision-making is now an essential business function, influencing various aspects of daily operations. However, data alone are not enough; organizations need systems to extract timely and actionable insights.

The introduction of Information and Communications Technology (ICTs) in the healthcare sector has been widely acknowledged for its positive impact. There is a clear correlation between the adoption of ICTs, the financial well-being of healthcare organizations, and their productivity levels. Business Intelligence (BI) encompasses all Information Systems (IS) dedicated to providing decision support by aggregating and analyzing raw data from operational systems. To track performance metrics in an automated way, health systems have increasingly adopted business intelligence software.

These applications, known as "dashboards," are specialized tools designed to collect, analyze, and present organizational data in user-friendly formats to support organizational objectives. Dashboards use data visualization to provide actionable feedback for improving performance, adhering to evidence-based practices, managing workflows, and optimizing resource utilization. When integrated with a business-oriented BI infrastructure, these dashboards empower healthcare managers to measure performance, monitor Key Performance Indicators (KPIs), identify deviations, understand unfavourable trends, and redefine objectives.

Measuring productivity is paramount for achieving a more efficient allocation of resources within a hospital organization. By leveraging BI capabilities, healthcare institutions can gain a comprehensive understanding of their performance. The visual representation of KPIs through dashboards facilitates the monitoring of progress, identification of areas for improvement, and effective strategic planning to optimize overall productivity in healthcare organizations. As a result, dashboards have increasingly gained importance in the health sector.

Creating an effective dashboard requires making multiple complex decisions. End users' information needs heavily depend on the clinical setting, professional roles, and patient population, which influence the selection of appropriate data elements, visualizations, and interactivity. Tailoring dashboards to meet the needs of the intended users is the first step in the health care performance improvement cycle.

A successful dashboard must strike a balance between visual appeal and the information it contains to be truly valuable for decision support. The challenge is to utilize visualization techniques effectively to facilitate the extraction of vital

information. Moreover, it should present information unambiguously, reducing the risk of misinterpretations by its users.

Detailing is deemed essential for dashboards by some experts. Even when a dashboard is well-designed, it is often not sufficient to present all the relevant performance metrics on a single page. Therefore, dashboards should have a drill-down capability. The inclusion of a drill-down feature within a dashboard empowers stakeholders with intelligent analysis capabilities. By filtering and zooming in, users can access a more detailed level of information, enabling deeper insights and a better understanding of underlying trends.[13]

To ensure successful dashboard implementation, developers and organizational leadership must employ strategies to promote uptake and use. This may include providing constant training for end users, and implementing policy changes that mandate or incentivize dashboard utilization. As developing and maintaining data-rich business intelligence tools like dashboards can be resource-intensive, it is crucial that these tools function effectively and lead to measurable improvements.

Iterative evaluation of dashboard performance throughout development, implementation, and beyond is critical. It helps identify user and system-level barriers to use and potential errors that may only surface after extended usage. This continuous evaluation process allows for necessary refinements and optimizations to enhance the dashboard's usability and effectiveness in supporting healthcare organizations' decision-making processes.[14]

2.2.1. Tool and dataset

As a part of this work, a productivity dashboard was designed and developed in response to the direct request of the hospital's General Director. Its primary objective is to facilitate a comprehensive overview of the sterilization processes conducted within the hospital's Central Sterile Services Department.

The dashboard is not a one-size-fits-all solution but rather a highly customized tool. This customization process involved close collaboration with CSSD personnel, ensuring that the dashboard aligns with their workflow and operational needs.

The dashboard was created using Power BI, a powerful business analytics service developed by Microsoft that enables users to visualize and analyse data from various sources quickly and efficiently.

The dataset employed in the development of the dashboard remains consistent with the one previously introduced in this chapter.

2.2.2. Evaluation of the impact of the productivity dashboard adoption

To assess the impact of adopting the productivity dashboard, a questionnaire was designed using Google Forms and distributed to the professionals involved in the sterilization process. The questionnaire aimed at gathering valuable feedback and insights from the staff to evaluate their experiences and perceptions regarding the dashboard's implementation.

The questionnaire (Appendix A.2) included a series of targeted questions related to the following aspects:

- **User-Friendliness**: the questionnaire sought to understand how user-friendly and intuitive the dashboard was for the sterilization staff (*questions 1 and 2*).
- **Impact on Decision-Making**: the questionnaire aimed to determine whether the dashboard had a positive impact on the decision-making process of the sterilization staff. Participants were asked if the data insights influenced their operational strategies or if it helped identify areas for improvement (*question 3*).
- **Time-Saving Benefits**: the questionnaire included questions about whether the dashboard streamlined data analysis and reporting processes, ultimately saving time for the staff (*questions 4 and 5*).
- **Relevance of the features**: professionals were asked to provide feedback on the relevance of the features present in the dashboard (*questions 6, 7 and 8*).
- **Relevance of the metrics**: professionals were asked to provide feedback on the relevance of the metrics present in the dashboard (*questions 9 and 10*).
- **Overall Satisfaction**: the questionnaire concluded with questions regarding overall satisfaction with the dashboard and whether the staff felt that it was a valuable addition to the sterilization process (*question 11*).

From questions from 1 to 9, the answer is given on a scale from 1 to 10, where 1 corresponds to 'absolutely no' and 10 corresponds to 'absolutely yes.' For question 10, the answer has to be chosen among the 7 options provided, while the last question requires a 'yes' or 'no' answer."

The responses collected from the questionnaire played a crucial role in evaluating the success and effectiveness of the productivity dashboard adoption. By considering the perspectives of the professionals directly involved in the process, the analysis gained valuable insights that informed further improvements, adjustments, and future developments of the dashboard to optimize its impact on productivity and overall process efficiency.

3 Results

3.1. Hp1: The adoption of new technologies reduces process time.

3.1.1. Process analysis

The dataset available for the analysis spanned from February 2022, which marked the inception of the current traceability system, through July 2023. However, it's noteworthy that the data employed to evaluate the impact of the new equipment solely encompassed the months of February to July for both years. This selection was driven by the fact that the sterilization process is intricately linked with surgical activities, which in turn are significantly influenced by holiday periods and other external factors.

By focusing exclusively on the months of February to July, the analysis aimed to mitigate the potential confounding effects of seasonality. Isolating these specific months ensured that the data considered for evaluation were directly influenced by the operational shifts attributed to the introduction of the new equipment, rather than being influenced by external factors that might affect the broader yearly dataset.

The process was evaluated both as a whole and delving deeply into each distinct phase: acceptance, washing, packaging, and sterilization. By dissecting every stage, the study aimed to unveil the nuanced impacts of the equipment upgrades not only on the overall process but also highlighting the efficiency improvements in individual steps.

3.1.2. Specific measures

From the given data, it was possible to compute some parameters which made evident that the introduction of the new sterilization equipment has had a significant impact on the sterilization process in the Central Sterile Supply Department.

The analysis can be broken down into the phases mentioned above, for which different values, representative of the productivity and efficiency of the step, are shown:

1. **Acceptance**: for the acceptance phase, the parameter computed was the time required for handling kits from their acceptance to the start of the washing process. The tables 4 and 5 show the median, the first and third quartiles and the interquartile ranges, measured in minutes, for the months considered in the analysis.

2022	February	March	April	May	June	July
Median [min]	18	19	20	22	17	18
Q1 [min]	9	9	9	9	9	9
Q3 [min]	37	38	36	41	33	34
IQR [min]	28	29	27	32	24	25

Table 4: statistics of acceptance duration in 2022

2023	February	March	April	May	June	July
Median [min]	15	13	14	14	13	8
Q1 [min]	8	6	7	7	6	4
Q3 [min]	25	22	26	28	29	19
IQR [min]	17	16	19	21	23	15

Table 5: acceptance duration in 2023

Median Duration: In 2023, there is a noticeable decrease in the median acceptance duration for each month compared to 2022. This suggests that, on average, the acceptance phase required less time in 2023.

Q1 (First Quartile) and Q3 (Third Quartile): The first quartile (Q1) values in both years appear relatively stable, indicating that the lower 25% of acceptance durations remained consistent. However, the third quartile (Q3) values vary more between the two years. In 2023, Q3 values tend to be lower for most months compared to 2022, suggesting that a greater portion (75%) of the data falls below these values. This indicates a reduction in the upper range of acceptance durations in 2023.

Interquartile Range (IQR): The IQR, representing the middle 50% of the data, also displays variability. In 2023, the IQR tends to be smaller for most months compared to 2022, indicating less variability in acceptance durations. Smaller IQR values can be a positive sign as they suggest that the majority of the data points are closer to the median, indicating more consistent process performance.

The box and whiskers charts in Fig.29 show a similar behaviour of the outliers in the two years.

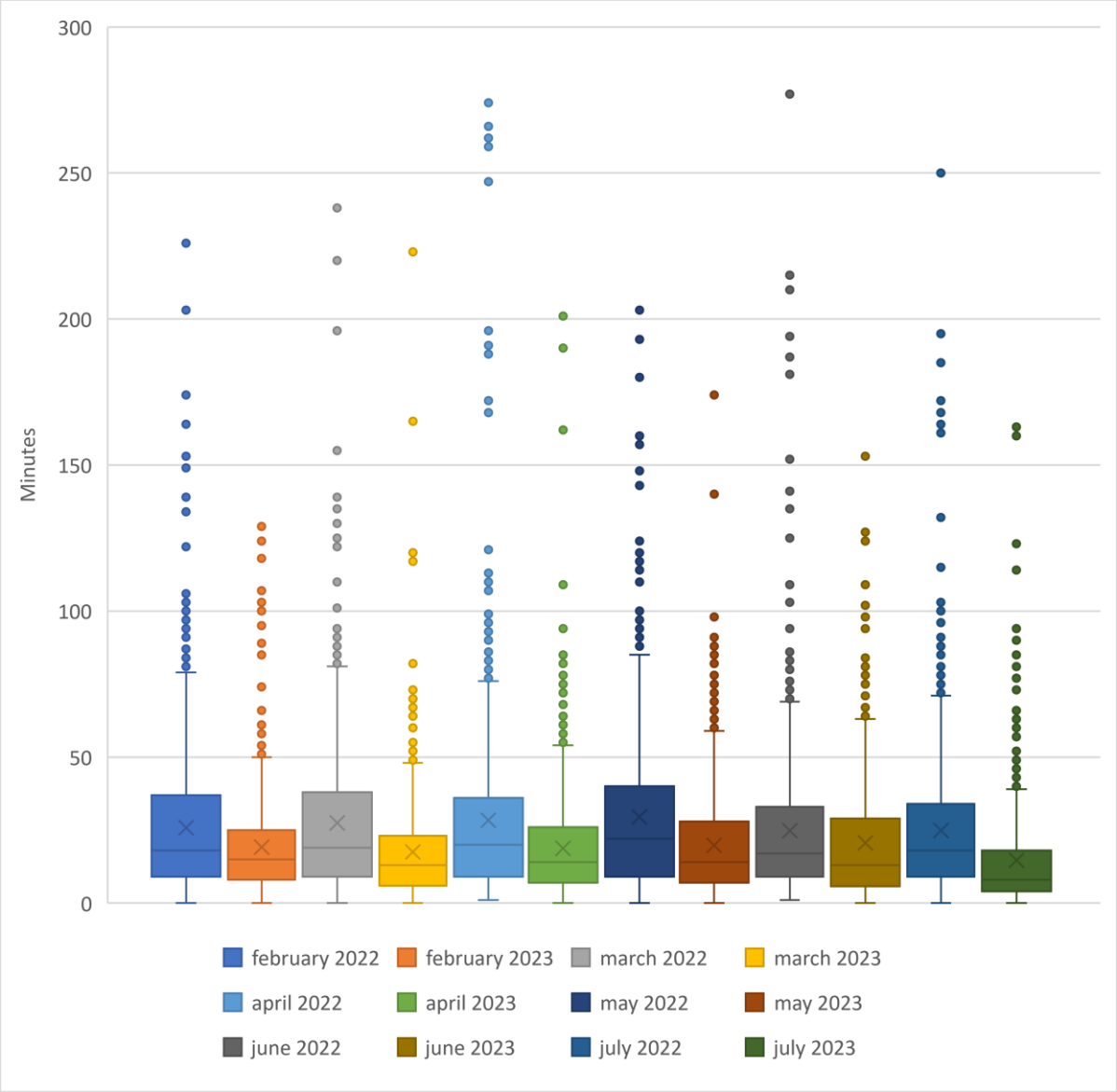


Fig. 29: Box and whiskers charts of acceptance duration in 2022 and 2023

2. Washing

- ***Washed kits per Month, monthly and daily statistics***: the following data illustrate the number of kits that underwent the washing process each month (Table 6), accompanied by some statistics on both a monthly (Table 7) and daily basis (Table 8).

	2022	2023	Difference	Difference %
March	6153	6961	808	13,1%
April	5259	5292	33	0,6%
May	6251	6426	175	2,8%
June	5772	5948	176	3,0%

Table 6: total number of kits washed per month

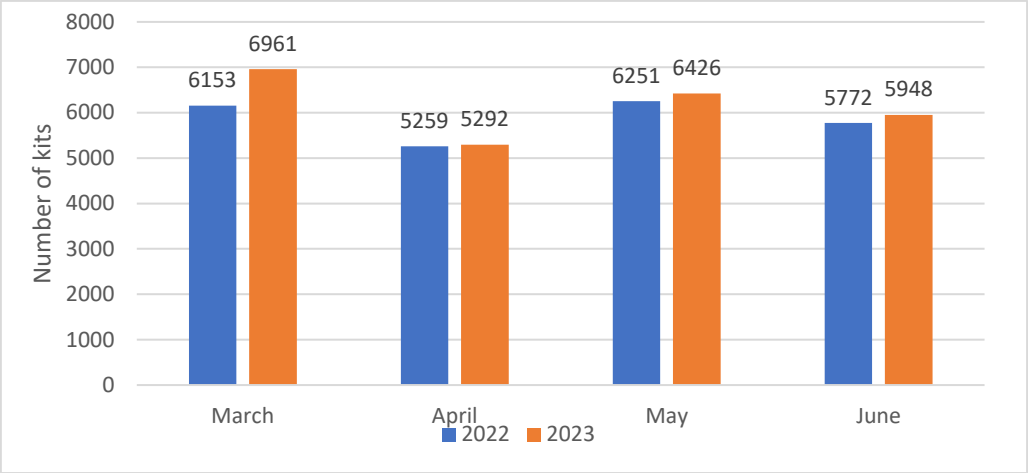


Fig. 30: total number of kits washed per month in the two years

As for the total number of kits washed monthly (Fig.30), March 2023 stands out with an impressive 13.1% increase in the total number of kits washed, translating to 808 more kits compared to the previous year. While the increase in April is more modest at 0.6% (probably due to the presence of higher number of holiday days in 2023), the consistent growth continues in May with a 2.8% rise and in June with a 3.0% increase.

	2022	2023
Median	5963	6187
Q1	5644	5784
Q3	6178	6560
IQR	534	776

Table 7: statistics of kits washed monthly in the two years

Considering the comprehensive statistics of the kits washed monthly, the median figures reveal an overall enhancement in the washing process, depicting an increase of 224 (+3.8%) in the number of kits washed per month. This growth is evident not only in the central tendency, as indicated by the median but also in the increased range of kit washing numbers, as reflected by Q1, Q3, and the IQR. This could reflect a higher demand for sterilization services in 2023 compared to 2022, which may result from increased healthcare activity or other variables.

	2022	2023
Median	265	288
Q1	247	270
Q3	287	301
IQR	40	31

Table 8: statistics of kits washed daily in the two years

The statistics regarding the number of kits washed daily show a growth in the production of washed kits between the two years. The median increased of 23 units (+8,7%), indicating more kits washed each day on average. As shown also in the box and whiskers chart (Fig.31), both the lower and upper ends of the daily counts also saw growth, showcasing a broader range. Moreover, there's reduced variability, implying more consistent operations. These changes could be attributed to enhanced efficiency or increased demand for sterilization services in 2023.

Fig. 31: Box and whiskers charts of kits washed daily in 2022 and 2023

- ***Washing duration***: the washing duration data reveal significant improvements in this critical aspect of the sterilization process.

  As shown in Table 9, the median washing duration experienced a remarkable reduction of 27% in 2023, with the process taking an average of 26 minutes less compared to the previous year. However, the IQR shows an increased variability in the middle 50%.

	2022	2023
Median [min]	96	70
Q1 [min]	89	61
Q3 [min]	108	88
IQR [min]	19	27

Table 9: statistics of washing duration in the two years

The chart below (Fig.32) clearly shows the presence of outliers, particularly skewed towards higher values: this could be due to exceptional circumstances, such as

technical issues with the equipment or slowdowns in the subsequent stages of the process.

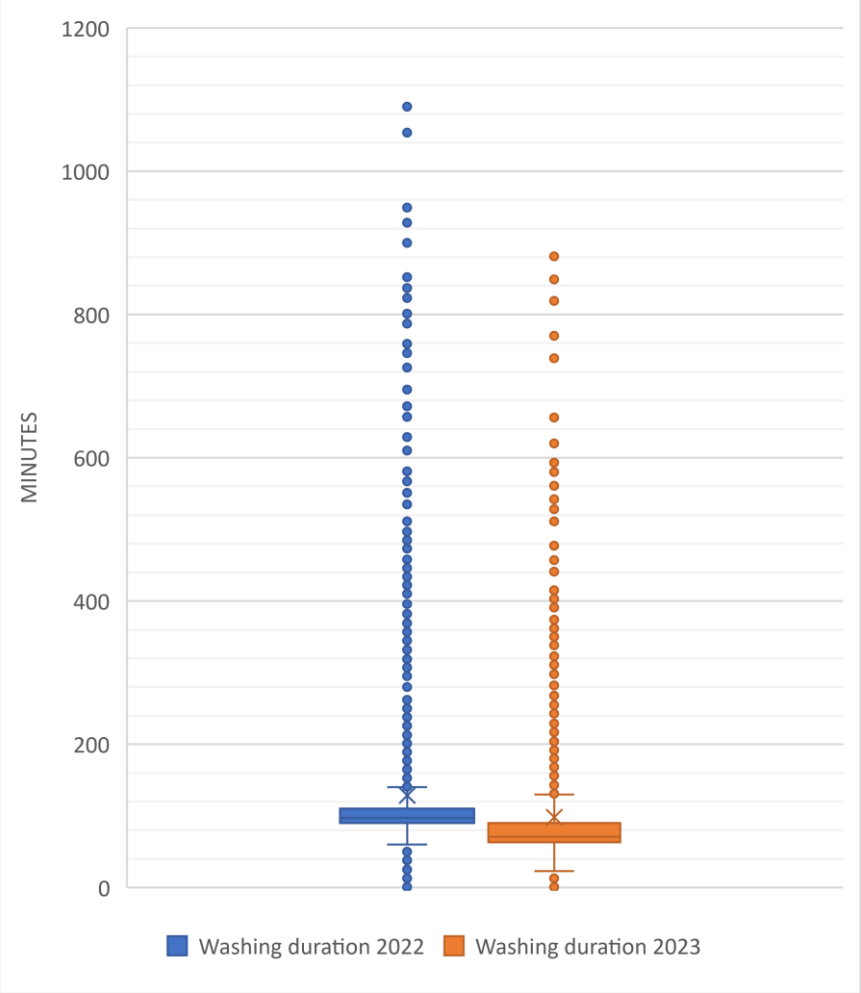


Fig. 32: Box and whiskers charts of kits washing duration in 2022 and 2023

- ***Washed kits per hour***: the data presented in Table 10 and Fig.33 offers a detailed breakdown of the number of washed kits per hour during the months from February to July for the years 2022 and 2023.

  In 2022, the hourly distribution of washed kits displayed varying patterns, with fluctuations observed across different hours of the day. However, the introduction of new equipment in 2023 has led to considerable changes with the data showcasing a mixed impact. While some hours experienced decreases in the number of washed kits, others saw substantial improvements. Hours like 1, 2, 4, 15, and 21 in 2023 have demonstrated remarkable growth in the number of washed kits per hour. This trend suggests the positive influence of the new equipment on specific operational hours. Nonetheless, a few hours in 2023 registered declines, indicating areas that could benefit from further optimization.

Hours	2022	2023	Difference	Difference %
0	173	140	-33	-19,1%
1	88	148	60	68,2%
2	59	81	22	37,3%
3	40	45	5	12,5%
4	23	37	14	60,9%
5	53	17	-36	-67,9%
6	118	13	-105	-89,0%
7	390	420	30	7,7%
8	253	47	-206	-81,4%
9	921	299	-622	-67,5%
10	2110	2075	-35	-1,7%
11	2808	2809	1	0,0%
12	3078	3340	262	8,5%
13	3502	3567	65	1,9%
14	2908	3078	170	5,8%
15	2947	3647	700	23,8%
16	3134	3140	6	0,2%
17	2588	2614	26	1,0%
18	2690	2704	14	0,5%
19	2296	2879	583	25,4%
20	1597	1897	300	18,8%
21	486	707	221	45,5%
22	115	198	83	72,2%
23	196	229	33	16,8%

Table 10: distribution of kits washed per hour

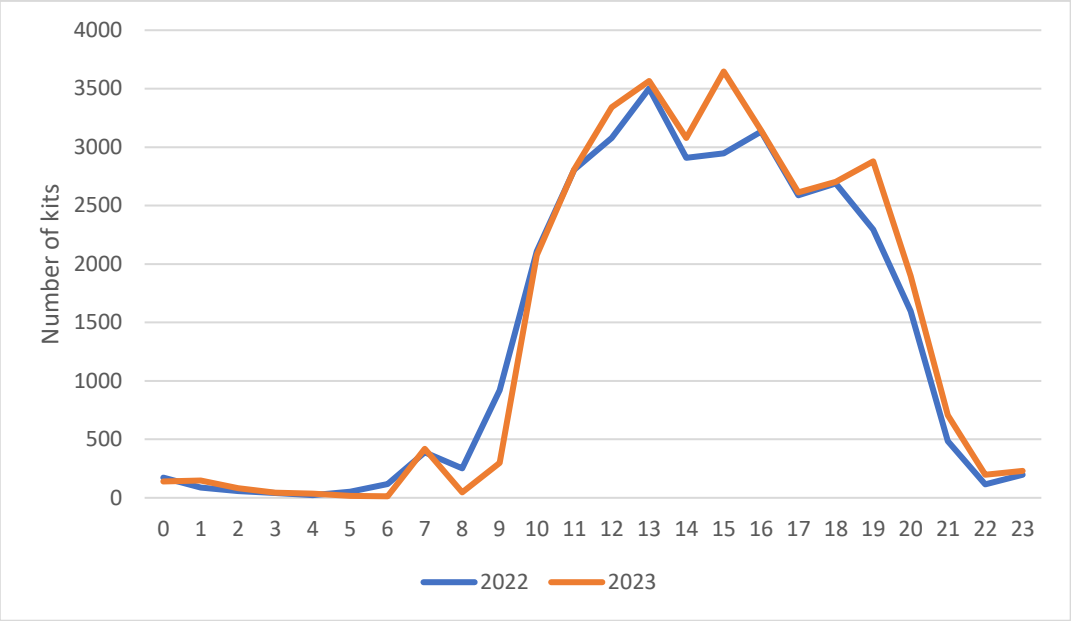


Fig. 33: total number of kits washed per hour

- ***Operativity and Cycles of Equipment:*** the data provided in Table 11, 12 and 13 present a comprehensive comparison of operativity and daily cycles for both the old and new washing equipment. The introduction of the new equipment in 2023 marked a distinct shift: although the number of daily cycles can be considered comparable with the 2022 values, the operativity appears to be substantially reduced, ranging from -3.3 to -2.7 hours per 24 hours. This highlights the improved efficiency of the new washing equipment.

2022	Operativity [h/24]	Daily cycles
STERIS HAMO T21/1	14	7
STERIS HAMO T21/2	13,3	7
STERIS HAMO T21/3	13,2	6
LAVAFERRI GETINGE	8,7	5

Table 11: operativity and daily cycles of washing equipment in 2022

2023	Operativity [h/24]	Daily cycles
AMSCO 7053 HP /1	10,7	8
AMSCO 7053 HP /2	10,8	7
AMSCO 7053 HP /3	10,3	7
One Vision 1300	6	2

Table 12: operativity and daily cycles of washing equipment in 2023

2022	2023	Difference in operativity [h/24]	Difference in daily cycles
STERIS HAMO T21/1	AMSCO 7053 HP /1	-3,3	1
STERIS HAMO T21/2	AMSCO 7053 HP /2	-2,5	0
STERIS HAMO T21/3	AMSCO 7053 HP /3	-2,9	1
LAVAFERRI GETINGE	One Vision 1300	-2,7	-3

Table 13: difference in operativity and daily cycles of washing equipment between the two years

3. **Packaging**: the following figures show some statics of the packaging durations, measured in hours.

2022	February	March	April	May	June	July
Median [h]	4,2	4	3,3	6	3,7	2,2
Q1 [h]	1,6	1,3	1,2	1,7	1,3	1
Q3 [h]	8,6	10,3	7,8	14	8,9	5,4
IQR [h]	7	9	6,6	12,3	7,6	4,4

Table 14: statistics of packaging duration in 2022

2023	February	March	April	May	June	July
Median [h]	4,3	3,9	3,2	5,6	2,9	2,9
Q1 [h]	1,3	1,5	1,1	1,5	1,1	1,1
Q3 [h]	12,3	10,1	8,4	13,6	7,4	7,1
IQR [h]	11	8,6	7,3	12,1	6,3	6

Table 15: statistics of packaging durations in 2023

The data on packaging duration in 2022 and 2023 reveals interesting variations. In 2022 (Table 14), the median packaging time ranged from 2.2 hours in July to 6 hours in May, with a notable interquartile range (IQR) of 7 to 12.3 hours, indicating a wide spread of values. This suggests that there were significant fluctuations in packaging times during that year, with some outliers, especially on the higher end. Notably, in 2022, there were outliers with packaging durations reaching up to 12,000 minutes (Fig.34).

In contrast, the packaging duration data for 2023 (Table 15) shows a different pattern. While the median packaging times still vary across months, they generally seem to be lower than in 2022, with a median range of 2.9 to 5.6 hours. The IQR for 2023 also appears to be more consistent, ranging from 6 to 12.1 hours. However, it's important to note that in 2023, there are outliers with much higher packaging durations, with some reaching up to 25,000 minutes, as evident from the box and

whisker charts in Fig.34. These outliers in 2023 have significantly longer durations compared to the outliers in 2022.

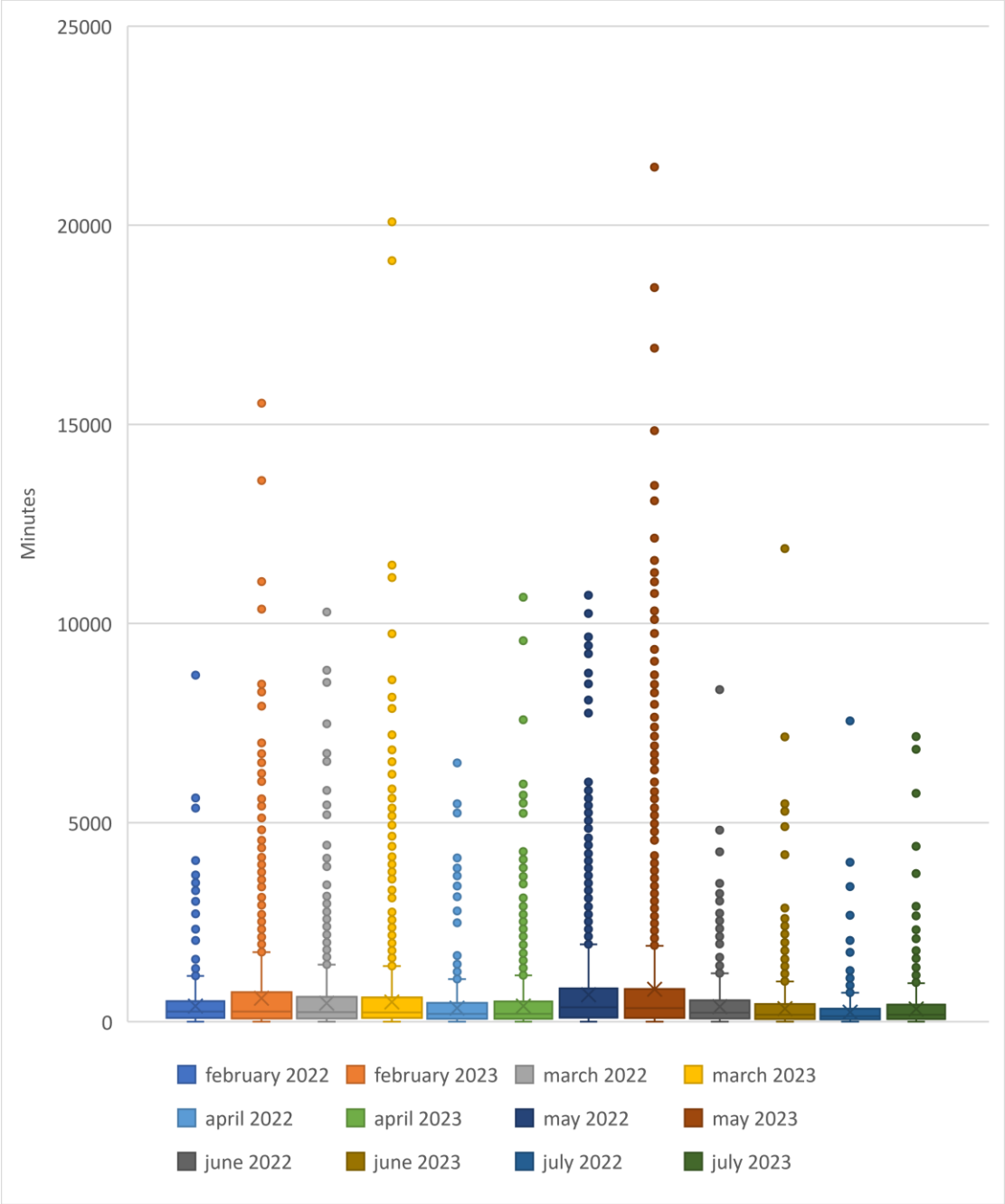


Fig. 34: box and whiskers charts of packaging duration in 2022 and 2023

This observation suggests that while overall packaging times in 2023 may seem more consistent and potentially improved, there are still instances of exceptionally long packaging durations that should be investigated further. Understanding the reasons behind these outliers can help in optimizing the packaging process and ensuring better consistency in the future.

4. **Sterilization**:

- ***Sterilized Kits per Month, monthly and daily statistics***: these data show the number of kits sterilized each month and some statistics, both on a monthly and daily basis. The observed trends highlight steady growth in the number of kits sterilized, with 2023 registering notable increases across all months compared to the previous year.

  As for the number of kits sterilized during each month (Table 16, Fig.35), March 2023 demonstrates around 7% increase, equivalent to 548 more kits sterilized, reflecting a robust enhancement in the process. Similarly, April, May, and June of 2023 show steady gains of 2.0%, 2.9%, and 2.0%, respectively, underscoring a consistent upward trajectory.

	2022	2023	Difference	Difference %
March	7888	8436	548	6,9%
April	6737	6874	137	2,0%
May	7663	7883	220	2,9%
June	7335	7487	152	2,1%

Table 16: sterilized kits per month

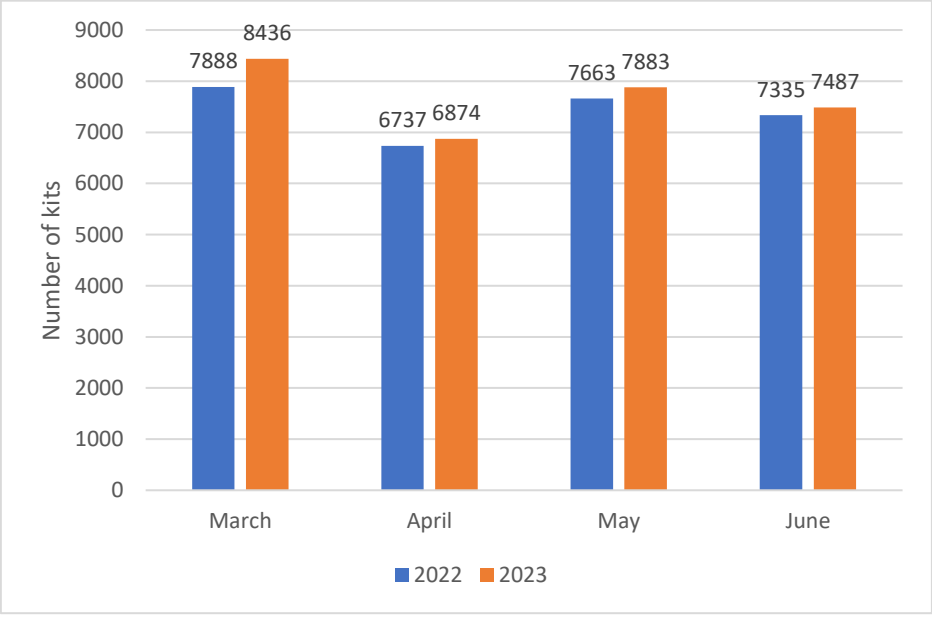


Fig. 35: number of sterilized kits per month in the two years

According to the statistics of kits sterilized monthly (Table 17), the median number of kits processed per month increased from 7499 in 2022 to 7685 in 2023 (+2.5%), indicating a positive trend in production. The interquartile range (IQR) widening suggests some variability in monthly production, but overall, the numbers have improved over the two years.

	2022	2023
Median	7499	7685
Q1	7186	7334
Q3	7719	8021
IQR	533	687

Table 17: statistics of kits sterilized monthly in the two years

The data regarding the number of kits sterilized daily (Table 18) show a growth in the production of sterilized kits between the two years. The median increased of 24 units (+7,6%), indicating more kits sterilized each day on average. As shown also in Fig.36, the first quartile (Q1) and third quartile (Q3) also saw slight increases over the same period while the interquartile range (IQR) showed a small reduction from 72 to 67.

	2022	2023
Median	313	337
Q1	266	297
Q3	338	364
IQR	72	67

Table 18: statistics of kits sterilized daily in the two years

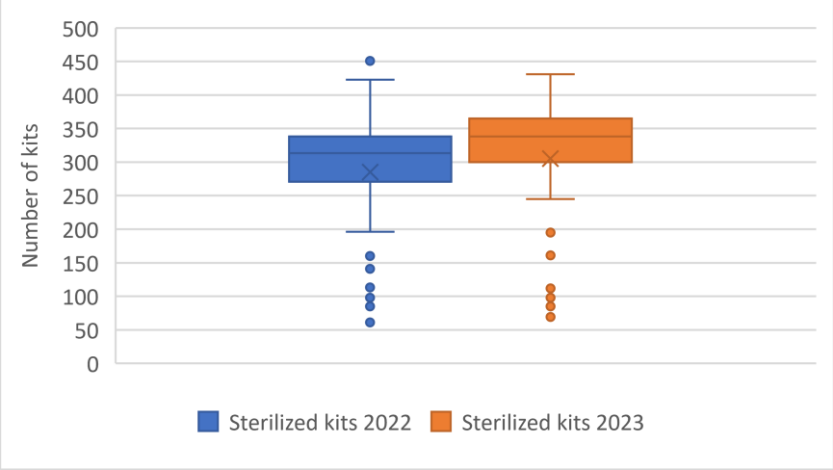


Fig. 36: Box and whiskers charts of kits sterilized daily in 2022 and 2023

- ***Sterilization Duration:*** as shown in Table 19 and Fig.37, the median sterilization duration in 2023 is notably lower than in 2022, with negative difference of -19.8%. Similarly, the first quartile (Q1) and third quartile (Q3) also saw reductions, indicating that the sterilization processes became faster on average in 2023. The interquartile range (IQR), which measures the data's spread, decreased from 44 minutes in 2022 to 32 minutes in 2023. These trends suggest that that the new

equipment has significantly streamlined the sterilization process, leading to quicker turnaround times.

	2022	2023
Median [min]	96	77
Q1 [min]	82	68
Q3 [min]	126	100
IQR [min]	44	32

Table 19: statistics of sterilization duration in the two years

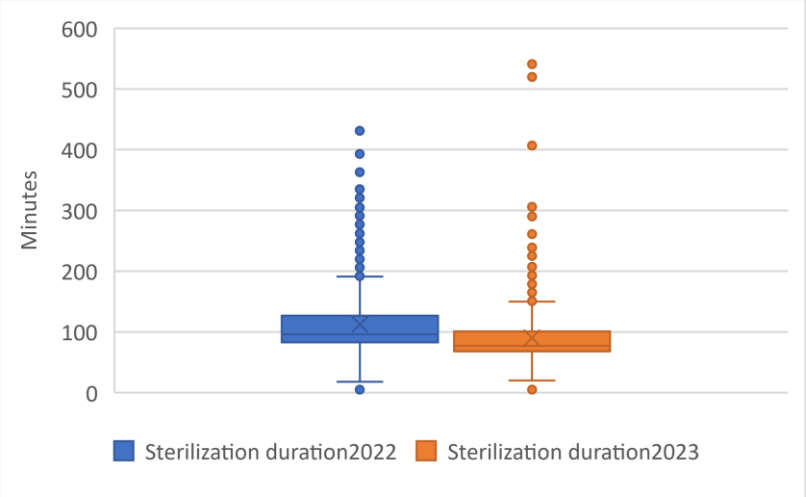


Fig. 37: Box and whiskers charts of kits sterilization duration in 2022 and 2023

- ***Sterilized Kits per Hour:*** the data in Table 20 and Fig.38 show a detailed hourly breakdown of sterilized kits, with both positive and negative differences between 2022 and 2023. The most notable improvements are seen in the early morning hours (e.g., hour 1 with a difference of 42.45%).

  Although there are a few negative differences in certain hours, the overall trend demonstrates increased productivity in the majority of the hours.

Hours	2022	2023	Difference	Difference %
0	1625	1731	106	6,5%
1	1020	1453	433	42,5%
2	1337	1269	-68	-5,1%
3	1755	2076	321	18,3%
4	1511	1630	119	7,9%
5	1848	2134	286	15,5%
6	1241	2100	859	69,2%
7	339	441	102	30,1%
8	1440	1304	-136	-9,4%

9	1820	1795	-25	-1,4%
10	1431	1380	-51	-3,6%
11	1394	1290	-104	-7,5%
12	1408	1631	223	15,8%
13	1584	1974	390	24,6%
14	1585	1371	-214	-13,5%
15	2386	2328	-58	-2,4%
16	2778	2539	-239	-8,6%
17	2727	2476	-251	-9,2%
18	2647	2601	-46	-1,7%
19	2792	2738	-54	-1,9%
20	2292	2259	-33	-1,4%
21	1091	1225	134	12,3%
22	1509	1248	-261	-17,3%
23	1533	1788	255	16,6%

Table 20: distribution of kits sterilized per hour

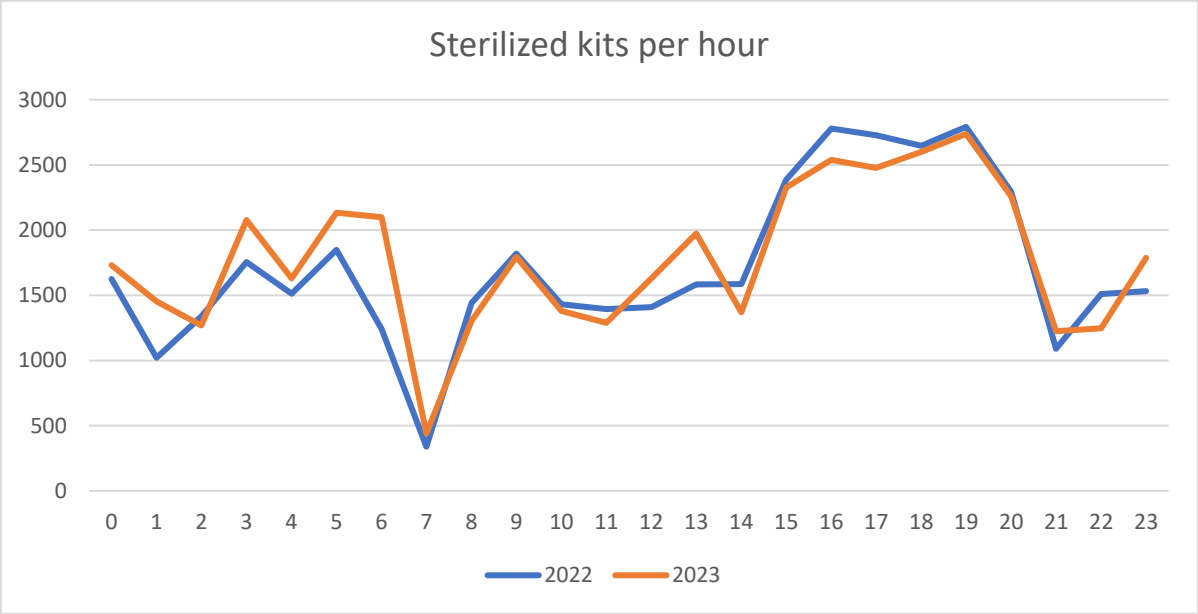


Fig. 38: total number of kits sterilized per hour

- ***Operativity and Cycles of Equipment:*** The comparison between the old autoclaves (Giada, Ametista, and Corallo) in 2022 and the new autoclaves (Dalila, Greta, and Sofia) in 2023 shows a reduction in operativity hours(Table 21, 22 and 23). Despite the reduced operativity, the new autoclaves manage to achieve similar or even slightly higher daily cycles, which indicates better utilization and efficiency of the new equipment.

2022	Operativity [h/24]	Daily cycles
GIADA	12,3	7
AMETISTA	13,7	7
CORALLO	13,3	8

Table 21: operativity and daily cycles of sterilization equipment in 2022

2023	Operativity [h/24]	Daily cycles
DALILA	11,4	8
GRETA	12,4	8
SOFIA	12,6	9

Table 22: operativity and daily cycles of sterilization equipment in 2023

2022	2023	Difference in operativity [h/24]	Difference in daily cycles
GIADA	DALILA	-0,9	1
AMETISTA	GRETA	-1,3	1
CORALLO	SOFIA	-0,7	1

Table 23: difference in operativity and daily cycles of sterilization equipment between the two years

3.1.3. Comprehensive measures

In order to get an overall evaluation of the process, some comprehensive parameters were computed as well.

The first ones are some statistics regarding the duration, measured in hours, of the entire process from acceptance to sterilization (Table 24 and 25).

2022	February	March	April	May	June	July
Median [h]	11	8,2	9	10	9,9	7
Q1 [h]	7,1	6	6,2	6,4	6,5	5,5
Q3 [h]	15,3	12,4	13,7	14,5	14,9	10,1
IQR [h]	8,2	6,4	7,5	8,1	8,4	4,6

Table 24: statistics on process duration in 2022

2023	February	March	April	May	June	July
Median [h]	8	8	6,9	8,8	9,6	8,2
Q1 [h]	1,3	5,1	1,1	1,5	1,1	1,1
Q3 [h]	12,3	14,2	8,4	13,6	7,4	7,1
IQR [h]	11	9,1	7,3	12,1	6,3	6

Table 25: statistics on process duration in 2023

The median values show a consistent trend. February and April demonstrate a substantial decrease of -27% and -23%, signalling an improvement in the process's overall speed. The remaining months show relatively smaller changes, with some experiencing marginal decreases and others remaining relatively stable. The interquartile range (IQR) also varied across months but generally fell within the range of 4.6 to 8.4 hours, seeing reductions in several months compared to the 2022 values.

These results shed light on the ongoing efforts to optimize and streamline the complete process, from acceptance to sterilization. While certain months exhibit improvements, others might present opportunities for further optimization.

Lastly, the analysis focus was put on the *remains,* the kits that are only partially processed within the same working day.

- **Remains to be packed**:

2022	February	March	April	May	June	July
Median	74	69	51	170	99	57
Q1	15	17	15	84	76	28
Q3	101	118	94	199	131	86
IQR	86	101	79	115	55	58

Table 26: statistics of daily remains to pack in 2022

2023	February	March	April	May	June	July
Median	134	116	62	160	76	96
Q1	56	90	5	86	2	12
Q3	164	159	138	200	102	140
IQR	108	69	133	114	100	128

Table 27: statistics of daily remains to pack in 2023

The statistics in Table 26 and 27 provide insights into the number of kits that were washed but not packaged on the same workday, for each month in both 2022 and 2023. In both years, there is significant variability between months, with the median values ranging from 51 to 170 kits in 2022 and from 62 to 160 in 2023.

Upon closer examination of the data, it is evident that there are some deteriorations in the number of leftovers in 2023 compared to 2022. In several months, including February, March, and April, the median and the interquartile range (IQR) have increased in 2023. This indicates that there were more remains on average and greater variability in the number of kits left unprocessed on the same workday in 2023.

These changes suggest that the process of handling remains may have faced some challenges in 2023, leading to increased inefficiencies compared to 2022. It's important to investigate the reasons behind these deteriorations, such as potential bottlenecks or operational issues, and implement measures to improve the situation in the coming months to ensure smoother operations and minimize delays in kit processing.

- **Remains to be sterilized**:

2022	February	March	April	May	June	July
Median	24	22	10	11	12	8
Q1	12	14	4	6	5	3
Q3	38	39	18	28	22	17
IQR	26	25	14	22	17	14

Table 28: statistics of daily remains to sterilize in 2022

2023	February	March	April	May	June	July
Median	13	24	7	13	29	27
Q1	8	11	3	6	16	6
Q3	26	32	12	28	58	60
IQR	18	21	9	22	42	54

Table 29: statistics of daily remains to sterilize in 2023

The figures in Table 28 and 29 show some statistics of daily remains to sterilize for each of the months of the analysis in the two years. Upon closer examination, it's evident that the values remain relatively stable between 2022 and 2023. While there are some fluctuations in certain months, like March, May, June, and July, where the median increased in 2023 compared to 2022, these variations do not seem alarming from a management perspective.

The overall stability in the data suggests that the sterilization process is generally well-managed. However, it's essential to keep monitoring these numbers to ensure that the sterilization workflow remains efficient and that any occasional increases in the number of leftovers are addressed promptly to maintain a smooth operation.

3.1.4. Analysis' summary

From the analysis of the process, it is evident that there has been an improvement in the acceptance duration (Fig.39).

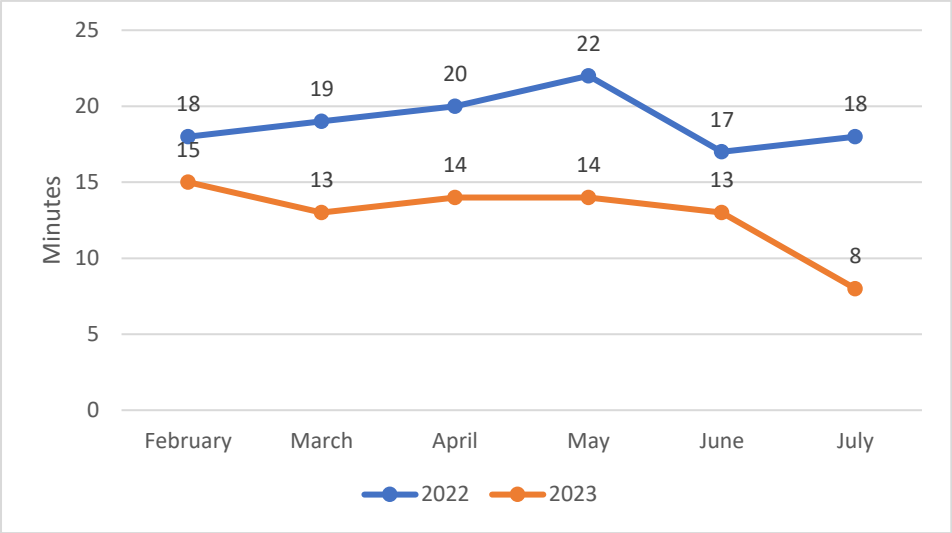


Fig. 39: median values of acceptance duration in the two years

Additionally, there has been a noticeable enhancement in terms of productivity and time efficiency in the washing and sterilization phases. These improvements are primarily attributed to increased throughput in terms of washed and sterilized kits (Fig.40) with shorter washing and sterilization durations (Fig.41).

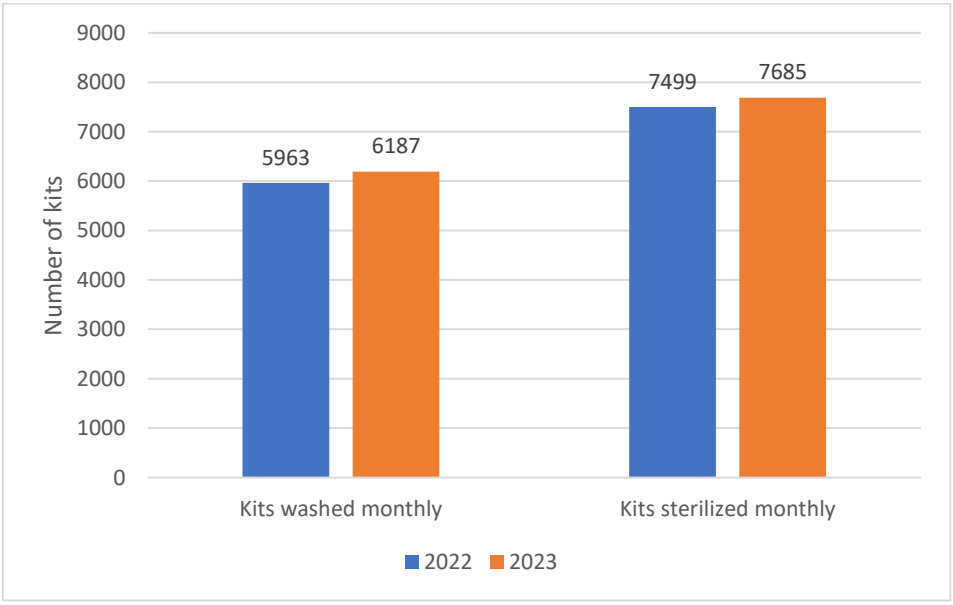


Fig. 40: median values of monthly washed and sterilized kits in the two years

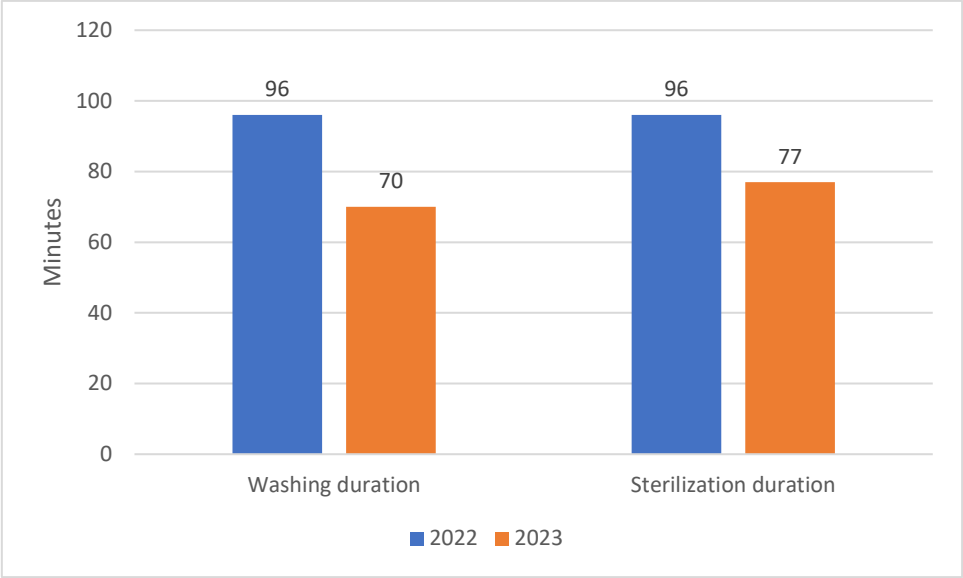


Fig. 41: median values of washing duration and sterilization duration in the two years

However, the packaging phase remains relatively stable or shows a tendency to deteriorate in terms of time efficiency (Fig.42).

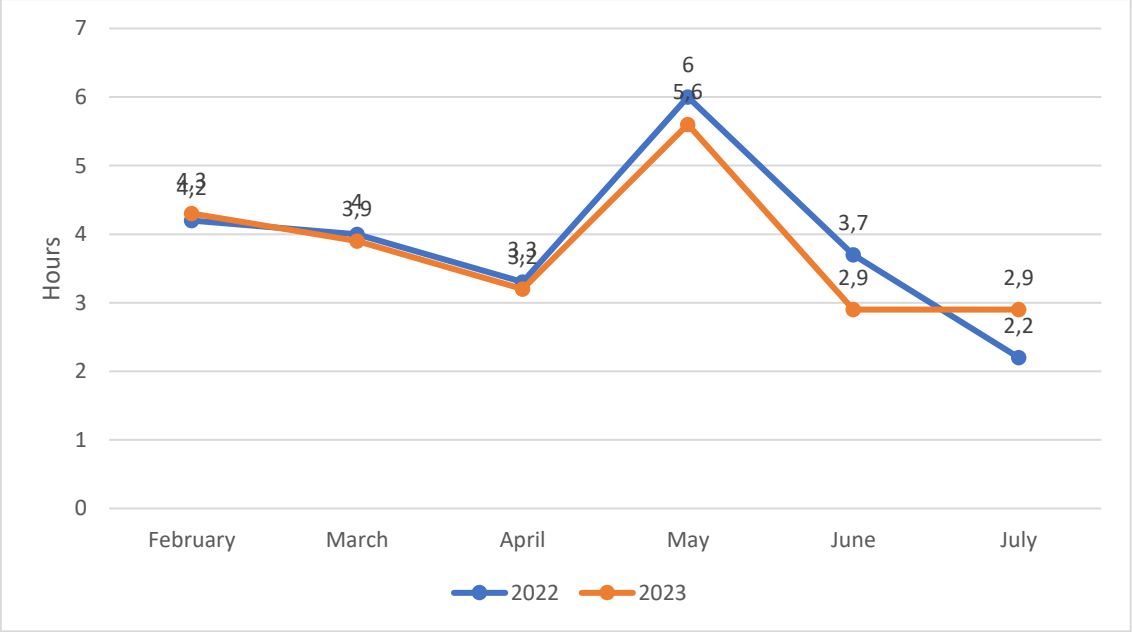


Fig. 42: median values of packaging duration in the two years

The management of remains shows a decline in efficiency, particularly in the packaging (Fig.43), while it remains relatively stable for items awaiting sterilization between the two years (Fig.44).

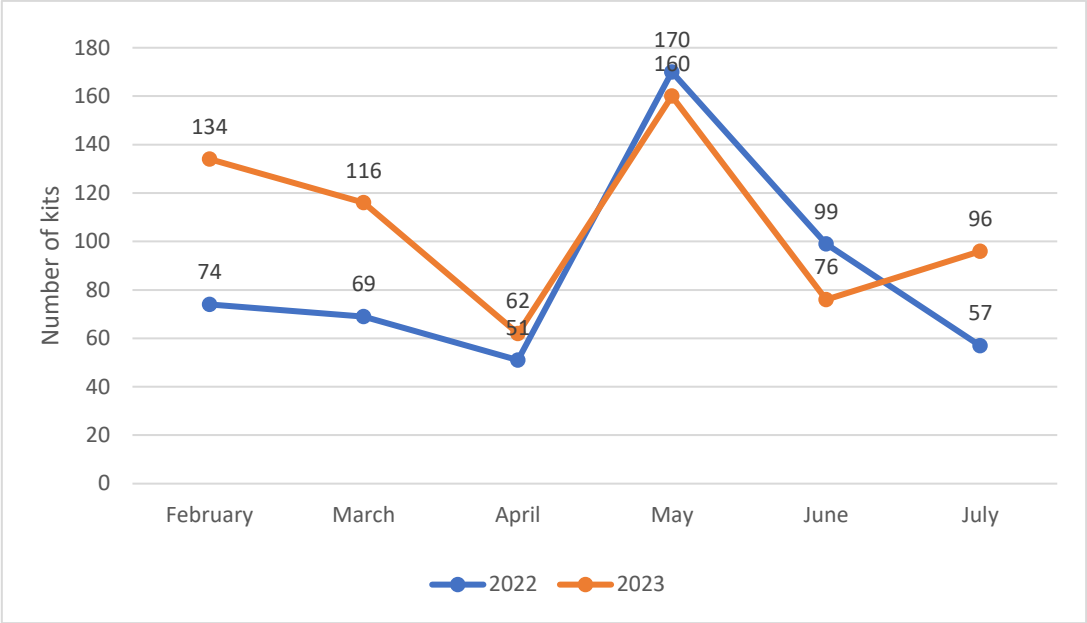


Fig. 43: median values of daily remains to pack in the two years

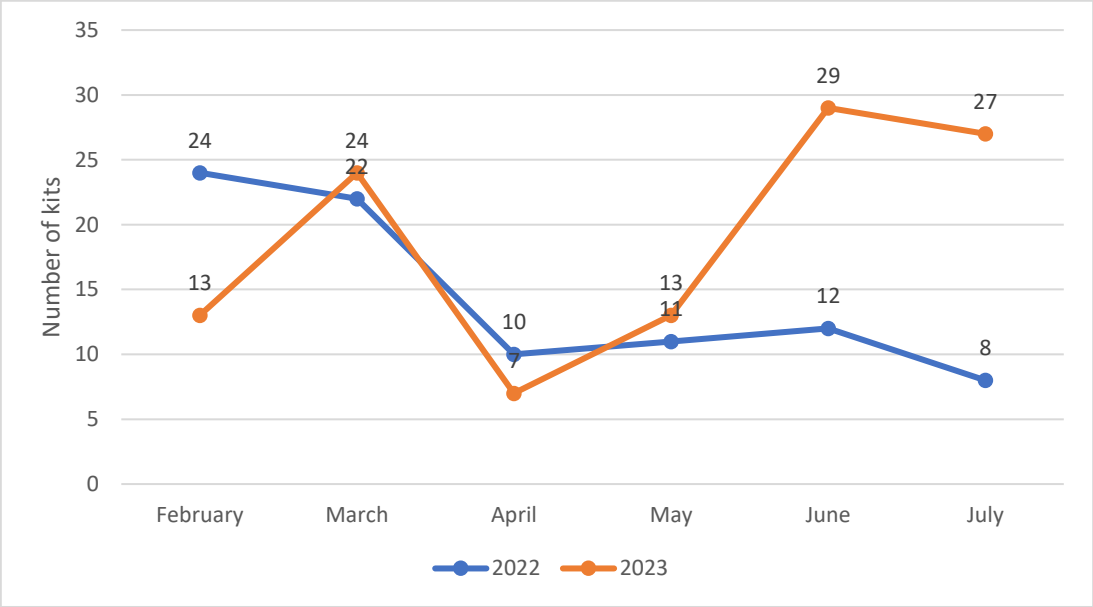


Fig. 44: median values of daily remains to sterilize in the two years

3.2. Hp2: The dashboard assists operators in monitoring production, facilitating the work of nursing staff.

3.2.1. Productivity dashboard

To facilitate real-time monitoring of the entire process, a productivity dashboard has been successfully developed. This comprehensive dashboard was meticulously crafted in response to the requests and needs of the personnel involved in the various stages. It is meticulously structured, offering a dedicated page for each process phase:

acceptance, acceptance of the clean kits, washing, packaging, and sterilization. Additionally, three pages are allocated to leftover items for packaging and sterilization and bagged items handling. Lastly, a final recap page is present.

For the initial five phases (Fig.45, Fig.46, Fig.47, Fig.48, Fig.49), the dashboard maintains a consistent layout. From left to right, users are presented with:

- A date filter enabling date selection;
- A filter to choose a specific data subset;
- A panel displaying the number of processed kits on the selected date;
- An hourly trend panel;
- A trend panel that allows users to analyze productivity over a user-defined period through a filter placed below;
- A detailed view of processed kits, including date and time.

3.2.2. Acceptance

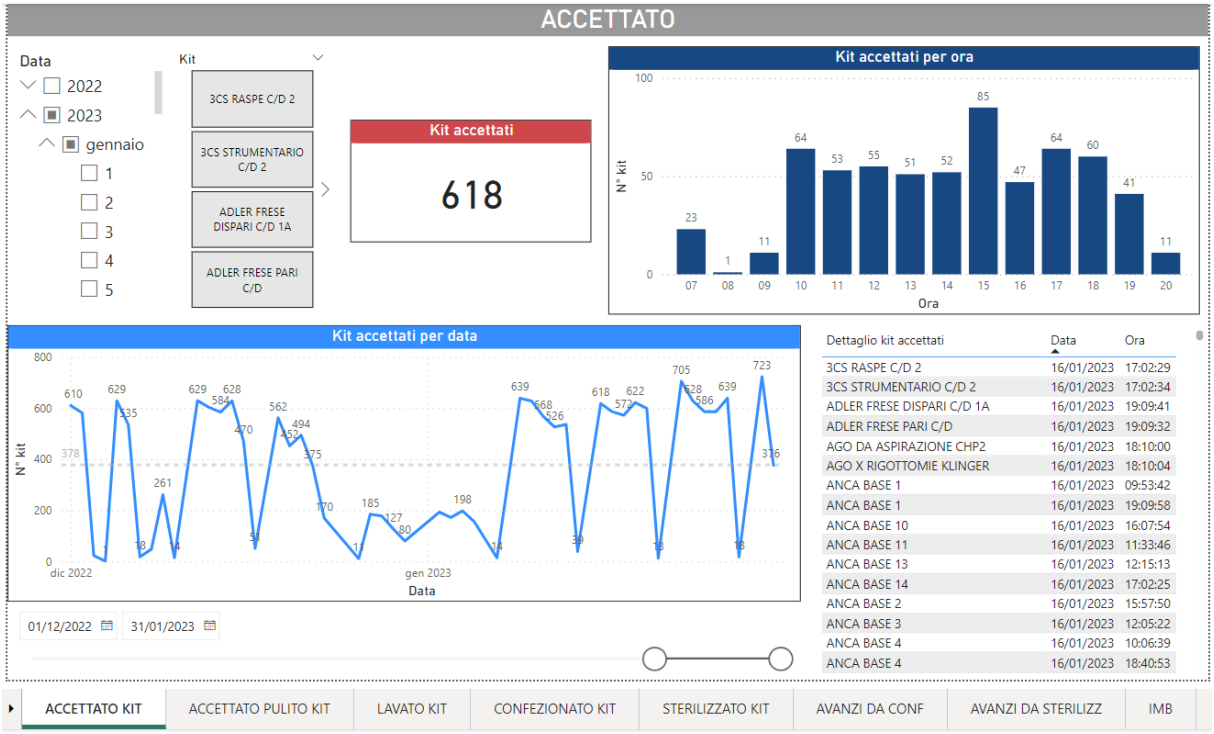


Fig. 45: page of the productivity dashboard for the acceptance phase

3.2.3. Clean acceptance

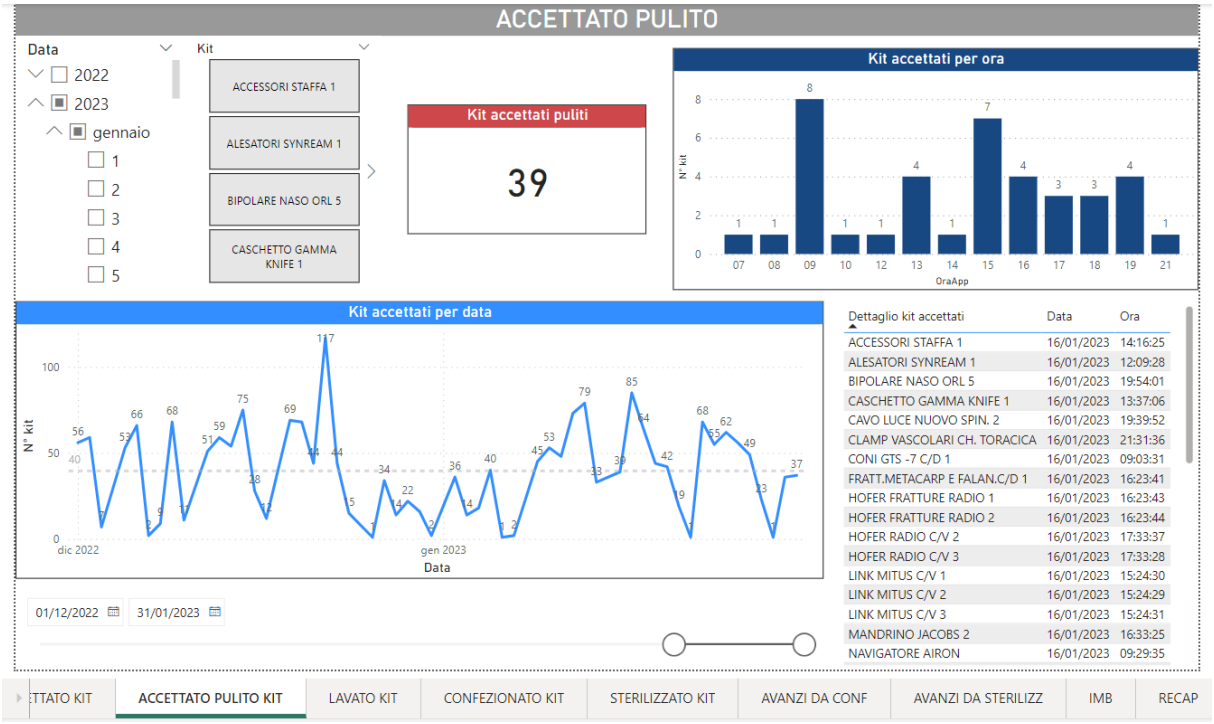


Fig. 46: page of the productivity dashboard for the clean acceptance

3.2.4. Washing

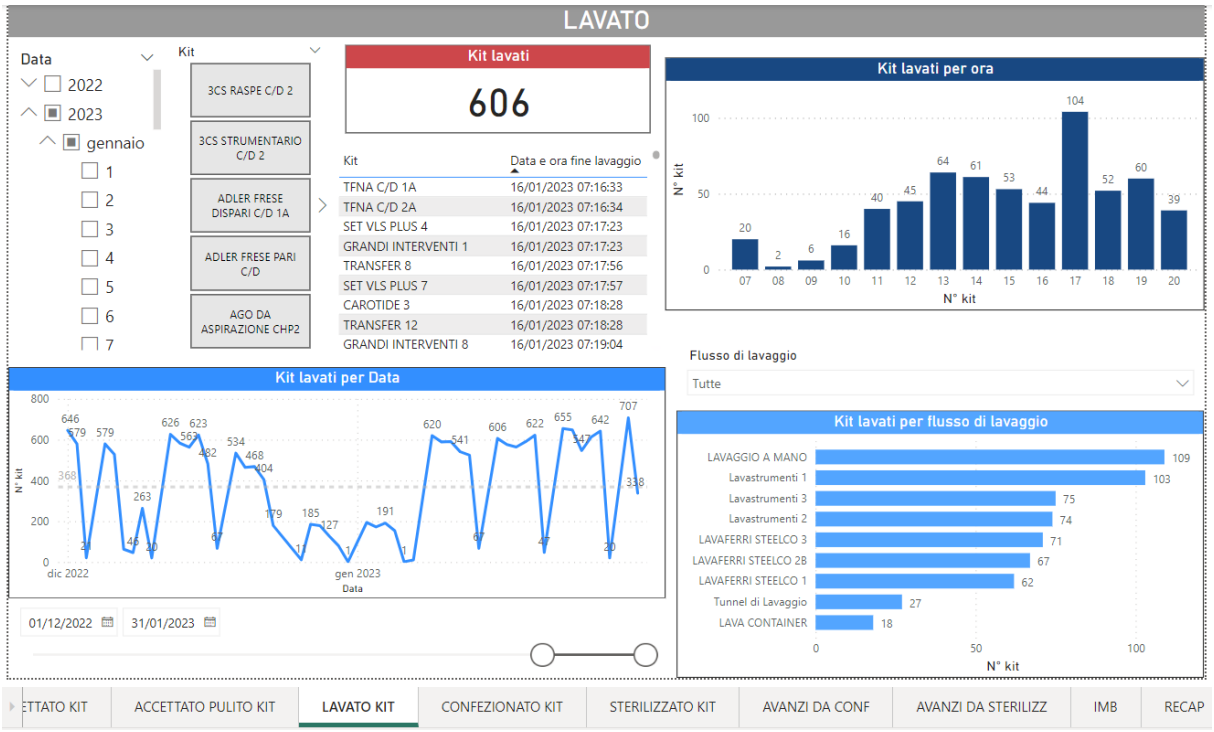


Fig. 47: page of the productivity dashboard for the washing phase

3.2.5. Packaging

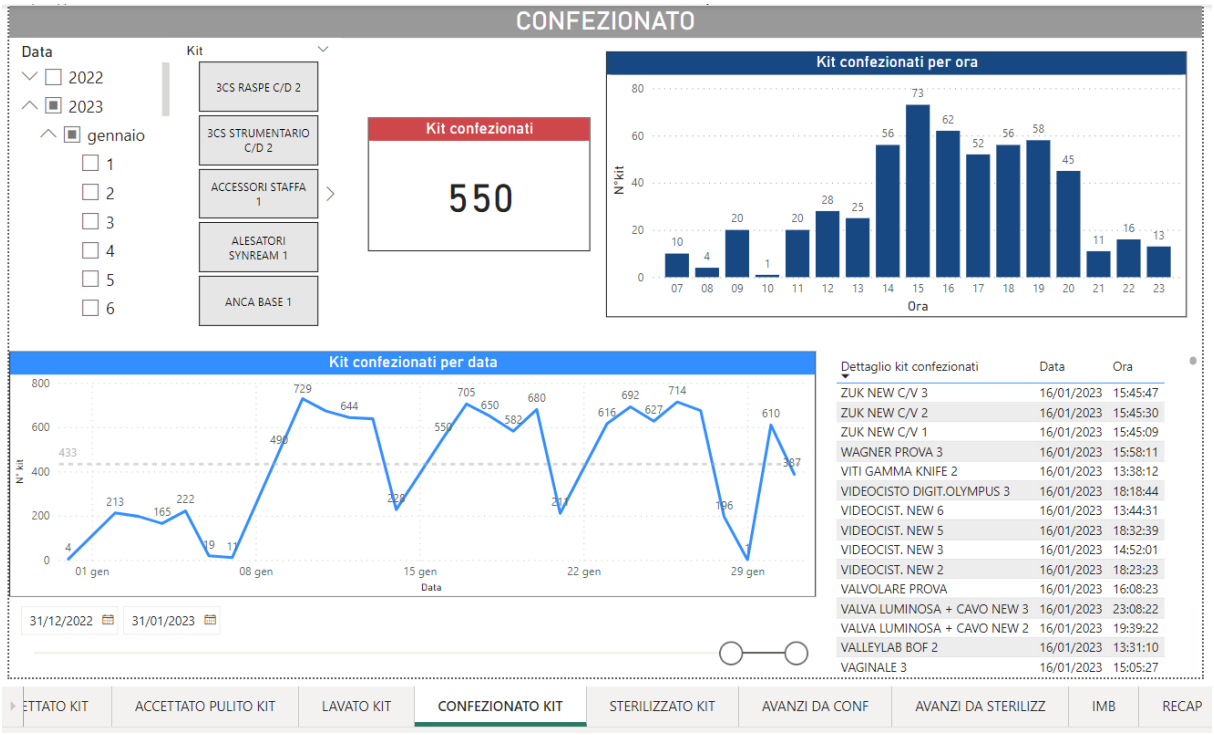


Fig. 48: page of the productivity dashboard for the packaging phase

3.2.6. Sterilization

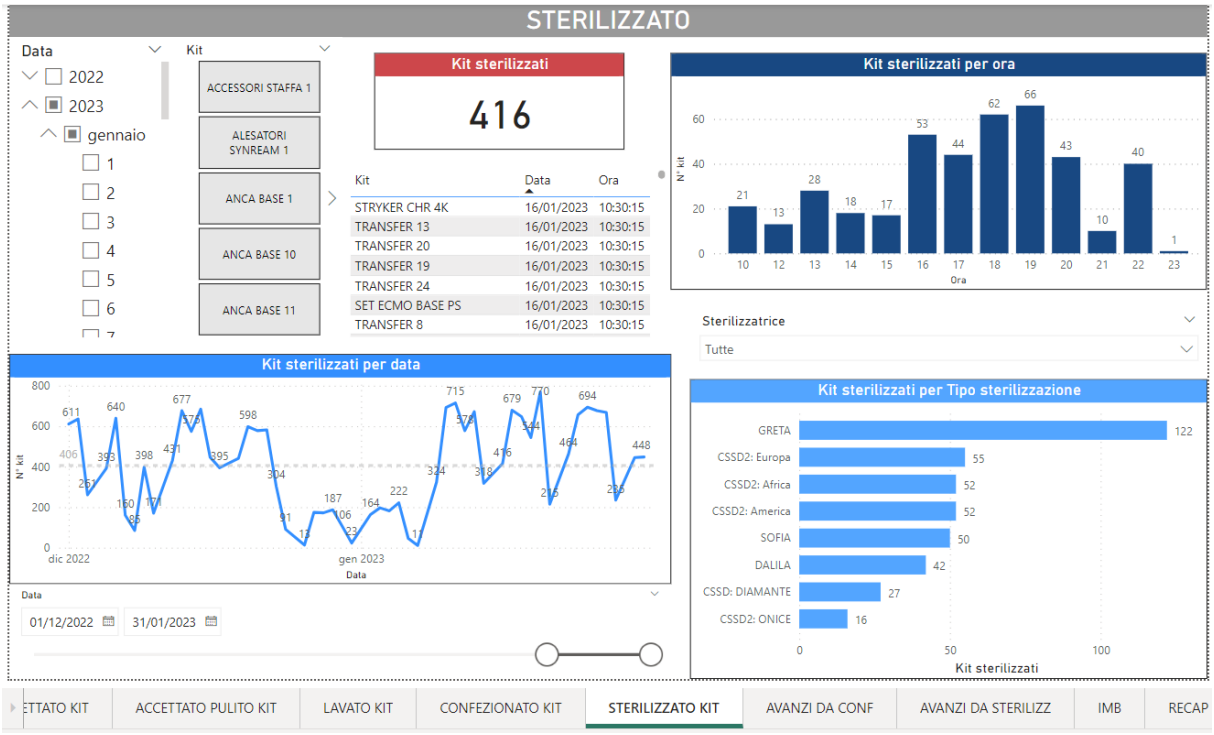


Fig. 49: page of the productivity dashboard for the sterilization phase

For the washing and sterilization phases, the dashboard includes the option to apply filters based on the equipment used, allowing users to dissect productivity between the two sterilization units.

3.2.7. Remains

The dashboard accommodates two separate pages for leftover items destined for packaging and sterilization (Fig.50, Fig.51). The structure of these pages is identical, with the following features:

- Trend analysis of leftover items over a user-defined time frame using the lower filter;
- Display of the count of leftover items on a user-selected date via the top-left filter;
- A panel displaying the number of remains on the selected date;
- Detailed listings of leftover kits, complete with end-of-washing (or end-of-packaging for sterilization leftovers) timestamps.

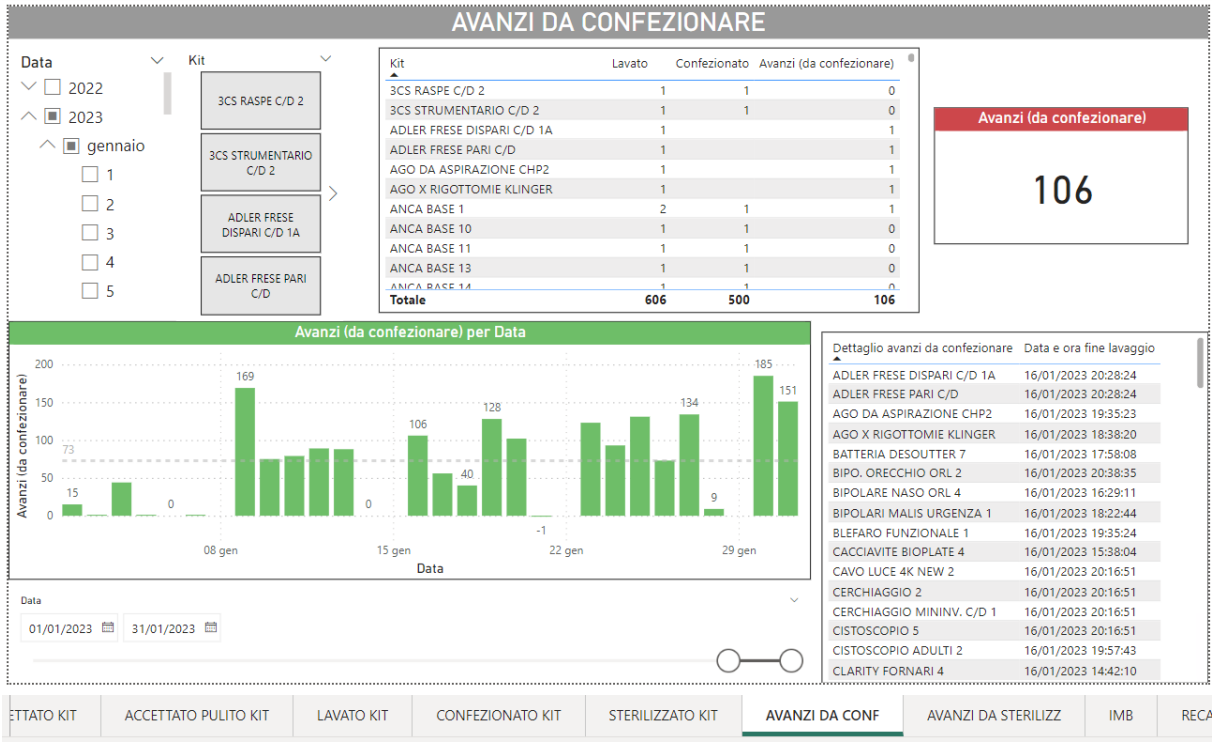


Fig. 50: page of the productivity dashboard dedicated to the remains to pack

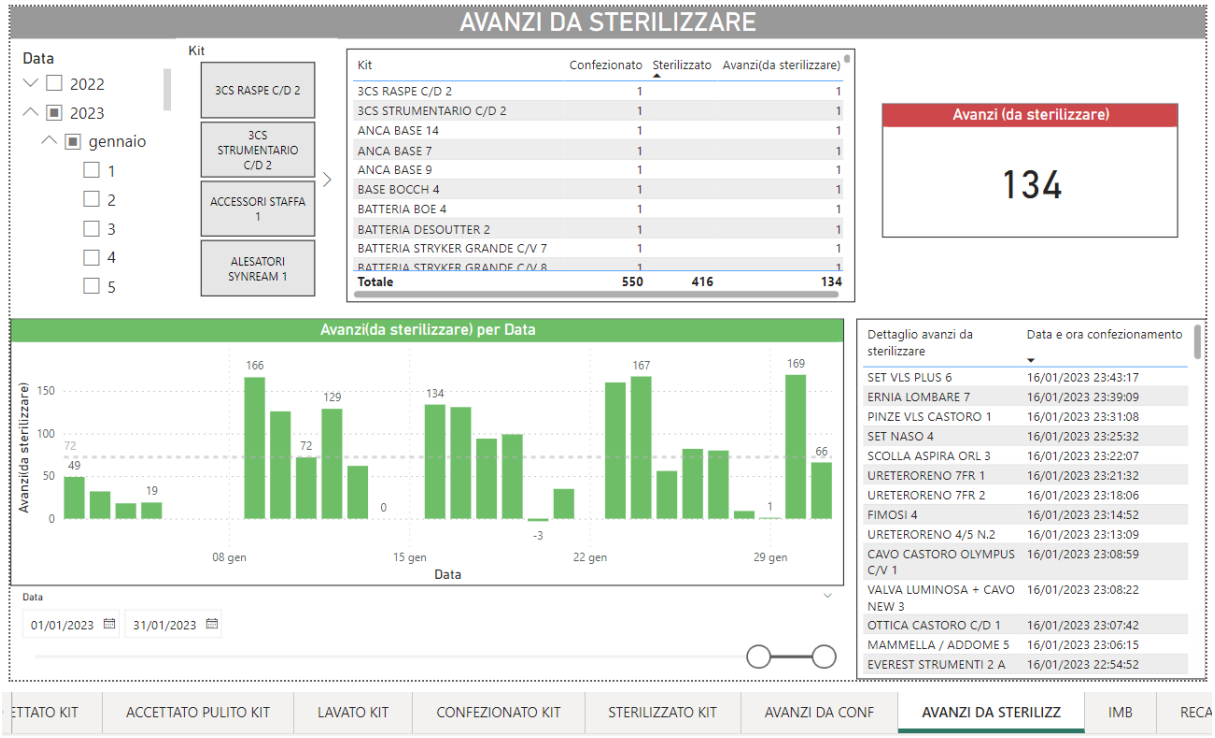


Fig. 51: page of the productivity dashboard dedicated to the remains to sterilize

3.2.8. Single bagged items

The dashboard includes a dedicated page for bagged items (Fig.52), which lack complete traceability within the process due to the absence of unique barcodes. As a consequence, the assessment of bagged items is limited to determining their quantity in the process, without the ability to pinpoint their individual identities.

From left to right, users are presented with:

- A date filter enabling date selection;
- A panel displaying the number of processed (packed and sterilized) items on the selected date;
- Two hourly trend panels, for packaging and sterilization;
- Two trend panels that allows users to analyze productivity over a period user-defined through a filter.

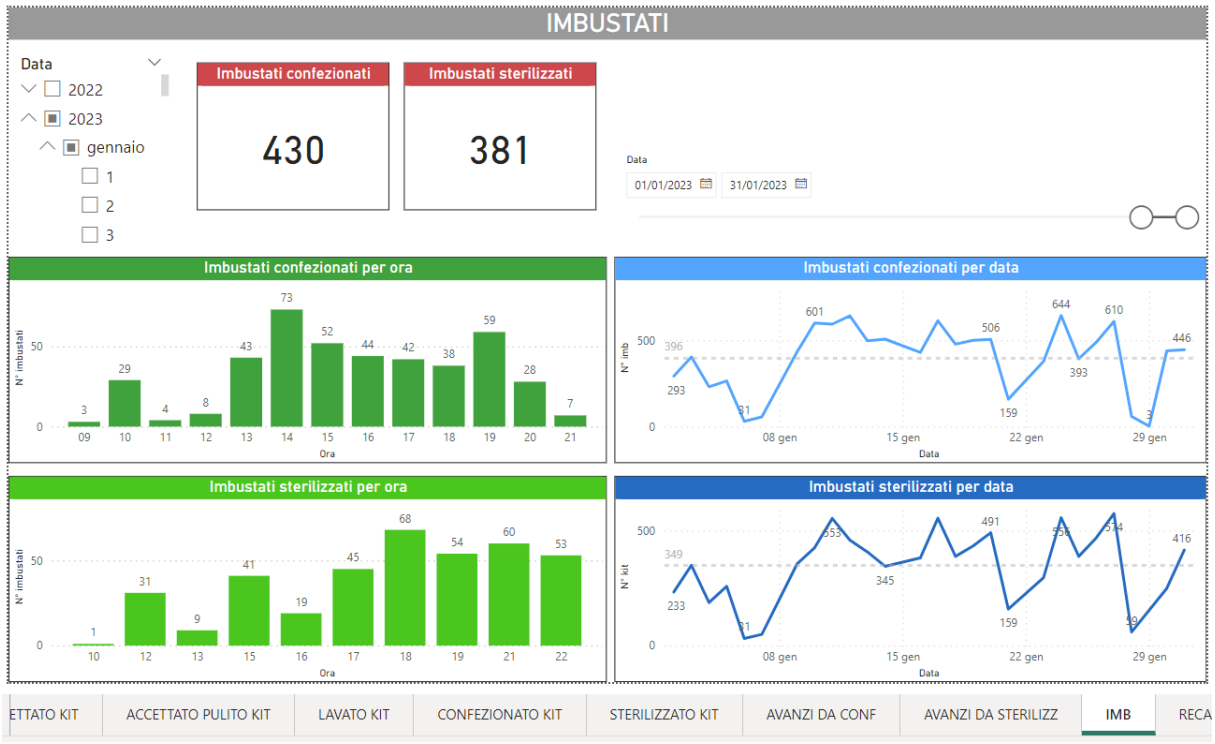


Fig. 52: page of the productivity dashboard dedicated to the single bagged items

3.2.9. Recap

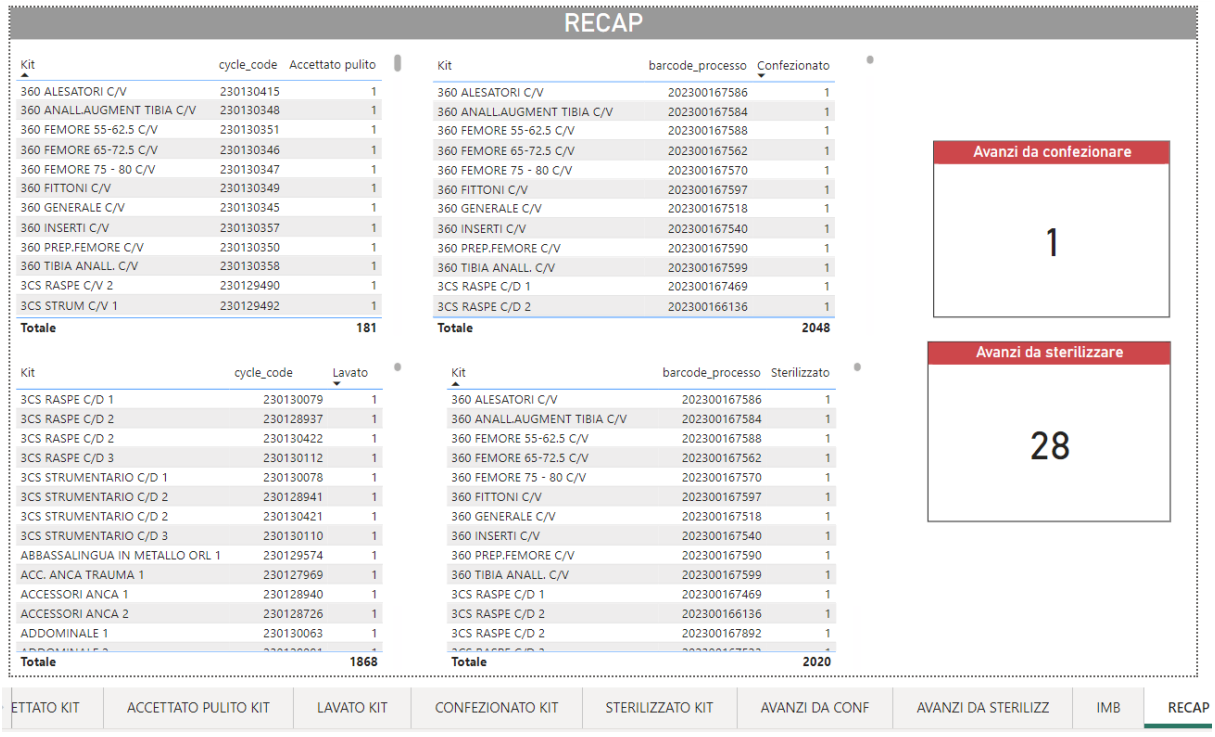


Fig. 53: recap page of the productivity dashboard

Lastly, the dashboard encompasses a recap page (Fig.53) that offers a comprehensive overview. This page permits users to examine processed kits during the most recent period and access the current count of leftovers intended for both packaging and sterilization.

3.2.10. Questionnaire results

In order to get valuable insights related to the implementation of the productivity dashboard, a questionnaire was administered to individuals actively engaged in the sterilization process within the Central Sterile Services Department (CSSD). Their constructive inputs sheds light on several critical aspects:

- **Clarity and Detail** (*question 1*): participants were asked whether they believed the dashboard provided a clear and detailed view of the sterilization process. Respondents, on a scale of 1 to 10, rated this aspect with an average score of 8.
- **Ease of Understanding** (*question 2*): concerning the comprehensibility of the information displayed in the dashboard, respondents again rated this aspect with an average score of 8.
- **Improvements in Work Planning** (*question 3*): respondents were questioned about whether they believed the dashboard could enhance work planning. The responses yielded an average score of 7.5.
- **Reducing Delays** (*question 4*): in terms of reducing delays in the sterilization process, respondents gave an average score of 6.5.
- **Identifying Inefficiencies** (*question 5*): participants were asked whether they thought the dashboard would help in identifying process inefficiencies. On average, they rated this aspect at 8, indicating optimism about the dashboard's potential to pinpoint inefficiencies.
- **Useful Filtering Features** (*questions 6, 7 and 8*): the questionnaire also inquired about the usefulness of various filtering features within the dashboard, such as filtering by date, set, or equipment. Respondents generally expressed positive views about these functionalities with an average of 9-9.5.
- **Pages Dedicated to remains** (*question 9*): regarding the dashboard's dedicated pages for remains, participants mostly perceived this as a valuable feature with an average rating of 8.5.
- **Process Phase Benefitting Most** (*question 10*): participants were asked which phase of the sterilization process they believed could benefit most from continuous monitoring. The respondents highlighted the remains and packaging phase as areas where constant monitoring could be particularly advantageous.
- **Overall Satisfaction** (*question 11*): all the respondents indicated they are satisfied with the dashboard's configuration.

Based on the provided answers, it is evident that the personnel generally hold a favourable view regarding the dashboard's configuration, features, and user-

friendliness. Additionally, there is a consensus among respondents that the dashboard can be a useful tool to identify process inefficiencies and enhance work planning. However, some uncertainties exist concerning its potential to effectively reduce process delays.

3.3. Hp3: Traceability in the operating room reduces packaging time.

One of the goals of this project was to implement the missing aspect of traceability within the operating rooms. This involved two key steps: the check-in of sets to be used during a surgical procedure, ideally performed at the beginning of the operation, and the check-out of utilized sets at the conclusion of the procedure. For the check-out process, it was necessary to associate each set with the corresponding storage grids, identified by unique barcodes. This approach differed significantly from the existing practice, which lacked such a requirement. In the current practice, used sets are randomly placed within storage grids, often leading to mixing and disarray. This mixing of items causes substantial challenges in the sterilization facility, particularly during the packaging phase, where operators had to search for individual kit components. The idea behind introducing traceability was that altering the way used kits were stored in the operating rooms would streamline the packaging process, resulting in reduced times.

While systematic implementation of traceability was not fully feasible, following a training period for both the operating rooms and sterilization personnel, a pilot test was conducted within the cardiovascular operating ward. This test showed that there was indeed a reduction in packaging times: this improvement not only contributed to overall efficiency, but also benefited the personnel by simplifying the reassembly of sets.

However, the check-out practice did lead to increased times within the operating room's post-procedure phase. In timed trials, it was observed that while the average time for storing sets without check-out was approximately 20-22 minutes, the introduction of the check-out process extended this time to 28-30 minutes. It's worth noting that this change introduced a learning curve, and with ongoing training and experience, it's expected that the efficiency of the check-out process can be further optimized, potentially narrowing the time gap between the two approaches.

4 Discussions and conclusions

4.1. Hp1: The adoption of new technologies reduces process time.

This section delves into the hypothesis that the adoption of new equipment contributes to the reduction of process durations. The results of the process analysis allow to differentiate between stages predominantly impacted by equipment operation and those strongly influenced by human actions.

During phases intricately linked to the functioning of the recently introduced equipment, like the washing and sterilization stages, noticeable reductions in process durations are observed. In terms of washing, the median duration has seen a decline of about 27%. This decrease in process time has yielded several productivity advantages: notably, the median of kits washed monthly has risen by around 4%, and the median of kits washed daily has increased by 9%.

A similar trend is observed in the sterilization phase, wherein a nearly 20% reduction in duration has been achieved. Productivity has improved by almost 3% in terms of sterilized kits per month and nearly 8% for the number of kits sterilized daily.

The reduction in processing times across these stages underscores the impact of incorporating modern machinery on efficiency and productivity. The automated and controlled nature of these stages, facilitated by the new equipment, seems to have positively influenced process completion times, resulting in enhanced overall efficiency.

The increase in efficiency is further highlighted by comparing the average operational duration over a 24-hour period. While maintaining a similar number of daily cycles, both the washer disinfectors and the sterilizers have managed to reduce the hours of operation. The implications of these efficiency gains extend beyond process enhancement alone. The reduction in operational hours directly translates into energy conservation, which aligns with sustainability goals. The minimized runtime of the machinery not only decreases the energy consumed but also contributes to prolonging the lifespan of the equipment, reducing maintenance requirements, and thereby lowering associated costs.

In addition to energy savings, the reduction in operational hours positively impacts water usage. With less time required for processes, the amount of water consumed for these steps is significantly reduced. This conservation aligns with responsible resource management and supports environmentally conscious practices.

These considerations are particularly true for the washing phase. The old washing disinfectors were operational around 13 hours a day, with a power consumption of 20 kW and a consumption of hot softened water, cold softened water and demineralized water of 50 l/min. The new washing disinfectors are operational around 10 hours a day, with a power consumption of 23 kW and a consumption of hot softened water, cold softened water and demineralized water of 40 l/min. By computing some calculations (Appendix A.3), it is possible to see that the new washing machines consume less energy (230 kWh/day compared to 260 kWh/day) and less water (72,000 liters/day compared to 102,000 liters/day) than the old washing machines. Therefore, with the new washing machines, there are savings both in terms of energy and water consumption.

Encouraging outcomes are also evident in the acceptance phase, where the median values of the duration express a trend of reduction in all the months of the analysis.

However, the scenario changes when the packaging stage is examined. Although the median values of the duration remains relatively stable across the different months between the two years, the presence of outliers on the higher side is significantly more evident in 2023 compared to 2022. The management of this specific phase has shown a decline between the two years, further accentuated by the rise in the count of daily remains to pack. It becomes evident that the packaging serves as a prominent bottleneck within the overall process, being the most challenging phase to automate and the most time-consuming.

Evaluating the process as a whole, the median duration in 2023 appears to be generally lower compared to 2022: this indicates increased consistency and process stability, aligning with the anticipated benefits of the new equipment.

To better showcase the improvements brought about by the adoption of new equipment across the entire process, it's essential to focus on enhancing the packaging phase following some strategic optimization steps.

First and foremost, comprehensive training for personnel involved in the packaging phase is imperative; additionally, increasing the number of dedicated staff for the packaging stage can help expedite the process. The introduction of visual aids, such as photographic guides, can play a pivotal role in facilitating the reassembly of kits. These guides would streamline the process and reduce the chances of errors, proving beneficial especially for the staff who is not very experienced.

Moreover, optimizing the coordination of activities between different phases is paramount. The limited usage window for washer disinfectors and the peak utilization time for autoclaves in the afternoon highlight the need for better synchronization. To address the accumulation of kits awaiting packaging, a potential solution could be the extension of the utilization hours of the washer disinfectors during the morning and night shifts, which might help distribute the workload and reduce the accumulation

of kits. This would require careful consideration of operational constraints and potential resource allocation.

Ultimately, it's crucial to address the outliers or extreme cases: by delving into the causes of extended timeframes, the central sterilization unit can pinpoint areas that require targeted interventions. Analysing these instances of outlier durations can offer valuable insights into the root causes, whether they stem from procedural inefficiencies, equipment malfunctions, or other variables. The direct consequence of this understanding is the development of corrective actions that target the sources of delays and contribute to process streamlining.

In conclusion, it's essential to view the process enhancements holistically, considering both statistical measures and the broader context. The efficiency gains achieved through the introduction of advanced equipment are not universally applicable across all process stages. The new equipment surely can lead to tangible improvements in automated and mechanized tasks, but this may not be true for human-dependent phases, which could experience different outcomes.

Hence, while the hypothesis suggesting that the incorporation of new equipment reduces process times holds true for equipment-intensive phases like washing and sterilization, the dynamics are more complex in human-involved stages such as packaging. This underscores the need for a comprehensive understanding of the interplay between technological advancements, human actions, and their combined influence on process efficiency.

4.2. Hp2: The dashboard assists operators in monitoring production, facilitating the work of nursing staff.

The hypothesis that the implementation of the dashboard enhances the operational process by aiding in production monitoring has been examined and yielded insightful results.

Through the implementation of this technology, operators have been provided with a user-friendly interface to conveniently compute KPIs and closely monitor production activities.

To further gauge the impact of the dashboard adoption, a questionnaire was administered to operators to solicit their feedback. The responses garnered from this survey underscored the positive response: operators expressed satisfaction with the ease of use, real-time insights, and the streamlining of their tasks facilitated by the dashboard. In particular, the figures involved in the sterilization process highlighted that the dashboard eliminates the need for them to manually compile data in Excel, as they did previously to monitor central productivity. This not only expedites the

monitoring process but also minimizes the chances of errors associated with manual data entry.

The collective sentiment expressed by the nursing staff indicates that the dashboard serves as a valuable tool that not only enhances their daily operations but also empowers them to make more informed decisions.

In conclusion, the integration of the dashboard has not only confirmed the hypothesis regarding its positive impact on production monitoring but has also demonstrated its potential to improve the work experience for nursing staff. The positive feedback received through the questionnaire reaffirms the significance of this technological upgrade and its potential to enhance efficiency and accuracy in the sterilization department.

4.3. Hp3: Traceability in the operating room reduces packaging time.

The hypothesis that implementing traceability in the operating room would reduce packaging time was investigated with a careful evaluation of its feasibility and impact. Although the concept of traceability exhibited potential benefits, it was challenging to consistently implement it in a manner that generated a sufficient quantity of data for a meaningful analysis.

Initial pilot tests did show promising results, indicating that traceability could indeed expedite and streamline the packaging process. However, these advantages came with the trade-off of increased time during the final stages of the surgical procedure in the operating room. This increase in time is expected to align with the learning curve and eventually diminish as familiarity with the traceability process grows.

Nevertheless, it became evident that successful implementation, especially in its early stages, requires the active involvement of operational management. Incorporating the additional time required for traceability into the surgery scheduling process is essential. This requires a strategic approach to ensure that the overall surgical workflow remains efficient despite the initial increase in time due to traceability processes.

Another critical consideration is defining a clear role within the operating room (whether the operating room nurse or the instrumentalist) for overseeing traceability management.

In conclusion, these findings indicate the potential benefits of traceability in terms of packaging time reduction. However, they also underscore the need for a comprehensive strategy that incorporates operational management and balances the short-term increase in time with long-term efficiency gains. As such, the incorporation

of traceability in the operating room process becomes an important aspect to explore in the realm of potential future advancements in this research.

Bibliography

1. Rowan NJ, Kremer T, McDonnell G. A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability. *Science of the Total Environment*. 2023;878. doi:10.1016/j.scitotenv.2023.162976
2. Rutala WA, Weber DJ. Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues. *Infect Dis Clin North Am*. 2021;35(3):575-607. doi:10.1016/j.idc.2021.04.004
3. Tlahig H, Jebali A, Bouchriha H, Ladet P. Centralized versus distributed sterilization service: A location-allocation decision model. *Oper Res Health Care*. 2013;2(4):75-85. doi:10.1016/j.orhc.2013.05.001
4. Volland J, Fügener A, Schoenfelder J, Brunner JO. Material logistics in hospitals: A literature review. *Omega (United Kingdom)*. 2017;69:82-101. doi:10.1016/j.omega.2016.08.004
5. Ozturk O, Begen MA, Zaric GS. A branch and bound based heuristic for makespan minimization of washing operations in hospital sterilization services. *Eur J Oper Res*. 2014;239(1):214-226. doi:10.1016/j.ejor.2014.05.014
6. Lastrucci V, Romolini A, Giusti M, Persiani N. The impact of outsourcing operating theatre support services on hospital performances: the case of the largest university hospital of the Albania. *Economic Research-Ekonomska Istrazivanja* . Published online 2022. doi:10.1080/1331677X.2022.2097102
7. Di Mascolo M, Gouin A. A generic simulation model to assess the performance of sterilization services in health establishments. *Health Care Manag Sci*. 2013;16(1):45-61. doi:10.1007/s10729-012-9210-2
8. Basu D, Das A, Rozario JD. A brief discussion on environmental quality monitoring required in a central sterile supply department: Evidence from a cancer center in eastern India. *Infect Control Hosp Epidemiol*. 2020;41(5):624-625. doi:10.1017/ice.2020.41
9. https://www.steris.com/healthcare/knowledge-center/sterile-processing/medical-washer-disinfector-cssd.

10. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html.

11. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/hydrogen-peroxide-gas.html.

12. https://www.iso.org/standard/59752.html.

13. Pestana M, Pereira R, Moro S. Improving Health Care Management in Hospitals Through a Productivity Dashboard. *J Med Syst*. 2020;44(4). doi:10.1007/s10916-020-01546-1

14. Helminski D, Kurlander JE, Renji AD, et al. Dashboards in Health Care Settings: Protocol for a Scoping Review. *JMIR Res Protoc*. 2022;11(3). doi:10.2196/34894

A Appendix A

A.1. Splunk codes

Acceptance duration 2022

index="cssd" source="ACCETTATO.csv" OR source="LAVATO.csv" tipo_articolo=KIT

| where date_month="*month*"

| transaction barcode_inventariale endswith=ASSOCIATED_WASH

| table _time barcode_inventariale prod_desc timestamp_carrello timestamp_accettato date_month desc_lav date_wday

| where NOT date_wday="saturday" AND NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST")

| where desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE"

| eval epoch_carrello=strftime(strptime(timestamp_carrello, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_accettato=strftime(strptime(timestamp_accettato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_acclav=epoch_carrello-epoch_accettato

| eval min_acclav=epoch_acclav/60

| stats median(min_acclav) as mediana, perc25(min_acclav) as Q1, perc75(min_acclav) as Q3

Acceptance duration 2023

index="cssd" source="dirty2023.csv" OR source="washed2023.csv" tipo_articolo=KIT

| where date_month="*month*"

| transaction barcode_inventariale endswith=ASSOCIATED_WASH

| table _time barcode_inventariale prod_desc timestamp_carrello timestamp_accettato date_month desc_lav date_wday

| where NOT date_wday="saturday" AND NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST")

| where desc_lav="Lavastrumenti 1" OR desc_lav="Lavastrumenti 2" OR desc_lav="Lavastrumenti 3" OR desc_lav="Tunnel di Lavaggio"

| eval epoch_carrello=strftime(strptime(timestamp_carrello, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_accettato=strftime(strptime(timestamp_accettato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_acclav=epoch_carrello-epoch_accettato

| eval min_acclav=epoch_acclav/60

| stats median(min_acclav) as mediana, perc25(min_acclav) as Q1, perc75(min_acclav) as Q3

Statistics of washed kits 2022

index="cssd" source="LAVATO.csv" tipo_articolo=KIT

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_month date_wday

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june"

| where desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE"

| where NOT match (barcode_inventariale, "TEST")

| stats count(barcode_inventariale) as Kit_lavati by date_month

| stats median(Kit_lavati) as mediana, perc25(Kit_lavati) as Q1, perc75(Kit_lavati) as Q3

index="cssd" source="LAVATO.csv" tipo_articolo=KIT

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| stats count(barcode_inventariale) as Kit_lavati by data

| stats median(Kit_lavati) as mediana, perc25(Kit_lavati) as Q1, perc75(Kit_lavati) as Q3

Statistics of washed kits 2023

index="cssd" source="washed2023.csv" tipo_articolo=KIT

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_month date_wday

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june"

| where desc_lav="Tunnel di Lavaggio" OR desc_lav="Lavastrumenti 1" OR desc_lav="Lavastrumenti 2" OR desc_lav="Lavastrumenti 3"

| where NOT match (barcode_inventariale, "TEST")

| stats count(barcode_inventariale) as Kit_lavati by date_month

| stats median(Kit_lavati) as mediana, perc25(Kit_lavati) as Q1, perc75(Kit_lavati) as Q3

index="cssd" source="washed2023.csv" tipo_articolo=KIT

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_lav="Tunnel di Lavaggio" OR desc_lav="Lavastrumenti 1" OR desc_lav="Lavastrumenti 2" OR desc_lav="Lavastrumenti 3"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| stats count(barcode_inventariale) as Kit_lavati by data

| stats median(Kit_lavati) as mediana, perc25(Kit_lavati) as Q1, perc75(Kit_lavati) as Q3

Washing duration

index="cssd" source="*LAVATO.csv*" tipo_articolo=KIT

| dedup timestamp_lavato

| dedup timestamp_lavastrumenti

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where *desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE*"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| eval epoch_lavastrumenti=strftime(strptime(timestamp_lavastrumenti, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_lavato=strftime(strptime(timestamp_lavato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval durata_lavaggio = (epoch_lavato - epoch_lavastrumenti)/60

| stats median(durata_lavaggio) as mediana, perc25(durata_lavaggio) as Q1, perc75(durata_lavaggio) as Q3

Washing equipment operativity

index="cssd" source="*LAVATO.csv*" tipo_articolo=KIT

| dedup timestamp_lavato

| dedup timestamp_lavastrumenti

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_lav="*STERIS HAMO T21 / 1*"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| eval epoch_lavastrumenti=strftime(strptime(timestamp_lavastrumenti, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_lavato=strftime(strptime(timestamp_lavato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval durata_lavaggio = epoch_lavato - epoch_lavastrumenti

| stats sum(durata_lavaggio) as durate by data

| stats avg(durate) as tempo_occ

| eval tempo_occ_ore = tempo_occ/3600

Washing equipment daily cycles

index="cssd" source=" *LAVATO.csv* " tipo_articolo=KIT

| dedup timestamp_lavato

| dedup timestamp_lavastrumenti

| table barcode_inventariale desc_lav prod_desc timestamp_lavastrumenti timestamp_lavato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_lav="*Lavastrumenti 1*"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%Y/%m/%d"),strftime(_time, "%d/%m/%Y"))

| stats count(timestamp_lavato) as cicli by data

| stats median(cicli) as mediana_cicli

Distribution of kits washed per hour

index="cssd" source="*LAVATO.csv*" tipo_articolo="KIT"

| table _time barcode_inventariale prod_code prod_desc source tipo_articolo date_hour date_month desc_lav

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where (*desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE"*)

| where NOT match(barcode_inventariale, "TEST")

| where (date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july")

| stats count(tipo_articolo) as Kit_lavati by date_hour

| sort date_hour

Packaging duration 2022

index="cssd" source="LAVATO.csv" OR source="CONFEZIONATO.csv" tipo_articolo=KIT

| where date_month="*month*"

| transaction barcode_inventariale startswith=WASHED

| table _time barcode_inventariale prod_desc timestamp_lavato timestamp_confezionato date_month desc_lav date_wday

| where NOT match (barcode_inventariale, "TEST")

| where desc_lav="STERIS HAMO T21 / 1" OR desc_lav="STERIS HAMO T21 / 2" OR desc_lav="STERIS HAMO T21 / 3" OR desc_lav="LAVAFERRI GETINGE"

| eval epoch_lavato=strftime(strptime(timestamp_lavato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_confezionato=strftime(strptime(timestamp_confezionato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_lavconf=epoch_confezionato-epoch_lavato

| where isnotnull(epoch_lavconf)

| eval min_lavconf=epoch_lavconf/60

| stats median(min_lavconf) as mediana, perc25(min_lavconf) as Q1, perc75(min_lavconf) as Q3

Packaging duration 2023

index="cssd" source="packed2023.csv" OR source="washed2023.csv" tipo_articolo=KIT

| where date_month="february"

| transaction barcode_inventariale startswith=WASHED

| table _time barcode_inventariale prod_desc timestamp_lavato timestamp_confezionato date_month desc_lav date_wday

| where NOT match (barcode_inventariale, "TEST")

| where desc_lav="Lavastrumenti 1" OR desc_lav="Lavastrumenti 2" OR desc_lav="Lavastrumenti 3" OR desc_lav="Tunnel di Lavaggio"

| eval epoch_lavato=strftime(strptime(timestamp_lavato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_confezionato=strftime(strptime(timestamp_confezionato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_lavconf=epoch_confezionato-epoch_lavato

| where isnotnull(epoch_lavconf)

| eval min_lavconf=epoch_lavconf/60

| stats median(min_lavconf) as mediana, perc25(min_lavconf) as Q1, perc75(min_lavconf) as Q3

Statistics of sterilized kits 2022

index="cssd" source="STERILIZZATO.csv" tipo_articolo=KIT

| table barcode_inventariale prod_desc codice_auto desc_auto prod_code timestamp_autoclave timestamp_sterilizzato _time date_hour timestamp_carrello date_month

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where desc_auto="CSSD: GIADA" OR desc_auto="CSSD: AMETISTA" OR desc_auto="CSSD: CORALLO"

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june"

| where NOT match (barcode_inventariale, "TEST") | stats count(barcode_inventariale) as Kit_sterilizzati by date_month

| stats median(Kit_sterilizzati) as mediana, perc25(Kit_sterilizzati) as Q1, perc75(Kit_sterilizzati) as Q3

index="cssd" source="STERILIZZATO mod.csv" tipo_articolo=KIT

| table barcode_inventariale prod_desc codice_auto desc_auto prod_code timestamp_autoclave timestamp_sterilizzato _time date_hour timestamp_carrello date_month

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where desc_auto="CSSD: GIADA" OR desc_auto="CSSD: AMETISTA" OR desc_auto="CSSD: CORALLO"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST") | where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="july" OR date_month="february"

| stats count(barcode_inventariale) as Kit_sterilizzati by data

| stats median(Kit_sterilizzati) as mediana, perc25(Kit_sterilizzati) as Q1, perc75(Kit_sterilizzati) as Q3

Statistics of sterilized kits 2023

index="cssd" source="sterilized2023.csv" tipo_articolo=KIT

| table barcode_inventariale prod_desc codice_auto desc_auto prod_code timestamp_autoclave timestamp_sterilizzato _time date_hour timestamp_carrello date_month

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where desc_auto="DALILA" OR desc_auto="GRETA" OR desc_auto="SOFIA"

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june"

| where NOT match (barcode_inventariale, "TEST") | stats count(barcode_inventariale) as Kit_sterilizzati by date_month

| stats median(Kit_sterilizzati) as mediana, perc25(Kit_sterilizzati) as Q1, perc75(Kit_sterilizzati) as Q3

index="cssd" source="sterilized2023.csv" tipo_articolo=KIT

| table barcode_inventariale prod_desc codice_auto desc_auto prod_code timestamp_autoclave timestamp_sterilizzato _time date_hour timestamp_carrello date_month

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where desc_auto="DALILA" OR desc_auto="GRETA" OR desc_auto="SOFIA"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST") | where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="july" OR date_month="february"

| stats count(barcode_inventariale) as Kit_sterilizzati by data

| stats median(Kit_sterilizzati) as mediana, perc25(Kit_sterilizzati) as Q1, perc75(Kit_sterilizzati) as Q3

Sterilization duration

index="cssd" source="*STERILIZZATO.csv*" tipo_articolo=KIT

| dedup timestamp_sterilizzato

| dedup timestamp_autoclave

| table barcode_inventariale prod_desc codice_auto desc_auto prod_code timestamp_autoclave timestamp_sterilizzato _time date_hour timestamp_carrello date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT match (barcode_inventariale, "TEST") | where NOT date_wday="saturday" and NOT date_wday="sunday"

| where *desc_auto="CSSD: GIADA" OR desc_auto="CSSD: AMETISTA" OR desc_auto="CSSD: CORALLO"*

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%d/%m/%y"))

| eval epoch_autoclave=strftime(strptime(timestamp_autoclave, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_sterilizzato=strftime(strptime(timestamp_sterilizzato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval durata_sterilizzazione = (epoch_sterilizzato - epoch_autoclave)/60

| stats median(durata_ sterilizzazione) as mediana, perc25(durata_ sterilizzazione) as Q1, perc75(durata_ sterilizzazione) as Q3

Sterilization equipment operativity

index="cssd" source="*STERILIZZATO.csv*" tipo_articolo=KIT

| dedup timestamp_sterilizzato

| dedup timestamp_autoclave

| table barcode_inventariale desc_auto prod_desc timestamp_autoclave timestamp_sterilizzato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_auto="*CSSD: GIADA*"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%Y/%m/%d"),strftime(_time, "%d/%m/%Y"))

| eval epoch_autoclave=strftime(strptime(timestamp_autoclave, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_sterilizzato=strftime(strptime(timestamp_sterilizzato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval durata_sterilizzazione = epoch_sterilizzato - epoch_autoclave

| stats sum(durata_sterilizzazione) as durate by data

| stats avg(durate) as tempo_occ

| eval tempo_occ_ore = tempo_occ/3600

Sterilization equipment daily cycles

index="cssd" source="*STERILIZZATO.csv*" tipo_articolo=KIT

| dedup timestamp_sterilizzato

| dedup timestamp_autoclave

| table barcode_inventariale desc_auto prod_desc timestamp_autoclave timestamp_sterilizzato _time date_wday date_month

| where date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july"

| where NOT date_wday="saturday" and NOT date_wday="sunday"

| where desc_auto="*CSSD: GIADA*"

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%Y/%m/%d"),strftime(_time, "%d/%m/%Y"))

| stats count(timestamp_sterilizzato) as cicli by data

| stats median(cicli) as mediana_cicli

Distribution of kits sterilized per hour

index="cssd" source="*STERILIZZATO.csv*" tipo_articolo=KIT

| table _time barcode_inventariale prod_code prod_desc source tipo_articolo date_hour date_month desc_auto

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| where *desc_auto="CSSD: GIADA" OR desc_auto="CSSD: AMETISTA" OR desc_auto="CSSD: CORALLO"*

| where NOT match(barcode_inventariale, "TEST")

| where (date_month="march" OR date_month="april" OR date_month="may" OR date_month="june" OR date_month="february" OR date_month="july")

| stats count(tipo_articolo) as Kit_sterilizzati by date_hour

| sort date_hour

Process duration 2022

index="cssd" source="ACCETTATO.csv" OR source="STERILIZZATO.csv" tipo_articolo=KIT

| where date_month="*month*"

| transaction barcode_inventariale endswith=sterilized

| table _time barcode_inventariale prod_desc timestamp_accettato timestamp_sterilizzato date_month desc_auto date_wday

| where NOT date_wday="saturday" AND NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST")

| where desc_auto="CSSD: GIADA" OR desc_auto="CSSD: AMETISTA" OR desc_auto="CSSD: CORALLO"

| eval epoch_sterilizzato=strftime(strptime(timestamp_sterilizzato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_accettato=strftime(strptime(timestamp_accettato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval min_ciclo=(epoch_sterilizzato-epoch_accettato)/60

| eval ore_ciclo=min_ciclo/60

| stats median(ore_ciclo) as mediana, perc25(ore_ciclo) as Q1, perc75(ore_ciclo) as Q3

Process duration 2023

index="cssd" source="dirty2023.csv" OR source="sterilized2023.csv" tipo_articolo=KIT

| where date_month="february"

| transaction barcode_inventariale endswith=sterilized

| table _time barcode_inventariale prod_desc timestamp_accettato timestamp_sterilizzato date_month desc_auto date_wday

| where NOT date_wday="saturday" AND NOT date_wday="sunday"

| where NOT match (barcode_inventariale, "TEST")

| where desc_auto="DALILA" OR desc_auto="GRETA" OR desc_auto="SOFIA"

| eval epoch_sterilizzato=strftime(strptime(timestamp_sterilizzato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval epoch_accettato=strftime(strptime(timestamp_accettato, "%Y/%m/%d %H:%M:%S"), "%s")

| eval min_ciclo=(epoch_sterilizzato-epoch_accettato)/60

| eval ore_ciclo=min_ciclo/60

| stats median(ore_ciclo) as mediana, perc25(ore_ciclo) as Q1, perc75(ore_ciclo) as Q3

Remains to pack

index="cssd" source="*CONFEZIONATO.csv*" OR source="*LAVATO.csv*" tipo_articolo="KIT"

| table barcode_inventariale prod_desc source desc_lav timestamp_lavato timestamp_confezionato _time date_hour date_month

| where date_month="*month*"

| sort 0 barcode_inventariale _time

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| streamstats count by barcode_inventariale data

| sort 0 data

| eval flag= if((isnotnull(timestamp_confezionato) AND count%2=1), 1, 0)

| eventstats count as count_avanzi by barcode_inventariale data

| eval avanzo=if(count_avanzi%2=0 OR flag=1, 0, 1)

| dedup barcode_inventariale data

| stats sum(avanzo) as Avanzi_da_confezionare by data

| stats median(Avanzi_da_confezionare) as mediana, perc25(Avanzi_da_confezionare) as Q1, perc75(Avanzi_da_confezionare) as Q3

Remains to sterilize

index="cssd" source="*CONFEZIONATO.csv*" OR source="*STERILIZZATO.csv*" tipo_articolo="KIT"

| table barcode_inventariale prod_desc source timestamp_confezionato timestamp_autoclave _time date_hour date_month

| where date_month="*month*"

| sort 0 barcode_inventariale _time

| eval data=if((date_hour>=0 AND date_hour<7), strftime(relative_time(_time, "-1d"), "%y/%m/%d"),strftime(_time, "%y/%m/%d"))

| table barcode_inventariale data _time date_hour source timestamp_confezionato timestamp_autoclave

| streamstats count by barcode_inventariale data

| eval flag= if((isnotnull(timestamp_autoclave) AND count%2=1), 1, 0)

| eventstats count as count_avanzi by barcode_inventariale data

| eval avanzo=if(count_avanzi%2=0 OR flag=1, 0, 1)

| dedup barcode_inventariale data

| stats sum(avanzo) as Avanzi_da_sterilizzare by data

| stats median(Avanzi_da_sterilizzare) as mediana, perc25(Avanzi_da_sterilizzare) as Q1, perc75(Avanzi_da_sterilizzare) as Q3

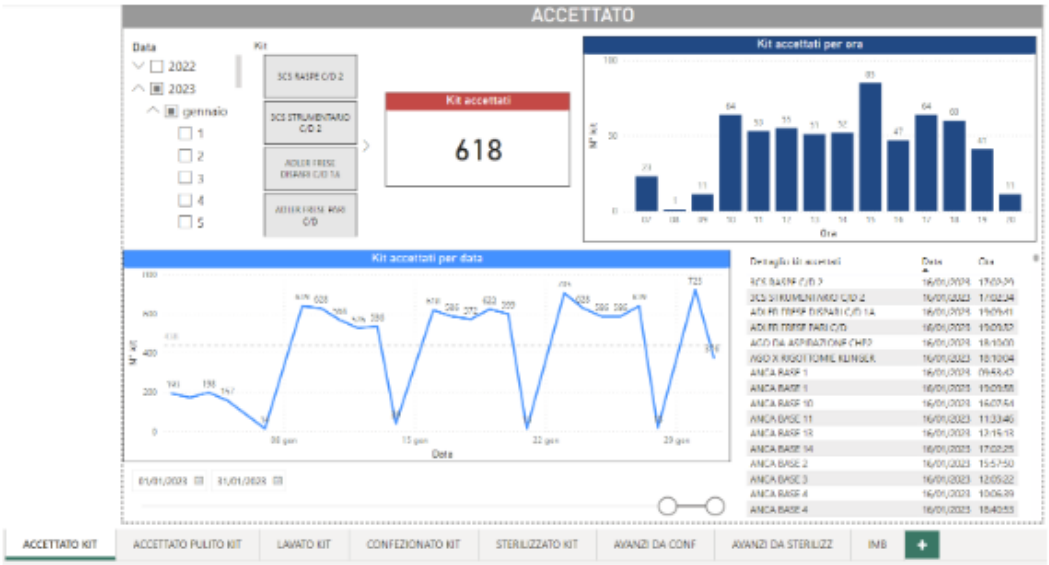
A.2. Questionnaire

Dashboard di produttività

Il presente questionario si pone l'obiettivo di valutare quale potrebbe essere l'impatto legato all'adozione di una dashboard di produttività del processo di sterilizzazione.

La dashboard è suddivisa per pagine, ciascuna dedicata a una fase del processo: accettazione, accettazione del pulito, lavaggio, confezionamento e sterilizzazione. Sono presenti tre ulteriori pagine dedicate agli avanzi da confezionare e sterilizzare e agli imbustati e una pagina finale di recap.

Per le prime cinque, la struttura è sempre uguale. Da sinistra a destra sono presenti:
- un filtro per selezionare la data;
- un filtro per selezionare un set specifico;
- un pannello che indica il numero di kit processati nella data scelta;
- un pannello che mostra l'andamento orario;
- un pannello che mostra l'andamento in un periodo selezionabile dall'utente tramite il filtro in basso;
- un pannello con un dettaglio dei kit processati, con data e ora.



Si ritiene che la dashboard fornisca una visione chiara e dettagliata dell'andamento del processo di sterilizzazione? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

Le informazioni visualizzate nella dashboard sono di semplice comprensione? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

Si ritiene che la dashboard possa apportare dei miglioramenti nella pianificazione del lavoro? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

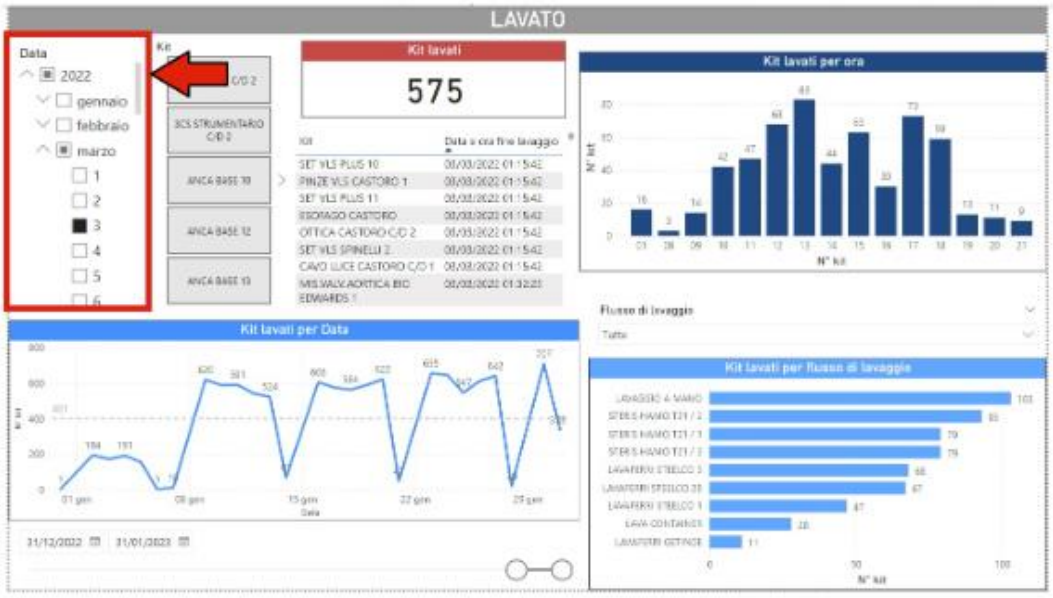
Si ritiene che la dashboard possa contribuire a ridurre i ritardi nel processo di sterilizzazione? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

Si ritiene di poter individuare eventuali inefficienze nel processo grazie alle informazioni presenti nella dashboard? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

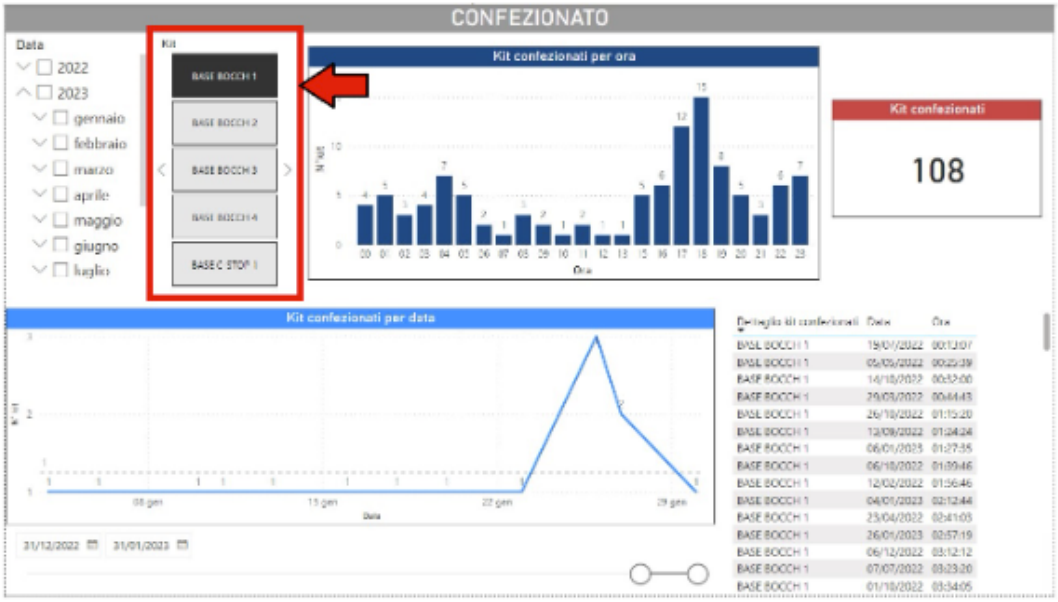
La dashboard offre la possibilità di applicare dei filtri per data, permettendo di visualizzare quanto fatto nei giorni precedenti.



Si ritiene che la possibilità di applicare dei filtri per data possa essere una funzione utile? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

La dashboard offre la possibilità di applicare dei filtri per set, permettendo di visualizzare quando uno specifico set è stato processato.



Si ritiene che la possibilità di applicare dei filtri per set possa essere una funzione utile? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

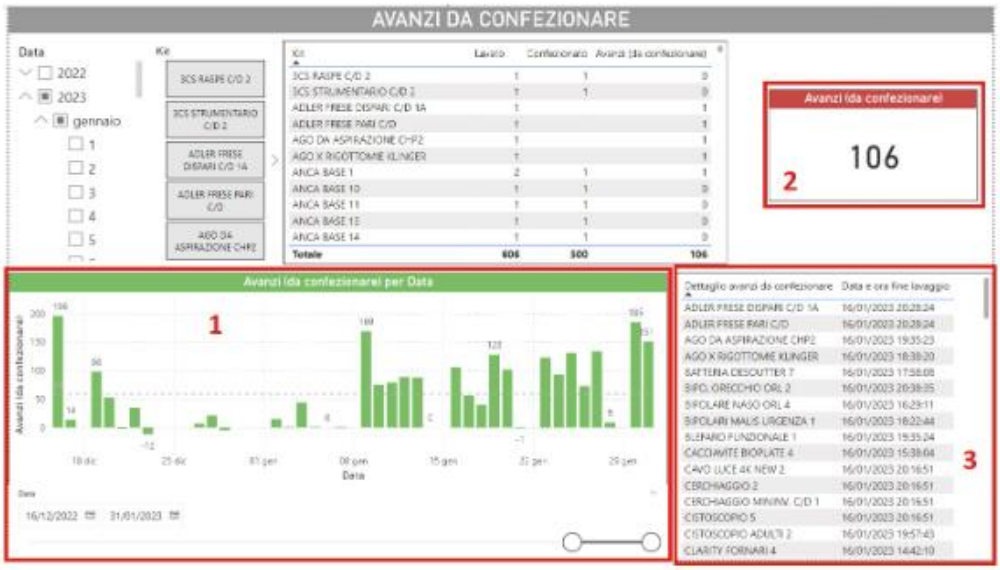
Per le fasi di lavaggio e sterilizzazione, la dashboard permette di applicare dei filtri per apparecchiatura utilizzata (permettendo di visualizzare separatamente la produttività delle due centrali).

Si ritiene che la possibilità di applicare dei filtri per apparecchiatura possa essere una funzione utile? *

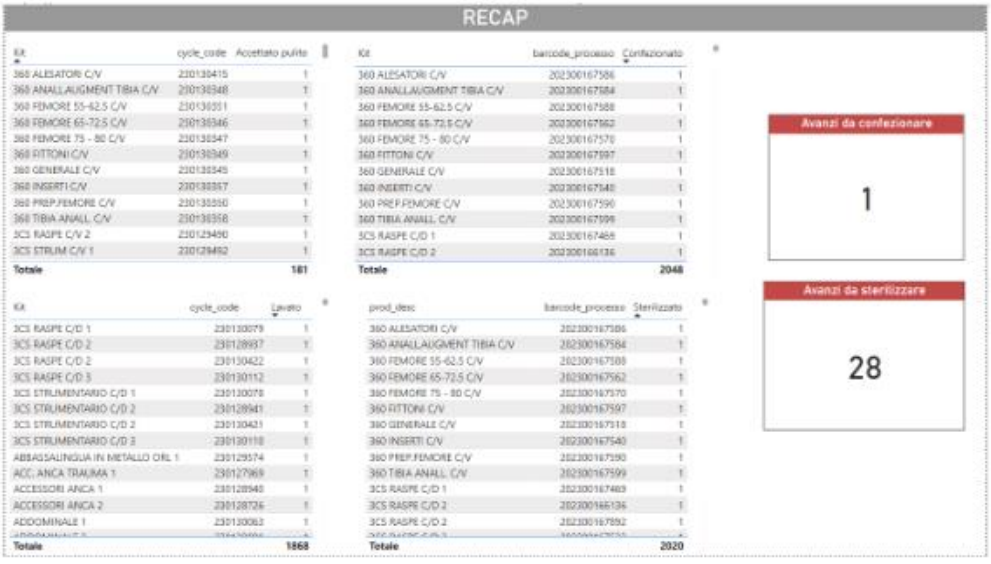
	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

La dashboard contiene due pagine dedicate agli avanzi da confezionare e da sterilizzare. La struttura è la stessa per entrambe; in figura la pagina dedicata agli avanzi da confezionare.

Queste pagine mostrano:
1. l'andamento degli avanzi in un periodo di tempo selezionabile dall'utente tramite il filtro in basso;
2. il numero di avanzi in una data scelta dall'utilizzatore (tramite il filtro in alto a sinistra)
3. un dettaglio contenente l'elenco dei kit in avanzo con gli orari di fine lavaggio (o fine confezionamento nel caso degli avanzi da sterilizzare).



Infine, la dashboard contiene una pagina di recap in cui è possibile visualizzare i kit processati nell'ultimo periodo e il numero ***corrente*** di avanzi da confezionare e da sterilizzare.



Si ritiene che le pagine dedicate agli avanzi possano essere una funzione utile? *

	1	2	3	4	5	6	7	8	9	10	
Assolutamente no	○	○	○	○	○	○	○	○	○	○	Assolutamente sì

Quale pensi possa essere la fase del processo che potrebbe beneficiare maggiormente della presenza di un costante monitoraggio? *

- ○ Accettazione
- ○ Accettazione pulito
- ○ Lavaggio
- ○ Confezionamento
- ○ Sterilizzazione
- ○ Avanzi
- ○ Altro...

Sei complessivamente soddisfatto della configurazione della dashboard? *

- ○ Sì
- ○ No

A.3. Water and energy consumption calculations

Old washing Machines:

Daily energy consumption = Power x Usage time = 20 kW x 13 hours = 260 kWh/day

Daily water consumption:

Hot softened water: 50 l/min x 60 min x 13 hours = 39,000 liters/day

Cold softened water: 50 l/min x 60 min x 13 hours = 39,000 liters/day

Demineralized water: 50 l/min x 60 min x 13 hours = 39,000 liters/day

New Washing Machines:

Daily energy consumption = Power x Usage time = 23 kW x 10 hours = 230 kWh/day

Daily water consumption:

Hot softened water: 40 l/min x 60 min x 10 hours = 24,000 liters/day

Cold softened water: 40 l/min x 60 min x 10 hours = 24,000 liters/day

Demineralized water: 40 l/min x 60 min x 10 hours = 24,000 liters/day

Energy savings: Daily consumption of old machines - Daily consumption of new machines

Water savings: Sum of the daily consumption of each type of water for old machines - Sum of the daily consumption of each type of water for new machines

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Acknowledgments

At the conclusion of this work, I would like to express my gratitude to all those who have been by my side throughout this journey of personal and professional growth.

First and foremost, I extend my heartfelt thanks to my advisor, Prof. Elena De Momi, for her availability, kindness, and understanding. Her guidance, advice, and timely direction have been instrumental in every phase of this study.

I am grateful to Eng. Paolo Oliva and Eng. Michele Gazzara from the Humanitas Clinical Institute for giving me the opportunity to experience this internship journey. Their support and assistance in shaping this work have been invaluabl