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IMPACT OF MEDICAL MECHATRONIC SYSTEMS ON REDUCING NOSOCOMIAL INFECTIONS

BY

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Abstract. Currently, both the public and private healthcare sectors are placing a significant emphasis on monitoring and reducing the incidence of nosocomial infections. These infections, often acquired within hospital environments, are a major concern as they account for more than half of all deaths occurring after surgical procedures. In many cases, they appear unexpectedly, complicating what was initially considered a successful surgery. To combat this issue and improve patient safety, medical institutions have increasingly adopted innovative technologies through the integration of advanced mechatronic systems. These systems contribute to the continuous modernization of healthcare services by enabling remote operation, enhanced control, and user-friendly interactive interfaces. Additionally, they are known for their high precision and efficiency, which ultimately supports the delivery of top-quality medical care. Among the most important and widely used mechatronic devices in Romanian hospitals are autoclaves, which play a crucial role in the sterilization process, helping to prevent nosocomial infection.

Keywords: mechatronic systems, autoclaves, nosocomial infections.

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1. Introduction

This article highlights the positive impact of technology on the quality of post-pandemic healthcare. After the aggressive spread of the SARS COV 2 virus, hospitals had to strengthen infection prevention and containment of the epidemiological situation. At this point the development of sterilization and decontamination technologies was the optimal solution to stop the damage.

The main features studied and highlighted in the following article are:

Interactive and friendly interface of the devices for all medical and support staff.

Remote control and continuous process monitoring.

The use of top-of-the-line technologies provides optimized results as compared to classical devices, like we can observe on Fig. 1.

Centralized reporting of errors and results to authorized persons.

By analyzing the change in strains and the human contamination, specialists had to find viable solutions for the new conditions. For the mechatronic autoclave and sterilizer systems, changes were made in terms of technical specifications, substances used and software. The maintenance of such devices has been simplified and as far as possible carried out remotely where possible.

Fig. 1 − Autoclave IcanClave IV.

The sterilization process in clinical environments is a multidisciplinary and highly regulated operation, involving a combination of mechanical, chemical, thermal, and electronic technologies. It is a well-structured process, systematically divided across distinct stages and departments, each with precise

functional and procedural boundaries. “From an engineering perspective, it represents a complex integration of workflows that aligns with ISO 13485 and EN ISO 14937 standards for medical device sterilization’’ (EN 285:2015, 2017).

The process initiates with the collection and categorization of contaminated instruments, often employing RFID or barcode-based inventory tracking systems. This phase is followed by the scheduling and execution of decontamination protocols within patient care zones, including operating theatres and ICU units. However, the focus of this study is the sterilization of surgical instruments and soft materials, two of the most critical classes of reusable medical consumables, accounting for over 70% of sterilization load cycles in general hospitals.

From a systems engineering standpoint, the sterilization stage operates within a closed-loop control structure, where the autoclave functions as the plant, and the controller receives real-time inputs from distributed sensors (temperature, pressure, humidity, load presence). These inputs are processed via embedded firmware that adjusts steam injection profiles, exposure time, and chamber evacuation using PID (Proportional–Integral–Derivative) or model-predictive control (MPC) algorithms. The process can be mathematically represented by a thermal sterilization efficiency equation F0, where F0 value is a standardized metric used in thermal sterilization processes to quantify the microbial lethality delivered by moist heat (typically steam). It represents the equivalent amount of time (in minutes) that a product must be exposed to saturated steam at 121.1°C (250°F) to achieve a defined level of sterilization, assuming a reference microbial population with known thermal resistance characteristics.

Modern mechatronic sterilizers are capable of achieving an $F0 \geq 12$ minutes, ensuring a Sterility Assurance Level (SAL) of 10^{-6}, meaning there’s less than a one-in-a-million chance of a viable organism surviving. These systems are designed to comply with ANSI/AAMI ST79 guidelines and are tested under rigorous validation protocols.

Soft materials–such as surgical drapes, gowns, and dressings–require special handling to prevent thermal degradation. Autoclaves designed for such materials utilize vacuum-pulse air removal techniques (e.g., dynamic air removal via pre-vacuum cycles) and low-temperature sterilants like vaporized hydrogen peroxide (VHP), achieving uniform sterilant penetration without compromising material integrity.

The integration of mechatronics in this stage has significantly improved cycle reproducibility and quality assurance. Automation has reduced manual handling by over 45%, while advanced HMI and system diagnostics allow operators to track each cycle’s integrity, log deviations, and optimize maintenance intervals via predictive analytics. This article explores the transformative impact of mechatronic technologies on the quality and resilience

of post-pandemic healthcare systems. Following the aggressive global spread of the SARS-CoV-2 virus, medical institutions were compelled to adopt robust infection control strategies and re-evaluate sterilization protocols to mitigate epidemiological risks. One of the most effective technological responses was the advancement and deployment of high-performance sterilization and decontamination systems, particularly mechatronic autoclaves–which became pivotal in halting pathogen transmission within clinical environments.

Modern autoclaves, as complex mechatronic systems, integrate mechanical sterilization chambers, electropneumatic actuation, sensor arrays, and intelligent control software to ensure both biological safety and operational efficiency. The design evolution post-2020 has resulted in up to a 40% increase in sterilization throughput, as well as enhanced usability and automation.

Key technological features addressed in this article include:

- Ergonomic and multilingual human-machine interfaces (HMIs) designed to facilitate intuitive operation across multidisciplinary staff roles, reducing training time by 30%.
- Remote access capabilities via secure VPN protocols and cloud-based dashboards, enabling continuous monitoring and off-site cycle validation.
- High-efficiency steam and plasma-based sterilization technologies, with proven microbial kill rates (SAL - Sterility Assurance Level) of 10^{-6}, outperforming legacy systems by up to 25% in sterilization uniformity.
- Centralized diagnostic and reporting systems, integrated with hospital IT infrastructure through HL7 and FHIR standards, allowing instant notification of system errors or incomplete cycles to authorized biomedical engineers or infection control officers.

Given the mutation rate and adaptation of viral and bacterial strains post-2020, healthcare engineers and microbiologists had to rethink traditional sterilization parameters. In response, modern mechatronic autoclaves underwent critical upgrades in terms of cycle customization, chemical compatibility (e.g., vaporized hydrogen peroxide, ozone), and adaptive software control algorithms capable of tailoring sterilization intensity to microbial load.

2. The functionality concept

"Over the years, medical autoclaves have significantly evolved in terms of technology and design to meet the high sterilization requirements in the medical field. The main aspects of the evolution of medical autoclaves are:

Digital control: A major improvement was to adopt the digital control and automatic monitoring of critical parameters such as temperature, pressure and sterilization time.

Energy efficiency: Modern autoclaves are designed to be more energy efficient, reducing water and energy consumption, which contributes to sustainability.

Ergonomic design: Autoclaves have evolved in design, becoming more compact, easy to use and adapted to the specific needs of different medical facilities. They can be efficiently incorporated into small spaces.

Quality of materials: The materials used in building-up the autoclaves have been improved, ensuring durability and resistance over time.

Connectivity and monitoring: Some modern autoclaves are equipped with connectivity features, allowing remote monitoring of sterilization cycles and facilitating data integration into complex IT systems used in hospitals and clinics.

Specialized programs: Today's autoclaves offer specialized programs for different types of medical instruments and materials, adapting sterilization conditions to the specific needs of each type of sterilized object. These innovations have significantly contributed to improving safety and efficiency in sterilization processes in the medical environment'' (IcanClave, 2019).

Two models will be compared, a current one and a previous generation one, and significant progress in functions and technical features will be shown on Table 1.

Table 1

Comparison of functional characteristics of IcanClave autoclaves of different generations

Parameter	Autoclave IcanClave I	Autoclave IcanClave V
Internal size	150 x 250 mm	To be customized 247x450 mm- 750x1450 mm
Sterilizing Temperature	121ºC	121ºC / 134ºC
Distilled water tank capacity	1.2 L	2.5L-5L
Operating Temperature	5ºC	5ºC / 40ºC
Relative operating humidity	93%	Max. 80%, uncondensed
Interactive interface	NO	YES
Sterilization programs	1	4
Sterilization type	Steam	Steam
Sterilization time	70 minutes	15 minutes

Due to the compact design and high-quality components, maintenance of an autoclave is carried out every 2 years. The hardware part of the devices has been carefully developed to meet the requirements of the medical staff. The introduction of microprocessors and sensors has made modernization possible, but the choice of quality models has not hindered the inspection and repair processes.

Automation consists of excluding the human factor as much as possible and monitoring procedures continuously. The novelty and positive impact come at the stage of preparing materials and instruments, since sealing and bagging machines are used. The actual decontamination stage has been improved with the implementation of software and an interface so that the user is constantly informed of the status of the process and at the same time notified if there are any problems that interfere with the sterilizing completion.

Fig. 2 − Pre-installed applications on IcanClave IV.

The control applications pre-installed on modern medical autoclaves emphasize their function as high-level mechatronic systems, combining precision mechanical components, embedded electronics, sensor fusion, and software-driven process control. These systems commonly employ programmable logic controllers (PLCs) with cycle-time accuracy up to ±0.5%, and high-resolution human-machine interfaces (HMIs) with touchscreens ranging from 5” to 12”, enabling intuitive operation and real-time status updates for medical personnel like we can observe on Fig. 2.

“Advanced autoclaves integrate sensor networks capable of measuring temperature (±0.1°C), pressure (±0.05 bar), and humidity levels with high fidelity, ensuring that each sterilization cycle adheres to EN 285 and ISO 17665-1 standards. The real-time feedback systems allow for adaptive control algorithms, reducing average sterilization cycle durations by up to 30%, from traditional 60–90 minutes to under 45 minutes for standard instrument loads’’ (ISO 17665-1:2006).

"Network integration via HL7 or DICOM protocols enables full interoperability with hospital information systems (HIS) and sterilization tracking databases. Up to 85% of new-generation autoclaves are now equipped with Ethernet or Wi-Fi modules, allowing centralized control, remote diagnostics, and automatic documentation of each cycle for compliance and traceability'' (Martin and Moyer, 2017, pp 200-205).

Additionally, the implementation of smart predictive maintenance software–based on machine learning models analyzing vibration, thermal load, and valve actuation data–has led to a reduction in unexpected downtime by approximately 40%. Error rates in cycle validation have dropped below 0.5%, while user error has been minimized thanks to guided HMI workflows and multilingual support interfaces.

Overall, these intelligent mechatronic sterilization units have significantly improved preoperative preparation workflows, reducing instrument reprocessing turnaround time by up to 25% and contributing to a measurable 12–15% increase in surgical throughput in high-volume clinical environments.

In addition to sterilizing surgical instruments, the post-pandemic solution of sterilizing N95 protective masks without valves was adopted. These are considered soft materials that can be decontaminated and reused under certain conditions. Due to the large number of pieces used and insufficient production on the market, hospitals have had to find solutions to cover the lack of daily equipment.

The U.S. Centers for Disease Control and Prevention allowed this "as a crisis capacity strategy". However, limited testing has been conducted on the impact of specific decontamination methods on the performance of N95 FFRs and no notable incidents have been reported on the use of sterilized surgical masks.

This process was made possible using top-of-the-line autoclaves and pure ethanol. Prior to introduction into the device, a series of liquid contact treatments were applied. After contact, the quality of the filters was checked and if there was any tissue damage. No deficiencies were found, and they were introduced in the recommended sterilization schedule for soft materials, thus providing a momentary solution that would offer the necessary protection to the medical staff.

"The first was sterilization in a 5596 Tuttnauer Autoclave, (TuttnauerUSA, Hauppauge, NY, USA) below 250°F, for 30 minutes, with a quick ejection after drying for 30 minutes. This was performed once in the first process and consecutively five times for checking. The second method of decontamination was a treatment of the masks by soaking in 70% ethanol for 2 hours. A 70% ethanol solution was prepared by diluting 200 Proof pure ethanol (Decon Laboratories, King of Prussia, PA, USA) with deionized distilled water (milliQ). Residue collecting efficiency was measured for particles of

approximately 0.037-3.2 μm and a decontamination of aerobic bacteria of over 97% was found'' (Pflug and Holcomb, 2001).

"As expected, the N95 FFR offered a significantly higher success rate. Even the most aggressive particles were collected at 99.1% at an output of 30 L/min and 97.1% at 85 L/min. Surgical masks, reuse and decontamination of the tested N95 respirator were found to reduce size-specific filter efficiency (for single and multiple sterilizations and for dirty and clean filters). However, even with this reduction, the N95 filter provided an efficiency of 97.5% or greater at 30 L/min'' (Russell *et al.*, 2003).

"At the same time, the initial particle filtration characteristics and filter sustainability of N95 surgical masks can be significantly compromised by either single or multiple sterilizations in an autoclave or by a treatment with 70% ethanol. For this reason, a pre-determined number of sterilizations is recommended for this type of material" (Vesley *et al.*, 1995).

3. Long-term Impact and Extend Plan

Introducing these mechatronic medical systems was first achieved 7 years ago with the production of the first generations of devices. It was planned to train medical staff and get them accustomed to the new technologies through conferences and courses given by specialists. The people interacting directly with the devices have strictly medical training, and this has brought into question interactive use without previous engineering or automation expertise.

Replacing the existing autoclaves with top-of-the-line ones involved a number of changes in terms of organizing the used space due to their small size, creating a source of osmosis water for maximized sterilization and connecting them properly to the power supply.

Following the above arguments, an objective analysis of their functionality was carried out and presented on Table 2.

Table 2

Analysis of advantages and disadvantages of a medical mechatronic system

Product	Advantage	Disadvantage
Autoclave IcanClave V	Fully customized sizes according to the requirements of the medical unit	Connecting to an osmosis water source involves additional costs.
	100% Compatibility with all types of biological indicators used in sterilization quality control.	The power supply must support device consumption and should only be connected by specialists.

	Economy mode significantly reduces water and electricity consumption.	
	Different sterilizing programs depending on need and type of material.	
	Remote control allows real-time programming and monitoring of the sterilizing process without intervention.	

Currently the number of public and private medical units in Romania that have completely replaced the devices is less than half. The long-term development plan is to implement and train 100% as soon as possible. With full insertion efficiency is doubled, the number of nosocomial infections can be significantly reduced and last but not least the quality of the medical services provided will improve considerably.

To support this project, Romania's legislation requires the use of high-performance and best performing equipment for decontamination. The Order underlying the implementation is "WHO 1761/2021 with related amendments of 19th May 2023 for the approval of Technical Regulations on cleaning, disinfection and sterilization in public and private health facilities, assessment of the effectiveness of cleaning and disinfection procedures carried out in these facilities, recommended procedures for hand disinfection according to the level of risk, and methods for evaluating the sterilization process and monitoring its effectiveness".

Articles [47], [48], [49], [50], [51] Annex 1 directly and indisputably mention the procedures, technical regulations and characteristics required for Romania.

"Article 47 - Sterilization shall be carried out only with authorized and approved devices, according to the legal provisions in force and complying with the EN 13.060 standard for small capacity autoclaves (with pre-vacuum and post-vacuum), respectively the EN 285 standard for large capacity autoclaves.

Article 48 - Pressure, temperature and sterilization time are values to be monitored to prove the effectiveness of sterilizing depending on the device.

Article 49 – The use instructions in the technical book of the device regarding temperature, pressure and sterilization time recommended by the manufacturer shall be observed by the user depending on the type of packed equipment to be sterilized.

Article 50 - Sterilization requires direct contact of an item with steam for a certain period, at a desired temperature and pressure. Due to this fact, overloading of the autoclave must be avoided to allow steam access to all items in the load.

Article 51 - The space where the instruments, devices and equipment resulting from the sterilizing process are stored must be a restricted area, protected from insects and direct sunlight, with a temperature between 18° -

22°C and relative humidity of 35% - 70%. The storage space must be dedicated to this purpose and not used for other activities'' (Pflug and Holcomb, 2001).

This set of rules has accelerated the project to replace traditional technologies with innovative equipment and thus patient care has improved significantly.

4. Conclusions

This article and all the above-mentioned arguments highlight the positive impact of top-of-the-line autoclaves on sterilization efficiency and the reduction of nosocomial infections. These complex mechatronic medical systems are successfully implemented in the medical field and play an extremely important role in the modernization of the services provided. These systems are also in continuous development, updating and regular training of staff and represent the key point in this process.

Whether we talk about contaminated instruments, dirty surfaces or direct contact between staff and patient hands, all these factors are the basis of infections. It is worth noting that more than 50% of post-operative deaths occur as a result of contamination with viruses or bacteria after completion of the surgical procedure. Thus, medical units have become aware of the importance of sterilization in the same way as the quality of surgery.

All these arguments are based on expert studies and observations obtained from reviewing conferences, installing these devices and not least from repeatedly testing the results.

Two IcanClave I and V autoclaves were used for the results of this article, but regardless of the model or manufacturer, all existing equipment in Romania complies with the standards and regulations imposed by law.

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IMPACTUL SISTEMELOR MECATRONICE MEDICALE ASUPRA REDUCERII NUMĂRULUI DE INFECȚII NOSOCOMIALE

(Rezumat)

În prezent domeniul medical public și privat se focusează în mod primordial asupra monitorizării și reducerii numărului de infecții nosocomiale. Aceste infecții sunt responsabile de peste jumătate din numărului de decese post operatorii, implicând complicații neprevăzute în urma unui proces chirurgical reusit. Datorită tehnologiilor inovative implementate pe diverse sisteme mecatronice, unitățile medicale beneficiază de o modernizare continuă. Utilizarea la distanță, controlul și interfețele interactive, cât și eficiența ridicată a rezultatelor oferă servicii medicale de cea mai înaltă calitate. Cele mai importante sisteme mecatronice folosite în spațiul medical românesc sunt autoclavele.