DESIGN OF A FAST CASSETTE AUTOCLAVES FOR MEDICAL DEVICES

THIẾT KẾ MÁY HẤP TIỆT TRÙNG NHANH DÙNG CHO CÁC DỤNG CỤ Y TẾ

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Abstract - Ensuring patient safety in healthcare necessitates the sterilization of medical devices. However, traditional autoclaves are impractical for certain medical settings due to their size, bulkiness, and time-consuming nature. To address this, a compact and portable alternative called a cassette autoclave was developed. This paper presents the design and manufacturing process of a high-speed cassette autoclave for medical devices. The autoclave features small dimensions, lightweight construction, and user-friendly operation. It achieves remarkable speed, sterilizing devices in approximately 3.5 minutes. Made of durable stainless steel, it includes a digital control panel for seamless management. Extensive testing and validation ensure compliance with sterilization standards. The results highlight the autoclave's effectiveness and safety, making a significant contribution to medical device sterilization.

Key words - Cassette autoclave; medical devices; fast; 3.5 minutes.

Tóm tắt - Để đảm bảo an toàn cho bệnh nhân thì việc tiệt trùng các thiết bị y tế được yêu cầu cao. Tuy nhiên, máy hấp truyền thống không phù hợp cho một số trường hợp do kích thước lớn, cồng kềnh và tốn thời gian. Để giải quyết vấn đề này, nhóm đã phát triển máy hấp tiệt trùng nhanh - một giải pháp nhỏ gọn và dễ di chuyển. Bài báo này trình bày quy trình thiết kế và chế tạo a máy hấp tiệt trùng nhanh cho thiết bị y tế. Máy có kích thước nhỏ, cấu trúc nhẹ và dễ sử dụng. Máy có thể hoàn thành một chu trình tiệt trùng thiết bị trong khoảng 3,5 phút. Vỏ máy được làm bằng thép không gỉ, chắc chắn với một bảng điều khiển số giúp việc quản lý được thuận tiện. Máy đã được thử nghiệm và xác nhận tuân thủ các tiêu chuẩn cần thiết để đảm bảo hiệu quả khử trùng. Kết quả nghiên cứu nhấn mạnh tính hiệu quả và an toàn của máy trong việc tiệt trùng các thiết bị y tế.

Từ khóa - Máy hấp tiệt trùng; thiết bị y tế; nhanh; 3,5 phút.

1. Introduction

Given the escalating societal demand for effective treatments of eye diseases, which significantly impact human health, various specific surgical procedures are employed, such as cataract removal, macular degeneration treatment, diabetic retinopathy management, intraocular pressure control, and glandular obstruction resolution. Consequently, the need for rapid sterilization of medical instruments used in eye surgeries has emerged. Typical devices for the eye surgery are presented in Figure 1. One method employed for sterilization is high-pressure and high-temperature steam sterilization, which utilizes steam to exert compression forces, enhancing the elimination of bacteria, viruses, and microorganisms from surgical instrument surfaces.

The concept of steam sterilization originated in the late 1870s when French microbiologist Charles Chamberland developed a steam sterilizer, known as a pasteurized steam boiler, for medical applications [1]. Subsequently, in 1881, Robert Koch conducted research on the disinfecting properties of steam and hot air within autoclave containers, marking the beginning of the science of sterilization and disinfection. Koch demonstrated that moist heat (low moisture content) exhibited superior penetration compared to dry heat [2]-[5].

Sterilization refers to the complete eradication of all forms of microbial life, including viruses, bacteria, and fungi, whether in the form of vegetative cells or spores [6-7]. Steam sterilizers and pasteurizing devices for medical purposes are already available on the market. However, advancements have been made to enhance the operational mechanisms of these machines, specifically targeting the sterilization time of medical devices, to accommodate the need for rapid sterilization.

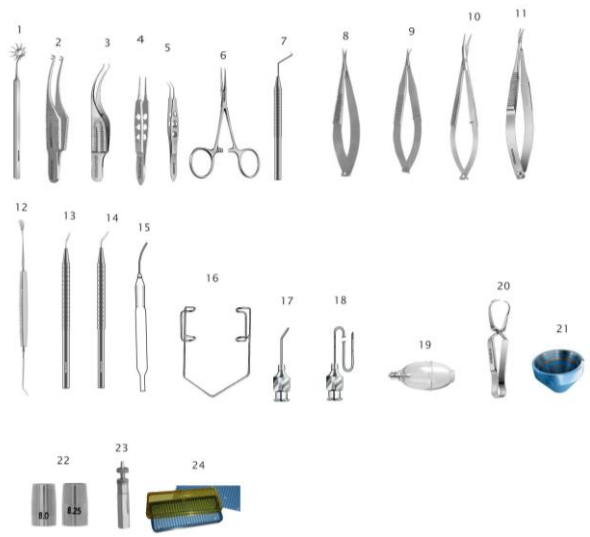

***Figure 1**. Typical devices for eye surgery [5]*

In terms of the operational mechanism of the rapid steam sterilizer, instead of maintaining a stable temperature within the sterilization chamber, the temperature and pressure are continuously adjusted through the discharge valve. It should be noted that the interior of the sterilizer chamber remains considerably hot throughout the process. This cycle is repeated until the predetermined sterilization time is achieved, thus completing the operational cycle of the machine. Instruments subjected to pasteurization, can be categorized into two main groups: those composed entirely of metal, typically stainless steel or titanium alloy, and those containing a combination of metal and rubber components. Consequently, the heat level within the pasteurization chamber can be adjusted based on the user's settings.

In the current Vietnamese context, there is a lack of domestic companies or enterprises officially manufacturing rapid sterilizers specifically designed for eye surgery. The majority of these devices are imported from countries such as Canada and the United States, resulting in high prices due to intermediate distribution channels and limited technological mastery. Consequently, the authors have undertaken the task of investigating, designing, and producing rapid medical instrument sterilizers specifically tailored for eye surgery, offering a more affordable alternative to imported devices while ensuring technological expertise.

The dimensions of the sterilizer were length×width×height: 485 × 415 × 150 mm. The sterilizer's container has length×width×height: 280 × 180 × 35 mm.

The sterilization time for metal tools is 3.5 minutes, while that for metal tools with rubber components is 10 minutes. The sterilization targets primarily include surgical instruments used in eye procedures. The glass size typically encountered is less than 200 mm.

2. Principle operation of machine

2.1. Types of Sterilizers

In both domestic and international markets, various types of medical sterilizers are currently employed, including dry sterilizers, ozone sterilizers, infrared radiation sterilizing machines, and evaporation-based sterilization machines. Among these options, steam sterilizers are the preferred choice in surgical applications due to their high level of safety, convenience, and overall stability when compared to other types of sterilizers. Figure 2 illustrates the structure of a steam evaporation-based medical instrument sterilizer specifically designed for eye surgery, comprising the following key components: pump (1); solenoid relief valve (2); boiler (3); sterilization chamber (4); sterilizer tray (5); distilled water tank (6); mainboard (7).

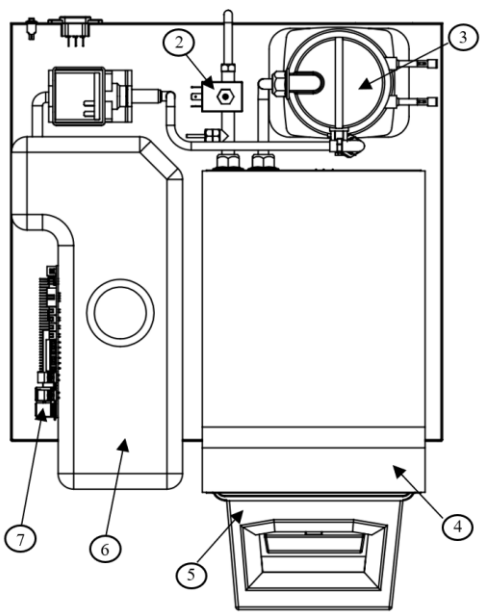

Figure 2. *Preliminary composition of the rapid sterilizer medical device used in eye surgery*

Steaming or boiling at temperatures below 100°C is insufficient to destroy microorganisms, spores, and bacteria effectively. Therefore, a more robust sterilization method is necessary to ensure the complete eradication of all microorganisms, spores, or bacteria present on the objects. At the core of the sterilizer is a sterilization tray constructed from 304 stainless steel. The tray is equipped with a heat-resistant sealing ring that ensures an airtight seal when attached to the sterilization chamber during operation. To eliminate bacteria, viruses, and fungi on surgical instruments, the sterilization tray was subjected to high-temperature saturated steam ranging from 121°C to 135°C. After the sterilization process, the surgical instruments are allowed to air-dry naturally upon removal from the sterilization tray [8].

Based on the research findings, sterilization at approximately 121°C for a duration of 15-20 minutes (varying depending on the size and quantity of instruments being sterilized) effectively destroys bacteria and microorganisms when subjected to high-temperature saturated steam [9].

2.2. Sterilization modes

2.2.1. Sterilization of metal instruments

To sterilize metal instruments (Figure 3), they are placed in a sterilization tray inside the sterilization chamber. The tray is made of 304 stainless steel to provide a secure and airtight environment. High-temperature saturated steam, usually ranging from 121°C to 135°C, is then used to sterilize the instruments in the tray. This process effectively eliminates bacteria, viruses, and fungi that may be present on the metal instruments. Once the sterilization cycle is complete, the instruments are left to air-dry naturally.

Figure 3. *Surgical instruments combining metal and metal-rubber components [10]*

2.2.2. Sterilization of metal tools with rubber

Metal tools with rubber components undergo a similar sterilization process. They are placed in a sealed tray within the sterilization chamber and exposed to high-temperature steam. This ensures the elimination of bacteria, viruses, and fungi from both the metal and rubber parts. The sterilization cycle takes approximately 10 minutes. After sterilization, the instruments are air-dried before use.

The sterilization time and temperature will be adjusted accordingly based on the size and quantity of instruments to be sterilized, as indicated in Table 1.

Table 1. *Sterilization time and temperature*

Mode	Time and Temperature
Metal tools	3.5 minutes 135°C
Metal tools mixed with rubber	10 minutes 135°C

The sterilizer is composed of three distinct components, as depicted in Figure 4. The upper tray functions as a seal and is equipped with high-temperature resistant steam to prevent the leakage of steam vapor. The lower tray is designed to accommodate the medical instruments requiring sterilization and features a rear joint that connects to the top drawer.

Figure 4. *Sterilization tray*

The sterilization process follows the sequential steps illustrated in Figure 5. Initially, the heating stage occurs, where a small amount of water is pumped into the steam by the pump. Subsequently, the high temperature and pressure generate steam vapor, which is then directed to the sterilizer pad through a one-way valve. Once the vapor reaches the required temperature, the electromagnetic discharge valve on the pad is activated. As a result of the pressure differential, the contaminated steam is directed to the wastewater tank.

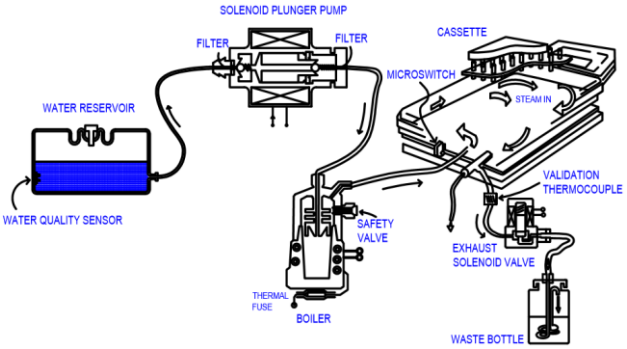

Figure 5. *Schematic diagram of the sterilization process with the saturated steam*

During the heating process, the controller regulates the valves to create pressure within the steam chamber. This increase in pressure causes the boiling and evaporation temperature of the water, typically at 100°C, to adjust to the desired temperature range of 121°C to 135°C. As a result, saturated steam is generated within the sterilization chamber, effectively disinfecting the instruments.

2.3. Surgical eye instruments and the role of rubber gaskets in the sterilization tray

Considering the unique nature of eye-related conditions, the composition of the eye surgery kit varies for each specific case (see Figure 1). Urgent surgical interventions, such as those needed for cataracts, glaucoma, hypertension, and retinal thrombosis, may be necessary [10]. The sterilizer incorporates various mechanisms, as depicted in Figure 6.

The materials used for manufacturing surgical instruments can be categorized into two main types:

- Type 1: Surgical instruments made of metal, commonly constructed from stainless steel or titanium alloy.
- Type 2: Metal surgical instruments with rubber components, often comprising fluid tubes with metal heads and medical rubber tubes.

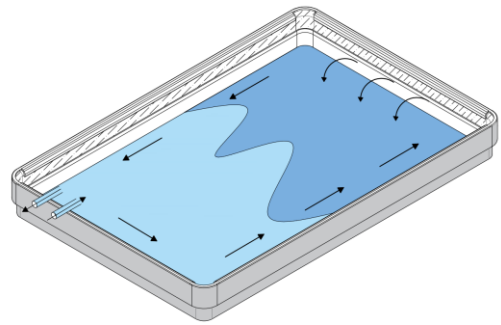

Figure 6. *Cassette seal and lube kit*

Water flows into the tray through a partially obstructed gate located at the rear. As the gate allows only restricted entry into the tray, steam is channeled through the rubber seal and into the tray. Simultaneously, the water entering the tray displaces the air, which exits through the exhaust gate at the back. This pulsating pressure action facilitates the removal of air and prevents the instruments from undergoing oxidation.

The rubber seal, positioned in the tray cover, ensures that steam does not escape. It is important to periodically inspect the tray for any steam leakage and replace the rubber seal if necessary. However, if there are no signs of steam leakage, the rubber seal functions properly and does not require replacement.

3. Mechanical design

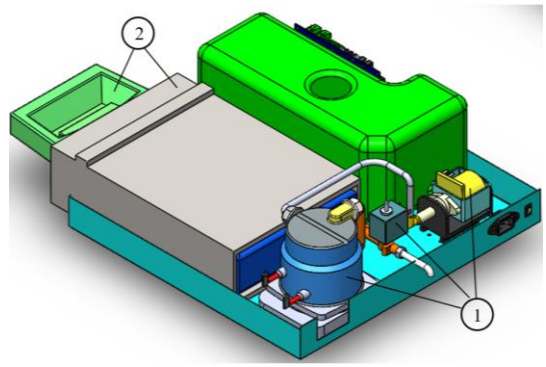

Figure 7. *3D drawing of a quick sterilizer for medical instruments used in eye surgery*

The authors utilized SolidWorks to design a 3D model of a rapid sterilizer specifically tailored for medical instruments used in eye surgery. Building upon the aforementioned research, the design for the sterilizer was

successfully completed. Figure 7 depicts a 3D rendering of this medical device rapid sterilizer.

The machine is composed of two primary components, working in synergy to achieve a sterilized medical instrument as the end product: mechanical part (1) and sterilization chamber (2).

The fast sterilizer operates based on the following working principles:

- Water quality and level evaluation: Sensors in the distillation tank assess water quality and monitor the minimum level. The trip switch checks tray positioning before proceeding.
- Heating the boiler: The boiler is heated to 102°C, and the solenoid valve closes.
- Temperature setting: Depending on the selected mode, the boiler heats to either 121°C or 135°C for sterilization.
- Water injection: A pump injects hot, pressurized water into the boiler, generating saturated steam.
- Steam distribution: Steam flows through a one-way valve to the sterilization tray.
- Achieving sufficient temperature: The steam reaches the needed sterilization temperature, activating the solenoid valve.
- Pressure differential and steam disposal: Contaminated steam is directed out of the tray toward the wastewater tank, effectively removing it from the system.

3.1. Mechanical part

The mechanical components of the fast sterilizer are strategically arranged to facilitate the smooth operation of the system. The arrangement ensures the following functionalities:

- Supply of saturated steam: Copper pipes are utilized to transport saturated steam from the boiler to the sterilization tray. These pipes are designed to withstand the high temperature and pressure of the steam, ensuring a reliable and consistent supply throughout the sterilization process.

- Heat retention: The system is designed to maximize heat retention to maintain the desired sterilization temperature. Insulation materials, such as thermal jackets or heat-resistant coatings, are employed to minimize heat loss from the boiler and piping. This helps to conserve energy and ensures the efficient operation of the sterilizer.

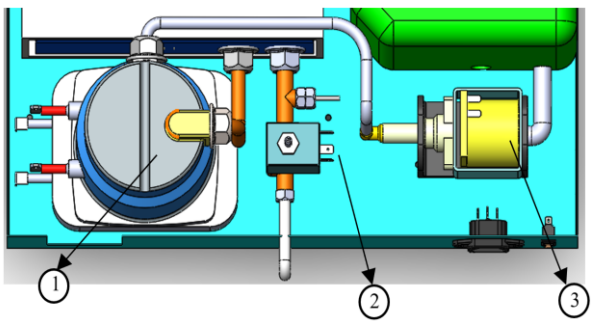

Figure 8. *3D drawing of mechanical parts*

3.1.1. Pump

To facilitate water circulation in the fast sterilizer, a pump is employed to transfer water from the distilled water tank. In this case, the ULKA Model E pump is utilized, which operates with the following specifications:

- Voltage: 230 VAC;
- Frequency: 50 Hz;
- Power consumption: 48 W;
- Pump pressure: 12 to 15 bar.

The pump is controlled to open and close in a continuous cycle with specific timing intervals. In this scenario, the pump operates for a duration of 1 second, followed by a 5-second pause or stop before the cycle repeats. This controlled pump operation ensures the regulated flow of water through the boiler, maintaining the needed pressure and facilitating the sterilization process within the fast sterilizer.

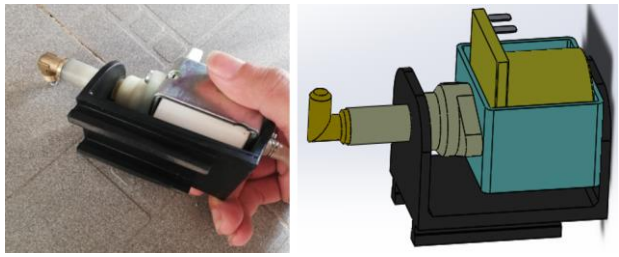

Figure 9. *Pump*

3.1.2. Boilers

The sterilizer employs two components to elevate the boiler temperature above 120°C, allowing water to vaporize and exit through the outlet as high-pressure steam. Safety measures include a pressure-relief valve to prevent overpressure and a thermal fuse to protect against overheating. The sterilizer operates with a current of 9 A, ensuring sufficient power supply for optimal component performance.

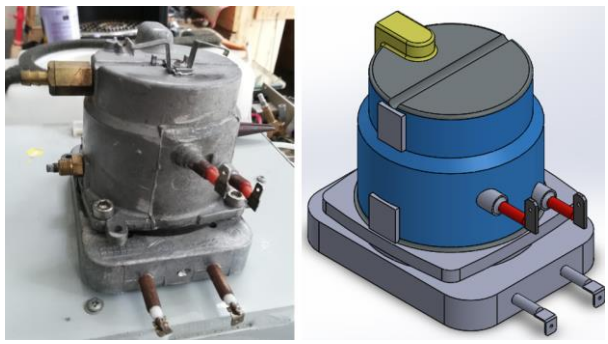

Figure 10. *Boiler*

3.1.3. Electromagnetic valve

Once the desired temperature is reached in the tray, the solenoid valve is activated to open. The solenoid valve used in this system is the CEME valve, operating at 230 VAC ~ 50 Hz. It is designed to withstand pressures ranging from 0.1 to 12 bar.

To control the solenoid valve, it is programmed to open and close in a continuous cycle. It opens for a duration of 1 second and then remains closed for 7 seconds before the

cycle repeats. This controlled opening and closing of the solenoid valve ensures the regulated flow of steam in the sterilizer, optimizing the sterilization process.

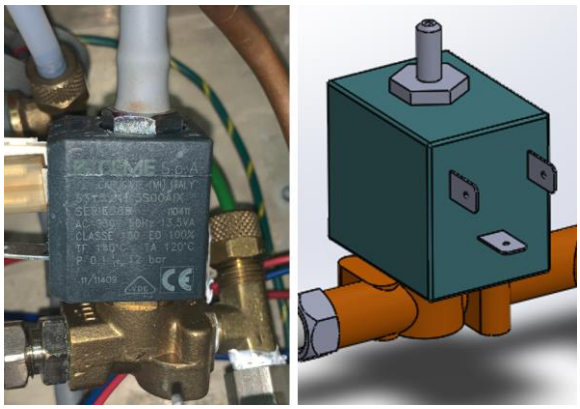

Figure 11. *Solenoid valve*

4. Control system

4.1. Circuit diagram

The control chart depicted in Figure 12 illustrates the overall system control for the eye surgical instrument disinfectant. The system utilizes an Arduino Nano as the main controller, which ensures stable programming and oversees the operation of the entire system. Alongside the button inputs, the system incorporates additional input signals, including PT1000, a water quality sensor, and a water flow sensor. These input signals provide crucial data for monitoring and controlling various aspects of the disinfectant system, such as temperature, water quality, and water flow.

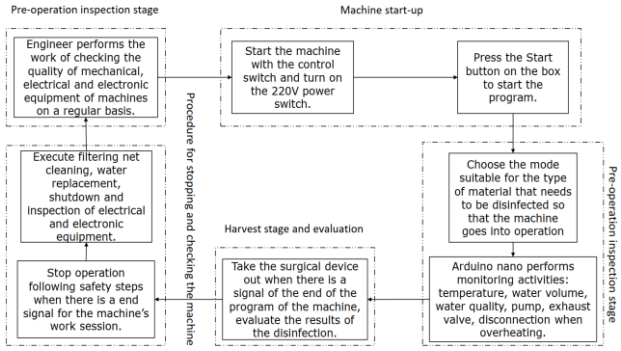

Figure 12. *System control diagram*

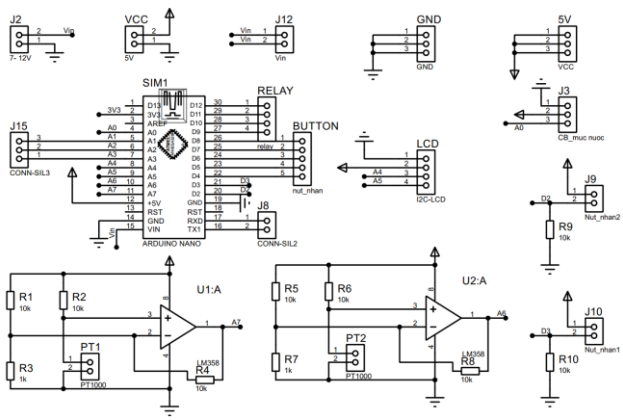

Figure 13. *Circuit diagram of a central circuit using Arduino*

Furthermore, the Arduino Nano will be connected to an LCD screen to exhibit input parameters and operating instructions. This display will provide users with real-time information regarding the system's status. The microcontroller will receive the resistance change values from the PT1000 temperature sensor through the analog input pins. By interpreting these values, users can determine the current temperature of the sensor, enabling effective monitoring and control of the disinfectant system.

Figure 14 displays the circuit diagram that governs the heater (damper) control for the system. The Arduino Nano serves as the controller, regulating a 10A power intermediate relay to interrupt the power supply to the heater. Additionally, a thermal fuse arrangement is incorporated to enhance safety measures. In the event of a failure in the microcontroller's ability to close the steam oven correctly, the thermal fuse arrangement prevents excessive temperature escalation. The relay acts as a protective measure by disconnecting the power supply to the oven, ensuring the safety of the user.

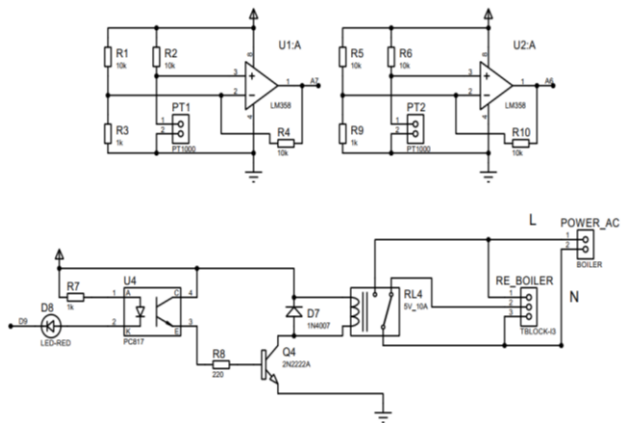

Figure 14. *Circuit diagram of the heater controller*

4.2. Temperature control

To satisfy the requirements of small setting error, short transition time, and small overshoot, a proportional-derivative (PD) controller should be employed [11-13]. When the boiler temperature (PV) starts far from the desired temperature (SP), a large output (U) is necessary to quickly bring the temperature (PV) close to the setpoint (SP). The output (U) is determined by multiplying the error (E) by the proportional gain (Kp): $U = Kp \times E$. The objective is to minimize the error (E) and bring it to zero as swiftly as possible.

However, with a large Kp value, the output (U) can become significant, potentially causing the PV temperature to go below the desired temperature (SP). This can lead to oscillations around the setpoint, resulting in an unstable temperature.

To address temperature overshoot, a "brake" component is introduced in the controller. This component's purpose is to reduce the boiler temperature as the PV approaches the SP temperature. The rate of change of the error (E) over time (dE/dt) is used to calculate this component, which is known as the derivative component

(D) in the PID controller. Therefore, the controller in this case is a PD controller.

$$F = Kp \times E + Kd \times \frac{dE}{dt}$$

In situations where the derivative gain (Kd) is larger than the proportional gain (Kp), the PV temperature tends to decrease toward the setpoint (SP). However, a problem arises when Kd is excessively large relative to Kp or when Kp itself is small. As the PV approaches the SP, the temperature may no longer increase because Kd×(dE/dt) becomes zero (since the PV temperature remains constant). Consequently, the output (U) becomes U = Kp×E, where both Kp and E are small. As a result, the temperature fails to increase despite the presence of a nonzero error (E). This error is known as steady-state error.

To mitigate steady-state error, an integral component is introduced to the controller, which accumulates errors over time. With the inclusion of the integral component, the controller now becomes a full proportional-integral-derivative (PID) controller.

$$F = Kp \times E + Kd \times \frac{dE}{dt} + Ki \times \int_0^t Edt$$

The method that authors employ for tuning the PID controller involves the following steps [12-14]:

- Set Ki (integral gain) and Kd (derivative gain) to 0 initially.
- Ki and Kd gradually increase until the system reaches stability, with the adjustment value closely matching the desired value and accepting a small overshoot.
- If the system fails to reach the desired stability point, Ki is further increased.
- If there is an overshoot issue, increase the value of Kd.
- This method is simple and effective in achieving the desired system response. However, it can be time-consuming as it requires multiple iterations and adjustments to find the optimal values for Ki and Kd.

By iteratively adjusting Ki and Kd, the PID controller can be fine-tuned to achieve the desired control performance for the system.

According to the provided chart, the heating process exhibits distinct phases. Initially, the temperature rises rapidly from 0 to 100ºC (point A). Subsequently, the heating process slows down as the temperature reaches the range of 100 - 135ºC (points B and C). At the temperature threshold of 135ºC (point D), the system interacts to maintain the temperature. After the sterilization cycle is completed, the temperature gradually decreases (points E and F).

Figure 15 visually represents the duration of the heating process for steam, showcasing the different temperature stages. Based on this heat time diagram, it is evident that the temperature remains around the threshold of 115 ºC. If desired, the initial temperature setting can be adjusted accordingly.

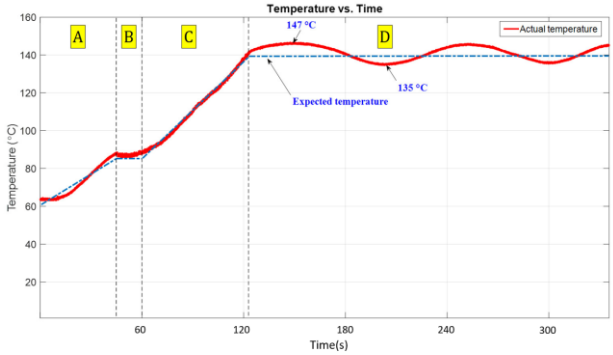

Figure 15. *Actual temperature of the stream during operation*

Figure 16 depicts the overall machine following installation, inspection, evaluation, and testing. It provides an overview of the complete system once it is fully assembled and ready for operation.

Figure 16. *Photo of machine*

After the operation cycle of the machine is finished, the next step is to assemble the body and the shell together. This involves connecting and securing the main body of the machine with the outer shell. The assembly process ensures that the components are properly aligned and fitted, creating a cohesive and functional unit. Proper care and attention should be given during this assembly to ensure a secure and reliable connection between the body and the shell of the machine.

5. Conclusions

In conclusion, the author's design research has reached its culmination, with the machine nearing completion. The primary objective is to create a stable and durable machine that meets customer demands while maintaining competitiveness in terms of pricing compared to imported machines available in the market. This practical device holds the potential to benefit both society and customers alike. Furthermore, the authors express great enthusiasm

for forging collaborations with companies to advance the development of medical support machines for hospital units in Danang and Vietnam. This collaborative effort aims to make significant contributions to the progression of medical equipment and bolster the healthcare sector within the local region as well as the entire country.

In the future, the authors will continue to develop a more advanced machine incorporating the following enhancements:

- Redesigning the machine with reduced mass.
- Implementing an advanced control algorithm to achieve a more stable temperature.
- Evaluating and mitigating vibration, as well as other unwanted oscillation factors during machine operation to minimize noise and resonance [14-15].

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