Design and implementation of automatic autoclave temperature and pressure data recording system

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Abstract. Sterilization data history is needed to maintain and examine an autoclave performance to minimize the risk of sterilization failure. This study aimed to develop a sterilization data recording system for an autoclave with external data storage using an SD card. The TFT LCD is used as the user interface to make it easier for users to monitor temperature and pressure during the sterilization process. The MAX 31865 temperature sensor and the MPX 5700 AP pressure sensor are used to monitor the temperature and pressure in real-time during the sterilization process. The entire sterilization process of the developed system is controlled using the ATMega 2560 microcontroller. Three testings have been carried out to determine the designed temperature, and the pressure data recording system has been a success. Temperature data recording, Pressure data recording, and Process data recording. Based on the conducting test results, the designed recording system gives an excellent performance to record the temperature, pressure level, and data sterilization process with a success rate of 100%.

1. Introduction

To ensure patients' safety and health, healthcare equipment operated must function properly, according to the requirements of quality, safety, and efficacy organized attempts quality maintenance of medical equipment and medical supplies[1, 2]. One of them is that all medical equipment, especially surgical equipment, must go through a reasonable and measured sterilization process before being used [3-5]. The sterilization process that is not optimal will leave bacterial spores that can grow and develop to cause surgical site infections, central line-associated bloodstream infections, nosocomial infections, and other infections [6]. According to WHO (World Health Organization) that nosocomial infections caused 1.4 million deaths every day in the world in 2010. In Indonesia, in 2010, there were ten general hospital education cases of high nosocomial infections, namely 6-16% with an average of 9.8%.

In sterilizing medical equipment in hospitals, alcohol use is one way to make medical equipment clean and sterile again [7]. However, the use of alcohol in the process of sterilizing medical equipment is considered ineffective and quite troublesome, especially if the equipment to be fixed is in enormous quantities and has large dimensions. Apart from using alcohol, another way to sterilize medical equipment is by using pressurized steam or commonly known as an autoclave [8-10]. An autoclave is
a sterilizer with a closed chamber and is made of metal. Sterilizing surgical equipment using an autoclave consists of 4 steps, pre-vacuum, rising temperature, sterilizing, and vacuum drying [11]. Given the importance of using autoclaves in cleaning medical equipment, many autoclave developments have been carried out, such as the use of solar power as an autoclave power source [12], the use of the neural network algorithm [13], the FDGA algorithm [14], and others.

Sterilization using an autoclave is considered useful in cleaning surgical equipment from unwanted microorganisms, but an autoclave performance must be adequately maintained and monitored. This sterilization equipment requires regular maintenance to keep it in a usable condition and work optimally in the sterilization process. The use of an uncalibrated autoclave can lead to sterilization failed which has the risk of increasing the transmission of various diseases [15]. The method of maintaining the sterilizer is carried out by observing and checking the tool's physical condition. Measurement of temperature and pressure data during the sterilization process will determine whether the device still has ideal sterilization performance. Besides, historical records of temperature and pressure measurements during the sterilization process are very decisive in the autoclave calibration step. In previous research, an autoclave was developed with internal data storage utilizing EEPROM (Electrically Erasable Programmable Read-Only Memory) [16]. However, the autoclave in this study can only store 1 data, and then it is deleted when the tool is used in another reading process. In further research, the autoclave data logger used an SD card as a storage medium. However, process data that can be stored on this tool can only hold 1 data stored when the device is used again; the data will write to the same file.

Because it is related to the need for maintenance and examination of medical equipment, the data are needed as a validity check for the device's performance. In this study, an autoclave was developed with external data storage using an SD card adapter module accompanied by a storage device. The memory size will increase the device's data storage capacity to store data based on the large degree of its external memory compared to storage using internal memory. This external data storage also aims to make it easier for users to process measurement data on other devices (computers) for various purposes. Also, the TFT LCD is used as the user interface to make it easier for users to monitor temperature and pressure during the sterilization process. The MAX 31865 temperature sensor and the MPX 5700 AP pressure sensor are used to monitor the temperature and pressure in real-time during the sterilization process. The ATMega 2560 microcontroller is used as the brain that controls the entire sterilization process.

2. Methodology
2.1 System Design
The system design of the proposed autoclave temperature and pressure data recording are given in the block diagram, as shown in Figure 1. The circuit block diagram is divided into three blocks, namely, Input, Process, and Output. The first block, the Input block, is defined as a data input block on the microcontroller. This block is consisting of Switch 1 and 2, pushbuttons, a temperature sensor, a pressure sensor, RTC, and a thermostat. Switches 1 and 2 are used as sensors for locking doors and door closers, pushbuttons for selecting the sterilization menu, resetting and starting sterilization. Temperature and pressure sensors to read temperature and pressure level, water level sensors as detectors the water level in the tank, RTC as a time series, and the thermostat as a safety overheat. The process block will process the input data in the input block according to the program commands given after getting the input voltage from the power supply. The process block will process the input data and command the output block to work.

The microcontroller provides a work order to the driver circuit connected to a 220 VAC voltage source. Selenoid door lock as a series of door locks during the sterilization process, the heater works as a heating element in the sterilization process, valve one as a pressure waster in the chamber, valve two as a waster of residual water from the sterilization process, and valve three as a water filling valve in the chamber. The motor pump works as a water filling pump system in a tank with an input voltage
of 5 VDC. The buzzer functions as an alarm on the device, the SD card is used as data storage, and the TFT LCD is used to display the results of temperature and pressure measurements.

2.2 Flowchart Process
The working process of the designed autoclave device with external sterilization process data storage is illustrated in Figure 2.

Figure 1. Block diagram of the system design

Figure 2. Flowchart of the designed system
The sterilization process will start when users pressed the power button in the autoclave, and the system will initiate the program. When the initialization process is complete, the tank sensor will measure the water level. The water level is below the minimum water level, so the water pump will automatically turn on to carry out the water filling process until the tank is full. The LCD will display the sterilization selection menu when the air filling process is complete. The operator selects the sterilization process menu and starts the sterilization process by pressing the start button. The sterilization process begins with filling the air in the chamber automatically to the standard air filling limit. To ensure that the door is tightly closed, the designed system utilized a buzzer as an alarm. When the door is not closed properly, the alarm will beep, and the sterilization process does not run. The heater will work if the door is closed correctly, with the door will automatically be locked. This process will work until the temperature and pressure level has been reached. The whole sterilization process is recorded on the SD card, and the heater will stop working and keep the set temperature stable for the sterilization process. The sterilization process is complete, and the valve automatically works to remove air and pressure until the chamber's pressure runs out (0 Bar). The door lock will automatically open when the chamber's pressure is in zero bar and the sterilization process is complete. All sterilization data is automatically recorded on the SD card.

2.3 Testing and Analysis Method

In this study, three testings have been carried out to find out wheater the designed temperature and pressure data recording system has been a success, Temperature data recording, Pressure data recording, and Process data recording. The recording of temperature data on the SD card is written in decimal form. The sensor readings' input data are processed into unsigned integer data types (positive integers) on the microcontroller with a digital identity pin. The value range for the unsigned integer data type is between 0 and 65535, with the starting point value setting at 0. The pressure data recorded on the SD card is written in decimal form. The sensor readings data are processed into an integer data type on the microcontroller with an analog input pin. This data type ranges from -32768 to 32768, with the starting point value at 0. The sterilization process data stored on the SD card is recorded in the form of a text file (.txt). The recording process starts when the sterilization process starts. The data recorded in the file are the date, time, temperature level, pressure level, and the ongoing sterilization process status. The value data for the sterilization process is written in the form of a decimal number.

3. Result and Discussion

3.1 Temperature Level Testing

![Temperature Level Data](image)

**Figure 3. Temperature data recording throughout the sterilization process**

Temperature testing is carried out during the sterilization process with temperature level set point of 134°C and 121°C. The test is done by recording temperature levels throughout the sterilization process.
and comparing the PT100 temperature sensor with an analog pressure gauge. Data were collected by reading the temperature level every minute. Temperature data recording throughout the sterilization process is shown in Figure 3. According to the test result, the initial temperature level rise value at 4.2 minutes on the 134°C set points and 2.55 minutes on the 121°C set points. The heating time needed to reach the temperature level target of 134°C is 27 minutes, while the target temperature of 121°C takes 21 minutes. The 134°C temperature level's stability is obtained 8 minutes after the target temperature is reached, while at 121°C, it takes 9 minutes after the set point temperature is reached.

3.2 Pressure Level Testing

The pressure data were collected five times by comparing the MPX5700 pressure sensor with an analog thermo-pressure gauge. The measurement result of the 1.1 Bar pressure level throughout the sterilization process at a temperature set point of 121 is shown in Table 1.

| No. | Thermo-pressure Gauge (Bar) | Designed System (Bar) |
|-----|-----------------------------|------------------------|
| 1   | 1.1                         | 1.18                   |
| 2   | 1.1                         | 1.17                   |
| 3   | 1.1                         | 1.17                   |
| 4   | 1.1                         | 1.17                   |
| 5   | 1.1                         | 1.17                   |
| Mean|                             | 1.172                  |
| Percentage of error | 6.14%               |
| SD  |                             | 0.0045                 |

Table 2. Pressure level of 134°C set point measurement result

| No. | Thermo-pressure Gauge (Bar) | Designed System (Bar) |
|-----|-----------------------------|------------------------|
| 1   | 2.1                         | 2.19                   |
| 2   | 2.1                         | 2.18                   |
| 3   | 2.1                         | 2.18                   |
| 4   | 2.1                         | 2.18                   |
| 5   | 2.1                         | 2.18                   |
| Mean|                             | 2.18                   |
| Percentage of error | 3.76%               |
| SD  |                             | 0.0045                 |

According to the test result (as shown in Table 1 and Table 2), for the temperature set point of 121, the average pressure level measurement is 1.17 Bar, with the lowest pressure value of 1.13 Bar and the highest pressure being 1.34 Bar for each process. The percentage of error in the pressure measurement by the designed system is around 6.14%. For the temperature set point of 134, the average pressure level measurement is 2.18 Bar, with the lowest pressure value of 2.14 Bar and the highest pressure being 2.22 Bar for each process. This measurement result gives a percentage of error of around 3.76%. The sensor's pressure level reading is good, with a not too high difference due to the well-functioning pressure control system.

3.3 Process Data Recording

The last test is the data process recording test. This test aims to determine whether the designed data recording system gives the best performance. The test was carried out by conducting ten repetitions of recording data of the sterilization process. The SD card's storage capability is tested by repeating the
sterilization process with different storage memories to determine the success of the recording process. The data process recording result is shown in Table 3 and Figure 4.

Table 3. Data recording test result

| Data Recording | Description |
|----------------|-------------|
| 1<sup>st</sup>  | Successes  |
| 2<sup>nd</sup>  | Successes  |
| 3<sup>rd</sup>  | Successes  |
| 4<sup>th</sup>  | Successes  |
| 5<sup>th</sup>  | Successes  |
| 6<sup>th</sup>  | Successes  |
| 7<sup>th</sup>  | Successes  |
| 8<sup>th</sup>  | Successes  |
| 9<sup>th</sup>  | Successes  |
| 10<sup>th</sup> | Successes  |

Accuracy: 100%

According to conducting test result, all of the data sterilization processes have been successfully recorded on the SD card with an accuracy rate of 100%.

4. Conclusion
This study aims to develop a sterilization data recording system for an autoclave with external data storage using an SD card. The TFT LCD is used as the user interface to make it easier for users to monitor temperature and pressure during the sterilization process. The MAX 31865 temperature sensor and the MPX 5700 AP pressure sensor are used to monitor the temperature and pressure in real-time during the sterilization process. The ATMega 2560 microcontroller is used as the brain that controls the entire sterilization process. Based on the conducting test results, the designed recording system gives an excellent performance to record the temperature, pressure level, and data sterilization process with a success rate of 100%.

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