CHAPTER 1

REAL-TIME DETECTION OF ETHYLENE OXIDE RESIDUE IN STERILIZATION PROCESSES USING IOT-BASED SENSORS

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1.1 INTRODUCTION

Medical devices have advanced significantly in recent decades. Medical devices help diagnose, monitor, and treat many diseases. The constant hunt for cutting-edge technology to better medical diagnosis, treatment, and patient care drives this sector. Robotic-assisted surgery and other diagnostic imaging modalities like X-ray, CT, MRI, and ultrasound have improved surgical equipment for more accurate and minimally invasive treatments. Pacemakers and prosthetic joints have transformed the treatment of musculoskeletal and chronic diseases. Remote diagnosis and customised therapy have also advanced thanks to wearable medical technology for ongoing health monitoring and point-of-care devices. Safety and regulatory compliance matter. Good manufacturing practices and ISO 13485 must be followed during design and production. With rising utilisation, ethylene oxide is a popular medical device sterilisation agent. This is due to its potency and compatibility with many materials. It is widely used because it prevents the harmful effects of heat and radiation from steam or radiation sterilisations. The modern market expects a wide choice of products, designs, materials, and packaging combinations, making this last point vital. Due to the toxicity of ethylene oxide (EO), this technology requires safeguards to protect staff and patients. Consequently, several governments have restricted its use, notably in healthcare settings. As a result, there is a critical need to examine emerging sterilization alternatives, particularly where traditional EO methods face increasing governmental restrictions[1].

Medical sterilisation, which prevents germs from contaminating patient care tools and devices, has been utilised in industries for years. Medical facilities incur large costs due to nosocomial infections and patient death or morbidity when sterilisation fails [2]. EO is mostly used to sterilise. Due to its molecular structure, EO interacts with several substances via ring opening. The Substitution Nucleophilic Bimolecular (SN2) mechanism and nucleophiles are common reactions. This disinfects bactericidally, fungicidally, and sporadically. This works against most bacteria, including viruses. EO affects microorganisms by alkylating cell-reproduction proteins. It gaseous sterilises heat-labile pharmaceutical and surgical products [3].

Ethylene oxide gas and carbon dioxide are used to sterilise goods under vacuum in a sealed chamber pressure vessel to prevent explosions from pure EO and air. Sterilises all product-accessible surfaces through porous packaging with EO. Because EO may penetrate many layers of porous packaging, it can sterilise many materials that traditional methods cannot. EO is associated to pancreatic leukaemia. Increased EO exposure worsens effects. High EO exposure can cause convulsions, paralysis, coma, liver, and kidney damage. Long-term exposure can cause cataract, brain, and nerve damage. Dermatitis, blisters, and burns can arise from EO contact. International Agency for Research on Cancer classifies ethylene oxide as Group 1 carcinogen [3]. The Internet of Things (IoT) enables smart applications like smart homes and smart cities. A new computing architecture uses the cloud to provide real-world services over the Internet. An IoT-enabled sensor can correctly measure ethylene oxide in ppm and send the data to the cloud for smart device viewing [4].

1.2 METHODOLOGY

The initial step involves conducting research and performing requirement analysis to gather relevant data regarding the sterilization process, ethylene oxide gas, and IoT-based ethylene oxide sensors. This knowledge is crucial for the successful development of the project. The subsequent vital phase involves the construction of an ethylene oxide sensor system, specifically focused on constructing the project prototype. Next on the agenda is the integration of Internet of Things (IoT) technology. This component is vital as the project incorporates real-time monitoring, which involves utilizing an application to observe the data and its patterns. Testing and validating involve doing field tests in order to guarantee that both the hardware and software are functioning as planned. The construction of a Graphical User Interface (GUI) is crucial, as it allows users to visually access and compare historical and current data in either tabular or trend format. This project utilises the Arduino Cloud for real-time monitoring and cloud storage for data in the application.

1.2.1 ETHYLENE OXIDE RESIDUE DETECTING METHOD

Implementing EO sensors for detecting ethylene oxide gas residue in medical devices post-sterilization is now regarded as the most effective approach. For sterilization, ethylene oxide gas was utilized as the sterilizing agent. The products may contain residual ethylene oxide gas. The products will undergo quarantine and observation for a few hours to ensure that no residue remains. The product will be sent through the EO sensors in order to detect any remaining residue. The sensor facilitates an oxidation-reduction reaction with ethylene oxide gas. The procedure discharges an electric charge and produces an electrical current. The current is directly proportional to the concentration of ethylene oxide gas. The concentration of the target gas can be determined by measuring the current value. Subsequently, the sensors will transmit the data to the Arduino Cloud for the user to observe. For the purpose of carrying out the research, a safety chamber was used to fill with EO gas. A product was placed into the chamber to undergo the sterilizing process. Following the sterilizing process, the product was placed in the chamber to detect any remaining ethylene oxide residue. The ethylene oxide sensor system will identify the residue, and the IoT-based EO sensor will send updates of the residue to the Arduino Cloud app every five minutes for monitoring. The cloud storage will securely store the data for convenient, immediate examination.

1.2.2 ETHYLENE OXIDE SENSOR SYSTEM DEVELOPMENT

This project develops an IoT-based system to detect EO gas, integrating sensors with IoT connectivity to provide real-time concentration readings in ppm. The system includes EO sensors with Wi-Fi or Bluetooth modules that communicate data to a central server via an IoT gateway. The gateway, which can be specialized hardware or software, ensures effective communication between sensors and the cloud platform.

For temperature measurement, DHT sensors (DHT11 and DHT22) were utilized. The DHT11 measures 0-50°C with ±2°C accuracy and 20-90% RH with ±5% accuracy. The more advanced DHT22 covers -40 to 80°C with ±0.5°C accuracy and 0-100% RH with ±2% accuracy. Dust sensors detect particulate matter concentration in the air, crucial for maintaining sterilization efficacy and safety. The project employs the ESP32S microcontroller for its built-in Wi-Fi, Bluetooth, and extensive peripheral support. The system design includes a sensor module housed in an acrylic box placed in the sterilization chamber. The sensor system monitors and reports EO levels every 15 minutes via the Arduino Cloud application, which allows users to access and observe data trends. The design, created using SolidWorks, ensures optimal functioning, safety, and integration, with precise dimensions for the sensor enclosure.

The Arduino Cloud platform is chosen for data storage, processing, and visualization, featuring robust security measures and automated alerts for anomalous ETO levels. The Arduino IDE is used for programming, and the Proteus Design Suite supports schematic capture, simulation, and PCB layout. The project also includes a graphical user interface (GUI) within the Arduino Cloud application to enhance user accessibility and interaction.

1.2.3 PARAMETERS DETECTION

Following the sterilisation procedure using EO gas, the product is placed in a specifically built chamber fitted with a prototype monitoring system. This chamber is equipped with a variety of sensors to measure the levels of EO residue, temperature, humidity, and dust particles. The product is kept in the chamber for a duration of one hour, enabling the sensors to precisely detect and measure these parameters. The gathered data is subsequently transmitted to an Arduino board equipped with a Wi-Fi module, the ESP32S. The data is broadcast to the Arduino Cloud every 15 minutes via the ESP32S module, enabling real-time monitoring in the Arduino Cloud app on any smart device. Users can remotely access and monitor data from any location, ensuring both flexibility and ease. Furthermore, the data is securely kept in a remote server network, commonly referred to as the cloud, to facilitate future retrieval and enable in-depth analysis over an extended period of time. The ability to save data is essential for monitoring past data, conducting trend analysis, and ensuring compliance with safety regulations. The system utilises powerful IoT capabilities to continuously monitor and save important parameters, ensuring the effectiveness and safety of the sterilization process.

1.3 RESULTS AND DISCUSSION

This project entails the incorporation of four crucial parameters. These are temperature, humidity, dust, and EO gas detection. Monitoring temperature and humidity is essential since they can considerably impact the stability and effectiveness of EO residue in the environment. Identifying dust is crucial for preserving.

1.3.1 TEMPERATURE

Temperature is a critical factor in the use of ethylene oxide (EO) for sterilization due to its impact on the efficacy, safety, and compliance of the process. Higher temperatures enhance the antimicrobial activity of EO, making sterilization more effective and efficient, typically within a range of 37°C to 63°C. Additionally, temperature affects EO's gas properties, influencing its distribution and penetration, while also mitigating the risk of fire or explosion by keeping EO within safe limits. Proper temperature control ensures compatibility with various materials and adherence to regulatory guidelines, ultimately ensuring the quality and safety of sterilized products [5]. Figure 1.1 shows the visual temperature gauge reading from the sterilized object for one hour in Arduino Cloud.

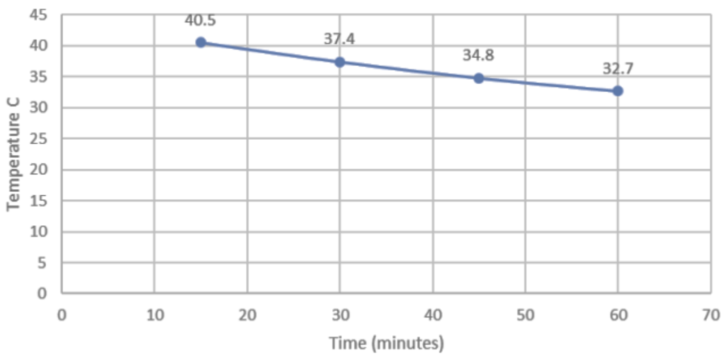

Figure 1.1: Trend for the temperature of sterilized product

The data shown demonstrates a persistent decline in temperature throughout time. At the start, after 15 minutes, the temperature is 40.5°C. The temperature decreases to 37.4°C after 30 minutes, further reduces to 34.8°C after 45 minutes, and eventually reaches 32.7°C after 60 minutes, as represented in figure 4.4. The data indicates a consistent decrease in temperature over time, with an average decline of approximately 3 to 4 degrees Celsius every 15 minutes. Upon analysing the cooling rate, it is evident that the temperature lowers at a rate of roughly 0.207°C per minute between 15 and 30 minutes, 0.173°C per minute between 30 and 45 minutes, and 0.14°C per minute between 45 and 60 minutes. This suggests that the rate at which the cooling occurs decreases as time goes on, which is a typical feature of numerous cooling procedures where the initial decrease in temperature is more rapid and then gradually decelerates.

1.3.2 HUMIDITY

Humidity is a critical factor in determining the efficiency and safety of ethylene oxide (EO) sterilization procedures. EO is frequently employed for the sterilization of medical equipment and other delicate things that are unable to tolerate elevated temperatures or moisture. Humidity promotes the permeation and dispersion of EO gas, hence increasing its efficacy in reaching and sterilizing all surfaces and crevices of the treated products. Maintaining optimal humidity levels is crucial for keeping the EO gas in a vapor form, which enhances the reliability and efficiency of sterilization. In addition, regulating humidity is crucial in preventing the occurrence of condensation, which can disrupt the sterilization procedure and potentially harm the sterilized goods.

Ensuring worker safety requires maintaining appropriate humidity levels, as fluctuations in humidity can impact the concentration of EO gas in the atmosphere, hence affecting its effectiveness and the risk of harmful exposure.

Consequently, maintaining accurate humidity levels is crucial in order to optimize the effectiveness of EO before and after sterilization, while also guaranteeing safety and adherence to regulatory guidelines [5]. Figure 1.2 shows the visualize humidity percentage reading from the sterilized object for one hour in Arduino Cloud.

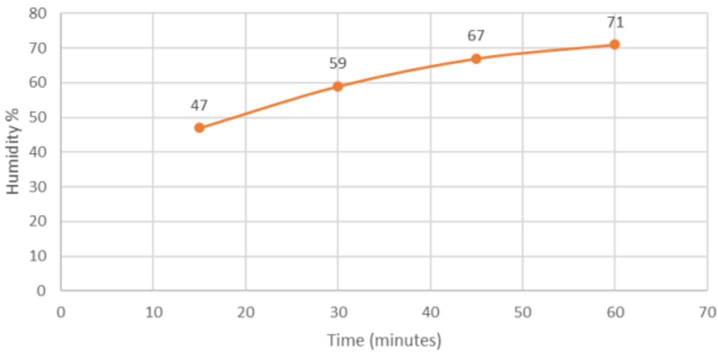

Figure 1.2: Trend for the humidity of sterilized product

The data provided demonstrates a dramatic and consistent increase in humidity as time progresses. The humidity levels at different time intervals are as follows: 47% at 15 minutes, 59% at 30 minutes, 67% at 45 minutes, and 71% at 60 minutes. The consistent upward trend suggests a notable surge in humidity over time. Upon examining the pace at which humidity increases, we observe that it grows at a rate of around 0.8% per minute between 15 and 30 minutes, 0.533% per minute between 30 and 45 minutes, and 0.267% per minute between 45 and 60 minutes. The declining rate indicates that the environment is reaching a point of saturation with moisture, resulting in a gradual decrease in the rate of growth over time.

1.3.3 DUST PARTICLE

Monitoring dust in situations where ethylene oxide (EO) is used is essential due to its impact on air quality and worker health, potential interference with the sterilization process, and substantial safety issues it poses. Dust particles might diminish the efficacy of EO sterilization by providing a barrier for bacteria and also enhance the risk of respiratory risks when inhaled.

Moreover, the presence of both dust and EO, which is a combustible gas, increases the likelihood of fires or explosions. Implementing effective dust control measures is crucial for creating a secure work environment, preserving the effectiveness of sterilization, and ensuring adherence to occupational safety requirements. Figure 1.3 shows the visualization of the dust particles reading from the sterilized object for one hour in Arduino Cloud.

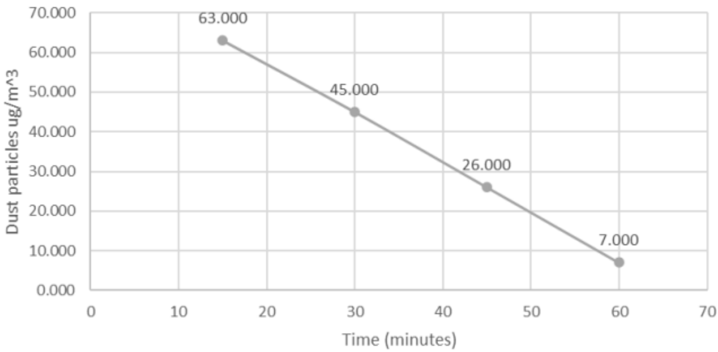

Figure 1.3: Trend for the dust particles of sterilized product

The data supplied indicates an impressive decrease in the concentration of dust particles over time, as measured in micrograms per cubic meter (μg/m³). At the start, after 15 minutes, the concentration of dust particles is 63,000 micrograms per cubic meter (μg/m³). The concentration reduces to 45,000 μg/m³ after 30 minutes, further decreases to 26,000 μg/m³ after 45 minutes, and ultimately reaches a significantly lower concentration of 7,000 μg/m³ after 60 minutes. The steady decreasing trend suggests that either the air is being efficiently purified or that the dust particles are gradually settling during the monitored period. Upon analysing the rate of reduction, it is shown that the concentration of dust particles falls at a rate of roughly 1.200 μg/m³ per minute from 15 to 30 minutes, 1.267 μg/m³ per minute from 30 to 45 minutes, and 1.267 μg/m³ per minute from 45 to 60 minutes. The continuous rate of decrease indicates a gradual decline in the concentration of dust particles over time.

1.3.4 ETHYLENE OXIDE RESIDUE

The presence of ethylene oxide (EO) residue during the sterilization process is a crucial determinant in guaranteeing the safety and effectiveness of sterilized medical equipment and supplies. EO is commonly employed because to its efficacy in sterilizing materials that are sensitive to heat. However, the presence of residual EO might potentially lead to health hazards, such as irritation or toxic responses. Hence, it is imperative to implement rigorous aeration and degassing protocols in order to decrease the presence of EO residues to acceptable levels prior to the discharge of products. The FDA and ISO have set rules for acceptable limits of EO residue, necessitating producers to perform comprehensive validation tests and regular monitoring to ensure adherence. The recommendations also establish the permissible amounts of EO and its by-products, ethylene glycol and ethylene chlorohydrin, and stress the need for ongoing monitoring and periodic revalidation to ensure product safety and conformity with regulations. Figure 1.4 shows the visualize of ethylene oxide residue reading from the sterilized object for one hour in Arduino Cloud.

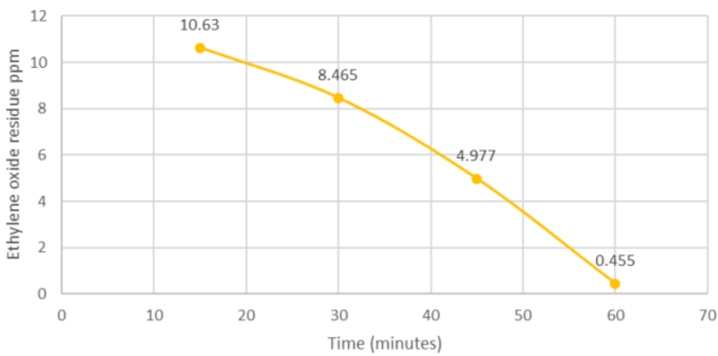

Figure 1.4: Trend for the ethylene oxide residue of sterilized product

The data supplied demonstrates a clear and substantial decline in the concentration of ethylene oxide residue over time, as measured in parts per million (ppm). At the start, after 15 minutes, the concentration of ethylene oxide residue is 10.63 parts per million (ppm). The concentration lowers to 8.465 parts per million (ppm) after 30 minutes, further decreases to 4.977 ppm after 45 minutes, and ultimately reaches a very low concentration of 0.455 ppm after 60 minutes. The measured period has shown a significant and continuous decrease in ethylene oxide levels, as indicated by the downward trend. Upon analysing the rate of decrease, it is observed that the concentration decreases by roughly 0.144 parts per million (ppm) each minute from 15 to 30 minutes. Between the time frame of 30 to 45 minutes, the rate of reduction is roughly 0.233 parts per million (ppm) per minute. From 45 to 60 minutes, the rate increases to about 0.301 ppm per minute. This indicates that the rate of decline in ethylene oxide concentration increases as time progresses, indicating a progressively more effective reduction process.

The analysis and the trend shown in Table 1.1 and Figure 1.5 reoffered a precise and accurate evaluation that assists in assessing ethylene oxide residue.

Table 1.1: The data obtain from observing the sterilized product for one hour via Arduino Cloud

Time (minutes)	Temperature (°C)	Humidity (%)	Dust particles (ug/m^3)	Ethylene oxide residue (ppm)
15	40.5	47	63.000	10.63
30	37.4	59	45.000	8.465
45	34.8	67	26.000	4.977
60	32.7	71	7.000	0.455

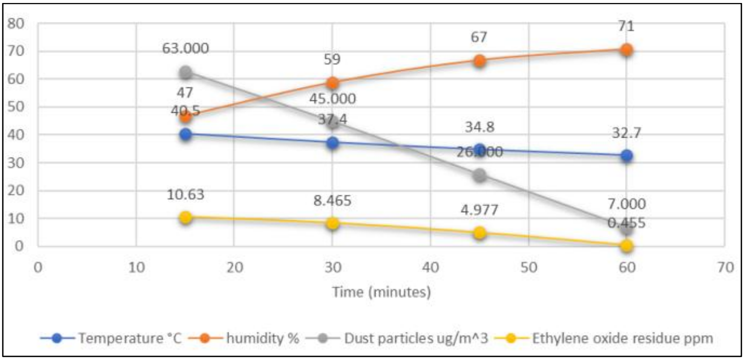

Figure 1.5: Trend comparison of all parameters

The data highlights the essential factors that impact the efficacy, safety, and adherence to regulations of the EO sterilisation process, with a particular focus on human welfare. Temperature, humidity, dust particle concentration, and EO residue were continuously measured for a duration of one hour using Arduino Cloud. The sterilised object experienced a decrease in temperature from 40.5°C to 32.7°C, with a gradual decrease in the rate of cooling. This indicates the presence of typical cooling patterns that are important for ensuring effective EO sterilisation and safety. The humidity increased gradually from 47% to 71%, which is crucial for keeping EO in its gaseous form and preventing condensation. The concentration of dust particles experienced a substantial reduction, decreasing from 63,000 μg/m³ to 7,000 μg/m³, resulting in improved air quality and enhanced safety.

The concentration of EO residue reduced significantly from 10.63 ppm to 0.455 ppm, which indicates that the degassing procedure was successful in removing the harmful substance. This is important for ensuring health and compliance with regulations. The analysis highlights the significance of accurate monitoring and management of these factors in order to maximise sterilisation, guarantee safety, and comply with regulatory criteria. The observed patterns offer valuable insights for improving process control and validation, hence guaranteeing the quality and safety of sterilised items and safeguarding human health throughout the sterilisation process.

1.4 CONCLUSION

This project aimed to ascertain the presence of ethylene oxide (EO) gas residue in medical devices following the sterilization procedure. The objective is to develop a reliable and precise method for detecting EO residue using an Internet of Things (IoT)-based EO sensor system. By leveraging IoT technology, this study seeks to provide continuous, real-time monitoring of EO levels, ensuring that residue concentrations remain within safe limits and enhancing overall safety in the workplace. The deployment of IoT-enabled sensors offers several advantages, including improved accuracy in detecting EO, enhanced data collection, and remote monitoring capabilities, which collectively contribute to more effective regulatory compliance and operational efficiency.

This approach underscores the potential of IoT in advancing computational psychiatry by providing robust models and methodologies that improve the precision, effectiveness, and accessibility of EO detection systems. Furthermore, the integration of IoT technology in EO sensor systems can significantly enhance user and staff outcomes by ensuring a safer environment, thereby improving the quality of life for individuals exposed to EO gas. This innovative use of IoT not only addresses critical safety concerns but also paves the way for future advancements in monitoring and managing hazardous substances in various industrial and healthcare settings.

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