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RESEARCH ARTICLE

# IoT-Enabled Design and Implementation of an Endotracheal Tube Cuff Pressure Controller Device

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**ABSTRACT** This work presents the design and implementation of an IoT enabled Endotracheal Tube Cuff Pressure Controller Device. This device, a fusion of electronics, control, and software engineering, aims to automatically regulate the cuff pressure of an Endotracheal Tube placed in a patient's trachea, ensuring that it remains within the optimal pressure range. The ideal pressure range, established to be between 20-30 cmH2O, can be adjusted to accommodate different patients' needs. The device is designed as an IoT device and includes an emergency button for shutting down the system in case of an emergency. The total cost of the system, which amounts to approximately 70 USD, makes it a cost-effective solution compared to other commercially available options. In order to verify the device's capability to accurately read and supply pressure, it is benchmarked against the gold standard (Fluke 729 300G FC) using quantitative tests including Pearson's r test, the paired t-test, and Bland-Altman analysis. The results from these assessments confirmed that the performance characteristics of the device are notably comparable to the Fluke 729 300G FC, which will be further examined in this study. These outcomes, along with the device's economic viability, validate it as a workable and reasonable alternative. The necessity for an automated and continuous monitoring system is further reinforced by the fact that manual cuff pressure measurement is prone to error and may even put the patient through discomfort.

**INDEX TERMS** Endotracheal tube cuff, IoT, trachea.

## I. INTRODUCTION

The process of endotracheal intubation which is a common practice in many cases and especially in general anesthesia before surgery, involves the insertion of an endotracheal tube into the airway of a patient who is unable to perform or experience difficulty with breathing functions [1]. Indications for intubation to secure the airway include respiratory failure (hypoxia or hypercapnia), apnea, low level of consciousness, sudden changes in mental status, risk of airway injury, high risk of aspiration, or larynx trauma (including neck, chest, or abdomen injuries) [2]. Annually, an estimated 13 to 20 million intubations are performed in the United States, creating a significant workload for healthcare systems and personnel [3], [4]. This observation, further affirmed by specialists in the field, provides a basis for the structural investigations that will be further explored in Section III-A. The endotracheal tube is connected to a ventilator that provides extra oxygen (O2) and helps regulate the patient's breathing by expelling carbon dioxide (CO2). A cuff, located between the endotracheal tube and the patient's tracheal wall, can be inflated to supply the proper level of oxygen and air to the patient during intubation. The cuff has two major functions: to ensure airway permeability

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and to limit inhalation of orogastric contents, which is the cause of Ventilator-associated pneumonia (VAP) [5]. To prevent possible harm to the patient, the cuff pressure must be maintained within a suitable range, typically 20 to 30 cmH2O [1], [4], [6], [7].

Endotracheal tube cuff pressure is a crucial factor in the management of mechanically ventilated patients [3] and various complications are associated with the improper adjusting of the tube cuff pressure [8]. Overinflation of the cuff may result in tracheal damage, including subglottic stenosis, scarring, hoarseness, nerve damage, fistula, and damage to the tracheal wall [9], [10]. Manual methods such as disappearance of audible air leak and the palpation of pilot balloon not only require years of experience and are not accurate but also might result in an excessive pressure [11]. Also, manual check of the cuff pressure is not a reliable practice in the first place as it suffers from very poor inter-individual performance [12]. It was reported that the manual detection by palpation method was not correct in 68% of cases; and only 10% of respondents could detect the pressure correctly within the desired range [13], motivating researchers to design systems for automatically detecting the pressure fluctuations [14]. Therefore, although manual checks of ETT cuff pressure are still commonly performed, this practice is not recommended due to various risks [15], [16].

To minimize the potential for adverse outcomes, alternative methods for monitoring cuff pressure should be utilized. A study conducted by Jain and Tripathi [11] divided 100 patients into two groups, with Group M having their ETT cuff pressure measured manually and Group C having it measured by an automated device. The results showed a reduction in complications when ETT cuff pressure was measured using automated systems (see Table 1).

**TABLE 1. Complications[a] observed in patients.**

| Complication | Group M | Group C |
|---|---|---|
| Sore throat | 10 | 4 |
| Cough | 6 | 4 |
| Hoarseness | 1 | 0 |

[a] Complications were identified in two cohorts, one utilizing conventional cuff pressure control techniques and the other utilizing an automated cuff controller.

Aside from the potential for adverse outcomes, the pressure of the endotracheal tube (ETT) cuff may fluctuate over time due to various patient-related factors, thus requiring continuous monitoring to guarantee it stays within the prescribed range. It is recommended that the cuff pressure be monitored every 8 hours, however, studies have shown that only 18% of patients maintain a constant cuff pressure within the range of 20-30 cmH2O. 54% of patients have readings that fall below 20 cmH2O at least once, while 73% have readings that surpass 30 cmH2O at least once [11].

*Related Technology and Objectives:* A thorough market analysis was carried out to assess the characteristics and prices of the industry's current products. Two different items that were aimed at different market segments and had distinctive features were both thoroughly investigated. Finding any gaps in the current manufacturers' solutions to satisfy end-user expectations was the examination's main goal.

The Intellicuff, developed by Hamilton Medical (Figure 1(a)), is designed to improve patient comfort during mechanical ventilation. It is classified as an Automatic Cuff Inflation (ACI) device, also known as Automatic Cuff Controller (ACC), which has the capability to monitor and adjust cuff pressure in real-time to achieve a target pressure level. The device utilizes closed-loop control and software-in-the-loop technology, offering a steady range of pressure. According to the device's technical specifications, the pressure range is 5 to 50 cmH2O, with a resolution of ±1 cmH2O and an accuracy of ±2 cmH2O, making it one of the reliable devices currently available on the market. Furthermore, there is no need for calibration, which adds to the device's ease of use.

With batteries included, the Intellicuff weighs 260 grams and can be charged up to 1500 times. It is available in the market at a price range between 2000-2500 USD [17].

The VBM Cuff Controller, manufactured by VBM Medizintechnik (Figure 1(b)), is a device that falls under the category of Automatic Cuff Inflation (ACI) devices. Its primary function is to adjust the pressure of the cuff of an endotracheal tube to maintain a target pressure level. The adjustable pressure range for this device is between 0 - 61 cmH2O, with an accuracy of ±1 cmH2O. The device weighs 520 grams. It features an auto-set function that inflates the cuff to 25 hPa (corresponding to 25 cmH2O or 18 mmHg) each time the device is switched on. The device is designed to adjust the pressure if the pressure decreases or rises. If the pressure decreases, the device immediately adjusts the pressure to the target value. If the pressure increases, the device automatically adjusts to the target value with a 5 second delay. The average battery life for this device is around 1000-1500 cycles. The device is priced at 1400 USD [18].

Examining the available technologies reveals that pricing remains a key impediment. The VBM Cuff Controller device, while being one of the most affordable automatic cuff controller devices on the market, is still cost-prohibitive in developing and low-income countries. Furthermore, ease of use is a crucial factor in the design and performance of endotracheal tube cuff controller devices. To ensure proper usage, the device should be intuitively designed and simple to use for healthcare practitioners. Features such as the elimination of the need for calibration, a clear and user-friendly interface, and lightweight design can greatly enhance the ease of use of the device. In terms of functionality, the device must be capable of achieving a desired cuff pressure range of 20-30 cm H2O without any difficulties in use. It is

(a) (b)

**FIGURE 1.** Two commercially available cuff controller devices compared to the present device. (a) Intellicuff; (b) VBM Cuff Controller.

important to note that the development of a low-cost IoT enabled endotracheal tube cuff pressure controller device is crucial, as it has the potential to serve as a prototype for future iterations that can be made available to the public through further research and development.

**Contribution and Novelty.**

The major novelties and associated contributions of the present device include:

1. IoT Enabled Design: The device is equipped with Internet of Things (IoT) technology, allowing seamless integration with mobile phones. This integration enables various functionalities and benefits.

2. Automatic Adjustment: The device can automatically adjust the ideal pressure range based on different patients' requirements. This feature enhances convenience and ensures optimal treatment for each patient without manual intervention.

3. Secure Shutdown Procedure: It provides a secure shutdown procedure, ensuring safe operation and minimizing risks associated with abrupt shutdowns or malfunctions.

4. Elimination of Separate Control Screen Panel: With the integration of mobile phone capabilities, the need for a separate control screen panel is eliminated. This simplifies the device's design and reduces manufacturing costs.

5. Cost Reduction: The cost of the present device is significantly reduced to around 70 USD. In comparison, similar alternatives in the market cost 20 times or more. This makes the device highly cost-effective and accessible to a wider range of users.

6. Pareto Optimization: Performance and cost were optimized through Pareto optimization, ensuring a proper balance between functionality and affordability.

7. Potential for Migration to Automatic Control: The device's cost-effectiveness and automated capabilities facilitate the transition from manual to automatic control in healthcare processes. This migration reduces the workload in healthcare settings and mitigates risks associated with manual practices.

Overall, the present device offers a cost-effective solution with advanced capabilities, potentially revolutionizing healthcare practices and improving patient care outcomes in the endotracheal intubation process.

## II. DESIGN METHODOLOGY

The proposed design of an ETT cuff pressure controller must have a secure immediate shutdown procedure feature, prevent air leakage, provide desired cuff pressure at intended environment since exceeding or falling down below desired range may have may result in a deficient seal, thereby potentially leading to cuff-leak and subsequent interruption of ventilation [19]. The integration of a mobile application for real-time data computation, in conjunction with the resolution of security issues through synchronization capabilities, has the potential to significantly reduce device cost by eliminating the need for a separate control screen panel. Furthermore, this integration would provide healthcare practitioners with the ability to check cuff pressure quickly and efficiently.

The microcontroller used in this project is the Arduino UNO, and the device has been engineered to incorporate Internet of Things (IoT) capabilities, thereby allowing for remote control, and monitoring through a mobile application. This was achieved through the integration of an ESP8266 NodeMCU module with the Arduino UNO, which enables connectivity to the internet and enhanced control through the mobile application. However, based on experiences, the ESP8266 NodeMCU, although proficient for enabling internet connectivity, has been found to be less than ideal for use as the primary microcontroller due to limitations in processing power and memory capacity. Consequently, the Arduino UNO was retained as the primary microcontroller for the project. Additionally, a web API was developed to store and manage patient and device data in a database. The control algorithm for the device aims to maintain the desired pressure range for the patient which is set via the mobile application, and utilizes an air motor to adjust the pressure in the two chambers and valves to control the airflow.

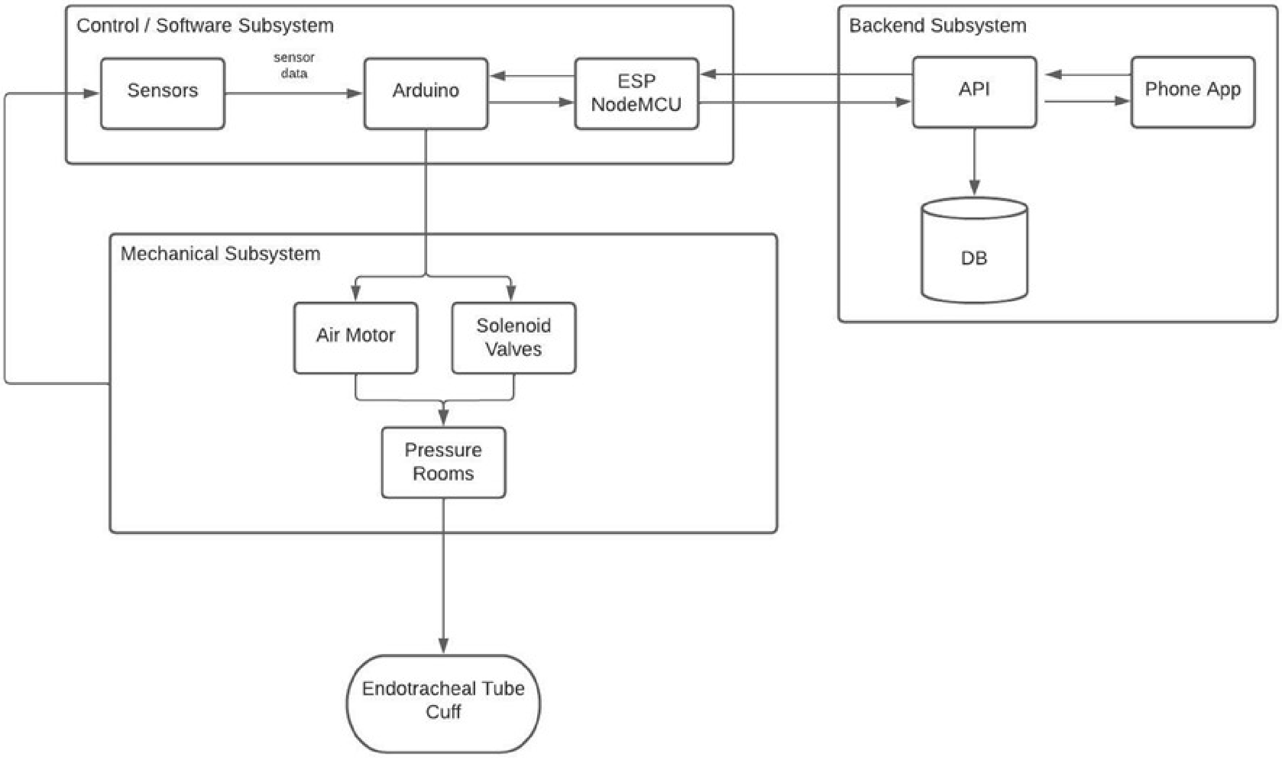


**FIGURE 2.** **The subsystem interconnection schematic of the device.**

This section details the methodology employed in the design of the mechanical aspects, electronic circuitry, and software control of the device separately with subsystem that can be seen in Figure 2 with an emphasis on the replaceability of components to facilitate size reduction or future development. Note that all components were chosen from their respective device families with the goal of creating a proper prototype, as it is classified as a small-scale prototype according to the Technology Readiness Level (TRL) system [20].

*Control / Software Subsystem:* The effective communication is of utmost importance in order to attain a functional core for the prototype device, which must be able to deliver the desired pressure, possess IoT capabilities and exhibit a relatively rapid response time. Furthermore, seamless integration with other subsystems is only feasible through strong communication. However, it is imperative to maintain cost efficiency, and thus the design of the device employs Pareto Optimization [21] by utilizing an Arduino and ESP in serial communication to strike a balance between cost and communication requirements. This is due to the fact that the selected microcontroller, Arduino, experiences a decrease in speed upon connection with ESP. Hence, this approach optimizes both cost and performance.

The communication capabilities of the device were further strengthened by connecting all sensors to an $I^2C$ multiplexer module, which facilitates communication with the Arduino. This arrangement enabled the alteration of the fixed addresses of the BMP180 sensors and addressed the inefficiency of the serial communication port derived from the Arduino. The utilization of the $I^2C$ multiplexer facilitated the concurrent reading of multiple sensor data, thereby allowing for a more efficient control of the system.

It is essential for ESP and Arduino to communicate effectively, as they both rely on each other for various data checks. ESP verifies the functionality of the Arduino card by determining if it is sending data, as depicted in Figure 3. On the other hand, Arduino checks the data received from ESP, which was fetched from API, as depicted in Figure 4. These two separate junctions encapsulate their interdependence.

As depicted in Figure 3, the ESP functions as the junction between the Backend Subsystem and the Control / Software Subsystem. It retrieves the device information data from the database (DB) and conducts a comprehensive evaluation of the data handling and transmission process between the Arduino and the API. This evaluation incorporates a systematic series of exception checks to ensure proper extermination or casting to subsequent steps. Upon fetching the device ID information from the DB, the ESP assesses whether any changes have occurred in the device. If any modifications are detected, it conducts a thorough evaluation of the newly registered device and transmits the device status data (on/off) and ‘‘manual mode open’’ data to the Arduino.

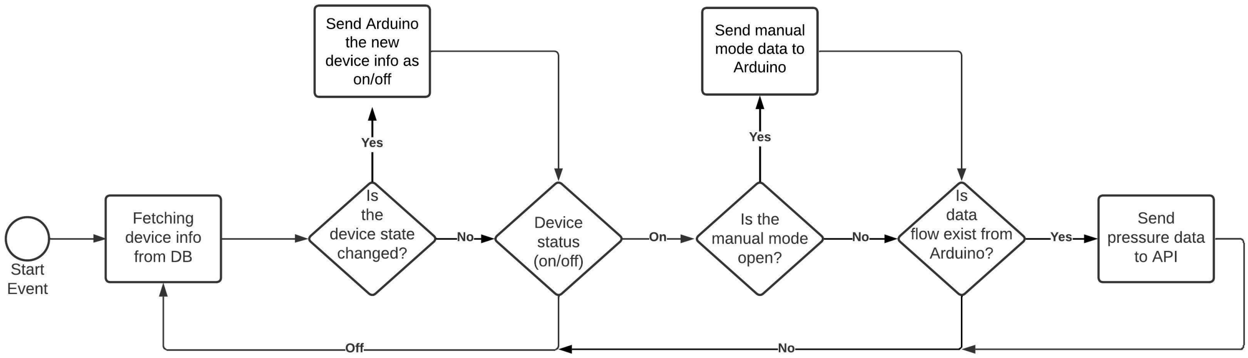


**FIGURE 3.** Algorithm of the embedded code in the ESP component.

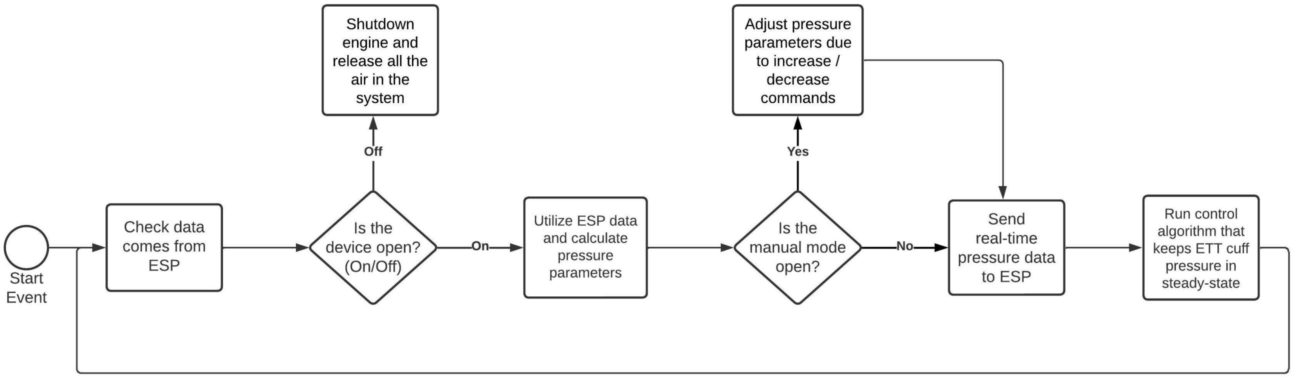


**FIGURE 4.** Algorithm of the embedded code in the Arduino component.

As depicted in Figure 4, following the decision-making processes of the Arduino, it initiates the transmission of pressure data, which Arduino acquires from sensors to the API for updating in the DB. The Arduino microcontroller plays a crucial role in evaluating the entire control process to ensure the attainment of the desired pressure level. The device status information obtained from the ESP is utilized to determine whether the air engine should be shut down and the system's air released or if the process should continue. If the latter occurs, the pressure parameters are calculated and prepared for incorporation into the control algorithm, taking into account the manual mode status. The real-time data is then transmitted to the ESP, and the control algorithm is executed to maintain the desired pressure level in a steady state. The Arduino leverages the data obtained from three BMP180 pressure sensors through the $I^2C$ multiplexer module, which are placed in various components of the device. The control algorithm also constantly monitors the atmospheric pressure level to dynamically adjust the pressure parameters based on the operating environment. Further elaboration on the sensor placement and pressure level control logic can be found in Part B, which covers the Mechanical Subsystem.

The control algorithm, which serves as the final step in the Arduino algorithm is presented in Figure 5. This algorithm was designed as an On-Off Controller utilizing the Bang-Bang strategy, as it offers a simple and cost-effective technical solution that can be easily implemented [22]. Further enhancements to the control algorithm, such as utilizing more advanced controller design techniques such as PID or PI-PD, will be discussed in Section III-D, Discussion and Future Work.

As depicted in Figure 5, the main loop of the Arduino algorithm, which serves as the core control logic for pressure level regulation, first checks if the pressure level falls below the predetermined value of 20 cmH2O. If so, the algorithm adjusts the pressure level to regain control within the desired range. If the pressure level is already within the desired range, the algorithm returns to the main loop. The adjustment process involves opening the air engine, the solenoid valve between pressure room-1 and room-2 which are shown in Figure 6(a), and closing the exfil valves to fill the pressure rooms. In the second phase, the control algorithm closes the middle valve between the pressure rooms to maintain a steady pressure level delivered to the ETT cuff from pressure room-2. In the third phase, the control algorithm checks if the pressure level in pressure room-1 has reached twice the average value, allowing the air engine to be shut down while ensuring a steady pressure level is delivered to the ETT cuff. The mechanical subsystem, including the pressure rooms,

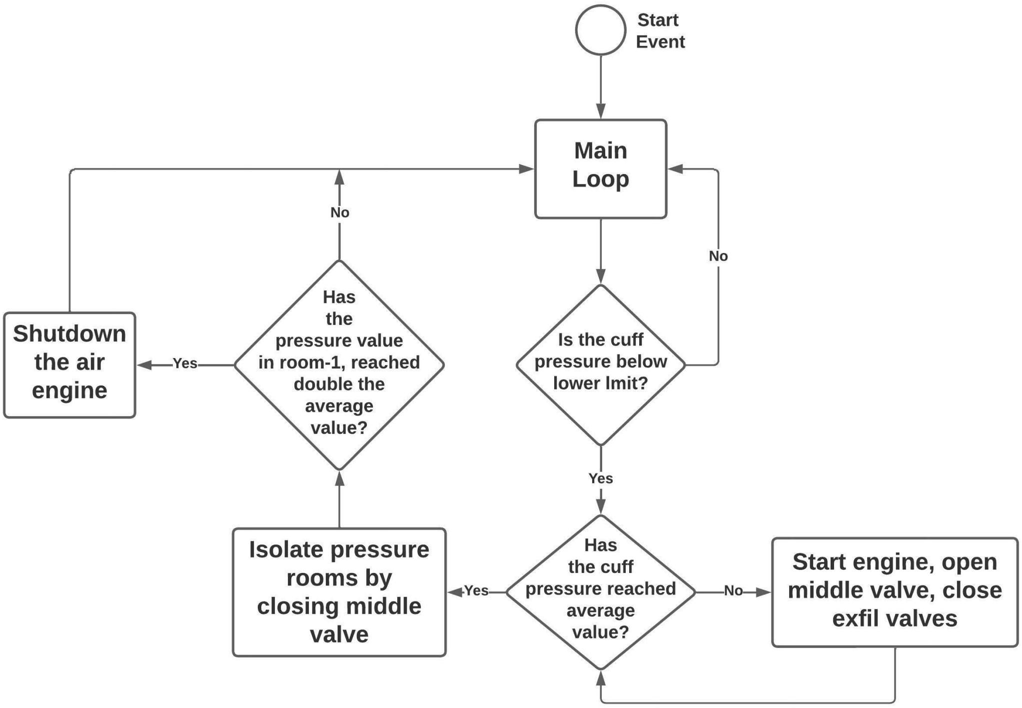


**FIGURE 5.** Control algorithm to keep pressure at steady-state.

valves, and other components used in the prototype, will be further discussed in Part B: Mechanical Subsystem.

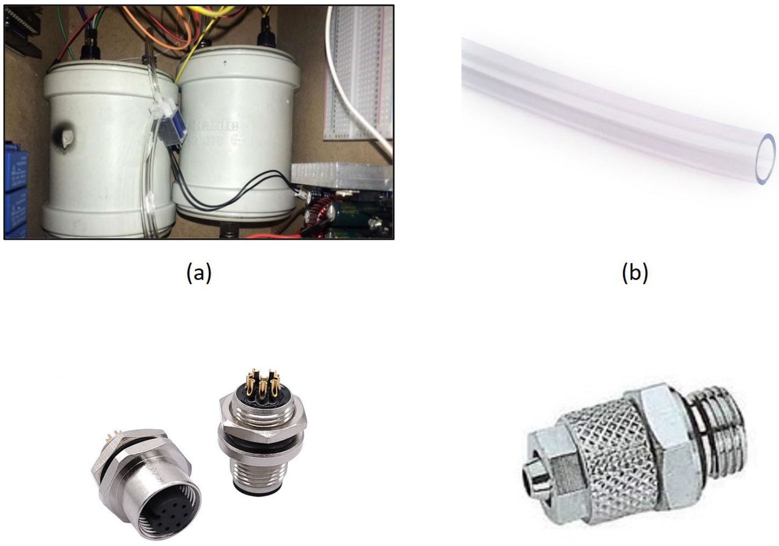
*Mechanical Subsystem:* The Mechanical Subsystem comprises of two pressure chambers fabricated from PVC that work in conjunction with solenoid valves to regulate the flow of air between them, as well as from the engine and the exfil of the air operation. These pressure chambers serve to maintain the optimal pressure levels for intubated patients. The pressure room-1 is connected to the air engine through a solenoid valve, while a middle solenoid valve is positioned between the two pressure chambers to separately control the pressure levels of both chambers. This middle valve is indicated in Figure 6(a). The last solenoid valve is located between the pressure room-2 and the ETT cuff. To facilitate communication between the Mechanical and Control/Software Subsystems, three BMP180 pressure sensors have been installed as their interconnecting points. Two of these sensors are placed in the individual pressure chambers to gather pressure data, while the third sensor is positioned outside the enclosed components to obtain the atmospheric pressure, as the device has the capability of automatically adjusting the pressure level using this information.

A 12V DC air engine, controlled by the Arduino microcontroller through a motor driver, has been employed in the prototype device. The operation of the engine is controlled by the controller layer, which starts and stops the engine as required. Although the engine is controlled by the controller, the flow of air is mainly managed by controlling the solenoid valves, which must be managed with great care to ensure accurate pressure at the cuff. A relay board is used to regulate the valves.

Given the requirement for the device to operate with pressure values expressed in cmH2O, it is crucial to ensure that the system is airtight. To achieve this objective, materials were carefully selected based on their ability to maintain airtightness, and airtight elements such as pneumatic pipes, connectors, and recorders as shown in Figure 6 (b,c,d respectively), have been implemented in the pressure chambers. Furthermore, a liquid gasket has been used both internally and externally within the pressure chambers.

*Backend Subsystem:* As previously highlighted, the response time of the device is of utmost importance given the criticality of the situation in which a patient who has been intubated may require immediate attention. It is for this reason that the Representational State Transfer (REST) architecture was selected as the preferred option for the API design. RESTful APIs have been shown to exhibit faster response times and improved performance in IoT projects compared to alternative architectures, as evidenced in pure web-based projects [23], [24].

Given the requirement for speed and efficiency, a NoSQL database was deemed appropriate for this application [25]. Due to its exceptional performance in querying objects, the chosen database from the NoSQL family was MongoDB. The database will be utilized by both the device and mobile device, serving as a communication layer for both systems. The API endpoints will facilitate key functions such as



(a) (b) (c) (d)

**FIGURE 6.** **Mechanical Subsystem components excluding electronic hardware. (a) Pressure chambers used in the prototype, right: room-1, left: room-2; (b) pneumatic pipes; (c) airtight connectors; (d) airtight pneumatic recorder.**

opening and shutting down the device, writing and updating ETT cuff pressure value data into the database, and manual mode utilization. To achieve this, two separate databases have been established within the launched MongoDB cluster, DevicesDB and PatientsDB, respectively, to manage the registration of device data and other pressure management operations.

Given that both the hardware device and mobile phone app will rely on the API, it is crucial that the environment in which the API runs is accessible via the internet. To create a lightweight environment for the API to run, Docker technology was employed, and the resultant DockerFiles were composed using Docker Compose and deployed as a cohesive unit to a Linux-based virtual machine (VM) rented from a private company.

*Integration:* The proposed ETT cuff pressure controller was designed with the integration of various subsystems, including the Control/Software Subsystem, the Mechanical Subsystem, and the Backend Subsystem. The integration of these subsystems is depicted in Figure 2, which shows the interconnection schematic of the device.

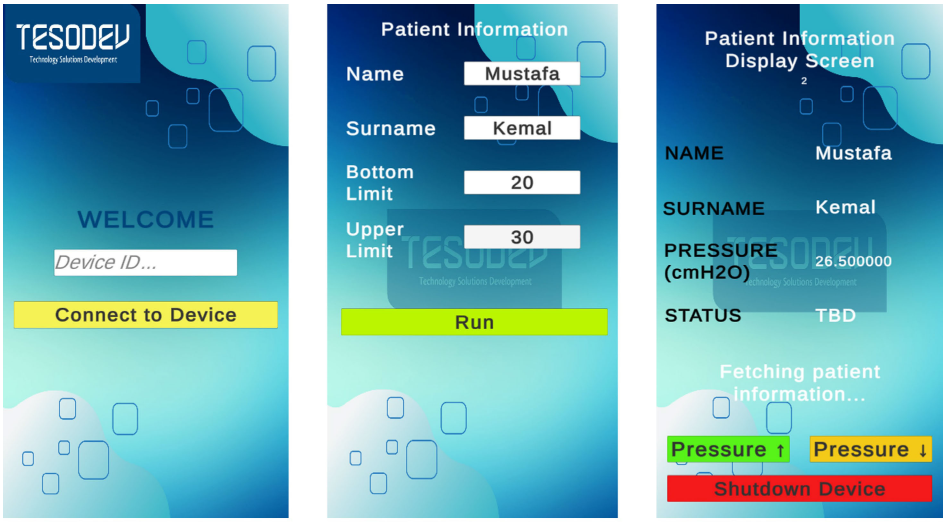
The Control/Software Subsystem is responsible for the communication between the device and the Backend Subsystem, as well as the execution of the control algorithm to maintain the desired pressure level. The integration of the Arduino UNO microcontroller and the ESP8266 NodeMCU module enabled the device to have IoT capabilities and remote control through a mobile application. As depicted in Figure 7, a comprehensive integration and control system has been achieved through the mobile application. The application includes various features, such as device synchronization, seamless integration with hospital databases for patient information entry, and a display screen equipped with manual control buttons.

The mobile application has successfully enabled complete integration and control of the device. Through seamless synchronization with the device, patients' information can be easily entered into the hospital's database, providing healthcare professionals with quick access to vital patient data. The display screen comes equipped with manual control buttons, providing healthcare workers with an additional layer of control over the device.

The Mechanical Subsystem provides the physical structure and components that support the device's pressure control mechanism. To facilitate size reduction or future development, this subsystem was designed with replaceability in mind. The sensors and air motor were incorporated into the device to adjust the pressure level and the valves to control the airflow.

The Backend Subsystem manages the device and patient information through a web API, which is connected to a database. The ESP component retrieves the device information from the database and verifies the functionality of the device, while the Arduino component evaluates the control process to ensure the attainment of the desired pressure level. The real-time data is transmitted between the ESP and the Arduino for proper updating of the information in the database.

The successful integration of these subsystems, as depicted in Figure 8, has facilitated the implementation of the proposed endotracheal tube (ETT) cuff pressure controller with robust functionality. This integrated system ensures a



Patient Information
Name: Mustafa
Surname: Kemal
Bottom Limit: 20
Upper Limit: 30

Patient Information Display Screen
2
NAME: Mustafa
SURNAME: Kemal
PRESSURE (cmH2O): 26.500000
STATUS: TBD
Fetching patient information...

(a) (b) (c)

**FIGURE 7.** Typical screens of the mobile application that employs device control functionality. (a) healthcare worker synchronizes the device with the mobile application; (b) healthcare worker is prompted to input the patient information and the custom pressure range; (c) patient name and surname, pressure level in units of cmH2O and patient status can be monitored.

secure immediate shut-down procedure, effectively mitigates air leakage, and consistently maintains the desired cuff pressure within the intended clinical environment. Moreover, the incorporation of a mobile application for real-time data computation, coupled with the synchronization capabilities employed to address security concerns, holds significant potential for substantial cost reduction while empowering healthcare professionals with an efficient means to monitor and regulate cuff pressure levels.

**TABLE 2.** List of medical staff involved in the implemented qualitative methods.

| Staff ID | Gender | Age | Profession |
|---|---|---|---|
| S1 | Female | 42 | ICU Doctor |
| S2 | Female | 58 | ICU Doctor |
| S3 | Female | 39 | ICU Doctor |
| S4 | Female | 27 | ICU Nurse |
| S5 | Female | 36 | ICU Nurse |

## III. METHODS

### A. QUALITATIVE METHODS

The selection of appropriate research methods is integral to the quality and validity of research outcomes. This section presents an in-depth discussion of the qualitative methods utilized to acquire data for this study. Qualitative research methodology serves to comprehend complex social phenomena by exploring subjective experiences, attitudes, and reviews of expert views. The methods employed in this study include interviews, focus groups, case studies, and ethnography, among others. The selection of these techniques is supported by their capacity to explore the research question thoroughly. This section expounds on the specifics of the qualitative methods employed in this study by comprising their rationale for selection. The staff members who participated in the structural observations and reviews are listed in Table 2. These individuals will be further referred to by their respective staff IDs in the subsequent sections.

*Structured Observations:* Structured observation serves as an efficacious technique for data acquisition, requiring cooperative efforts between investigators and study subjects. As listed in Table 2, these subjects included various medical staff who were integral to the study [26]. This approach proves to be especially beneficial within the realm of qualitative research for device design. Through systematic observation and documentation of pre-specified behaviors or events in relation to the device usage, these medical staff provided valuable insights about the user experience. Adherence to a structured observation schedule assures consistency and standardization in data acquisition. The qualitative data derived from such structured observations is robust and insightful, contributing significantly to the design and advancement of devices that augment user experience. The employment of structured observations guarantees that the devices fulfill their intended objectives and meet the user requirements effectively.

*Interview:* Interviewing is a widely used approach in qualitative research to gain insight into the opinions, experiences, and beliefs of experts on particular topics [27]. There are three main interview methods: structured, semi-structured, and unstructured. In this study, a semi-structured interview method was used by preparing important topics and questions while also allowing for discussions on various topics. Staff S5 was further interviewed to gain insight into her

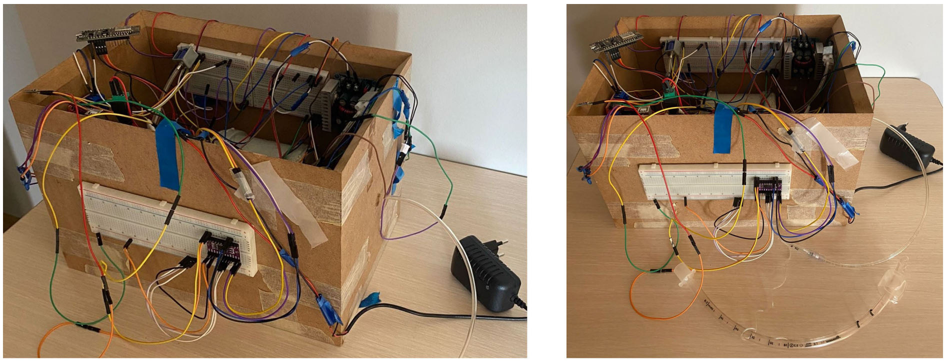

(a) (b)

**FIGURE 8.** The prototype version of the designed device with all subsystems assembled. (a) Diagonal view; (b) front view.

extensive expertise in emergency services and her valuable contributions to the field through her publications [28], [29].

*Focus Group:* The utilization of focus groups as a data collection method involves gathering a group or groups of participants in a communicative environment to obtain their viewpoints collectively. Essentially, it is a form of group interview where individuals share and deliberate their experiences and perceptions concerning a specific topic. In the context of this study, the participants that constituted these focus groups were staff members identified as S1, S2, S3, and S4.

### B. QUANTITATIVE METHODS

In order to verify the device, quantitative methods were employed to compare the measurement data with a chosen device's data (gold standard). The chosen device as error-free for the calibration and quantitative testings was the Fluke 729 300G FC (abbreviated as FLK-729), supplied by Netes Engineering.

*Paired t-Test:* The first method used to compare two sets of data from both FLK-729 and the cuff pressure data read by the designed endotracheal tube cuff pressure controller device was the paired t-test. After obtaining the data, the first step was to correlate the mean values of the data sets. After that, the difference between the devices was found by performing the paired t-test [30].

*Pearson's Correlation Coefficient:* The Pearson's Correlation Coefficient measures the linear correlation between two sets of data. A coefficient value close to 1 indicates a strong positive correlation, while a value close to $-1$ indicates a strong negative correlation. A value close to 0 indicates no correlation between the two datasets [31].

*Bland-Altman Plot:* The Bland-Altman plot is a graphical method used to evaluate agreement between two datasets, such as those obtained from an ETT cuff pressure controller and an error-free calibration device. The plot displays the difference between the two datasets on the vertical axis and the average of the two datasets on the horizontal axis. The plot can identify any systematic bias and evaluate the agreement between the datasets [32]. The device functionality was verified using the gold standard, the Fluke 729 300G FC device.

### C. RESULTS

The necessity of developing an automatic endotracheal tube cuff controller with an affordable price has arisen from the findings of 120 hours of structural observations conducted with staff S1, S2, S3 and S4 and interviews with S5. According to the official data provided by the Ministry of Health of the Republic of Turkey in 2020, there were 1429 general hospitals established in the country [33]. Market research reveals that only approximately 1.4% of hospitals in Turkey use automatic endotracheal tube cuff pressure devices. By combining the qualitative findings with quantitative data on hospital and device usage, it has become clear that there is a critical need for a cost-effective automatic endotracheal tube cuff pressure controller. This need is driven by factors such as the extended duration required for pressure readings and checks due to the busy schedules of healthcare workers, as well as the potential for over or under inflation of the cuff due to human error during the reading and adjusting process. Consequently, a low-cost IoT enabled automatic endotracheal tube cuff pressure controller may lead to a reduction in patient complications associated with the aforementioned factors, thereby increasing the usage percentage of automatic endotracheal tube cuff pressure devices.

On the other hand, structural observations had lead this study in various technical specifications according to field needs. Such as arrangeable pressure ranges for different patients, automatic calibration of the cuff pressure readings and arrangement algorithms due to a change in the open air pressure, an immediate shut down procedure and most importantly, a reliable pressure reading. In this context, it is noteworthy that there was a unanimous interest expressed in this device from all members of the focus group. This

**TABLE 3.** Data obtained from the gold standard pressure reading device FLK-729 and from the designed device in each time instance t.

| t | Designed Device | FLK-729 | t | Designed Device | FLK-729 |
|---|---|---|---|---|---|
| 1 | 2.79 | 2.9 | 42 | 30.93 | 28.6 |
| 2 | 5.65 | 6.9 | 43 | 29.93 | 27.9 |
| 3 | 11.59 | 12.7 | 44 | 29.2 | 27.5 |
| 4 | 16.37 | 16.2 | 45 | 28.33 | 26.3 |
| 5 | 20.22 | 17.7 | 46 | 27.54 | 24.8 |
| 6 | 23.12 | 21.9 | 47 | 26.86 | 24.2 |
| 7 | 25.72 | 23.6 | 48 | 26.04 | 23.4 |
| 8 | 27.79 | 24.9 | 49 | 25.37 | 22.5 |
| 9 | 29.51 | 26.8 | 50 | 24.58 | 22.6 |
| 10 | 31.04 | 28.6 | 51 | 23.85 | 21.1 |
| 11 | 32.08 | 29.5 | 52 | 23.39 | 20.3 |
| 12 | 33.16 | 30.2 | 53 | 22.65 | 19.9 |
| 13 | 34.05 | 31.1 | 54 | 22.25 | 19.5 |
| 14 | 34.97 | 31.5 | 55 | 21.47 | 19.2 |
| 15 | 35.62 | 32.5 | 56 | 20.9 | 18.5 |
| 16 | 36.13 | 33.4 | 57 | 20.48 | 17.6 |
| 17 | 36.75 | 33.7 | 58 | 19.88 | 17 |
| 18 | 37.23 | 34 | 59 | 19.45 | 16.4 |
| 19 | 37.66 | 34.6 | 60 | 18.82 | 16 |
| 20 | 38.02 | 34.9 | 61 | 18.31 | 15.8 |
| 21 | 38.42 | 35.4 | 62 | 17.87 | 15.3 |
| 22 | 38.82 | 35.6 | 63 | 17.35 | 14.5 |
| 23 | 39.02 | 36 | 64 | 16.94 | 14.1 |
| 24 | 41.31 | 38.3 | 65 | 16.52 | 13.8 |
| 25 | 41.35 | 38.3 | 66 | 16.15 | 13.4 |
| 26 | 41.28 | 38.3 | 67 | 15.7 | 13.1 |
| 27 | 41.41 | 38.4 | 68 | 15.25 | 12 |
| 28 | 41.33 | 38.4 | 69 | 14.8 | 11.8 |
| 29 | 41.32 | 38.4 | 70 | 14.43 | 11.5 |
| 30 | 41.4 | 38.4 | 71 | 14.22 | 11.3 |
| 31 | 41.4 | 38.4 | 72 | 13.71 | 10.9 |
| 32 | 41.33 | 38.4 | 73 | 11.97 | 8.9 |
| 33 | 41.18 | 38.4 | 74 | 11.71 | 8.7 |
| 34 | 39.63 | 36 | 75 | 11.36 | 8.4 |
| 35 | 38.25 | 35.1 | 76 | 11.21 | 8 |
| 36 | 36.9 | 33.9 | 77 | 9.76 | 6.9 |
| 37 | 35.82 | 33 | 78 | 9.66 | 6.7 |
| 38 | 34.7 | 32.2 | 79 | 9.37 | 6.3 |
| 39 | 33.73 | 31.5 | 80 | 9.12 | 6.2 |
| 40 | 32.74 | 30.3 | 81 | 8.99 | 6 |
| 41 | 31.85 | 29.8 | 82 | 8.02 | 5.1 |

**TABLE 4.** t-Test summary statistics.

| | Designed Device | FLK-729 |
|---|---|---|
| Observations | 82 | 82 |
| Obs. with missing data | 0 | 0 |
| Obs. without missing data | 82 | 82 |
| Min | 2.79 | 2.9 |
| Max | 41.41 | 38.4 |
| Mean | 25.817 | 23.196 |
| Standard Deviation | 11.097 | 10.842 |
| 95% confidence interval on the difference between the means | (-0.056 , 5.298) | |
| Difference of means | 2.621 | |
| DF | 160 | |
| Two-tailed p-value | 0.128 | |
| Alpha ($\alpha$) | 0.05 | |
| t-value | *Observed*<br>2.175 | *Critical*<br>1.994 |

**TABLE 5.** Pearson correlation matrix.

| Variables | Designed Device | FLK-729 |
|---|---|---|
| Designed Device | 1 | **0.997** |
| FLK-729 | **0.997** | 1 |

**TABLE 6.** Bland-altman analysis parameters.

| Bias | Standard Error | CI Bias (95%) |
|---|---|---|
| 2.621 | 1.278 | (-5.298, 0.056) |

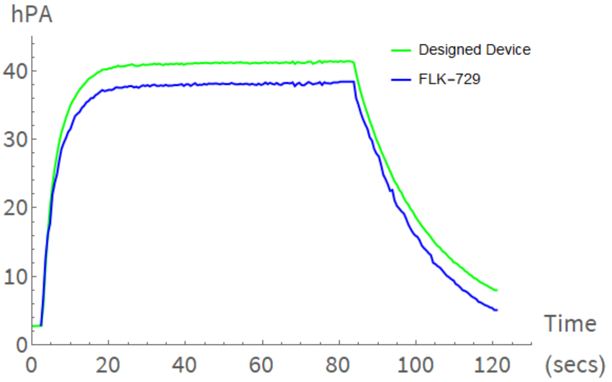


**FIGURE 9.** The dataset of the gold standard measurements have been plotted, where the green color represents the designed device, and the blue color corresponds to FLK-729.

group-wide approval, importantly, included the endorsement from S2, who is a professor and also Clinical Education and Administrative Officer for further evaluating the device's potential value and utility in clinical settings.

In the validation stage, the gold standard pressure reading device FLK-729 supplied by Netes Engineering was utilized as detailed in the Methods section. Two datasets were obtained from the two-minute measurements using the present device and FLK-729 with over 200 data points which are plotted in Figure 9 for a clear observation of the correlation. Then, 82 distinct data points were extracted from each dataset with exactly the same timestamps for further investigation explained below, using the Python package *Cosdem* [34]. The two datasets are presented in Table 3 with corresponding time indices.

*Paired t-Test:* The study extensively analyzed the worked dataset, utilizing various statistical measures to assess the proximity of two measurements. Notably, the t-Test results presented in Table 4 and Figure 10 demonstrate a significant similarity between the measurement results. In order to enable more detailed analyses, Pearson correlation coefficient, intraclass correlation coefficient, and the construction of a Bland-Altman plot were studied. These supplementary analyses are discussed further in subsequent sections.

*Pearson Correlation Coefficient*: Table 5 presents the findings of Pearson's correlation test, where values that deviate significantly from zero with a significance level $\alpha = 0.05$ are indicated in bold. This denotes that the results fall within the prescribed bounds of Pearson's correlation test. Consequently, the variation in measurement values between

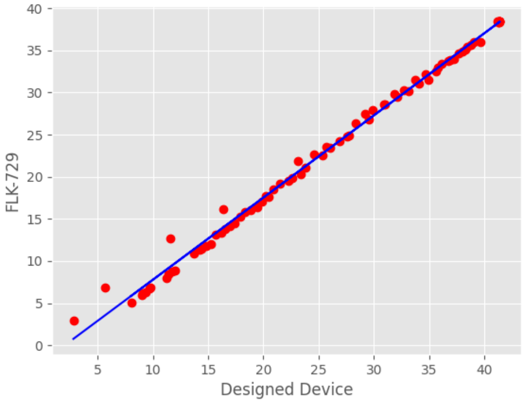


**FIGURE 10.** **Paired t-test results.**

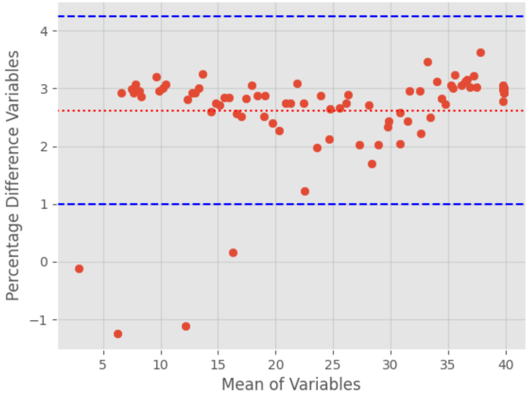


**FIGURE 11.** **Bland-Altman plot.**

the two devices has been ascertained to be in a suitable range, thereby allowing for the inference that the devices exhibit comparably similar characteristics.

*Bland-Altman Analysis:* The findings of the Bland-Altman analysis are displayed in Table 6 and in Figure 11, where the corresponding results are presented.

The test findings demonstrate that the designed endotracheal tube cuff pressure controller and Fluke 729 300G FC (FLK-729) can be deemed as interchangeable devices concerning pressure measurements of the endotracheal tube cuff. This, in turn, suggests that the designed ETT cuff pressure controller device may serve as an affordable alternative for cuff pressure control.

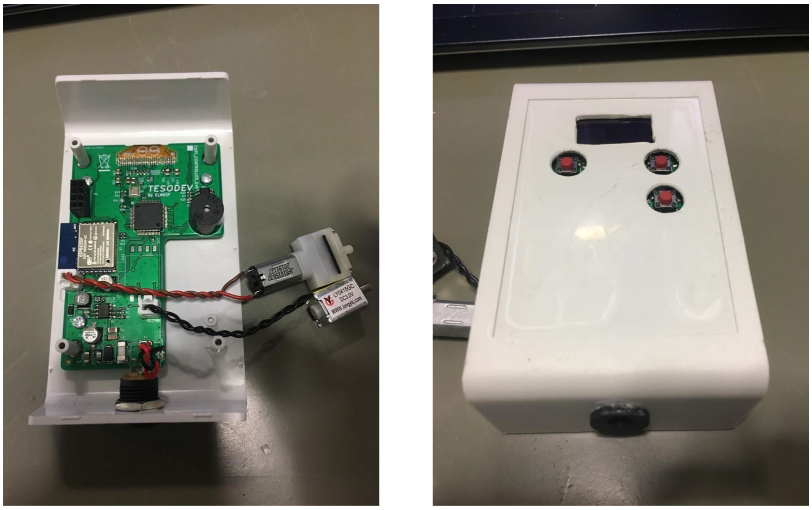
### D. DISCUSSION AND FUTURE WORK

*Technology Readiness Level System Roadmap:* The discussion regarding the future development of the device necessitates a brief understanding of the Technology Readiness Level (TRL) system, a concept initially proposed by NASA [20]. This system consists of a scale from 0 to 9, where each level signifies a distinct stage of technological maturity. TRL 0 refers to the ideation phase, where the scientific research commences. This is followed by TRL 1 and 2, which are the early stages of technology development, where basic principles are observed, and concepts are formulated. TRL 3 signifies the experimental proof of concept. TRL 4, where the device currently sits, represents the technology validation in a lab setting, typically through a small-scale prototype. TRL 5 entails the large-scale prototype which validated in an appropriate environment, demonstrating significant advancements. TRL 6 includes a demonstration of the prototype system in an operational environment. The device designed under consideration, a small-scale prototype, aligns with TRL 4.

The incorporation of components such as Arduino UNO may necessitate size optimization of the device to achieve a more compact form. This could entail alterations in the electronic hardware layout and the selection of components used. Concerning the future developments, the objective is to progressively ascend along the TRL system roadmap, with the overarching goal of reaching TRL 9, which signifies full maturity of the commercial device application. This progression from TRL 4 to TRL 5 would require validating the device in a relevant environment. The device's design and functionality will be continuously refined based on feedback from healthcare professionals and patients. New features, such as the ability to control multiple devices simultaneously from the phone app, will be incorporated. Subsequent to further optimization, the device is expected to progress to TRL 6, where a demonstration system will be produced and tested in operational environments such as ICU services. Finally, the evolution of the manufacturing process will continue, aiming to reach fully commercial application, represented by TRL 8 and TRL 9 [20]. Towards reaching TRL 9, utilizing the state-of-art battery technology, the present device is aimed to be used continuously for the duration of intubation on every patient.

This progress will ensure that the device evolves from a small-scale prototype to a fully operational, commercially viable product. The design of the commercially viable product has been completed, and regional patent application was made with that design [35]. The Minimum Viable Product (MVP), as depicted in Figure 12, was manufactured following a fast-paced production phase in order to obtain reasonable feedback from the field. Approval from a research and education hospital ethics committee is awaited to conduct further research in ICU services.

In the context of this study, it is essential to underscore that a technical comparison between the prototype device and existing models in the market, such as the Hamilton Medical Intellicuff and the VBM Cuff Controller, has not been conducted thus far. This decision is informed by the current developmental status of the device under scrutiny, which presently exists in a prototype phase. At this developmental juncture, the benchmark measures and quantitative assessments have been deemed sufficient for the evaluation and validation of the nascent prototype. The intent is to undertake a comprehensive comparative analysis



(a) (b)

**FIGURE 12.** The manufactured minimum viable product. (a) Inside view; (b) front view.

**TABLE 7.** Comparing key aspects of the designed device (DD) against two leading alternatives for validating the effectiveness of the model.

| | Intellicuf | VBM | DD |
|---|---|---|---|
| Cost (∼USD) | 2000 | 1400 | 70 |
| Resolution (cmH2O) | 1 | 2 | 1 |
| Accuracy (cmH2O) | 2 | 1 | 1 |
| Calibration | No need | No need | No need |
| Weight (gr) | 260 | 520 | n/a |
| Charge up to | 1500 times | 2000 times | n/a |
| Mobile app support | n/a | n/a | Exists |

with incumbent devices in subsequent stages, as the device progresses along the TRL continuum, transitioning from the prototype stage to more advanced levels of readiness and maturity.

Nevertheless, in order to validate the effectiveness of the designed device, in Table 7, it is compared against two leading alternatives in the market in terms of key aspects.

*Potential Advances in the Controller:* An On-Off Controller was chosen as the controller type due to the low-cost nature of the small-scale prototype device. However, future work should include controller improvements, such as type change and data collection from patients to obtain the system transfer function through system identification, as data-driven modeling has become an increasingly critical aspect of contemporary design techniques [36].

There are certain requirements that the automatic endotracheal tube cuff pressure control system must meet, such as a fast response, no overshoot, and a low error tolerance in steady state or at any point. To meet these requirements, a Proportional-Integral-Derivative (PID) controller may be a suitable option due to its ability to quickly adjust the control output in response to changes in the system, to prevent overshooting, and to provide accurate control with low error tolerance requirements [37].

Model Predictive Control (MPC) can be a viable choice for the automatic endotracheal tube cuff pressure control system due to its ability to predict the future behavior of the system and optimize control inputs to meet performance objectives [38]. MPC is equipped to handle constraints on control inputs and system outputs, making it well-suited for applications with limitations on the control inputs or outputs. Furthermore, MPC is capable of handling multi-variable systems and providing robust control under changing conditions, and is widely recognized as a state-of-the-art multiple-input multiple-output (MIMO) control technique for industrial processes [38], [39].

State-Space controllers can be a viable option for the automatic endotracheal tube cuff pressure control system due to their ability to model the system in its state-space representation, providing a clear and concise description of system behavior. State-Space controllers are versatile, capable of handling both linear and nonlinear systems, and can be designed to achieve desired performance in both the time and frequency domains, offering greater flexibility in control design and robust data-driven state-feedback design [40].

*Potential Advances in Computation:* The present study aims to investigate an alternative solution to the existing communication mechanism between the ESP8266 NodeMCU v3 and the API. Currently, the ESP8266 NodeMCU v3 utilizes an Hyper-Text Transfer Protocol (HTTP) layer to transmit PUT requests for updating the ETT cuff pressure on the API, which is subsequently stored in a database. Upon request from the smartphone, the API retrieves and sends the updated pressure level through a GET request. However, based on the feedback obtained from field workers and optimization issues, the proposed solution is to convert the HTTP layer into a full or semi-Transmission Control Protocol / Internet Protocol (TCP/IP) layer, enabling real-time computation of the cuff pressure. This TCP/IP layer is a vital component for the next stages of the product's Technology Readiness Level (TRL). In the realm of networking, TCP/IP and HTTP are fundamental protocols employed to facilitate inter-device communication across a network. While TCP/IP is a low-level networking protocol known for its reliable and efficient data transfer mechanism, HTTP is a high-level protocol specifically designed for accessing web resources, including web pages, files, and APIs. TCP/IP presents several advantages over HTTP, including its exceptional reliability, low latency, and efficient use of network resources, as it guarantees the delivery of all data packets in the order they were sent, thereby ensuring the integrity of data transmission [41]. In contrast, HTTP lacks such guarantees and may lead to packet loss or corruption during transmission. Furthermore, TCP/IP is optimized for low-latency data transfer, making it well-suited for real-time applications that require minimal delays in data transfer. Additionally, TCP/IP makes efficient use of network bandwidth and memory, making it an ideal option for high-volume data transfer or networks with limited resources. In conclusion, the proposed adoption of TCP/IP in lieu of HTTP presents a superior option for real-time data transfer and remote monitoring and control systems, which require dependable, low-latency, and efficient data transfer mechanisms. While HTTP is a valuable tool for accessing web-based resources, it may not be the optimal choice for applications that require minimal delays or high volumes of data transfer.

## IV. CONCLUSION

This paper presents a functional and cost-effective design, as well as the implementation of the TRL 4 level prototype of a small-scale endotracheal tube cuff pressure controller device. The device's ability to supply the endotracheal tube cuff with the appropriate pressure level and to operate with a mobile application developed through the creation of an API was demonstrated successfully. Through innovative approaches such as enabling IoT, integration with mobile phone through a dedicated application and successful design of the communication and computation systems, the overall cost of the device is reduced to around 70 USD, while two leading alternatives cost 20 times or more. Both the novel functionalities and the seamless cost efficiency of the designed device indicate its potential to accelerate the migration from manual to automated processes in endotracheal intubation.

The average response time, which is less than 350 milliseconds, indicates that the endotracheal tube cuff controller device is capable of meeting the requirements of the intubation process and is suitable for real-world utilization. The pressure reading performance of the designed device have been confirmed by comparing against the gold standard FLK-729 device through Paired t-Test, Pearson's Correlation Coefficient, and Bland-Altman Plot. Future areas of improvement have been identified, with a focus on adding the capability to control multiple devices simultaneously from a single mobile phone, reducing size, and optimizing the controller design in a systematic way to reach the TRL 9 level.

Compared to existing market offerings, this prototype demonstrates the feasibility of creating a significantly more affordable endotracheal tube cuff controller device through the application of innovative techniques.

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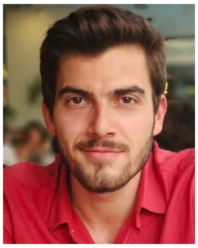

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