An Internet of Things-based Predictive Maintenance Architecture for Intensive Care Unit Ventilators

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***Abstract*—Intensive care units commonly utilize mechanical ventilators to treat patients with different medical conditions, which are crucial for patient care and survival. ICU ventilators have evolved through four distinct generations, each displaying unique features. Despite progress made since the 1940s, contemporary designs are insufficient to meet the increasing needs of patients and hospitals. Malfunctions in mechanical ventilators pose significant dangers to patients, highlighting the importance of focusing on their safety, security, precision, and dependability. Our study aims to address the significant issue at hand. Furthermore, the IoT industry has garnered significant attention because of rapid progress in smart devices, sensors, and actuators. The healthcare industry has seen a notable increase in health data as a result of the growing utilization of IoT and cloud computing technologies. To enhance growth, new models and distributed data analytics strategies must be developed to fully utilize the value of the vast datasets generated, including the incorporation of embedded machine learning. The study focuses on conducting Pareto and Failure Modes and Effects Analysis (FMECA) on ventilators in a specific hospital's ICU, specifically those manufactured by the same company and unit. The analysis aims to identify the most critical and failure-prone component. Subsequently, we propose an IoT-focused framework for a predictive maintenance system implemented at the component level. The architecture comprises a monitoring framework and a data analytics module to predict potential system failures in advance, enhancing overall reliability.**

Keywords*—Internet of things; predictive maintenance; embedded Machine learning; data analytics; failure modes; mechanical ventilator

I. Introduction

Nowadays, an average to large-sized hospital houses around 10,000 different types of medical devices, and one of the most pressing challenges for healthcare institutions throughout the world is to guarantee the safety of these devices and manage the risks connected with their use. Medical devices are tools or machinery used to detect, monitor, treat, or prevent illness or other disorders [1]. Providing health services through the use of diagnostic and therapeutic technologies is an essential component of health care, particularly in hospitals. In addition to being necessary for safe and effective patient care, medical equipment has a substantial impact on the income and consequently the viability of healthcare institutions [2]. Their rapid advancement has considerably benefited the health of individuals and society. This technological advancement has increased patients' survival in the face of sickness or injury, as well as considerably improved their life quality via improved diagnostic and therapy outcomes [3]. However, without effective maintenance management, the delivery of healthcare services to communities suffers dramatically. Medical equipment maintenance management is critical to ensuring that a machine performs by manufacturer specifications and ensures the safety of patients and users [4]. Inadequate maintenance of medical equipment causes downtime, reduces device performance, and wastes costs and resources. As a result, medical equipment requires both scheduled and unscheduled maintenance throughout its useful life and close monitoring by healthcare administrators [5]. Hospitals should ensure that medical equipment is kept in working order, is safe, accurate, and reliable, and functions at the appropriate level of performance successfully. Therefore, the ultimate goal of maintenance is reliability and safety. It should always be safe for both patients and users [6]. To that aim, the World Health Organization (WHO) specifies a standard regulation for periodic maintenance of medical devices that includes the rate of failure of specific types of replaceable components (e.g. batteries, valves, pumps, and seals) to assure device dependability and safety [7].

Thanks to digitalization in the healthcare domain, the generated health-related data have grown exponentially in the past decades with the increasing use of the Internet of Things (IoT) and cloud computing technologies in this field. As a result of this digitalization, a large volume of data is generated from these various IoT sources and information services. This motivates the health business to create new models and distributed data analytics approaches to maximize the value of the generated data [8]. In addition to this, advancements in information and communications technology, big data technologies, and analytics tools were the key elements in realizing the transition from traditional maintenance approaches to predictive maintenance (PdM) [9]. The IoT sector has attracted substantial interest due to the rapid pace of technical breakthroughs in smart device, sensor, and actuator technologies. A multitude of these IoT devices can potentially generate significant amounts of big-data streams which are not only too voluminous but also too fast and complex to be processed and stored using traditional data analytics approaches. Therefore, predictive maintenance systems should be highly scalable, resilient, and fault-tolerant to process and store big data in an effective manner [10]. Through the use of information and communication technologies, specifically intelligent devices (such as IoT sensors, edge devices, and computing), data collection has increased as a result of the incorporation of autonomous and smart systems where data and advanced data analytics (i.e., big data, artificial intelligence (AI) / Machine Learning (ML)) can be used [11]. With this development, PdM solutions, such as those for estimating remaining usable life, detecting anomalies, and monitoring machine health (condition), also increased. PdM entails making optimum decisions to sustain a system's capacity and functioning by monitoring its performance in real-time using huge data streams provided by the system. The use of predictive maintenance approaches enables us to reduce operational maintenance costs for medical devices, enhance operational activity without breakdowns, and thereby improve healthcare quality.

In other words, PdM is described as a set of procedures used to assess the state of equipment and predict future failures. These estimations are then utilized to schedule maintenance activities through smart scheduling of maintenance procedures, which aids in preventing or at least minimizing the impacts of unanticipated breakdowns. PdM requires employing analytical tools to analyze machine-generated data to get valuable insights. Further, create a machine learning (ML) model using this data to forecast upcoming failures. Sensors with limited data processing capabilities are used for data collecting. Due to this, edge devices were developed and are now capable of processing data, cleansing data, and many other functions in addition to acting as sensors [12]. PdM techniques are very similar to medical diagnostic techniques. A symptom appears whenever a human body is experiencing a problem. The information is provided by the nervous system; this is the detection stage. Pathological tests are also performed if necessary, to diagnose the problem. On this basis, appropriate treatment is suggested. Similarly, defects in a machine always produce a symptom in the form of vibration or some other parameter. However, on machinery systems with human perceptions, this may or may not be easily detected.

The rest of the paper is organized as follows; in Section II, the maintenance strategies are described and the related works are reviewed. Section III describes the functioning of the mechanical ventilator. Section IV addresses the study case and discusses the proposed architecture for predictive maintenance in the big-data era. The opportunities and challenges of the proposed architecture are discussed in Section V. We conclude paper and give directions for future research in Section VI.

II. Background and Related Works

A. Background

In light of the technological advances in the medical field, medical equipment has become widely used in all aspects of health care, including prevention, screening, diagnosis, monitoring, and therapeutics, as well as rehabilitation. It is now nearly impossible to provide health care without them. Medical equipment, unlike other types of healthcare technologies (such as drugs, implants, and disposable products), requires maintenance (both scheduled and unscheduled) throughout its useful life. Inadequate and improper maintenance and safety procedures have always been the leading cause of major incidents frequently involving patients that result in serious injuries or deaths.

Maintenance can be defined as the function of keeping a machine, or system (whether simple or complex) in working order by using it properly, repairing broken parts or components, or replacing some of the broken parts so that it is available and fit for the intended purpose whenever the need arises. A maintenance strategy is a methodical approach to device upkeep that includes actions like "identification, investigations, and execution of many repairs, replace, and inspect decisions". According to [13] a maintenance strategy includes a set of policies and actions that are used to "retain" or "restore" equipment as well as the decision support system in which maintenance activities are planned. As the sophistication and cost of medical equipment have increased, so has the complexity and cost of its maintenance over the last few decades.

Maintenance philosophy has always evolved in pari-passu with the ever-changing technological innovations in designing simple machines and equipment that have now metamorphosed into complex, sophisticated, and indispensable systems. Maintenance strategies have evolved gradually, and the process is still ongoing. Over the last two decades, maintenance strategies and reliability engineering techniques have been significantly improved, and they have been successfully applied in many industries to improve the performance of equipment maintenance and management. Maintenance strategies can be categorized as first, second, third, and recent generations, as depicted in Fig. 1.

Corrective maintenance (CM) [14] is a reactive maintenance policy that is applied following a machine malfunction. The following sentence serves as the foundation for the concept of corrective maintenance: Fix it when it breaks. CM is classified as first generation as it was the standard practice until the 1960s when preventive maintenance (PM) concepts emerged and gained public recognition.

PM [15] categorized as second generation, entails inspecting and maintaining equipment while it is in operation to reduce the likelihood of a breakdown. Preventive maintenance can be scheduled in advance (time-based schedule) or as needed (usage-based schedule). While this strategy reduces failures thus improving equipment efficiency, reducing downtime, and extending the life of your equipment by ensuring it is always in good working order. The issue with the PM strategy is that it can be excessively proactive. Because you are following a standard timetable, you can schedule a part replacement well in advance of when it is required. This will increase the cost of maintenance.

Condition-based maintenance (CBM) [16] classified as third generation, emerged in the second half of the 1980s as a result of sensor and condition monitoring technology development. To reduce unnecessary scheduled tasks, this strategy limits the number of times maintenance activities are initiated to when there is clear evidence of deterioration. Monitoring the condition of the equipment and performing necessary maintenance are all part of CBM. When compared to preventive maintenance, there is no need to be concerned about performing condition-based maintenance too soon. When something goes wrong but before it stops working, sensors notify you that maintenance is required at the optimal time. Condition-based maintenance is also known as condition-based monitoring because it requires regular monitoring of your equipment. The major drawback is that you can't plan for maintenance because you won't realize you need it until the changes happen.

The concept of prognostics, which deals with fault prediction before it occurs, was recently introduced to the proactive maintenance community in recent years. In this context, PdM [17] is a CBM policy that incorporates prognostics into its decision-making process. As a result, PdM contains more information about asset degradation, such as the remaining useful life (RUL). PdM represents the recent generation of maintenance philosophies.

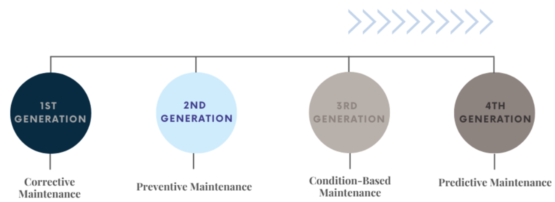

Fig. 1. Evolution through time of maintenance strategies.

B. Related Works

Several articles in the literature propose a system architecture for predictive maintenance in the healthcare domain. Two different architectures for PdM systems were proposed in 2013. D. Andriţoi, C. Luca, C. Corciovă, and R. Ciorap, have developed a novel application with a robust evaluative facility. Using the medical equipment maintenance records stored in this application's database, a mathematical model for predictive maintenance can be developed [18]. A second method was proposed by M. Ullrich, K. Ten Hagen, and J. Lässig, who described a new approach for categorizing maintenance visits according to PdM [19]. To enhance medical device decision-making, the following study [20] details a comprehensive PdM management system that makes use of Information and Communication Technologies (ICT) and predictive analysis tools. This paper [21] proposes the following guidelines for a PdM model: It is important to 1) conduct daily QA treatment; 2) transfer and automatically interrogate the resulting log files; 3) analyze daily operating and performance values using statistical process control (SPC) once baselines are established; 4) determine if any alarms have been triggered; and 5) notify facility and system service engineers. A significant part of this research involved the development of software modules to automate the interrogation of trajectory log files, perform the SPC evaluation, and display the results in a graphical dashboard interface.

In 2018, [22] and [8] outline a PdM architecture for medical devices that makes use of modern big data, cloud, and IoT technologies. The following work [23] also delves into the challenge of healthcare organizations' maintenance by examining an autonomous integrity monitoring approach for devices that transmit massive amounts of real-time data via the Internet of Things. By combining an integrity monitoring framework with a data analytics module, the proposed architecture provides full visibility into medical devices and permits the anticipation of future problems.

In [24] a theoretical design employing Internet of Things technology is proposed. Furthermore, infrared cameras, such as those used for infrared thermal imaging, which have the incredible capacity to observe things that conventional diagnostic instruments cannot, are proposed as an effective tool for PdM strategy in the following paper [25]. Finally, [26] proposes a methodology that takes into account data sets, features, evaluation strategies, prediction strategies, ML algorithms, and performance evaluation.

III. Mechanical Ventilator

A. Evolution of Mechanical Ventilator

A mechanical ventilator is a device that facilitates or replaces spontaneous breathing, it aids in respiration or takes breaths for the patient. Mechanical ventilation is lifesaving when natural breathing is ineffective or has ceased. The patient's ventilation is increased by the ventilator, which fills their lungs with oxygen or air and oxygen. Mechanical ventilators have made significant advancements since their introduction, in addition to their use in the intensive care unit (ICU), Mechanical ventilators have many applications inside and outside of hospitals. Ventilators are crucial in the management of patients undergoing general anesthesia inside the operating room, in patients' homes for extended treatment, and the transporting vehicles. This was accomplished by combining advances in our understanding of respiratory physiology, pathophysiology, and clinical patient management with technological advancements in mechanical, electronic, and biomedical engineering. New devices and an increasing number of ventilation modes and strategies are introduced to improve outcomes, patient–ventilator interactions, and patient care in the present day. The primary indication for mechanical ventilation is difficulty in the patient's ventilation and/or oxygenation due to any respiratory or other condition. The objectives of mechanical ventilation are to provide adequate oxygen to patients with a limited vital capacity, to treat ventilatory failure, to reduce dyspnea, and to allow breathing muscles to relax. There are two types of ventilation: Positive pressure ventilation (PPV) involves forcing air into the lungs through the airways, while negative pressure ventilation (NPV) involves drawing air into the lungs.

The use of assisted ventilation dates back to biblical times. In the early 1800s, however, mechanical ventilators in the form of NPV first appeared. The negative-pressure ventilator was the standard method of providing respiratory support throughout the latter half of the 19th century and the first half of the 20th. These devices were capable of applying alternating subatmospheric pressure around the body and were used to restore ventilation in patients by expanding the chest wall. The initial description of a negative pressure ventilator involved a full-body ventilator. In 1838, the "tank ventilator" was described for the first time by the Scottish physician John Dalziel. It consisted of an airtight box in which the patient was held in a seated position. By manually pumping air into and out of the container, negative pressure was created.

Sauerbrach even created a negative-pressure operating chamber in 1904. Except for the head, the patient's body was maintained within the chamber. Numerous other types of negative-pressure chambers, such as the "raincoat" and the "chest cuirass," were developed and used with varying degrees of success over time.

In the 1960s, however, there was a shift away from negative-pressure ventilation due to several factors. For example, access to the patient was limited, and "tank shock" was a recurring problem with full-body ventilators. However, mechanical ventilation became widespread only after the introduction of positive-pressure ventilation during the resurgence of poliomyelitis in the 1950s. This global pandemic has limited the availability of cabinet ventilators. To overcome this challenge, Bjorn Ibsen, a Danish anesthesiologist, utilized a modified anesthetic circuit with a squeezed bag to provide intermittent positive pressure ventilation (IPPV).This demonstrated a dramatic reduction in mortality in patients manually ventilated via tracheostomy led to the development of the intensive care unit.

In 1940, the first positive-pressure mechanical ventilators became commercially available. Even though they possessed a high level of sophistication, they could only deliver a predetermined tidal volume at a given respiratory rate (volume-control ventilation mode) and had no or very limited monitoring capabilities for ventilation variables.

The field of respiratory physiology had already established its foundations and was expanding rapidly at the time. In 1903, Dixon and Brodie introduced the application of mathematical modeling to describe the relationships between flow and pressure, which marked the beginning of the mechanics of breathing. They modeled the lung as resistance and compliance. In 1946, Rahn et al. presented pressure–volume diagrams of the lung and thorax as well as the concept of relaxation curves, laying the groundwork for the development of respiratory energetics. These and other studies provided the physiological foundation that led to the clinical application of positive-pressure ventilation.

Beginning in the early 1970s, ventilators began incorporating more advanced monitoring of flow and pressure variables due to advances in electronics. Improvements in monitoring also permitted the use of real-time variables to control the action of the machine, with the intermittent mandatory ventilation mode paving the way for the development of assisted mechanical ventilation as a means to wean patients from volume-controlled ventilation.

Beginning in the early 1980s, the introduction of microprocessors in mechanical ventilators led to the introduction of improved technologies for monitoring ventilation and lung conditions, as well as the introduction of new, advanced ventilation modes.

From the original ventilators of the 1940s to the present day, there have been four generations of ICU ventilators, each with features distinct from the previous generation.

B. Operation Principle of Mechanical Ventilator

Mechanical ventilation (MV) functions by applying a positive pressure breath and is dependent on the airway system's compliance and resistance. During spontaneous inspiration, the lung expands as transpulmonary pressure (P) is primarily generated by the inspiratory muscles' negative pleural pressure. During controlled mechanical ventilation, on the other hand, a positive airway pressure forces gas into the lungs, resulting in a positive P. The tidal volume (VT) is the volume of air that enters or leaves the lungs during each respiratory cycle. Physiologically, VT is dependent on a person's height and gender and ranges from 8 to 10 mL/kg of ideal body weight. Multiple modes of MV delivery exist, including mandatory mode and assisted mode. In the assisted mode, the patient's inspiratory effort activates the MV to deliver the breath, while P is the product of negative pleural pressure and positive alveolar pressure. The most prevalent modes of MV include: Volume-limited assist control ventilation (VAC), Pressure-limited assist control ventilation (PAC), and Synchronized intermittent mandatory ventilation with pressure support ventilation (SIMV-PSV).

Once a ventilation strategy has been determined, it should be administered to the patient in the most precise manner possible. To accomplish this, the machine must accurately detect all variables that define the breathing pattern and adapt its action in real-time. Modern ventilators accomplish this by combining sophisticated data processing algorithms with cutting-edge actuators, sensors, and digital electronics.

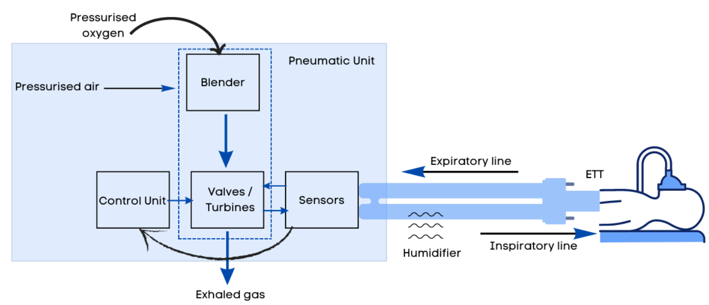

Fig. 2. Representative illustration of the mechanical ventilator functioning.

Fig. 2 depicts a representative illustration of the mechanical ventilator functioning, with the operation principle including:

1) Pneumatic unit: The pressure source provides the energy necessary to overcome the elastic and resistive load imposed by the patient's respiratory system and is used to reduce the patient's work of breathing. The pressurized air is mixed with the appropriate amount of oxygen by the blender and delivered to the patient through fast valves that modulate the amount of gas flowing into and out of the patient. In some modern ventilators, instead of using valves, a fast-response, brushless-driven turbine functions as a variable pressurized air source, making the device independent of centralized medical compressed air distribution while still delivering excellent performance.

2) Sensors: In contemporary mechanical ventilators, all relevant ventilation parameters like pressure, flow, and F_iO_2(The fraction of oxygen in the inspired air or gas that is being provided from a ventilator) are measured by sensors that provide information to the control unit so that the valves/turbines can be adjusted in real time to deliver the desired ventilation mode.

IV. Study Case : CARESCAPE R860

A. Objective

The ICU ventilator is characterized by its long-term use. Indeed, it must be able to act continuously on the same patient for multiple days. Any ICU ventilator malfunction has the potential to be catastrophic and fatal for patients. Despite the presence of alarm systems, continuous monitoring is required to minimize machine-related errors. Therefore, this study aims to propose an IoT-based architecture for predictive maintenance of the CARESCAPE R860 ICU ventilators.

The primary objective of our architecture surpasses the limitations of a single healthcare facility. The objective of this study is to establish the potential for widespread implementation of the suggested approach on CARESCAPE R860 ICU ventilators within a wide range of healthcare institutions. To establish a comprehensive and adaptable predictive maintenance (PdM) system, our objective is to develop a flexible framework that can effectively accommodate diverse hospital structures. This endeavor is driven by the goal of establishing a centralized approach that effectively harmonizes with a multitude of healthcare settings.

This study was conducted on a collection of CARESCAPE R860 ICU ventilators located in various medical centers.

B. General Description of the CARESCAPE R860

The CARESCAPE R860 is a sophisticated ICU ventilator that integrates modern technology with a user-friendly interface, as shown in Fig. 3. The icons in the interface reflect customizable depictions of historical patterns, patient status, and clinical decision assistance for future patient needs. The ventilator includes a display, ventilator unit, trolley with optional AC plug, optional EVair compressor, and module bay with optional gas module.

Users have complete control over the system setting due to the wide range of performance options provided. This comprehensive ventilator system includes breathing, monitoring, and the ability to connect with central monitoring systems. The user-friendly touch screen allows quick and easy access to information and operations, catering to adult, pediatric, and neonatal patients.

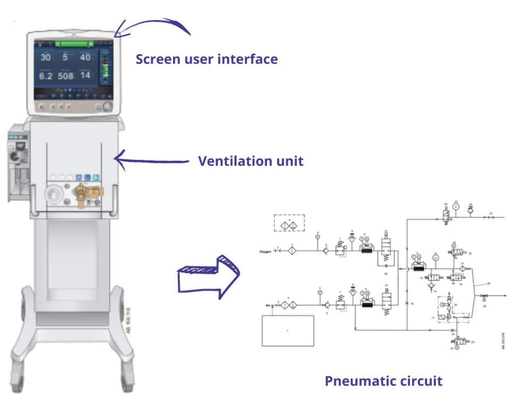

Fig. 3. Overview of the ICU ventilator.

1) Screen user interface: The interactive panel screen displays the patient's and ventilator's current status. Even during normal ventilation, all modes, controller, alarm, and monitoring windows are accessible directly from the main screen. The menu, the menu for the current patient, alarm management, and the user's favorite procedures are grouped at the top of the screen in the user interface. The status of the patient (the airway pressure bar) and the workspace/monitoring area are located in the center of the display. At the bottom of the screen are the navigation bar, message areas, battery status, standby button, and shortcut keys.

2) Ventilation unit: The ventilation unit is located on the front of the ICU ventilator, below the screen user interface, and is equipped with all the necessary ports for connecting the various breathing circuit accessories.

3) Pneumatic circuit: The pneumatic circuit of the ventilator provides patient gases from compressed air and oxygen sources. Two distinct inspiratory channels (air and O_2) are incorporated into the system to provide dynamic O2 percentage mixing control.

4) Electronic circuit: The electronic unit contains the various electronic circuits used to control and adjust the pneumatic system, the monitoring represented by the ventilator's alarm set, and the machine user interface.

C. Pareto Analysis for the CARESCAPE R860

The ABC method or Pareto analysis permits the analysis of the most significant malfunctions. It enables us to assert that 20% of the causes are accountable for 80% of the problems encountered and, as a result, to analyze all of the problems in order to formulate an appropriate response.

In our case, we have performed a Pareto analysis on different CARESCAPE R860 ventilators from the same unit. This method will allow us to identify the CARESCAPE R860 component that is most failing.

The Pareto analysis is accomplished by following the steps outlined below:

- Step 1: Sort the failures according to the number of failures in descending order
- Step 2: Determine the percentage
- Step 3: Determine the cumulative percentage
- Step 4: Draw the curve and identify the three zones: A, B, C

Fig. 4 depicts the outcomes of the Pareto analysis of a CARESCAPE R860. The curve illustrates a convexity with the selection of three zones; each zone contains a certain number of components in proportion to the significance of their total number of breakdowns; the following are the three zones that I discovered:

1) Zone A: Highest risk area. 80% of the risks originate from the five following components and processes:

⇒ Changing the air block

⇒ Changing the backup batteries

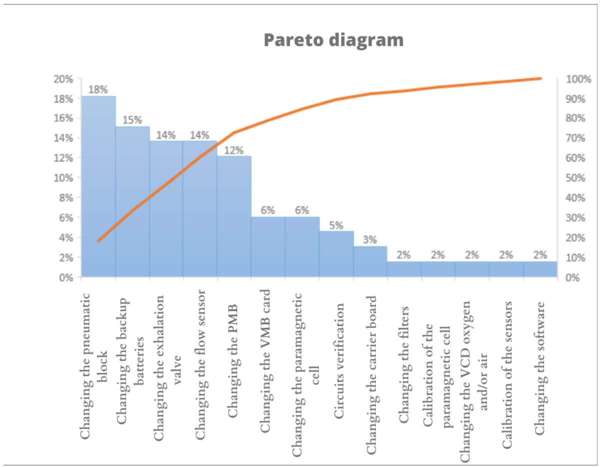

Fig. 4. Pareto analysis of a CARESCAPE R860.

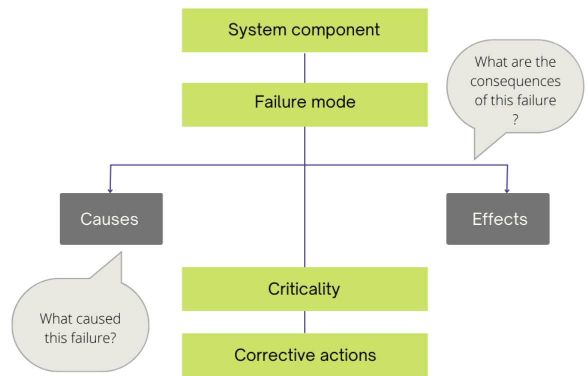

Fig. 5. FMECA analysis of the system.

⇒ Changing the exhalation valve

⇒ Changing the flow sensor

This means that we will be concentrating our solution-finding efforts on these parts, as their failure would have the most severe consequences.

2) Zone B: Medium risk area. 15% of the risks are caused by the following five parts or procedures:

⇒ Changing the PMB

⇒ Changing the VMB card

⇒ Changing the paramagnetic cell

⇒ Circuits verification

⇒ Changing the carrier board

3) Zone C: Low risk area. 5% of the risks are caused by the following parts or procedures:

⇒ Changing the filters

⇒ Calibration of the paramagnetic cell

⇒ Changing the VCD oxygen and/or air

⇒ Calibration of the sensors

⇒ Changing the software

After conducting this analysis on the different CARESCAPE R860, it has revealed that all ICU ventilators have the same pneumatic block issue.

D. Develop a Failure Mode and Effects Analysis for the CARESCAPE R860

To conduct this investigation, we also performed a Failure Mode and Effects Analysis (FMEA), also known as a Failure Mode, Effects, and Criticality Analysis (FMECA), on the selected equipment. The FMECA is a technique for predictive analysis that estimates the risks of failure and their effects on the equipment's proper operation and then implements the necessary corrective actions. Its primary objective is to maximize availability. This analysis will allow us to determine which component of the machine is the most critical and malfunctioning in our scenario.

The FMEA method is based on a multi-step process as shown in Fig. 5. The different steps are described as follows:

1) Identify possible failures and their effects: This step involves identifying all potential failure modes, determining the effects of each, and searching for their most probable causes.

2) Determine Gravity (G): The gravity G represents the severity of the effects of a failure. G is rated on a scale from 0 to 4, with 0 being the least severe and 4 being the most severe.

3) Determine the occurrence frequency (F): The frequency of occurrence F represents the failure occurrence frequency. This frequency represents the probability of the failure mode occurring in conjunction with the failure cause. F is rated on a scale from 0 to 4, where 0 represents the probability that a failure is practically impossible to occur and 4 represents the certainty of a failure occurring.

4) Failure detection (D): Detection mode D refers to the likelihood that a user will detect the occurrence of a failure. Detectability is a crucial component. Failure to predict a failure will increase the likelihood that the system will shut down. D is rated on a scale from 0 to 4, where 0 indicates the presence of sensors capable of detecting the onset of a failure and 4 indicates that the malfunction is undetectable or that its location requires extensive knowledge.

5) The criticality evaluation (C): Criticality is a quantitative evaluation of risk based on the combination of the three previously mentioned factors:

⇒ The frequency with which the mode-cause pair occurs.

⇒ The severity of the effect.

⇒ The possibility of employing detection methods.

Calculated using the formula $C = G \times F \times D$, it is intended to assess the risk associated with equipment functionality.

We have divided criticality into four categories:

→ Level A: Negligible criticality

→ Level B: Medium criticality

→ Level C: High criticality

→ Level D: Very high criticality

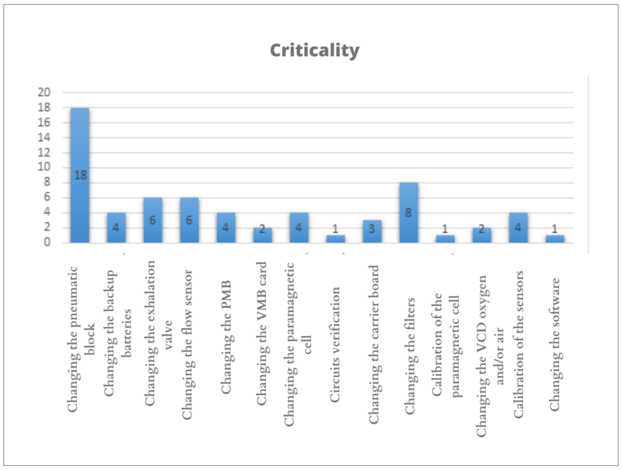

Fig. 6. Criticality Rate Diagram based on the number of failures.

After identifying the various potential failures that the ICU ventilators may encounter during their operation, we analyzed and investigated the effects of these failures on the CARESCAPE R860's proper operation, the user, the patient, and the environment. We then determined for each failure the three previously mentioned parameters, namely severity, occurrence frequency, and mode of detection, in order to calculate the criticality of each failure. Fig. 6 illustrates the results of the FMECA analysis.

With a criticality of C=18, we can conclude that the pneumatic block is the ICU ventilator's most critical component. If the pneumatic block fails, this can directly result in an outage of our ventilators, which can alter the patient's course of treatment or be fatal.

E. Proposed Architecture

Following our primary objective of achieving centralization, the architectural framework we have developed is intricately connected with the knowledge acquired through our extensive research. The present investigation was carried out with a specific emphasis on intensive care unit (ICU) ventilators, with particular attention given to the CARESCAPE R860 model. The study was conducted within a single hospital unit, aiming to achieve a comprehensive comprehension of the challenges associated with this particular model. The present study employed the Pareto and Failure Modes and Effects Analysis (FMECA) methodologies to conduct an analysis, thereby facilitating the identification of the critical parameters and components that exhibit a higher susceptibility to failure.

Patients are put in an intolerable position of risk when their mechanical ventilators malfunction, so ensuring the safety of these devices is crucial [27]. It is more cost-effective to perform preventative maintenance on the mechanical ventilators rather than repair work on them. An organization or a person with expertise in technical installations is required to perform continuous monitoring and maintenance on the air unit that serves as the source of air for both the ICU service and the neonatology service. The performance of the installation is something that must be guaranteed, which is why maintenance is performed. The following are the components of maintenance:

→ Ensure that optimal filtration is maintained at all times by performing follow-up and monitoring of filtration. Regularly dispose of and replace filters.

→ Perform routine maintenance on the motor-fan assembly in order to ensure consistent flow rates.

→ Ensure that power plants are kept clean in order to preserve the quality of the air.

→ Ensure that all of the electrical, regulatory, and safety equipment is in proper working order (antifreeze thermostat, smoke detection, etc.)

It is necessary to ensure that the maintenance actions implemented have been properly carried out. As a result, the system ought to be monitored in a manner that is both sustainable and capable of ensuring that the ventilators continue to function normally without exhibiting any signs of performance degradation. As a result, we propose incorporating a humidity monitoring system at the chain level of the medical air filtration process. Consequently, we propose an IoT-based architecture for predictive maintenance that collects and processes a massive data stream from several CARESCAPE R860 in real-time.

Our proposed structure comprises four layers (Fig. 7):

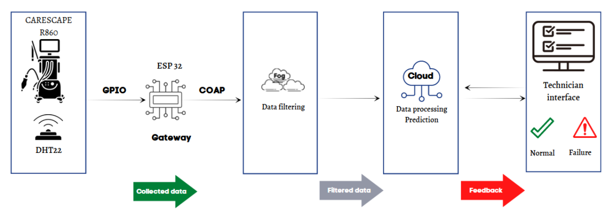

Fig. 7. Proposed architecture for the CARESCAPE R860.

1) The first layer: The first layer is the input layer. It is composed of a humidity and temperature sensor known as DHT22 which is an inexpensive digital temperature and humidity sensor. Using a capacitive humidity sensor and a thermistor, it monitors airflow and outputs a digital signal on the data pin. It sends information every two seconds. The DTH22 will be installed in the air filtration chain of the machine in order to monitor the performance of the pneumatic block. The data, which consists of the measured humidity levels at a variety of time intervals, will be transmitted to the fog through the Constrained Application Protocol (CoAP) by utilizing the ESP32 microcontroller as a gateway.

2) The second layer: The second layer within our Predictive Maintenance (PdM) framework is an essential element referred to as the fog computing layer. The present layer is strategically situated in the intermediary position between the peripheral devices, specifically the ventilators equipped with DHT22 sensors that are deployed across various hospital services, and the centralized cloud server. The principal aim of integrating the fog computing layer is to augment the efficacy, responsiveness, and scalability of our predictive maintenance system.

a) Centralized data processing and filtering: In the context of fog computing, the data coming from the distributed ventilators is gathered, subjected to real-time processing, and subsequently filtered. The adoption of a decentralized approach in information processing has been shown to have significant benefits in terms of reducing latency and facilitating prompt analysis of critical information within local networks. This approach effectively minimizes the dependence on distant cloud servers for immediate decision-making purposes.

b) Local anomaly detection and classification: The utilization of fog computing technology facilitates the implementation of localized anomaly detection and classification algorithms, thereby facilitating the rapid identification of potential issues that are unique to each ventilator system. The presence of localized intelligence plays a crucial role in effectively addressing immediate concerns and mitigating the negative impacts of faults on patient care. The fog layer functions as a discerning filter, selectively transmitting solely pertinent and practicable data to the central cloud server.

c) Bandwidth optimization: In light of the limitations imposed by bandwidth constraints and the unpredictable nature of network conditions, the fog layer exhibits intelligent behavior in order to optimize the transmission of data. The proposed system effectively employs a filtering mechanism to eliminate redundant or non-critical information, thereby significantly reducing the overall volume of data that necessitates transmission to the cloud. The optimization of system efficiency is not only observed but also found to be positively correlated with cost savings in the context of data transfer and storage.

d) Edge machine learning for quick decision-making: The utilization of machine learning models implemented at the fog layer significantly contributes to the facilitating of localized decision-making processes. These models are trained on historical data and regularly updated to promptly detect patterns and trends related to potential malfunctions in ventilators. The significance of localized intelligence becomes especially apparent in situations necessitating prompt intervention to prevent detrimental impacts on patient well-being.

e) Scalability and interoperability: The integration of ventilators from various hospital services is facilitated by the fog computing layer, ensuring a seamless and efficient process. The proposed solution offers a scalable and interoperable framework, thereby enabling the predictive maintenance system to effectively adapt to diverse ventilator models and configurations. The establishment of interoperability within the healthcare sector is of the highest priority to facilitate extensive acceptance and utilization across diverse healthcare facilities.

f) Centralization objective: The primary objective of incorporating fog computing within our predictive maintenance architecture is to establish a centralized framework for managing predictive maintenance operations associated with a diverse range of ventilators sourced from multiple services and hospitals. The process of centralization facilitates the efficient management of operations, and maintenance of algorithms, and offers a comprehensive assessment of ventilator performance within the hospital network.

In this study, we propose a novel approach to enhance the utilization of computing resources and facilitate effective coordination of predictive maintenance operations by implementing a centralized management system through the fog. The fog computing paradigm is leveraged to achieve these objectives. By adopting this approach, we aim to optimize the allocation and utilization of computing resources, thereby improving the overall efficiency of predictive maintenance operations. This approach additionally facilitates the comprehensive observation of failure patterns, rates of maintenance, and operational efficacy, thereby presenting a comprehensive methodology for the management of crucial equipment.

3) The third layer: The cloud computing layer plays a crucial role in our Internet of Things (IoT) predictive maintenance architecture by serving as the fundamental infrastructure for centralized data storage, processing, and analytics. Per our objective of attaining thorough centralization, this particular layer assumes a crucial function in the consolidation and administration of the extensive volume of data produced by the predictive maintenance system for CARESCAPE R860 ICU ventilators.

The cloud infrastructure is designed to efficiently handle real-time data streams originating from a multitude of ventilators distributed across diverse healthcare institutions. The primary objective of this infrastructure is to ensure a seamless and uninterrupted flow of data, encompassing reception, storage, and processing operations. By capitalizing on the built-in scalability and flexibility offered by cloud computing, our proposed architecture guarantees the adaptability of the system to accommodate diverse data volumes and computational demands. The necessity of scalability in healthcare environments is of utmost importance, as it addresses the inherent dynamism of such settings by effectively accommodating variations in patient load and ventilator usage.

The cloud-based analytics module within our architectural framework incorporates cutting-edge algorithms and machine learning models to conduct a comprehensive analysis of the gathered data. It aims to investigate the identification of patterns, anomalies, and potential failure indicators within the specific setting at hand.

Furthermore, the presence of the cloud layer enables the convenient and efficient retrieval of essential maintenance insights from remote locations. In this study, we investigate the ability of authorized personnel, regardless of their geographical location, to securely access real-time analytics, performance trends, and predictive alerts.

In the context of security, our cloud-based architecture implements an extensive range of measures that strengthen the safety of patient data and guarantee adherence to healthcare regulations. The implementation of encryption protocols, access controls, and secure communication channels is crucial in safeguarding sensitive information that is transmitted and stored within cloud environments. These measures are designed to mitigate potential risks and threats to the confidentiality, integrity, and availability of data. By employing robust encryption protocols, data is transformed into an unreadable format, thereby preventing unauthorized access and ensuring that only authorized individuals can decipher the information.

The present study aims to investigate the utilization of cloud computing capabilities in the architecture for predictive maintenance of CARESCAPE R860 ICU ventilators. By leveraging these capabilities, the proposed architecture not only facilitates the centralization of data processing and analysis but also establishes a platform that is scalable, secure, and accessible.

4) The fourth layer: The fourth layer is the output or interface for technicians. The system indicates when humidity levels approach a dangerous threshold and alerts the technician to perform preventative maintenance before machine failure. Initially, we will implement supervised machine learning; the technician will report malfunctions to better train the algorithm through reactive decision-making. Then, proceed to semi-supervised machine learning, followed by unsupervised machine learning. The effectiveness of these methods for fault classification, anomaly detection, and real-time prediction will then be evaluated.

a) The getaway: By utilizing the ESP32 microcontroller as the gateway, we can effectively bridge the CoAP communication between the DHT22 sensor and the cloud server for predictive maintenance of the CARESCAPE R860 ventilator. Its built-in Wi-Fi, processing power, MicroPython support, community backing, and cost-effectiveness make it an excellent choice for this IoT application. The ESP32 ensures smooth data transmission, preprocessing, and security features, providing a reliable and efficient gateway solution for your predictive maintenance architecture.

b) Communication: CoAP's lightweight design and RESTful architecture make it an optimal choice for resource-constrained IoT environments, such as healthcare. By seamlessly enabling communication between the DHT22 sensor and the cloud server, CoAP efficiently transmits crucial environmental data, including temperature and humidity, in real time. This real-time data monitoring empowers prompt detection of anomalies and proactive measures for predictive maintenance. The simplicity and elegance of CoAP facilitate straightforward implementation, while its broad community support offers a rich array of libraries, tutorials, and resources, easing development efforts. CoAP is an indispensable tool in this context, showcasing its efficacy in bridging the gap between resource-constrained sensors and cloud-based infrastructure, elevating predictive maintenance capabilities, and enhancing patient safety in healthcare settings. To facilitate accurate and reliable data acquisition from the DHT22 sensor, we meticulously implemented a data retrieval method utilizing the MicroPython environment on the ESP32 microcontroller. A critical step in this process involved the installation of the "Adafruit DHT" library, a reputable external library developed by Adafruit Industries. Leveraging the advanced features and robust error-handling mechanisms inherent to the "Adafruit DHT" library, we ensured a seamless data acquisition process from the DHT22 sensor. Installing the "Adafruit DHT" library involved utilizing the "ampy" tool, a commonly used utility in the MicroPython ecosystem. This tool enabled us to efficiently copy the "Adafruit_dht" library to the ESP32 board, allowing it to interact with the DHT22 sensor effectively.

The library installation process was methodically executed by adhering to proper software engineering practices and following established protocols. Subsequently, we crafted a specialized data retrieval function within our MicroPython script. This function, designed to interact with the DHT22 sensor, effectively accurately retrieved temperature and humidity data. Utilizing the GPIO pins and communication interfaces of the ESP32, the data retrieval function measured environmental parameters from the DHT22 sensor. The successful execution of the data retrieval method on the ESP32 microcontroller facilitated the collection of vital environmental data from the DHT22 sensor. The retrieved temperature and humidity data were foundational inputs for our predictive maintenance model, enhancing the CARESCAPE R860 ventilator's operational efficiency and patient safety. The data transfer process from the microcontroller to the cloud through CoAP in our IoT-based predictive maintenance architecture involves a systematic and efficient approach. Following the successful retrieval of environmental data from the DHT22 sensor, the ESP32 microcontroller, armed with the "Adafruit DHT" library, acts as the intermediary gateway to facilitate seamless communication between the sensor and the cloud infrastructure. Upon data retrieval, the ESP32 microcontroller employs the CoAP protocol to package the acquired temperature and humidity data into CoAP messages, adhering to the lightweight and RESTful principles of CoAP. With the help of the built-in Wi-Fi capabilities, the ESP32 initiates a secure communication link to the cloud server, where the CoAP messages are transmitted. The CoAP server on the cloud, configured to host specific resources corresponding to the sensor data types, promptly receives the incoming CoAP messages. Using CoAP's resource observation feature, the cloud server continuously monitors the environmental data in real-time, facilitating immediate responsiveness to fluctuations in temperature and humidity levels. CoAP's Datagram Transport Layer Security (DTLS) extension is employed to ensure data integrity and privacy during transmission, safeguarding sensitive operational data from potential threats. The implementation of CoAP over DTLS provides robust security critical to the protection of patient information and the preservation of data integrity. Once the CoAP messages reach the cloud server, the data is processed, analyzed, and stored for further predictive maintenance operations. Cloud-based algorithms and analytics are employed to detect anomalies, predict potential equipment issues, and facilitate proactive maintenance actions, thus enhancing the CARESCAPE R860 ventilator's operational efficiency and reducing the risk of unplanned breakdowns. The system will continuously adjust a threshold based on the detected humidity levels that led to the failure of the ICU ventilators (Fig. 7).

The Predictive Maintenance Process for the CARESCAPE R860 involves a dynamic system that modifies a threshold based on observed humidity levels, as shown in Fig. 8. This adaptive technique is based on observations where high humidity levels were a key factor in the malfunction of ICU ventilators. The predictive maintenance technology enhances the reliability and performance of the CARESCAPE R860 ventilators by continuously monitoring and adjusting settings to proactively address possible faults.

F. Practical Deployment: Node-RED within the Proposed Architecture Framework

In this simulation (Fig. 9), we simulate the transmission of environmental data from a simulated DHT22 sensor to the cloud for processing and visualization via a secure communication method. It is important to highlight that this simulation is intended to act as a conceptual visualization to aid in understanding the proposed architecture. There is currently no active data flow; instead, it represents the projected data travel.

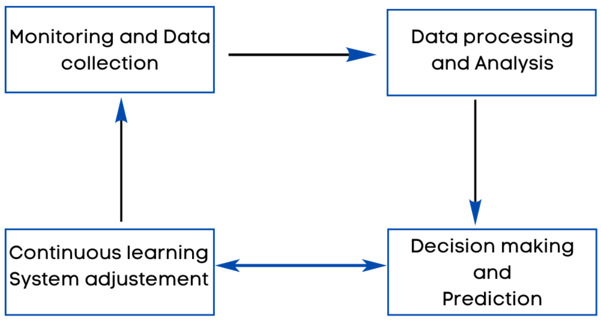

Fig. 8. Predictive maintenance process for the CARESCAPE R860.

A simulated DHT22 sensor injects data, a security function applies protection measures, CoAP communication from the ESP32 microcontroller, and fog processing layer operations are all part of the sequence. Following that, the encrypted data is processed in the cloud, where it is subjected to further processing before being stored. A Debug node is strategically situated to monitor in real-time, whereas a Dashboard node is the endpoint for seeing processed data.

It is critical to note that, while this simulation assists in the conceptualization of the architecture, the real data flow implementation is part of our planned future projects.

V. Discussion

When developing our predictive maintenance architecture, we chose this specific framework based on important factors. The focus was on centralization, aiming to create a cohesive system to effectively handle predictive maintenance operations for various ventilators, with a specific emphasis on the CARESCAPE R860 model. Thorough research was conducted on the details of this particular model in a hospital unit, with a focus on key parameters that are prone to failure. This thorough approach guided the architectural design to create a customized solution for the issues related to ICU ventilators. To overcome current constraints, our design incorporates a humidity monitoring system into the chain level of the medical air filtration process. This new feature improves the capability to identify and address potential problems associated with humidity, a crucial factor highlighted in past cases of ICU ventilator malfunctions. Utilizing IoT-based predictive maintenance allows us to gather real-time data from various CARESCAPE R860 ventilators, providing a comprehensive and flexible method for monitoring equipment.

The suggested design for predictive maintenance of CARESCAPE R860 ICU ventilators is notable in the field of related studies for its thorough and inventive approach that combines IoT, fog computing, and cloud computing technologies. Standing out in the realm of predictive maintenance in healthcare, this architecture boasts a well-defined four-layer structure that covers centralized management, humidity monitoring, and real-time analytics. It is worth mentioning that the integration of adaptive threshold techniques for proactive maintenance, focus on local processing via the fog computing layer, and the use of machine learning models all play a role in its distinctiveness. This study presents a more comprehensive and innovative approach to enhancing the safety, reliability, and performance of critical medical equipment in healthcare settings, building upon previous research.

VI. Advantages and Challenges

The proposed IoT architecture represents a significant advancement in healthcare, employing predictive analytics to improve the management of mechanical ventilators. Utilizing extensive data analysis, the proposed framework holds the potential to enhance the quality and effectiveness of healthcare services by addressing the challenges posed by equipment malfunctions. This is vital for ensuring the well-being of patients and optimizing organizational expenses.

This architecture uses a centralized data approach to consolidate information from multiple CARESCAPE R860 ventilators, allowing for unified analysis and proactive maintenance strategies. The incorporation of IoT technology guarantees the ability to monitor in real time, facilitates effective communication, and enhances the dependability of the system. Intuitive interfaces and comprehensive training enable healthcare professionals to effectively analyze machine learning insights, enhancing the efficiency of the predictive maintenance model.

The architecture offers a versatile solution that can be applied to various hospital settings, showcasing its strengths in scalability and adaptability. This novel approach effectively streamlines predictive maintenance, optimizes workflows, and enhances patient safety, thereby contributing to the advancement of healthcare services.

However, due to their complex infrastructures and programming models, emerging data technologies necessitate a high level of data science and IT domain expertise in order to be utilized and installed. This is the main challenge of the proposed framework. This may impede the adoption of big data technologies in the healthcare industry.

The successful deployment of a system of this nature necessitates addressing not only the technical challenges but also the ethical implications that arise. The issues regarding the preservation of patient confidentiality, acquisition of informed consent, and the conscientious utilization of health-related information. The delicate balance between maximizing the advantages of predictive analytics and safeguarding the confidentiality of sensitive patient data necessitates diligent contemplation and adherence to ethical principles.

The issue of security presents itself as a significant challenge within the context of implementing the suggested architectural framework. The system deals with the management of sensitive health data, emphasizing the necessity of implementing robust security measures to effectively protect against unauthorized access, data breaches, and potential misuse. The preservation of patient data integrity and confidentiality is of utmost importance to achieve optimal performance and widespread adoption of the predictive maintenance system [9].

The utilization of embedded systems presents a set of obstacles, particularly within the realm of healthcare envi-

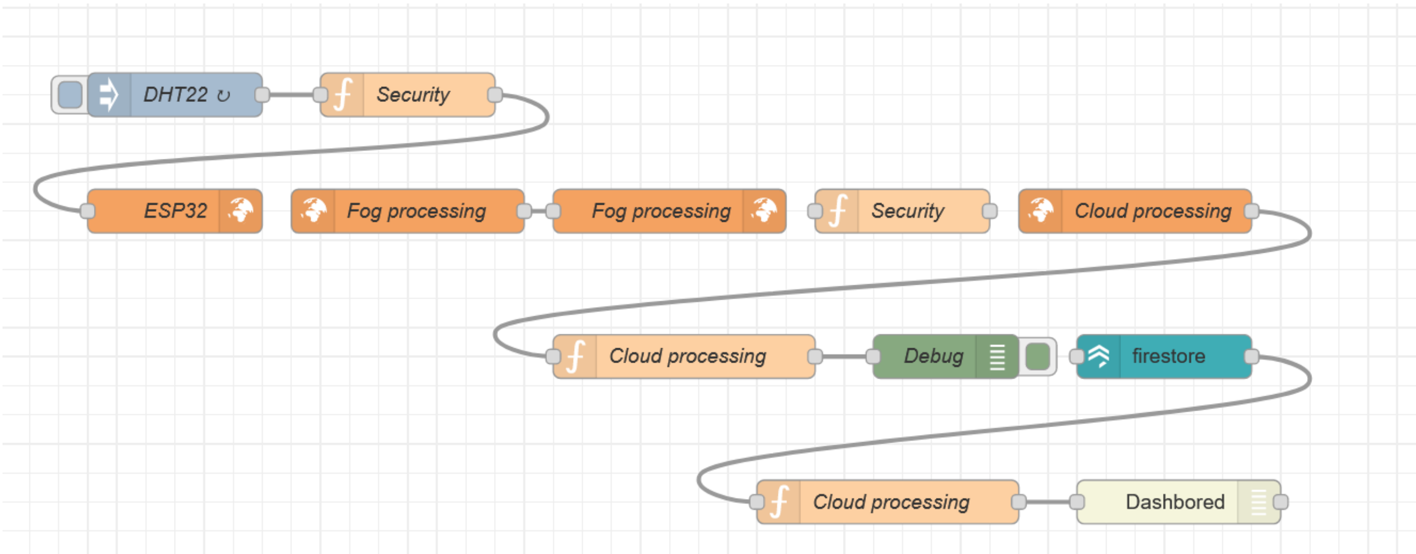

Fig. 9. Visual diagram of Node-RED implementation.

ronments, wherein the crucial role of reliability and real-time responsiveness is evident. The successful integration and ongoing maintenance of embedded systems in the context of ventilators necessitates a meticulous and methodical approach to guarantee seamless functionality and reduce any potential disruptions to healthcare services.

The human factor is a challenging aspect that requires careful analysis and attention when implementing predictive maintenance systems. In healthcare, healthcare professionals and staff must acquire the necessary knowledge and skills to effectively use and understand the data generated by the predictive maintenance system. This is essential for ensuring high-stakes patient care.

One notable facet of this challenge is the necessity for healthcare personnel to have knowledge and skills in machine learning for this to succeed [8]. Healthcare professionals need to have a thorough understanding of the machine learning algorithms used in the predictive maintenance system to accurately interpret the predictions and recommendations provided by the model. This knowledge enables them to differentiate between typical system functioning and possible irregularities, facilitating prompt and well-informed decision-making.

Moreover, Healthcare personnel need a thorough understanding of how the predictive maintenance system works. Understanding a system requires knowledge of both its technical components and its operational intricacies. Training programs should provide healthcare professionals with a comprehensive understanding of the functioning of the system, including its data inputs and the underlying logic used for making predictions.

In addition to their expertise in machine learning, healthcare personnel need to have a comprehensive understanding of the healthcare system and how it integrates with existing hospital workflows. This comprehension guarantees a seamless cooperation between predictive maintenance technology and the everyday functions of healthcare environments. It facilitates the integration of system insights into healthcare professionals' decision-making.

It is important to consider the concerns and preferences of healthcare workers. Effective communication, thorough training, and continuous support are crucial for establishing confidence and trust in predictive maintenance technology. Healthcare professionals should be knowledgeable and confident in using technology to improve patient care and make maintenance processes more efficient.

The complex nature of introducing AI and IoT technologies in healthcare is underscored by a range of challenges, including technical complexity, ethical considerations, security, embedded systems integration, and the human factor. The successful resolution of these obstacles is of utmost importance to fully unlock the capabilities of predictive maintenance systems and guarantee their beneficial effects on patient care and operational efficacy.

VII. Conclusion

This article presented a real-time monitoring architecture for inspecting and maintaining ICU ventilators in several healthcare organizations. Since the quality and quantities of medical devices in hospitals have increased, traditional maintenance techniques could have been more efficient and practical. The proposed architecture enables biomedical engineers or technicians to monitor the outcomes of data analysis, the predicted health status of ICU ventilators, and maintenance schedules in real time through device notifications and live charts. Consequently, the occurrence of a significant event on the selected devices can be detected and communicated to interested parties in real time. This architecture uses big data and IoT technologies to identify any component wear or breakage and monitor the status of these ventilators. It is founded on the monitoring and surveillance of the pneumatic block. Implementing an intelligent humidity detection system is optimal, as humidity monitoring significantly contributes to product quality. Sufficiently dry and only compressed air can reduce the risk of corrosion and condensation, equipment failures, and poor product quality.

As for our future projects, we aim to achieve a system-wide predictive maintenance system by implementing an integrity monitoring framework.

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