Waveform Tracker Alarm for Automatic Patient-Ventilator Asynchrony (PVA) and Mechanical State Recognition for Mechanical Ventilators Using Embedded Deep Learning

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Abstract The Ateneo Innovation Center designs and develops a modular approach to medical alarm and alert systems for mechanical ventilators that enable clinicians to remotely monitor patient conditions and ventilator circuit status in near real-time, providing decision support that allows for a better diagnosis. It monitors and tracks the alarm events related to the ventilator waveform consisting of pressure, flow, and volume curves by using automatic peak detection of the curves and real-time recognition of time-series waveforms. The developed system combines the threshold alarms with embedded Artificial Intelligence to automatically detect complex alarms that need medical expertise such as issue detection on asynchrony, anomalies, and mechanical. It also differentiates the critical types of alarms, assisting clinicians via alarm prioritization, and remote patient monitoring via a near cloud system. Storing data in the near cloud system as a medical database enables building a rich dataset for upgrading the predictive model of alarm recognition.

Keywords Emergency ventilator · Biomedical monitoring · TinyML · Near cloud · And circular electronics manufacturing

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1 Introduction

In 2020, the COVID-19 pandemic disrupted the world by spreading at unprecedented rates and causing tens of thousands of fatalities within a few months [1]. Even with vaccines, its mutations unpredictably develop into various strains, and the number of infections and deaths are still on the rise, especially in regions where the number of patients in need of hospital care exceeds the availability of care. According to the Office of Inspector General for the U.S. Department of Health and Human Services, hospitals have reported a scarcity of skilled physicians needed to meet the anticipated patient surge. Many hospitals also stated that they lacked trained personnel who could operate ventilators and treat patients requiring that degree of care [2].

A mechanical ventilator machine is a life-support device, when the machines record measurements outside of normal parameters, it beeps, and alarms ring out to alert medical staff to potential problems. The data from the bedside monitor is usually lost as the monitor screen refreshes every few seconds. It requires intensive monitoring to identify early signs of clinical worsening and to minimize the risk of iatrogenic harm [3, 4]. With A-vent [5], the efforts of the Ateneo Innovation Center (AIC) to design, develop and operate a modular and low-cost ventilator alarm were described. The updated system currently triggers an alarm with the patient-ventilator asynchrony (PVA), anomalies, and mechanical problems as the previous system's alert system was limited only to its waveform parameters such as pressure, flow, and volume that alerts clinicians when the parameters fall below or above the set limits. This development of an alarm system is a design and engineering study with no humans involved.

2 Review of Related Literature

"Fighting the ventilator" is a common occurrence when the patient's demand does not match the machine's delivery, one of the reasons users' training is necessary to assure positive patient outcomes [3, 6]. The interaction between the patient and the machine is difficult to manage, hence the ventilator should be synced with the patient's normal inhalation and exhalation cycles.

Different ventilator designs emerged worldwide during this time of the pandemic. Corey et al. [7] presented a low-cost and easy-to-produce electronic sensor and alarm system for pressure-cycled ventilators that utilized an algorithm inspired by those used in hearing aids that required little memory that it can run on a microcontroller. The device estimated clinically useful metrics such as pressure and respiratory rate and sounds an alarm when the ventilator malfunctions. The application of the Internet of Things (IoT) protocol on medical equipment, as demonstrated by Mashoedah et al. [8], was intended to protect medical workers dealing with COVID-19 patients, particularly while medical personnel is monitoring and setting up such devices. Data was collected through testing, observation, and limited field tests using their "Define, Design, Develop, and Disseminate (4D)" approach. Rehm et al. [9] developed an intelligent decision support system using a Raspberry Pi that collects data from the ventilator unit and was able to store the stream of ventilator waveform and physiological data and analyzed it using supervised Machine Learning (ML) to classify the double triggering, breath stacking asynchronies, and acute respiratory distress syndrome (ARDS). It used IoT wireless connectivity to visualize the ventilator waveform and relied on a cloud platform to store and process the data.

The current ventilator system does not have a self-monitoring feature, which is critical for ensuring that the ventilator machines are working properly and that the settings are appropriate for the patient's conditions in real-time. This prompted the team to spearhead and start this project.

3 System Description

3.1 Experimental Setup

The conventional ventilator machines are threshold-based alarms that are prone to frequent false alerts. There are currently no intelligent systems embedded in emergency ventilators to automatically detect cycling asynchrony and generate alerts to clinicians. This study presented a new approach in which the patient and ventilator interactions characterized by a stream of ventilator waveform data were recognized in a real-time and stand-alone manner. Figure 1a describes the simple design of the A-vent unit and its experimental setup for emulating the different alarm events, including types of PVA, ventilator airway circuit status, anomalies, and high/low threshold levels occurrence.

The supplied air goes into the patient's airway circuit through a 1 L test lung that mimics a patient's lungs. The experimental setup is subject to a constant air supply and a one-second inspiratory and expiratory ratio. When the ventilator unit delivers pressurized air, the test lung expands and contracts accordingly with the given inspiratory and expiratory (I:E) ratio. The alert events are emulated as a proof of concept. The methods for emulating the patient and ventilator interactions are given in Table 1. Asynchrony and ventilator circuit-related alerts are the two types of modeled patient and ventilator interaction alarms. The emulated waveforms consist of eight classes, labeled as (1) normal waveform (NW), the common types of PVA include (2) delay cycling (DC^1), (3) double triggering (DT^1), (4) reverse triggering (RT^1), and (5) ineffective effort (IE^1) and alerts related to ventilator airway circuit status include (6) disconnected pressure port (DPP^2), (7) disconnected tube (DT^2), and (8) machine failure (MF^2).

To create a unique pattern of waveforms, the patient and ventilator interactions are modeled by altering the open-close state of the ventilator unit's manual air release valve during the inspiratory period, disconnecting components of the airway circuit, and shutting down the ventilator unit. The emulated asynchrony waveforms are

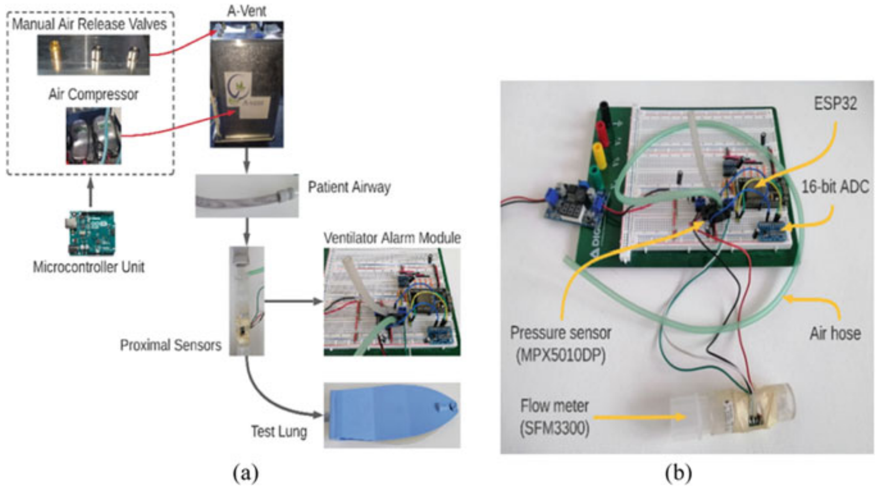

Fig. 1 Experimental setup **a** for emulating and capturing ventilator waveform data, and **b** modular intelligent ventilator alarm system prototype

Table 1 Summary of emulated ventilator waveform

Labels	Types of asynchronies	Emulation method
NW	Normal waveform	Valve is opened a little bit
DC[1]	Delay cycling	Valve is opened then close
DT[1]	Double triggering	Valve is closed, opened, then closed
RT[1]	Reverse triggering	Valve is closed then opened
IE[1]	Inefficient effort	Valve is fully opened
DPP[2]	Disconnected pressure port	The pressure sensor is disconnected
DT[2]	Disconnected tube	Test lung from the tube is removed
MF[2]	Machine failure	The ventilator unit is shut down

[1] Alarms related to common types of PVA
[2] Alarms related to ventilator airway circuit status

comparable to actual types of PVA associated with cycling and patient effort criteria and have been evaluated by a physician. The rest are machine and airway circuit issues such as power failure, air hoses, and circuit tube disconnection.

3.2 *Alarm Algorithm*

We achieved significant improvements to a conventional ventilator alarm system in this study by embedding Artificial Intelligence (AI) within a sensor-equipped

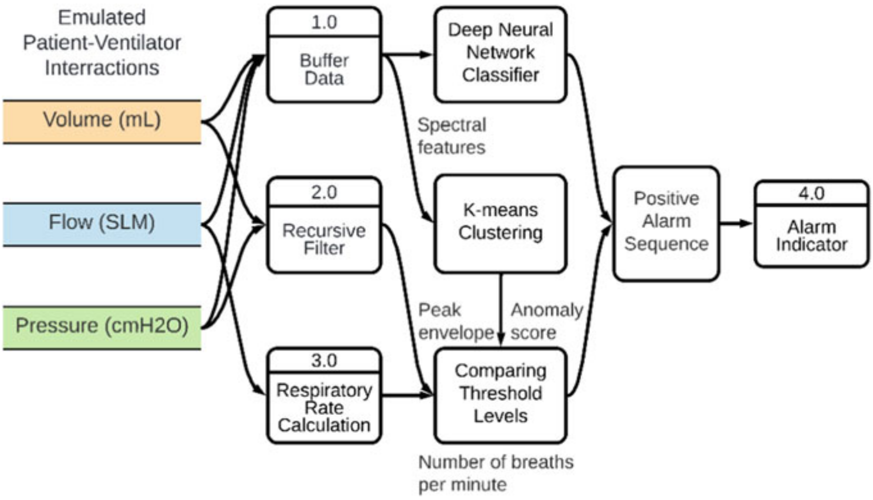

Fig. 2 Data flow for A-vent modular intelligent alarm device

ventilator machine. We performed built-in testing of the ventilator operation and analyzed its waveform for the recognition of time-series alarm events. When deviations from regular operations occur, ML together with data processing and sequencing algorithms alert medical staff.

Figure 2 illustrates the data flow describing the processing and algorithms of the alarm module for detecting the critical and important types of alerts. The ventilator waveforms comprise three parameters which include (1) pressure, (2) flow and (3) volume that was captured by a medical-grade flow meter and pressure sensor. The real-time data from the sensors are processed by the microcontroller unit. There are three algorithms used to develop the intelligent ventilator alarm module: (1) a couple of recursive filter algorithms, (2) K-means clustering, and (3) a deep neural network. Each algorithm specializes in detecting different types of alarms.

We employed the study of Corey et al. [8] to track the peak-to-peak pressure cycling (i.e., PIP, and PEEP) and the peak tidal volume. The respiratory rate is calculated by measuring the inspiratory period with the number of breaths per minute given by the I:E ratio. The PIP, PEEP, peak tidal volume, respiratory rate, and anomaly score are the five parameters for the threshold-based alarm. The decisions of these alarms are based on whether the current parameter falls above or below the set thresholds.

On the other hand, the raw data needed to be buffered for the processing which converts the time-series data to data suitable for ML algorithms. The spectral analysis used the extracted features of the raw data to model the PVA and mechanical state and then feed it to the deep neural network classifier. The basis of the decision for alarms was the predictions of the model represented by labels and accuracy.

The K-means clustering algorithm was used to find the natural pattern of the data and to detect anomaly data from the dataset. If the ventilator waveform data samples do not belong to any data clusters, the observation is categorized as anomalous [10]. The K-means anomaly returns a value called anomaly score if the observation score is greater than the threshold score, which it identifies as anomalous. The K-means clustering complements the classifier detection model, which detects the observation outside the dataset also known as an anomaly.

The false alarm triggering was avoided by utilizing the positive alarm sequence function. However, it provides an alarm delay for investigating the alarm sequence before triggering the alarm indicators. The delay varies with the data processing latency and the number of occurrences determines a positive alarm. The positive alarm sequence function ensures the series of alarm events occurred. If the series of alarms exceeds the set number of occurrences, it is characterized as a positive alarm and the alert indicator may trigger.

3.3 Data Gathering and Dataset

The ventilator waveform is captured using a medical-grade Sensirion flow meter (SFM3300) and differential pressure sensor (MPX5010DP) are shown in Fig. 1b. Figure 3 shows the ventilator waveforms comprising three parameters which include (1) pressure, (2) flow and (3) volume, which are captured by the sensors interfaced to a microcontroller.

The MPX5010DP is a differential pressure sensor designed to interface with a microcontroller or microprocessor that has an analog to digital (A/D) converter. It is an analog device with a high-resolution analog voltage signal ranging from 0 to 5 V that are proportional to the applied pressure of 0 to 10 kPa. The pressure is proportional to the output voltage, the measured pressure $P_{\mathrm{cmH_2O}}$ in centimeter of water (cm-H_2O) can be described as:

$$P_{cmH_2O} = \left(\left(V_{out} - V_{offset}\right)\right)/Sensitivity/10 \tag{1}$$

where the V_{out} is the output voltage of the pressure sensor in millivolts which is fed to a 16-bit A/D converter. The parameters offset voltage, V_{offset}, and *Sensitivity* which values can be seen in the operating characteristic section in the datasheet is 0.2V and 4.413 mV/mmH_2O respectively. The Sensirion SFM3300 is a digital and bidirectional flow sensor for proximal flow measurement in respiratory applications that can measure a flow range of ±250 standard liters per minute (SLM). Based on the product technical specification the flow F_{SLM} measured in SLM is described as:

$$F_{SLM} = \left(value_{I2C} - value_{offset}\right)/scale\ factor \tag{2}$$

where the $value_{I2C}$ is the integer return value by the flow meter from the I2C communication interface. The parameter $value_{offset}$ and *scale factor* (1/SLM) can be seen in the electrical characteristic section of the product specification, where the given values are 32,768, and 120 respectively. The calculation of tidal volume was derived

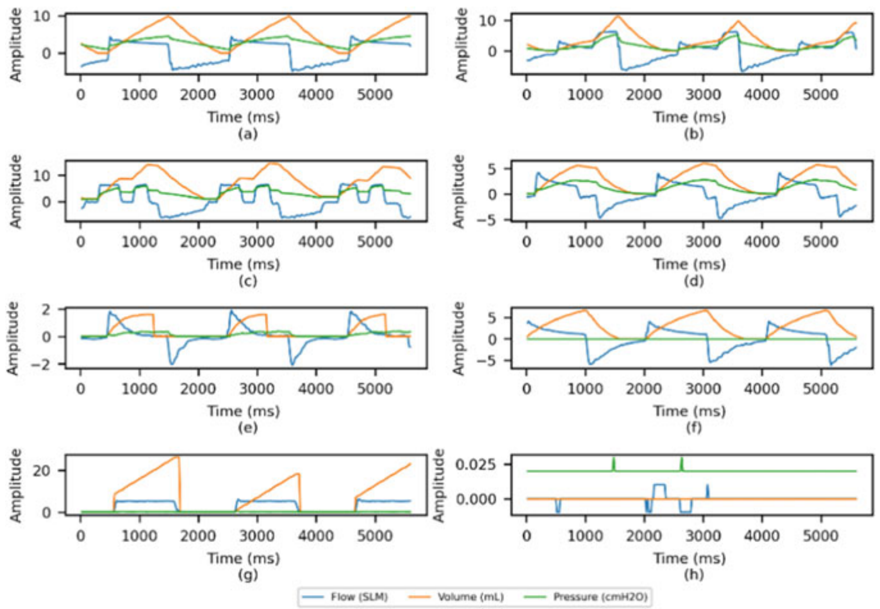

Fig. 3 The pressure, flow, and volume emulated ventilator waveforms as captured by the sensors; **a** normal waveform, **b** delay cycling, **c** double triggering, **d** reverse triggering, **e** inefficient effort, **f** disconnected pressure port, **g** disconnected tube, and **h** machine failure

from flow measurements. Given that the A-vent unit delivers pressurized air at the rate of a one-second I:E ratio, the tidal volume TV_{mL} measured in millimeters (mL) is described as:

$$TV_{ML} = \sum F_{SLM}/60 * \Delta t \tag{3}$$

where the F_{SLM} is the flow rate expressed in standard liters per minute, and Δt is the sampling interval obtained from the sampling rate. The continuous time-series waveform data are stored as comma-separated values (CSV) files with the timestamp in millisecond intervals given by the sampling rate to create a dataset. The emulated waveform was sampled at the rate of 50 Hz and captured continuously for 10 min for each class. The dataset was randomly divided into training, validation, and testing set. Before training the PVA and machine state recognition model, the dataset was processed to reduce its samples represented by its features as inputs to ML algorithms.

3.4 Features Extraction

Embedded devices such as microcontrollers have limited computational power and memory, making it vital to optimize the processing of large amounts of data. Feature

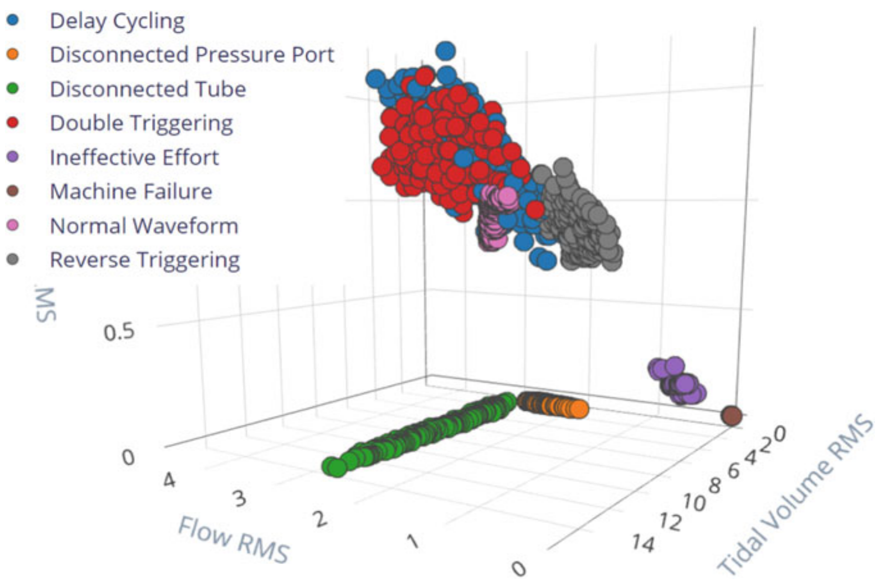

Fig. 4 3D graph of features extracted from the raw data of the emulated ventilator waveforms

extraction is a dimensionality reduction technique that reduces a large set of raw data into smaller groups for processing while retaining the information in the original data set [11, 12]. Analyzing time-series signals such as sensor data from the ventilator, this study employed spectral analysis as a features extraction algorithm. It processes the ventilator time-series signal to convert it into a frequency domain that extracts its spectrum characteristics. Figure 4 shows a 3D graph of RMS features extracted from the raw data of the emulated ventilator waveforms. The spectral analysis was able to group each class, making it easier for the ML algorithm to generalize the data. The algorithm extracted 11 spectral features of the raw data per axis; there were 33 features as input to the Neural Network classifier.

3.5 *Ventilator Asynchrony Recognition Model and Near Cloud System*

This study employed the optimized deep neural network enough to run on micro-controllers that classify the deviation of time-series waveform signal from the normal operation in real-time and standalone. Microcontrollers have limited memory and processing power, which places constraints on the sizes of machine learning models. The model was trained through the TensorFlow-based AutoML platform and converted the final model into the TensorFlow Lite version which allowed running the model on a microcontroller. The researchers chose ESP32-based processors (e.g., DOIT DevKit V1) to combine AI/ML capability with its IoT applications.

The researchers developed a data caching system, a wireless mesh network called AIC Near/Mobile Cloud, a private cloud infrastructure that was also included in some projects i.e., the A-vent, and a phototherapy light system for jaundice treatment that allows IoT devices to communicate [5, 13, 14]. The local data caching system can collect real-time data from sensor-equipped medical machines and perform real-time data analysis for hospital medical staff on multiple machines. The device's server connects the IoT medical machines to the time-series database that can store real-time data and analysis performed by AI/ML. It automatically stores the data in Unix timestamp format that allows graphing the historical clinical data with descriptive analytics in the remote monitoring dashboard for clinician reference.

4 Results and Discussions

4.1 Ventilator Asynchrony Recognition Alarms

The team employed the TinyML approach to classifying various types of asynchrony beyond the normal waveform that generates an alert. The results were obtained from 30 to 50 s of breath cycling, where the asynchronies and ventilator circuit status were emulated after 3 normal breath cycling. Figure 5 shows the alarms for emulated PVA. The breath cycling consists of pressure, flow, and volume represented by blue, orange, and green lines, respectively. The alarm signal is represented by a red line, if its amplitude is high, the sequence of positive alarms is detected to generate an alert signal.

It shows the delay cycling (DC), double triggering (DT), ineffective effort (IE), and reverse triggering (RT) asynchronies. The embedded neural network was able to recognize the asynchronies from normal waveforms in near real-time. The basis of alarm is the prediction accuracy and its labels. The positive alarm event is described if the predicted breath cycling is other than the normal waveform, and when the prediction accuracy surpasses the confidence level threshold of 0.80. The waveforms are sampled at 50 Hz with 5 sequence samples of positive alarm to avoid triggering of false alarm. The alarm algorithm took ~6–15 s (3–7 breath cycles) to trigger the alarm signal. It only took 1–2 normal breath cycles to reset the alert signal.

Figure 6 shows the machine, ventilator circuit, and anomaly alarms that include the disconnected pressure port (DPP), disconnected tube (DT), machine failure (MF), and emulated anomalous asynchrony. The alarm algorithm took ~10–25 s to generate an alert signal, which is somehow longer for asynchrony alarms. Furthermore, it took ~2–12 s (1–6 breath cycle) to reset the alert signal. The anomalous waveform was taken by rapidly turning around the air release valve from side to side. The anomaly detection took ~4 s (2 anomalous breath cycles) to trigger the alarm signal when the anomaly score exceeds the normal threshold. It took ~10 s (5 normal breath cycles) to

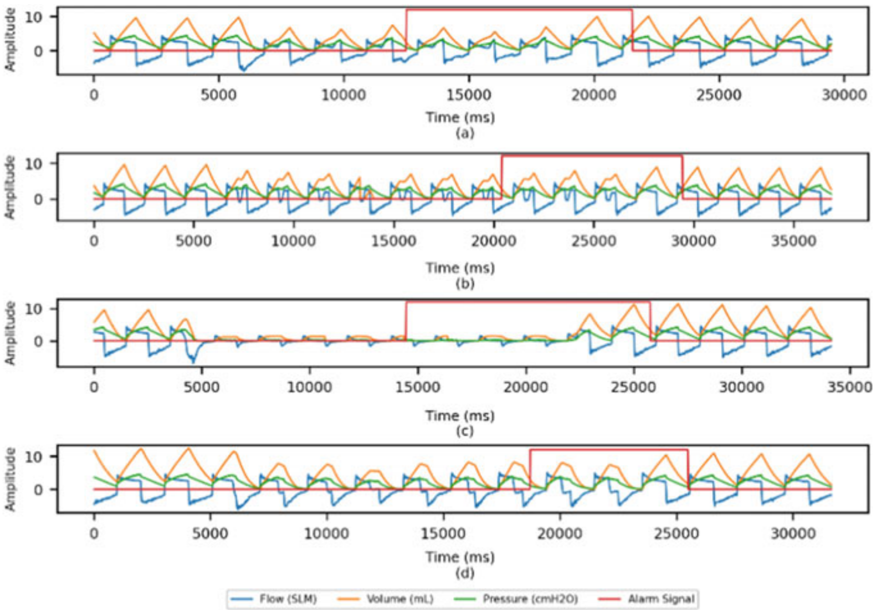

Fig. 5 Ventilator asynchrony alarms: **a** delay cycling, **b** double triggering, **c** ineffective effort, **d** reverse triggering

reset the alarm signal. Hence, this study proves that the future mechanical ventilator device can detect time-series types of alarms in near real-time, which assists the healthcare workers to reduce their workload and sustain the critical services of the healthcare system.

4.2 Ventilator Asynchrony Recognition Model Performance

To evaluate the model, the researchers randomly divided the dataset into (a) training, (b) validation, and (c) testing sets with 60%, 20%, and 20% partitions respectively. The model was evaluated using 10 k-fold cross-validations. The model performance for validation and testing sets was summarized using a confusion matrix as provided in Tables 2 and 3. It consists of m rows and n columns, where m is the actual emulated asynchrony and n is the asynchrony predicted by the algorithm. The diagonal elements show the accuracy of the predicted breath cycling matched with the actual emulated waveforms.

The weighted model accuracy resulted from validation and test sets are 97.8% and 98.01%, respectively. Both accuracies are relative to each other, thus the PVA and mechanical state recognition model can well generalize the emulated ventilator waveforms. The performance of the classifier model reflects how the features were

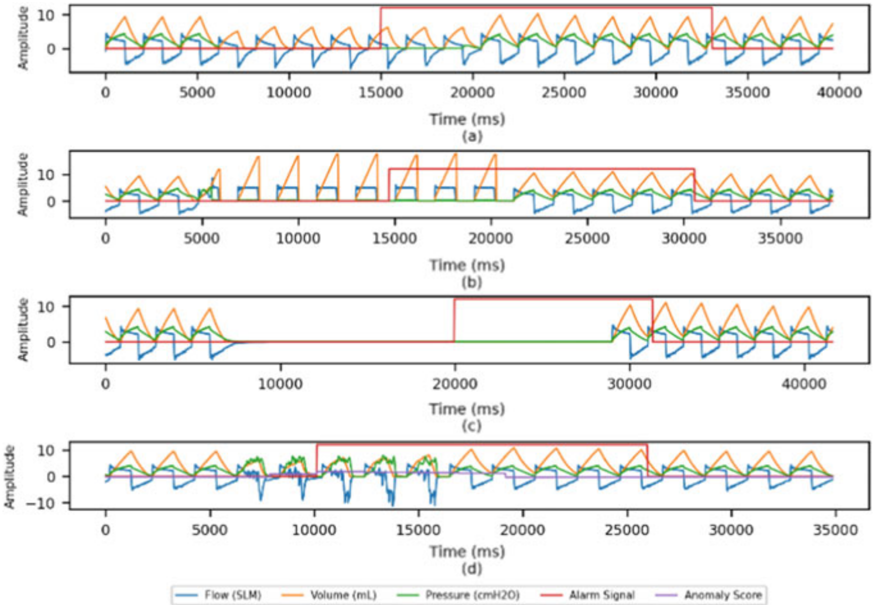

Fig. 6 Machine, patient airway circuit, and anomaly-related alarms: **a** disconnected pressure port, **b** disconnected tube, **c** machine failure, **d** anomalous asynchrony

Table 2 Model performance from validation set

	DC[1]	DPP[2]	DT[2]	DT[1]	IE[1]	MF[2]	N	RT[1]
DC[1]	0.93	0	0	0.04	0	0	0.01	0.02
DPP[2]	0	1.0	0	0	0	0	0	0
DT[2]	0	0.01	0.99	0	0	0	0	0
DT[1]	0.08	0	0	0.91	0	0	0.01	0
IE[1]	0	0	0	0	1.0	0	0	0
MF[2]	0	0	0	0	0	1.0	0	0
N	0	0	0	0.1	0	0	0.99	0
RT[1]	0	0	0	0	0	0	0	1.0

grouped as shown in Fig. 4. The delay cycling and double triggering overlapped each other causing confusion between them. The features for normal waveform and reverse triggering are concentrated. However, the data points were plotted near delay cycling and double triggering which has an insignificant effect on its performance. The rest of the classes were clustered independently which enabled the ML algorithm to be able to generalize data easily.

Table 3 Model performance from test set

	DC[1]	DPP[2]	DT[2]	DT[1]	IE[1]	MF[2]	N	RT[1]
DC[1]	0.90	0	0	0.02	0	0	0.01	0
DPP[2]	0	1.0	0	0	0	0	0	0
DT[2]	0	0	1.0	0	0	0	0	0
DT[1]	0.04	0	0	0.95	0	0	0	0
IE[1]	0	0	0	0	1.0	0	0	0
MF[2]	0	0	0	0	0	1.0	0	0
N	0	0	0	0	0	0	0.99	0
RT[1]	0	0	0	0	0	0	0	0.99

The ESP32 was able to process the stream of ventilator waveform data with 19 ms and 1 ms latency for the features extraction and inferencing, respectively. The features were buffed within 2000 ms given by its window length; thus, the inferencing results were printed after the data had been processed. This result proves that future ventilator machines can be embedded with AI/ML to detect time-series alarms in near real-time and stand-alone assist clinicians in monitoring critical patients.

5 Conclusion

As we embrace a circular economy for the development of biomedical devices, this study demonstrated a low-cost solution to upgrading medical machines such as ventilators with new AI/ML analysis and real-time data storage in the Near Cloud network. We modeled the patient-ventilator interaction by varying the airflow within the ventilator unit. The captured ventilator waveform was validated by the physician, as a proof of concept. The AIC team further improved the functionalities of the previous minimum viable ventilator by integrating a standalone alarm system utilizing embedded deep learning for near real-time detection of ventilator asynchrony and machine status, and clustering for detecting anomalies to assist clinicians in monitoring patients who require respiratory support. This development demonstrates how a conventional ventilator can be improved and linked to a new generation of medical machines/devices.

This study proved that the future mechanical ventilator machine can detect time-series types of alarms in near real-time, which assists the healthcare workers to reduce their workload and sustain the critical services of the healthcare system. Its AI predictive capabilities are supposed to support physicians in decision-making, not replace their expertise. The team also presented how the system can be integrated into the AIC Near/Mobile Cloud with the multiple sensor-equipped medical machines as part of the IoMT system initiatives.

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