

Personalized patient ventilation at large scale: Mass Ventilation System (MVS)

Ventilación personalizada del paciente a gran escala: Mass Ventilation System (MVS)

Ogbolu Melvin Omone¹, Bence Takács², Roland Dóczy³,
Tivadar Garamvölgyi⁴, László Szücs⁵, Péter Galambos⁶,
Tamás Haidegger⁷, Miklós Vincze⁸, Kristóf Papp⁹, Daniel
Drexler¹⁰, György Eigner¹¹, Abdallah Benhamida¹², Ezter
Koroknai¹³, Peter Dombai¹⁴, Miklos Kozlovsky¹⁵

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- 1 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: ogbolu.melvin@nik.uni-obuda.hu
 <https://orcid.org/0000-0002-4943-8922>
- 2 Antal Bejczy Center for Intelligent Robotics, EKIK, Óbuda University, Hungary. E-mail: b.takacs@irob.uni-obuda.hu
 <https://orcid.org/0000-0003-4262-7461>
- 3 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: doczi.roland@nik.uni-obuda.hu
- 4 Antal Bejczy Center for Intelligent Robotics, EKIK, Óbuda University, Hungary. Correo electrónico: tivadar.garamvolgyi@irob.uni-obuda.hu
- 5 Antal Bejczy Center for Intelligent Robotics, EKIK, Óbuda University, Hungary. E-mail: laszlo.szucs@irob.uni-obuda.hu
 <https://orcid.org/0000-0001-8310-0979>
- 6 Antal Bejczy Center for Intelligent Robotics, EKIK, Óbuda University, Hungary. E-mail: peter.galambos@irob.uni-obuda.hu
 <https://orcid.org/0000-0002-2319-0551>
- 7 Antal Bejczy Center for Intelligent Robotics, EKIK, Óbuda University, Hungary. E-mail: tamas.haidegger@irob.uni-obuda.hu
 <https://orcid.org/0000-0003-1402-1139>
- 8 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: miklos.vincze@biotech.uni-obuda.hu
 <https://orcid.org/0000-0003-3220-7535>
- 9 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: kristof.papp@biotech.uni-obuda.hu
- 10 Physiological Controls Research Center, EKIK, Óbuda University, Hungary. E-mail: daniel.drexler@physcon.uni-obuda.hu
 <https://orcid.org/0000-0001-6655-4354>
- 11 Physiological Controls Research Center, EKIK, Óbuda University, Hungary. E-mail: gyorgy.eigner@physcon.uni-obuda.hu
 <https://orcid.org/0000-0001-8038-2210>
- 12 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: benhamida.abdallah@biotech.uni-obuda.hu
- 13 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: eszter.koroknai@biotech.uni-obuda.hu
- 14 BioTech Research Center, EKIK, Óbuda University, Hungary. E-mail: peter.dombai@biotech.uni-obuda.hu
 <https://orcid.org/0000-0002-2175-1300>
- 15 John von Neumann Faculty of Informatics, Óbuda University, Hungary. Medical Device Research Group, LPDS, MTA-SZTAKI. E-mail: kozlovsky.miklos@nik.uni-obuda.hu, kozlovsky.miklos@sztaki.hu
 <https://orcid.org/0000-0001-8096-9628>

Keywords

Mass ventilation system; covid-19; medical ventilator system.

Abstract

This paper describes a Mass Ventilation System (MVS) which serves as a medical ventilator system. It can be used to ventilate large number of COVID-19 patients in parallel (5 – 50+) with personalized respiratory parameters. The system has been designed to be medically suitable for both non-invasive and invasive patient ventilation. It protects healthcare workers with its centralized air filtering solution, it increases the effectiveness of the healthcare workers with its networked communication and it can be operated in a temporary emergency hospital setup. In this paper, we describe the basic concept and building blocks of the system.

Palabras clave

Sistema de ventilación masiva; covid-19; sistema de ventilación médica.

Resumen

Este artículo describe un sistema de ventilación masiva (MVS) que sirve como sistema de ventilación médica. Se puede utilizar para ventilar un gran número de pacientes con COVID-19 en paralelo (5 - 50+) con parámetros respiratorios personalizados. El sistema ha sido diseñado para ser médicamente adecuado para ventilación de pacientes invasiva y no invasiva. Protege a los trabajadores de la salud con su solución de filtrado de aire centralizado, aumenta la efectividad de los trabajadores de la salud con su comunicación en red y se puede operar en una configuración de hospital de emergencia temporal. En este artículo, describimos el concepto básico y los componentes básicos del sistema.

Introduction

The Corona-virus Disease 2019 (COVID-19) pandemic across the globe [1] have caused several new diseases which have emerged in different geographical areas, with pathogens including Ebola virus, Zika virus, Nipah virus, and coronaviruses (CoVs causes downturn in the socio-economy [2] and an increasing mortality rate. Most of the patients experience various severity of respiratory problems. COVID-19 is described as the third kind of coronavirus that has emerged as a pandemic in the 21st century affecting the human respiratory system [3]. Based on the information recorded by World Health Organization (WHO), the COVID-19 outbreak started in 2019 in Wuhan, China [1] several new diseases have emerged in different geographical areas, with pathogens including Ebola virus, Zika virus, Nipah virus, and coronaviruses (CoVs, [4]. According to the National Cancer Institute (NCI), COVID-19 is an eminently infectious life-threatening disease and categorized as a respiratory disease. It spreads from one person to another by having a direct or an indirect contact with an infected person. Oftentimes, the patients experience respiration difficulties as the virus spreads around the respiratory system. Small percent of the patients further develops Acute Respiratory Disease Syndrome (ARDS) like symptoms [5]. Hence, the therapy of such patients involves the usage of medical ventilators. The history of medical/mechanical ventilation started in the beginning of the 20th century. Firstly, the short-term ventilation and resuscitation and later, the long-term ventilation solutions have been realized. The development of such medical ventilator devices are still ongoing as new technologies, methods, requirements, and therapies showing up. This paper provides the description of a new concept-based Mass Ventilation System (MVS) that can be used to

ventilate large number of patients in parallel (5 – 50+) with personalized respiratory parameters [6], [7]. This paper is organized as follows. The second chapter gives a brief summary about the problem, following the state of the art. The fourth chapter presents the MVS architecture and its main building blocks. In the conclusion chapter we conclude our work with a brief provisioning of possible future research directions.

Motivations - Problem definition

1. Medical ventilators currently in use are capable of supplying only one person, and each patient must be provided with a separate ventilator. ARDS patients are using the medical ventilators more than one week long in average, so the available quantity runs out fast [8].
2. Exhaled infectious air exits into the common hospital airspace by the respiratory equipment currently in use, whereby doctors and nurses are at increased risk as they work in an air contaminated environment with high concentration of viruses [9], [10].
3. An important factor for setting up mass health camps is to consider which equipment can be used in the absence of hospital infrastructure, especially in places where there are no drainage pipe outlets and where power distribution is limited to each camp bed [11].
4. Medical ventilators are expensive devices, some countries cannot afford proper medical equipment for the entire population in the case of a pandemic [12], [13].
5. As COVID-19 pandemic is increasing the effective patient monitoring/handling and optimized human resource allocation is crucial by the healthcare system [14]. The health status of the patient should be available in real-time for medical professionals, as they do not have time to acquire the data personally during large scale medical crisis situations [15].

State of the Art

A mechanical ventilator is a medical device which is capable of moving air in and out of the patient's lung in a reliable and safe manner. The history of medical/mechanical ventilation begins with the resuscitation devices such as the Pulmotor, which was introduced by the Dräger company (Lübeck, Germany) in 1907 [16]. After the Second World War, a serious polio epidemic broke out and long-term ventilation was urgently needed at large scale. Starting in the 1980s, ventilators were increasingly equipped with electronic components that made ventilation more and more precise [17], [18]. The devices started to display airway pressure, flow of breathing gas, and other vital information on a monitor as ventilation waveforms. Modern measurement and control technology became possible to regulate ventilation parameters more and more precisely. Medical ventilator systems are highly adjustable and complex devices. The medical professional can set many parameters on the device (pressure, volume, respiratory rate, PEEP, oxygen percentage, etc.) according to the predefined treatment. The two major patient ventilation mode is the non-invasive (e.g., using a face mask) and the invasive (using an endotracheal tube) mode [12]. In non-invasive mode the patient can breathe and has consciousness [19]. Regarding modes of ventilation, there are several types in use such as assist-control (AC), synchronized intermittent mechanical ventilation (SIMV), and pressure support ventilation (PSV). The ventilator can then be set to provide a given volume/pressure. In each mode, certain parameters must be set on the ventilator, including respiratory rate (RR), inspiratory flow rate (IFR), the fraction of inspired oxygen (FIO_2), and positive end-expiratory pressure (PEEP). Three main ventilation concepts are available recently (Fig. 1). The single person ventilation is the traditional concept (we will not detail this concept more in this paper), co-ventilation was invented during the COVID-19 pandemic as a fast hacking, problem fixing solution to deal with the huge shortage

of medical ventilators. Mass ventilation setups, as the one proposed here in this paper, are new innovative concepts, which provide cost effective and feasible solutions to the resource shortage problem and has opened a new niche market in the medical ventilator field.




| Single person ventilation | Co-ventilation | Mass ventilation |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1 patient/device | 1-4 patients/device | Many (50+) patients/system |
| Restricted setup, use dedicated resources, robust and reliable | Reuse free, unallocated capacity, non-reliable, performance at the edge of the capacity | Large scale setup, heavy duty components, robust, reliable use dedicated resources |
| Individual/personalized ventilation setup | Group ventilation setup | Individual/personalized ventilation setup |
| No cross-contamination possible | Cross-contamination possible | No cross-contamination possible |
|  |  |  |
| Analogy: Car/moped/bicycle | Analogy: Car/moped/bicycle sharing | Analogy: Public transport |

Figure 1. Overview of a ventilation concepts

A good example of “co-ventilation” was developed by Dr. Alain Gauthier, who has doubled the number of patients per ventilator at his hospital in March 2020 during COVID-19 crisis [20]. A more hybrid co-ventilation solution is the recently developed Individualized System for Augmenting Ventilator Efficacy (iSAVE) system built at MIT, which has overcome some constraints of the co-ventilation method [21].

Mass Ventilation System (MVS) solutions

A fully functional mass ventilation system (the Breathing Aid from Germany) was announced late March 2020 almost immediately after the MassVentil project was officially announced on the Internet [22]. This system contains similar innovations as our KTG-type MVS, but it is only able to do non-invasive ventilation using face mask, in the so called Continuous Positive Airway Pressure (CPAP) mode. Their extended prototypes can ventilate 10 - 30 patients in parallel.

The KTG-type Mass Ventilation System (Mass Ventil - MVS)

The Mass Ventilation System builds up from many components. A KTG-type Mass Ventilation System (MVS) has four essential features [23]:

- Centralized air management unit provides pressurized air for several patients at the same time;
- Patient ventilation parameters (such as oxygen concentration, pressure, respiration rate, PEEP) can be adjusted individually for each patient according to the doctor’s treatment strategy at the bedside of the patients;
- Transporting exhaled infectious air from the common airspace, thereby significantly reducing the risk of infection for all medical workers/staff;
- The system may be installed on an ad-hoc basis in a non-hospital environment.

And the following main technical features [7]:

- Each patient ventilation unit can perform pressure and volume control as required by the treatment.
- All generic ARDS ventilation modes are supported by the system such as: CMV, CPAP, BiPAP, CIMV, APRV, IPPV, PCV.
- PEEP is available till 25 mbar (with fine grain adjustment) for each patient.
- Maximum continuous flow supported by the system is: 120 L/min/patient.
- Patient triggered free breathing support (inhale and exhale) for each patient is supported.
- Possible to cough into the system for each patient.
- O₂-tank or O₂ concentrator can be connected to the system at the patient ventilation units.
- FiO₂ (oxygen level) adjustment is supported from 21%-100% (with fine grain adjustment) for each patient.
- Humidity and temperature are controlled by HME (HME booster is optional but can be used); optionally, temperature can be controlled in the inhale bus too.
- Exhaled air is always carried out from the patient area and filtered 2x with centralized HEPA (ULPA is optional) air filters before releasing into the air.
- Patient interface: Patient ventilation unit can be connected to standard patient ventilation masks (for non-invasive ventilation), using endotracheal tubes (for invasive ventilation) or special Covid-19 masks with tube type connectors, or to nasal prongs. We are about to carry away the infectious air from the patient in order to protect medical professionals, thus patient interfaces with direct exhale valves are not preferred.

In contrast with single person ventilators, the KTG-type MVS consists of a central duct system alongside a personal ventilator unit equipped with a KTG-type valves for each patient (as shown in Fig. 2.). The central inhalation and exhalation duct system supplies air to and collects gases from all the personal ventilator units. In such system both the air management and the data management are centralized to increase effectiveness and resource allocation [6].

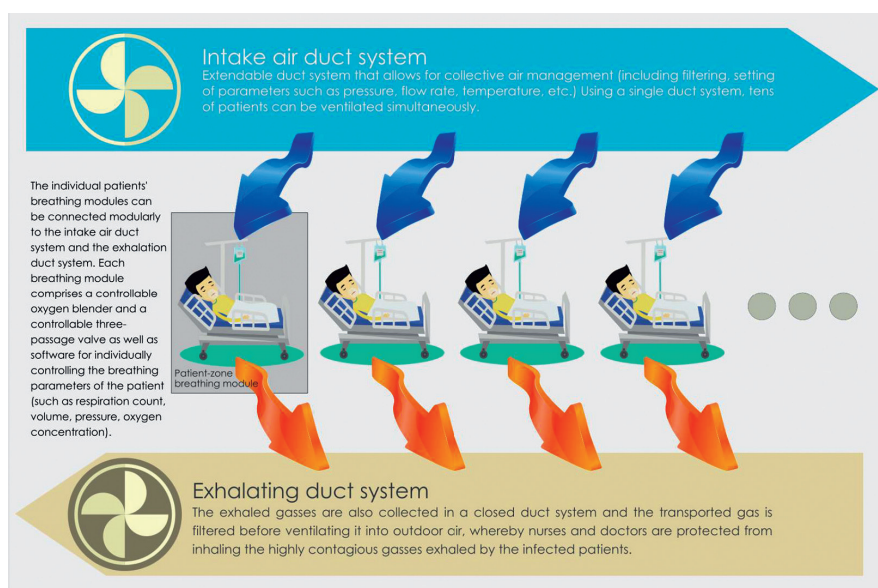


Figure 2. Mass Ventilation System (MVS) design concept

Mass Ventilation System (MVS) Architecture

Figure 3 shows the implemented MVS architecture with its components [23].

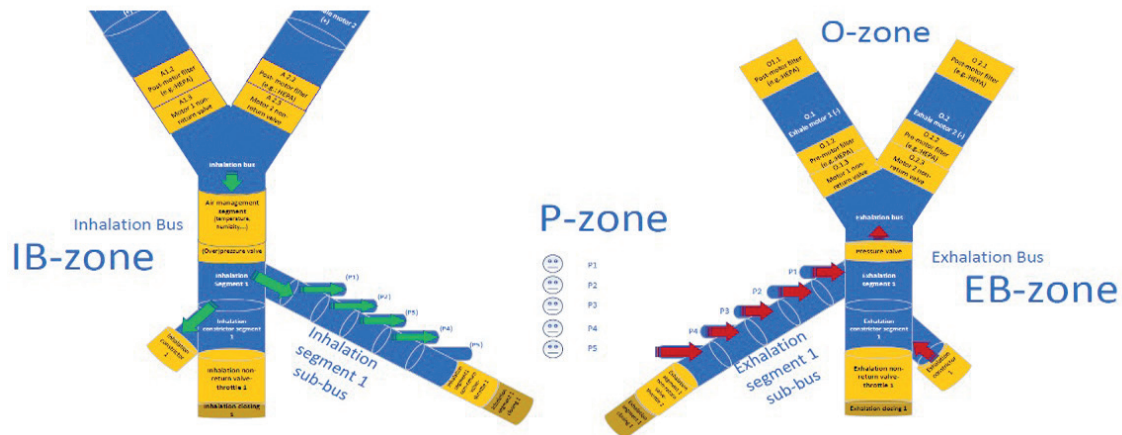


Figure 3. Mass Ventilation System(MVS) architecture [7]

Due to the modularity of the system, new patients can be integrated into the system at the P-zone up to the system's maximum capacity without having to stop ventilating connected patients. The maximum capacity of the system is mainly determined by the diameter of the duct system and the capacity of the motors used in the inhalation and exhalation system. The inhalation air generator system (A-zone) can receive air from different sources. These can be hospital pre-installed aeration tubing, or dedicated ventilator or compressor-based air supply systems. The combination/multiplication of different types of air-generating systems increases the capacity and robustness of the ventilator system (i.e. increasing similar parameters of the entire mass ventilator system). On the inspiratory side (IB-zone), an excess pressure of at least 80 mbar is required. Both the inhalation air supply system and exhalation air dispensing system are redundant in order to remain operational in case of hardware problems and to be able to perform maintenance work (e.g. replacement of filters). A minimum of two fans per inhalation and exhalation subunit is required to achieve adequate redundancy. Fans are fitted with filter(s) to exclude contaminants and pathogens (e.g. COVID-19 virus) of different sizes. Each fan is connected to the duct system via non-return valves (IB-zone and EB-zone). The duct system pressure can be set to the desired value by means of adjustable valves located at the end of the inhalation and exhalation ducts (the main ducts). The flow rate is continuously measured in the main duct to ensure robust operation. In the exhaled air transporting system, there is compression up to the pressure side of the fan, the pressure can be adjusted with a valve at the end of the exhalation duct and it is about 40 mbar lower than the outside air pressure. Due to the lower atmospheric pressure, the pathogens cannot escape from the duct system. The pressure side of the fan is designed in such a way that the air can escape only after appropriate filtering. The duct systems are connected to the personal ventilator unit (as shown below, Fig. 4b.) at the patient's bed via a separate shut-off device, so that new patients can be integrated into the system without any interruption in the whole system. A shut-off fitting is provided at the end of the main ducts for the purpose of scalability. In the personal ventilator unit, a KTG-type valve is controlling the air flow to and from the patient. In the P-zone, the system provides several options for adjusting the O_2 concentration of each patient: oxygen delivery can be achieved by concentration-based or even time-based control. The constant amount of gas delivered per unit time by a mechanical O_2 flow control valve is delivered to the patient by controlling the solenoid

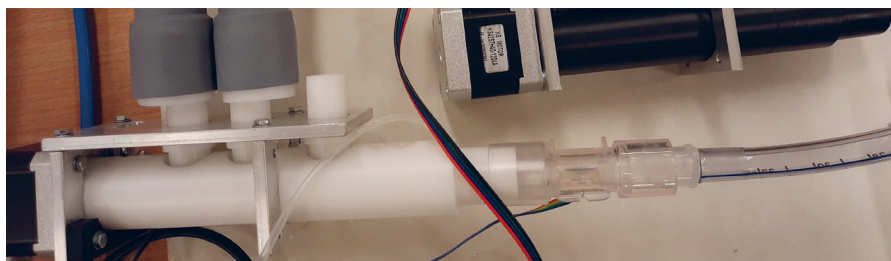
valve at suitable time periods. O₂ gas is delivered to the patient in a separate duct system, thus each patient can have different O₂ level during therapy. The temperature and humidity of the air supplied to the patient is controlled in the P-zone. As in the P-zone humidity and temperature control is easier, thus using passive (e.g. HME – Heat and Moisture Exchangers) or active solutions (e.g. HME Booster) [23]. The whole mass ventilator system and all ventilated patients are monitored by a secure SCADA like unified monitoring system. Measurement data, derivative values and statistics are transmitted to the local server over a communication network using an appropriately encrypted communication channel [7].



(a)



(b)



(c)

Figure 4a. Main air management unit (A and O-zones); 4b. Patient ventilation unit (P-zone); 4c. Patient valve (KTG-type) extracted from the patient ventilation unit (P-zone)

Medical ventilators are classified as a life-critical system - because any mechanical failure may result in death [24], they are highly reliable and carefully designed so that no single point of failure can endanger the patient [25]. The MVS has manual backup mechanisms to enable hand-driven respiration in the absence of power. It has safety valves, which opens to the atmospheric air pressure in the absence of power to act as an anti-suffocation valve for spontaneous breathing

of the patient. It has the possibility to integrate batteries to provide ventilation in case of power failure or defective gas supplies, and methods to operate or call for help if their mechanisms or software fails.

Conclusion

We have designed and realized a Mass Ventilation System (MVS) based on a new so-called mass ventilation concept. The builds up from a centralized air management subsystem, and a patient ventilation unit with a KTG-valve. The system is capable to ventilate many patients in parallel with personalized ventilation parameters. The system supports invasive and non-invasive ventilation modes. The system can save all acquired data from the patient(s) into a database in the background which opens a door into the big data science. The system has been tested successfully in various test environments. The pre-clinical animal trials have been started recently. With the realized MVS, we are planning to ventilate large number of patients in a scalable, safe, reliable and cost-effective way.

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