EMERGENCY VENTILATOR "DIEGO"

Device for Inspiration and Expiration, Gravity Operated

Data:	**May 16 2020**
Authors:	Luciano Fadiga (fdl@unige.it); Giulio Sandini (giulio.sandini@iit.it); Diego Torazza (diego.torazza@iit.it)
Description:	Emergency Ventilator DIEGO
Revision:	3

Contents

Credits

- Luciano Fadiga, Giulio Sandini, Diego Torazza (physiology and engineering design)
- Alberto Papi (pulmonology)
- Carlo Alberto Volta, Piero Di Pasquale, Valentina Ajello, (anaesthesiology and emergency care)
- Federico Ratti, Elia Baggiarini, Michele Mazza, Alessandra Benedetti (SCM - industrial design and manufacturing)
- Guido Bonapace (Isemed, CE safety rules consultant)
- Rosario Canto, (technical and mechanical support)
- Massimiliano Turci (support for cam design)
- Davide Dellepiane, Marco Crepaldi (Electrical/Electronic)
- Alberto Parmiggiani, Roberto Puddu (IIT Mechanical Workshop)
- Carlo Tacchino e Antonella Fontana (Certification procedure)
- Giuseppe Giardina, Marcella Impoco e Nicolò Sanguineti (Technology Transfer)

Contacts

- Prof. Luciano Fadiga
  Section of Human Physiology - University of Ferrara
  Center for Translational Neurophysiology of Speech and Communication - IIT
- Prof. Giulio Sandini
  Robotics, Brain and Cognitive Sciences - Istituto Italiano di Tecnologia
- Ing. Diego Torazza
  Robotics, Brain and Cognitive Sciences - Istituto Italiano di Tecnologia -

For more information: diegovent@iit.it

1. MOTIVATION AND SCOPE

The most fearful complication for COVID-19 patients is represented by respiratory failure which, without a rapid ventilation support can in a few hours evolve towards death. The availability of suitable ventilation equipment becomes even more serious when the affected geographical area is unable, for economic and logistical reasons, to purchase the necessary medical devices.

For these reasons, a group of Italian researchers from the Italian Institute of Technology and the University of Ferrara has conceived and designed an "open source" system for emergency mechanical ventilation (compassionate use) very simple and robust but yet physiologically plausible, clinically tested and complying to international safety rules.

Physiological, pneumological, anesthesiological and engineering skills were called for, to design a system based on a mechanical solution easily reproducible anywhere with commonly available components and basic workshop tools.

Starting from the experimental prototype realized to allow adequate control of the parameters during the initial clinical testing, industrialization of the project has been completed by SCM Group and the manufacture of a first series of devices is ongoing. SCM is an Italian multinational company leader in the production of numerically controlled machining machines that has offered to provide the necessary components for free..

The project is entirely open source and all documentation will be accessible through a Zenodo Repository

DIEGO has been designed to allow the adjustment by the operator of all the relevant ventilation parameters, such as tidal volume, respiratory phases duration (inspiration: expiration ratio), respiratory frequency and end-expiratory pressure (PEEP). It has been conceived as an emergency tool to be used temporarily in situations of serious need. In its basic configuration it will be usable on patients maintained in deep sedation and possibly curarization condition and it should be used under close medical supervision. In the event of any malfunctions, the operator can immediately switch to manual mode. The electromechanical assembly of the device, given its simplicity and its analog operation, is considered an accessory of an Ambu®-like resuscitator bag. All the necessary procedures to comply with European safety rules have been followed (electromagnetic compatibility and electric safety testing, ethical approval, clinical study, Italian Ministry of Health notification).

2. DESCRIPTION

2.1 ELECTROMECHANICAL DESCRIPTION

The following picture shows a possible implementation of the working principle proposed:

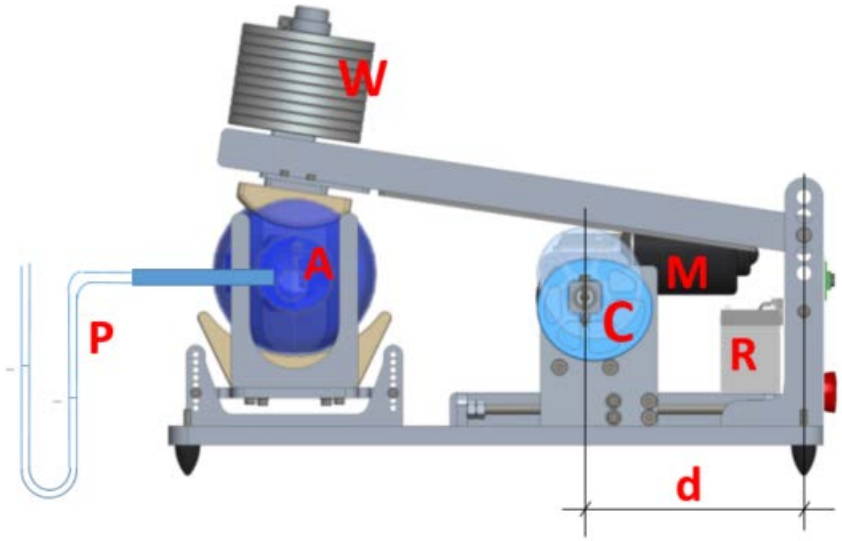


Figure 1: Schematic of the Experimental Prototype (see text)

The respiratory bag (A) (Ambu®-like) is housed in a cradle designed to adapt to the majority of available bag models. The gearmotor (M), thanks to the cam (C) cyclically raises and accompanies downward the mass (W) that compresses the bag under the action of gravity. Through the regulator (R) it is possible to vary the frequency of respiratory acts (in our first prototype from 5 to 30 per minute). The schematic pressure gauge (P) indicates the instantaneous pressure of the system. Tidal volume is easily adjustable, for example, by varying the distance (d) between the fulcrum of the lever and the point of contact of the cam with the lever itself. Video tutorials explaining the main principles and control procedures are available on YouTube (links at the end of this document).

The mechanism is intrinsically safe, as the maximum pressure that can be generated depends solely on the mass (W) and force of gravity. In the event of a malfunction, it is always easy to extract the resuscitator by manually lifting the lever and proceed with manual ventilation.

In the experimental prototype used for clinical testing the gearmotor (automotive component) is powered by a medical grade AC-DC (12 V) converter. A buffer battery (7Ah) guarantees system operation for about 4 hours in the event of a mains power loss. The gearmotor consumption is about 1.0 A on average.

The figure below schematically shows the 3D CAD of the experimental prototype (left) and of the industrially engineered device (right) developed at SCM which, for safety, is enclosed in a plastic fairing and is fully sanitizeable.

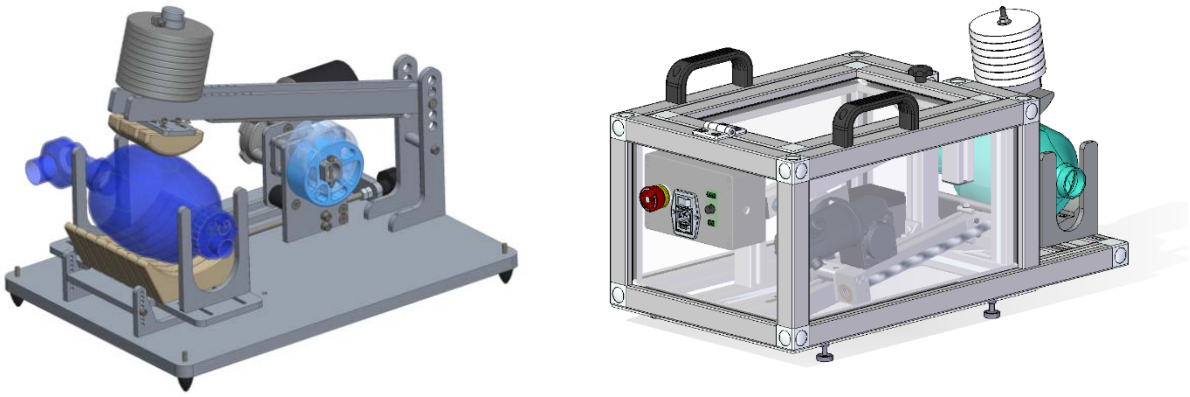


Figure 2: CAD of the experimental prototype (left) and of the industrial implementation (right)

2.2 PATIENT CIRCUIT DESCRIPTION

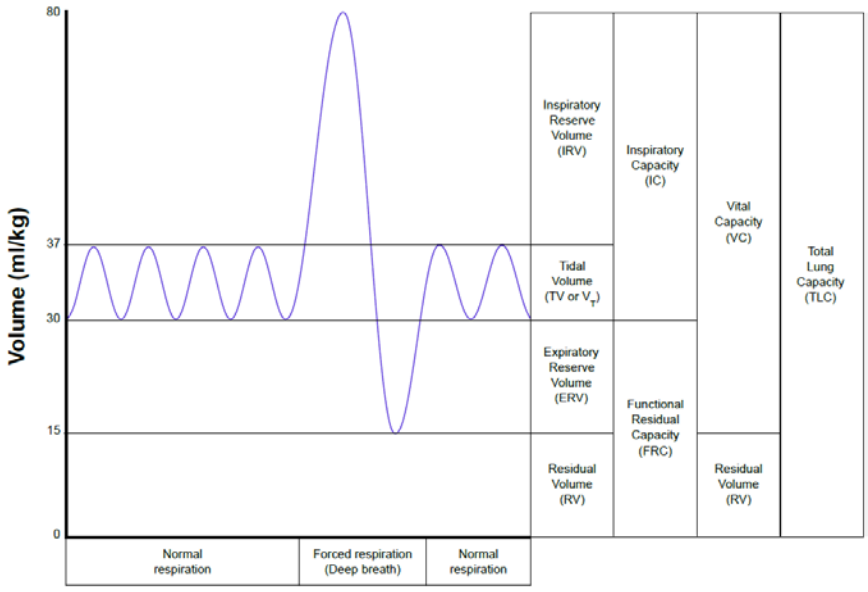
The patient circuit consists of an Ambu®-like bag, single patient use or autoclavable (right), preferably equipped with an overpressure safety valve, connected by a corrugated breathing tube of adequate diameter (min. 24 mm) to a patient valve (left) to which to connect (green arrow) the endotracheal tube (mount catheter) through an antibacterial / antiviral filter (not shown in the figure).

The patient valve is cheap and normally available on the market as an accessory of resuscitator bags. It should host an end-expiratory pressure valve (PEEP, red arrow). The PEEP valve is necessary in COVID-19

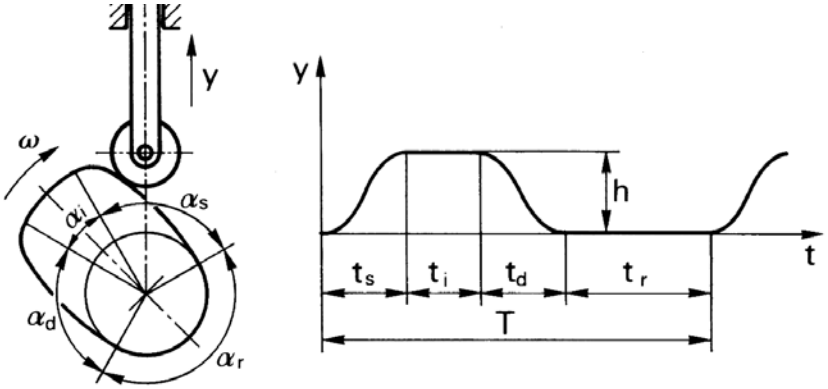
patients to facilitate alveolar recruitment and has to be adjusted based on the characteristics of the individual patient. IMPORTANT: ALWAYS use a patient valve at the end of the breathing tube. Without doing so it would increase the dead space, the patient would continually inhale his/her own exhalation and this would cause patient death by asphyxiation. In case of extreme emergency and missing an additional second patient valve, one can remedy this by detaching the resuscitator patient valve and by connecting it to the breathing tube, always keeping the valve as close as possible to the patient's mouth. The other end of the tube will be connected to the outlet of the bag either directly or by means of an adapter made for this purpose.

The measurement of the pressures in the system is fundamental to assess the correct functioning and to regulate end-expiratory and end-inspiratory pressures. This can be done either by a low-cost electronic manometer or by a simple U-shaped water manometer (use a thin tubing not to significantly increase the dead space of the system). Note that several Android smartphones are also equipped with barometer (sampling rate, 10 Hz; iPhones are not suitable because their sampling frequency is 1 Hz only). They can be easily placed in parallel with the breathing circuit by means of a simple low volume (to minimize dead space) container. Wireless connection between Android phones and PC has been tested in our laboratory and looks reliable enough.

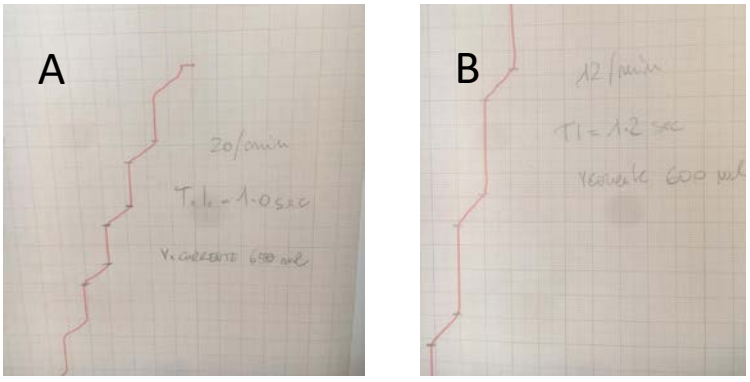
3. WORKING PRINCIPLE



The figure above shows the physiological pressure values that characterize the respiratory function. The DIEGO device is able to provide a tidal volume varying between 200 and 700 ml, the adjustment of which is achieved by advancing or retreating the point of contact of the cam supporting the lever with respect to the fulcrum (distance d in Fig. 1). The rising/falling dynamics of the pressure is determined by the geometric profile of the cam itself.



The relationship between kinematic profile and cam shape is shown by the exemplificative figure above. The sector angles (α_s, α_i, α_d, α_r) which describe the rotation in time and space correspond to the time segments t_s t_i t_d t_r of the kinematic diagram shown on the right. Therefore, the manufacture (for example by 3D printing) of cams with specific profiles, may vary the temporal characteristics of respiratory parameters, such as the inspiration / expiration ratio, the inspiratory time and the duration of the inspiratory plateau. The spirometric measurements performed on the prototype indicate that the DIEGO is able to widely vary these parameters producing suitable respiratory patterns for the emergency treatment of respiratory insufficiency in COVID-19 patients. The figure below shows some spirometric



profiles recorded at the respiratory rates of 12 and 20 acts / min.

A, example of tidal volume of 650 ml at the frequency of 20 acts / minute. Inspiration time, 1.0 sec. B, example of a tidal volume of 600 ml at the frequency of 12 acts / minute. Inspiration time, 1.2 sec. Paper speed, 600 mm/min. 1 cm, 500 ml.

The following picture shows the prototype realized to test the system. On the left the box with the electronics and the battery. Some of the controls were included for testing purposes and the complexity of the mechanical part has been reduced in the first industrial implementation once the optimal ranges of control have been identified.

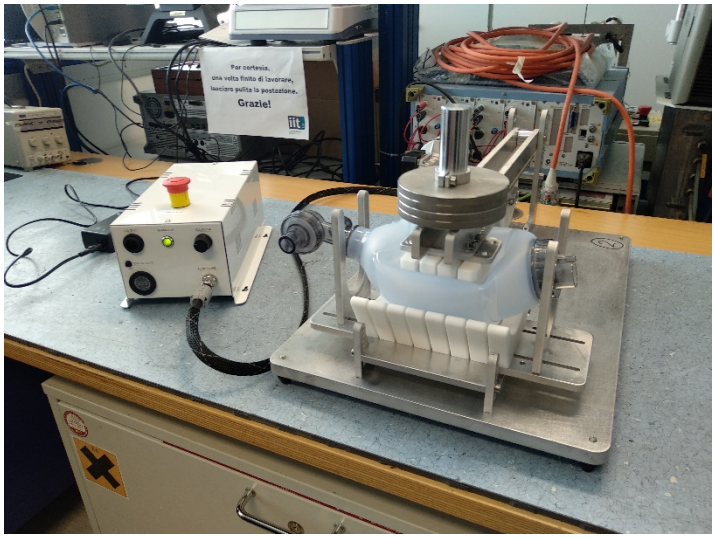


Figure 3: The experimental prototype with the box containing the battery and the PCM controller.

The prototype has been successfully tested according to ISO 80601-2-12: 2020 for volume controlled ventilators performance (in normal atmosphere), with compliances of 50 and 20 ml/cm H_2O and resistances of 5 and 20 cm H_2O/l/s.

Test number	Test lung parameters		*Ventilator* settings				
	Compliance ml/hPa ±10 %	**Linear resistance**[17][18][19] hPa/l/s ±10 %	***Tidal volume*** ml	***Set rate***[a] breaths/min	***Inspiratory time*** s	O_2 %	***BAP*** hPa (cmH_2O)
1	50	5	500	20	1	30	5
2	50	20	500	12	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	12	1	90	10
7	10	50	300	20	1	30	10
8	10	10	200	20	1	90	5

4. WARNINGS

1) DIEGO is an accessory of an Ambu®-like resuscitator bag and replaces the mechanical force normally exercised by hand by the health care professional.
2) The DIEGO device represents an emergency system that does not replace a traditional ventilator. In extreme emergency conditions, however, keep in mind that it has been designed for continuous use.
3) All requirements relating to the use and characteristics must be considered and respected, including the duration and sterilizability of the flask used. A terminal antibacterial/antiviral filter must be used.
4) In the event of any malfunctioning, it is necessary to remove the balloon from its housing and continue ventilation manually.
5) Behind direct responsibility of the sanitary responsible for resuscitation, in the case of use of a breathing tube, this can be connected to the exit valve of the flask ONLY IF at the end of the tube there is an additional patient valve. The patient valve must be equipped with an inspiratory non-return valve, an overpressure safety valve and an expiratory valve (better if equipped with an end-expiratory pressure regulation, PEEP).
6) The DIEGO system is supplied to be assembled. The manufacturer must therefore be understood as the person who mechanically assembles the pieces and any responsibility for incorrect assembly, malfunction and incorrect use falls on him/her.
7) This is a device that can save lives but which must be used ONLY if traditional alternative methods are not available (compassionate use).

5. ADDITIONAL SAFETY CONSIDERATIONS

The DIEGO device is an accessory for Ambu®-like resuscitator bags and not a pulmonary ventilator. This accessory is able to provide the bag with the correct pressures, timings and frequencies that allow the bag to perform the function for which it is conceived. The system has been designed to accommodate different brand resuscitator bags and has already been tested with disposable GIMA, autoclavable Boscarol OB, and disposable Ambu® II Spur bags for the purpose of demonstrating the interchangeability of the bags in the equipment. Based on the definition of "accessory", as defined in the directive 93/42/EEC on medical devices, accessories are classified separately from the medical device used in combination. In the specific case, this accessory uses the force of gravity to generate the pressure on the bag while the motor is used to raise the weight to accumulate the potential energy provided by the gravitational field. Based on these and other considerations, the DIEGO accessory can be considered as a EEC class I device.

The DIEGO accessory is intended to be monitored on sight by health personnel during its operation. In the event of a malfunction it is possible to immediately extract the bag from its seat and continue ventilation manually. It was therefore not designed for unattended use and only allows to save patients' life in an emergency situation, in the absence of standard ventilation systems. In other words, it is intended as a

backup solution that allows medical personnel to keep the patient alive for the time necessary to find a more adequate accommodation.

The device is built respecting all the mechanical and electrical safety criteria to prevent risks, including crushing, despite this risk being decidedly mitigated by the fact that the maximum forces involved and the rotation speeds (up to 30 revolutions per minute) can hardly exert significant harmful effects. The device is protected by a fairing in washable plastic material.

The DIEGO device got the approval of the Ethics Committee of Emilia Romagna Region for a preliminary testing on human patients and it has been notified to the Italian Ministry of Health.

6. STRUCTURE OF ZIP FILES OF DIEGO'S PROTOTYPES IN ZENODO REPOSITORY

The design of the implementations of the DIEGO's mechanical principle are distributed through a ZENODO repository (http://doi.org/10.5281/zenodo.3842345). At this time only the design files of the so-called *experimental version* are published while those of the *industrial version* are being prepared and will be published in a future revision.

6.1 STRUCTURE OF THE ZIP FILE OF THE EXPERIMENTAL PROTOTYPE

The file included in the ZENODO (Zenodo.org) repository *DIEGO_Ventilator_Design.zip* is structured as follows

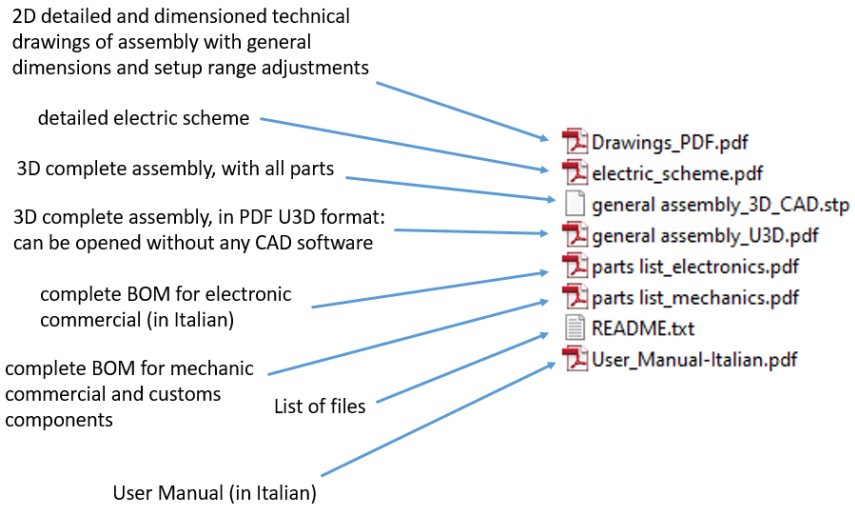


Figure 4: Structure of the file DIEGO_Ventilator_Design.zip

6.2 THE INDUSTRIAL DESIGN

Details of the so-called *industrial prototype* will be published in a future revision

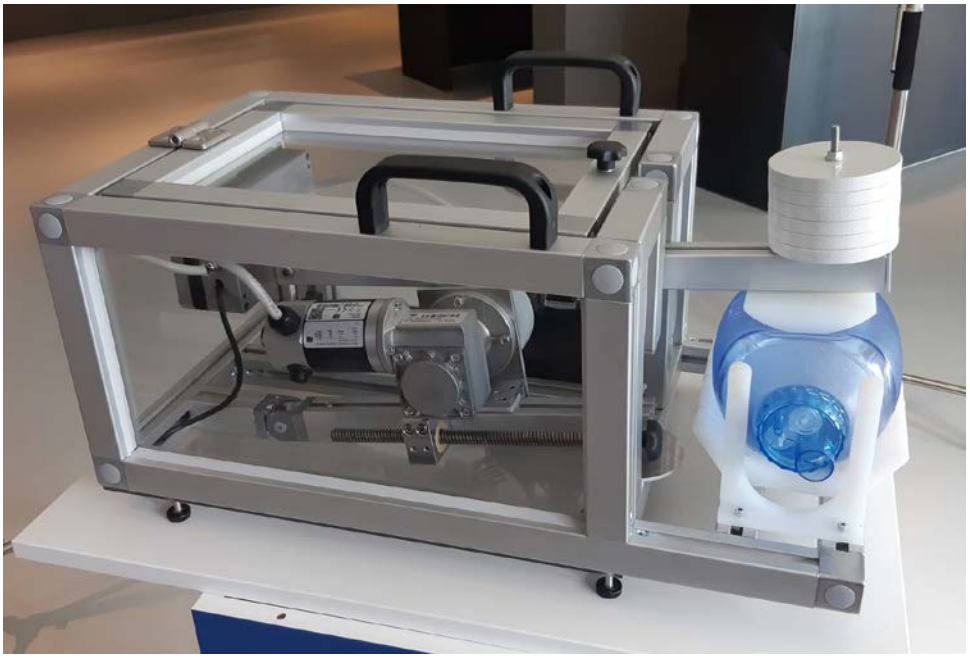
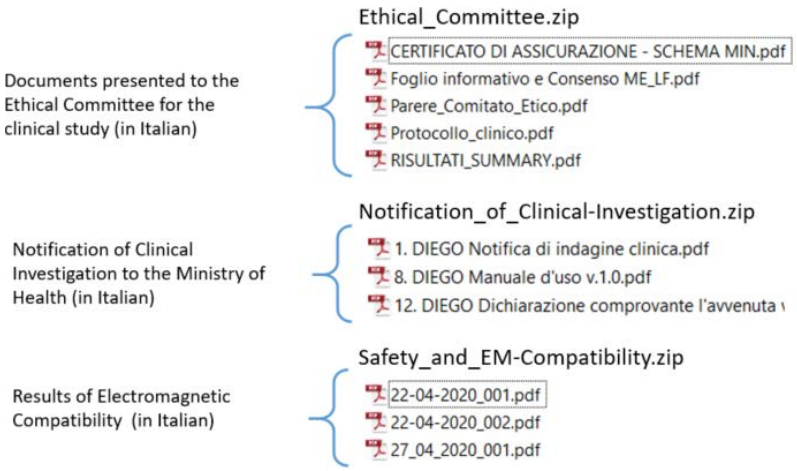


Figure 5: Industrial Version of DIEGO

6.3 ZIP FILES WITH CLINICAL PROTOCOLS AND ETHICAL COMMITTEE APPROVAL

Documents presented to obtain the approval for clinical investigation of the device and the notification to ministry of health and results of safety and electromagnetic compatibility tests.



7. LINKS TO VIDEO TUTORIALS

Video Tutorials can be found in to illustrate the principles of DIEGO and how the respiratory parameters can be adapted to the requirement of individual patients. A vide of a calibration procedure to be carried out in emergency situations is also provided.

1. https://youtu.be/KmhrXXin3xo Introductory video (4:20 min)
2. https://youtu.be/lO7aka40oSg Specifications (4.10 min)
3. https://youtu.be/8n5AUDEDy5A How to control the parameters (3:43 min)
4. https://youtu.be/UXPAUAVM0OU How to connect to a patient (8:43min)
5. https://youtu.be/J7Z1eaZoRpk Testing the Performance (6:30)
6. https://youtu.be/jKJEo3J4zx4 Emergency Calibration (20:12)