



## NONINVASIVE VENTILATION: THE IMPACT OF MACHINE CHOICE

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Successful application of noninvasive mechanical ventilation (NIV) in the acute and chronic settings depends on both clinical and technical issues. Clinical decisions, such as the correct indication of NIV or the adequate selection of the ventilation mode and settings are an obvious prerequisite for a successful treatment. However, technical aspects, such as the ability of the ventilator to deliver the prescribed respiratory support or to co-operate with the patient's spontaneous breathing instead of fighting against them, also play a major role in the definition of the outcome of NIV.

Although NIV is technically demanding and complex, the requirements imposed by European

and other international standards for lung ventilators are poorly defined. Therefore, the commercially available ventilators (all of them with CE mark in agreement with the European Directive on Medical Devices) exhibit a wide range of performances. Accordingly, the machine choice may have a considerable impact on the ventilatory support delivered to the patient, on patient compliance and, consequently, on the final clinical outcome of NIV.

### STRUCTURE OF A MECHANICAL VENTILATOR FOR NIV

The basic components of a typical mechanical ventilator are shown in

figure 1. The pressurised air provided by the pressure source is blended with the appropriate amount of oxygen and delivered to the patient through the pneumatic unit, which is activated by the control unit on the basis of the measurements provided by the built-in sensors and the ventilator parameters entered by the physician.

The pressure source provides the energy required to overcome the elastic and resistive load imposed by the patient's respiratory system and used to reduce their work of breathing. Current mechanical ventilators use two different approaches. On one hand, when the ventilator is designed to be used in an appositely structured environment (such as intensive or sub-intensive care units), the driving pressure is supplied to the ventilator by centralised medical gas distribution networks and special wall plugs (fig. 1a). The advantage of this approach is the high efficiency of the centralised system, the low noise of the machine and the improved reliability of the ventilator. On the other hand, if the ventilator is designed to operate where centralised compressed gas networks systems are not available, such as at a patient's home or in most hospital wards, it has to incorporate its own pressure source, which is most commonly constituted by a turbine driven by an electrical motor (fig. 1b).

Regardless of the pressure source, if the ventilator is able to control the oxygen fraction on the inspired gas ( $F_{I,O_2}$ ) the pressurised air is mixed with the appropriate amount of oxygen by the blender, and delivered to the patient by the pneumatic unit, which incorporates fast pneumatic valves that modulate the amount of gas flowing to the patient. Thanks to the recent progress in electronics and motors, in some modern units, the turbine is able to change its

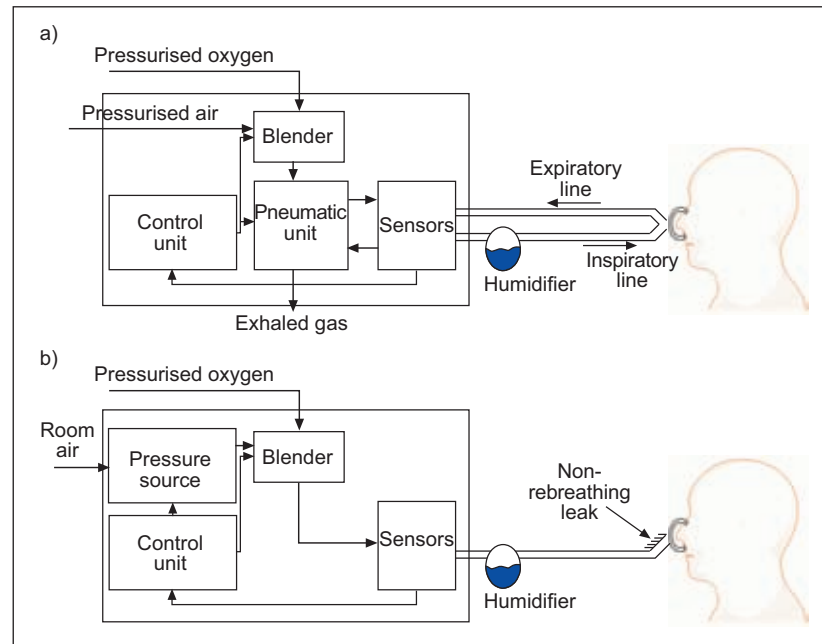


Figure 1. Schematic of the structure of commercial mechanical ventilators. a) Mechanical ventilator for intensive or sub-intensive care units. These machines are characterised by the use of an external pressure source (pressurised medical gas networks) and, in some instances, by the use of two different tubes, one for inspiration and the other for expiration, to connect the patient. b) Typical mechanical ventilator for home noninvasive ventilation. In this case, the machine incorporates its own pressure source, typically a turbine, and connects to the patient through a single tube. Re-breathing is avoided by the use of an intentional leak placed at the inlet of the mask. See text for details on the different components.

speed quickly enough to deliver the appropriate waveform of pressure or flow without the need of the pneumatic valve.

The magnitudes of pressure, flow and, eventually,  $F_{I,O_2}$  are continuously monitored by appropriate sensors inside the ventilator. These measurements are used by the control unit, the core of any modern mechanical ventilator, to control the pneumatic unit in order to provide the pressure and flow waveforms required by the modality of mechanical ventilation in use and by the prescribed ventilatory parameters. The availability of microprocessors able to execute several millions of operations per second has dramatically improved the performance of mechanical ventilators. Indeed, thanks to

these devices, it is possible to implement very complex control laws continuously defining the instantaneous expected value of flow or pressure and promptly adjusting the pneumatic valves if the measured values differ from the desired ones. These advanced control units have also allowed the introduction of new modalities of mechanical ventilation, such as proportional assist ventilation or adaptive pressure support to help nocturnal ventilation in patients with unstable central drive as for instance in patients exhibiting Cheyne–Stokes breathing.

The gas delivered by the pneumatic unit is applied to the patient through the breathing circuit. The tubing, including humidification systems, could add significant dead space to the ►

patient. Two different approaches are used by commercial ventilators to reduce dead space and hence re-breathing. In the first approach (fig. 1a), the ventilator is connected to the patient's interface by two different tubes, one is used for inspiration and the other for the expiration. In this configuration, which is widely used in intensive care unit ventilators, the total dead space added to the patient is limited to the volume of the connectors between the Y piece connecting inspiratory and expiratory lines and the interface to the patient. In the second approach (fig. 1b), which is the most widely used in NIV, there is a single tube connecting the ventilator to the patient. In this case, an intentional leak is added either to the mask or at the connection between the tube and the mask. The leak is designed to avoid re-breathing by facilitating all the expired gas to flow to the atmosphere before the following inspiration starts. This configuration has the important advantage of improving the comfort for the patient because the reduced connections with the ventilator makes easier for him/her to move while wearing the mask. However, to avoid re-breathing, the ventilator must impose a minimum pressure, typically 4 cmH<sub>2</sub>O, which constitutes the minimum positive end-expiratory pressure provided by these machines.

During NIV, the interface connecting the ventilator to the patient is typically a full-face or nasal mask. To reduce injuries on the patient's skin and, more generally, to optimise patient's comfort and tolerance, mask fitting to the patient has to minimise unintended air leaks without applying excessive pressure on the patient's skin. Therefore, the design and quality of the mask and its adaptation to the patient has important consequences in the final clinical outcome of NIV.

## PATIENT-VENTILATOR INTERACTION

The current technological advances in sensors, actuators and control systems allow the modern mechanical ventilators to provide very well controlled amounts of flow, volume and pressure to the patient. In NIV, however, one of the most challenging technical requirements is the need of a very accurate synchronisation with the patient because the ventilator should automatically adapt its cycling to his/her breathing. For this reason, it is very important that the control system in the ventilator

is able to adequately detect and respond when the patient starts either inspiration or expiration. Whereas most devices trigger the inspiration by detecting a small pressure/flow change induced by patient inspiration, the end of inspiration (and thus the start of expiration) can be set either by time (by indicating for how long an inspiration should be supported by the ventilator) or volume (by indicating the desired tidal volume) criteria.

During NIV, patient comfort is the major determinant of compliance to the treatment, finally compromising

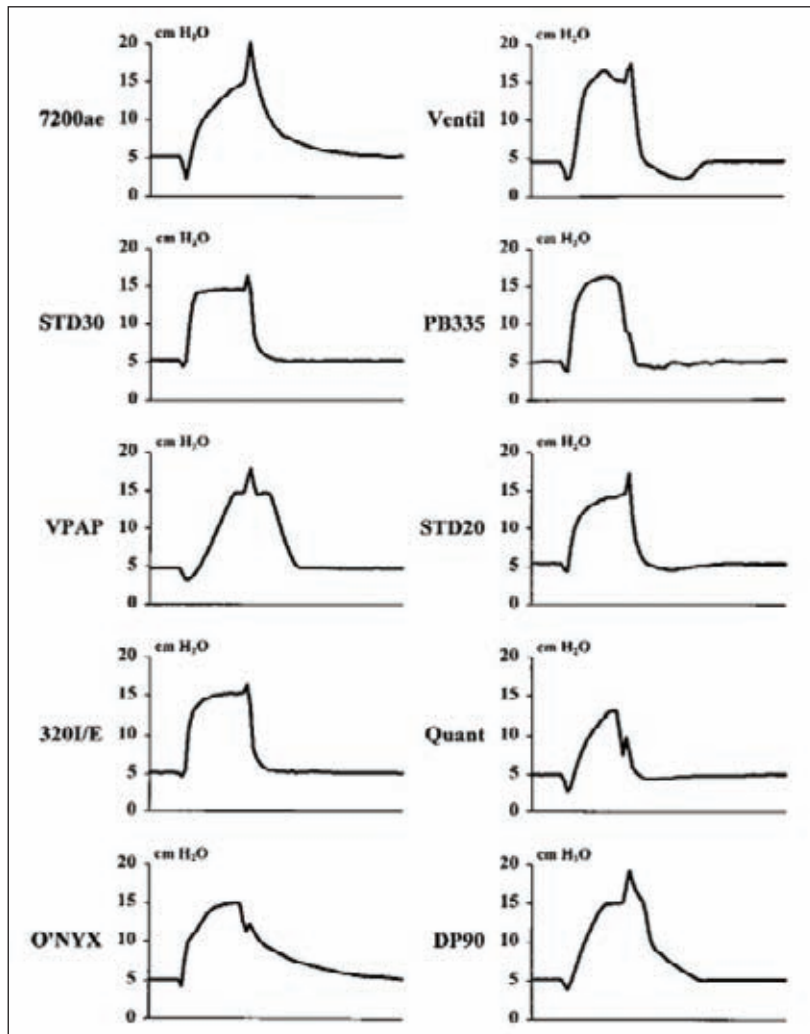


Figure 2. Airway pressure waveforms generated by different ventilators evaluated in a bench study. Lung model compliance was 50 mL H<sub>2</sub>O·cm<sup>-1</sup>, peak flow 60 L·min<sup>-1</sup> and pressure support at 10 cmH<sub>2</sub>O. Reprinted with permission from [1].

the overall effectiveness of the mechanical ventilation treatment. For this reason, several small but crucial details are likely to be the most characterising feature of a given device; among them, the rate of increase of flow or pressure during early inspiration, the inspiratory trigger sensitivity and the end inspiration cycling. It is noteworthy that nowadays these important technical issues, determining the actual quality of a ventilator, are neither standardised nor regulated by guidelines. Figure 2 shows an example of the different pressure waveforms produced by several device models operating with the same ventilatory parameters [1]. Consequently, there can be important differences in how an individual ventilator actually performs on an individual patient, despite using the same ventilatory parameters.

### **LEAKS DETECTION AND TRIGGERING**

The most characterising feature of NIV is the impossibility to provide a connection to the patient without air leaks. Even if major improvements in masks materials and design have significantly increased patient's comfort, unintended leaks (to distinguish from those intended to avoid re-breathing in single-tubing settings such as in fig. 1b) are always present. Moreover, the magnitude of these air leaks changes continuously with patient movements, postures and activity and with the amount of pressure (or volume) provided by the ventilator. The presence of unintended air leaks makes it impossible to have a direct precise measurement of the actual flow / volume inspired by the patient. As measuring ventilation is essential to provide the desired breathing support, actual patient ventilation must be estimated from the pressure and flow measured by the sensors in the machine through appropriate mathematical ►

algorithms. These algorithms, which are usually not disclosed by producers, are very important in determining the quality of a given ventilator. The efficacy of the algorithms operating the device is one of the most characterising features of a noninvasive mechanical ventilator. Indeed, these algorithms strongly affect the overall behavior of the ventilator mainly in two ways. First, they determine the ability of the ventilator to guarantee that the ventilatory support received by the patient really corresponds to the prescribed one. A second reason why ventilator algorithms are crucial in defining the performance of a ventilator is that the measured ventilation signals are used by the device to trigger inspiratory support as soon as inspiration is started by the patient. Accordingly, an error in the estimation of the amount of unintended air leaks affects the estimation of the patient's actual flow, likely resulting in ineffective inspiratory efforts from the patients (fig. 3) [2], long delays in recognising the beginning of inspiration (fig. 4) [3] or in ventilator auto-triggering.

### PERFORMANCES OF NIV MECHANICAL VENTILATORS: EVALUATION DURING BENCH TESTING

There are many variables which can affect the efficacy of NIV. On one hand, the characteristics of the patient's breathing pattern and the mechanical properties of the patient's respiratory system (namely his/her respiratory resistance and compliance) may affect the overall behavior of the device. On the other hand, the presence of unintended leaks and their change in magnitude with time may affect the inspiratory/expiratory trigger sensitivity and general performance of the ventilator. For this reason, several bench studies have been conducted to compare the functioning of different mechanical ventilators during NIV in ►

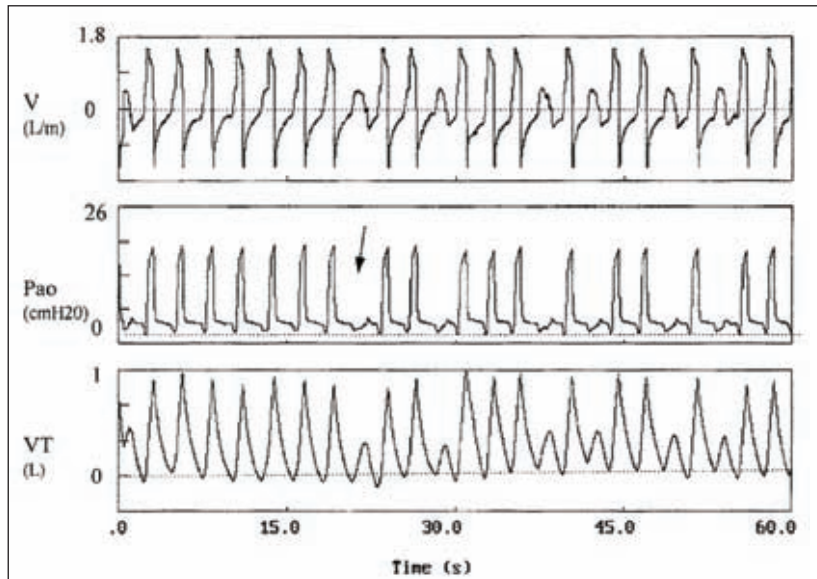


Figure 3. Signals recorded during assisted ventilation in a representative patient. An ineffective effort from the patient (arrow) is demonstrated by the presence of airflow in the absence of corresponding increase in the pressure applied to the airway opening of the patient ( $P_{ao}$ ). This was due to the failure of the ventilator in detecting the beginning of the patient's inspiration.  $V$ : patient flow;  $VT$ : tidal volume. Reprinted with permission from [2].

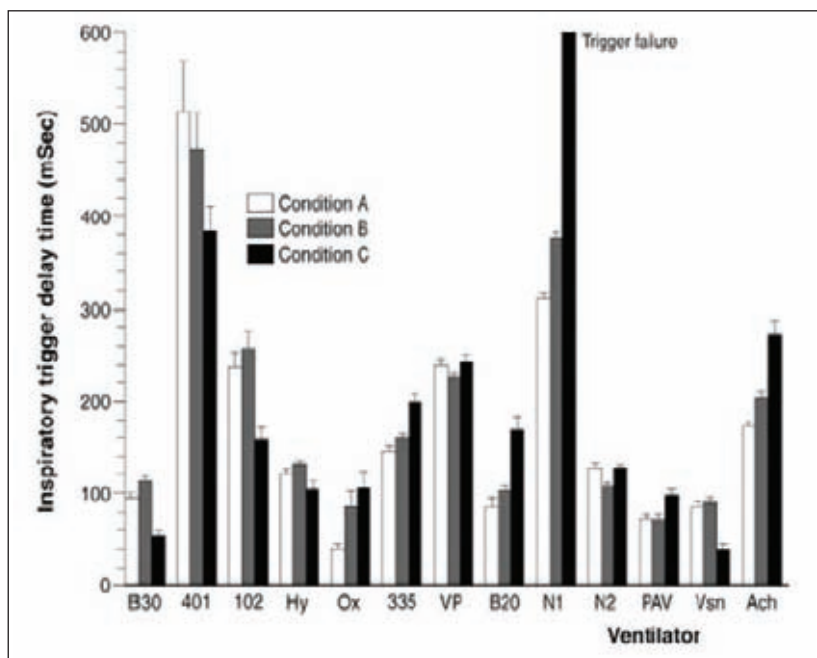


Figure 4. Comparison of inspiratory trigger delay times ( $\pm 95\%$  CI) obtained during bench testing by connecting the ventilators to a test lung simulating COPD with three levels of severity and varying the combinations of physiologic parameters and tidal volume. Condition A (the mildest) combined a resistance of  $3.6 \text{ cmH}_2\text{O}\cdot\text{s}\cdot\text{L}^{-1}$  and  $3.3 \text{ L}$  functional residual capacity (FRC); condition B combined a resistance of  $20 \text{ cmH}_2\text{O}\cdot\text{s}\cdot\text{L}^{-1}$  and  $3.3 \text{ L}$  FRC; and condition C combined a resistance of  $20 \text{ cmH}_2\text{O}\cdot\text{s}\cdot\text{L}^{-1}$  and  $6.3 \text{ L}$  FRC. Reprinted with permission from ref. [3].

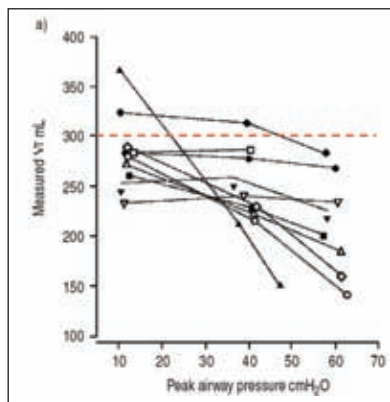


Figure 5. Tidal volumes (VT) observed for various ventilator devices tested when the VT set at 300 mL for various levels of inspiratory pressure (mechanical impedance of the simulated patient). Reprinted with permission from ref. [4].

well-characterised experimental conditions.

There are mainly two types of test lungs which have been used to assess mechanical ventilators during NIV: passive respiratory system models, which replicate the passive mechanical properties of the respiratory system (*i.e.* resistance and compliance) with different levels of detail, and active respiratory system models, which are usually made of a passive model connected to a computer-controlled actuator simulating the activity of patient's respiratory muscles.

Several studies have been published on the evaluation of NIV devices with test lungs. These studies showed that the performance of each model of mechanical ventilator is differently affected by changing patient conditions. For instance, figure 5 shows how the tidal volume delivered to a simulated patient subjected to volume control ventilation was affected by increasing the degree of airway obstruction [4]. Similarly, figure 6 shows that the tidal volume actually delivered to the patient by different machines also depends on the amount of leakage [5].

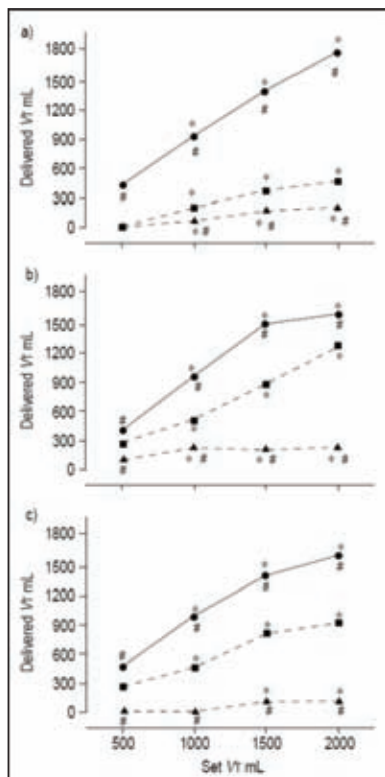


Figure 6. Effect of alterations in actually delivered tidal volume (VT) for different values of set VT in the absence and presence of leak for three different ventilators (a, b, c). ●: no leak; ■: small leak; ▲: large leak. Reprinted with permission from ref. [5].

It is important to underline that it is quite difficult to extrapolate the results of bench studies to predict how a ventilator will behave when applied to a specific patient. The reason is that it is impossible to realistically simulate the patient's characteristics (including artefacts, such as cough, speaking, swallowing, *etc.*). Moreover, it is very difficult to build a test lung able to respond by modifying its behavior as a consequence of the activity of the ventilator in order to mimic real patient-ventilator interactions.

### PERFORMANCES OF NIV MECHANICAL VENTILATORS: EVALUATION ON PATIENTS

Evaluating the performance of mechanical ventilators in patient

studies has the great advantage of testing the device under real-life conditions, including all the important features which cannot be simulated during bench testing. Unfortunately, the results of these studies have to deal with great variability and reduced repeatability.

A first question to address, when evaluating the performance of NIV in patients, is that the adequacy of a given device greatly depends on the ventilation mode, which is usually dependant upon the type of patient pathology. For instance, a given ventilator can operate optimally in pressure support mode and present some problems in volume control mode. Also, testing ventilators in patients is difficult because what clinical studies actually evaluate is not only the quality of a device but also the adequacy of the ventilator settings. Indeed, an apparent bad performance of a device could be due to an inadequate titration of the setting for the specific patient involved in the test.

Moreover, as it is not completely clear what are the features of NIV which are affecting patient comfort, there is a great variability in the reported degree of comfort between patients evaluating different devices (fig. 7) [2].

Given that NIV is progressively being used in the patient's home environment, where there is no continuous surveillance by health staff, quality control issues are very important. In a European survey, it was reported that quality control procedures were not standardised, showing great variability of procedures among centres and countries [6]. It was also found that some issues of quality control were insufficiently developed. In fact, it has been reported that ventilators used for long-term home therapy may actually provide a ventilatory assistance which does not coincide with that prescribed for the patient [7]. This fact may be relevant in clinical trials aimed at testing NIV ►

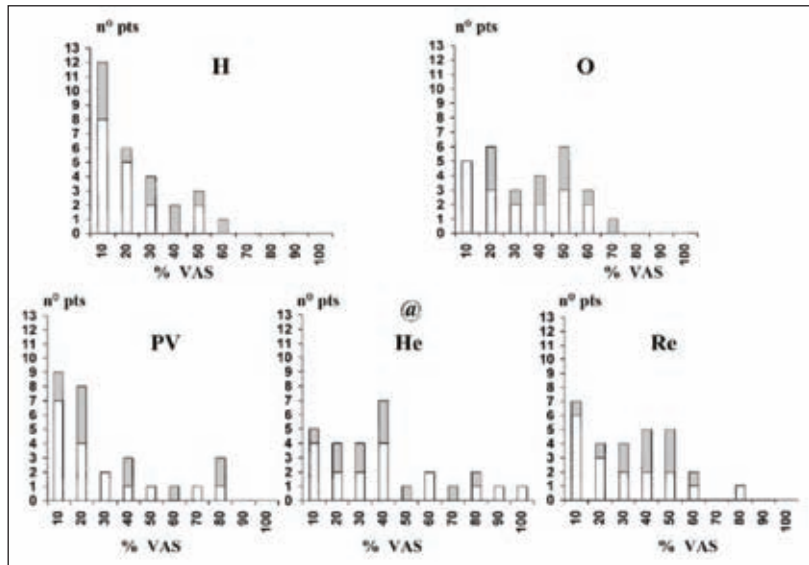


Figure 7. Distribution of patients according to the reported comfort level (VAS: visual analog scale) with different ventilators (H, O, PV, He, Re). Shaded portion of the bars: restricted chest wall diseases patients; non-shaded portion of the bars: chronic obstructive pulmonary disease patients. Reprinted with permission from ref. [2].

modes or cost-effectiveness in the home setting. Indeed, some negative results could be due to the fact that the patient is actually receiving inadequate ventilation. Accordingly, it is very important to monitor and store the ventilation data (pressures, volumes, leaks, frequency, etc.) so that the potential clinical effectiveness of NIV is evaluated, taking into account the

actual ventilation the patient has been receiving at home over the days and weeks. Fortunately, modern NIV devices provide digital storing and downloading capacity in this regard. In this context, systems for real-time monitoring of home ventilation would be of interest to improve ventilation comfort and effectiveness in difficult patients [8].

## CONCLUSIONS

The extensive published data available indicate that the actual performance of the different commercially available ventilators varies considerably. Specifically, the delivered airway pressure/volume and the inspiratory/expiratory triggering performance could depend on the patient characteristics and breathing pattern, with the result that the ventilatory support actually received by the patient could not exactly correspond to the ventilator settings. Although there are few patient studies comparing the impact of the ventilator performance in NIV, the available data indicate that machine-dependent issues such as pressurisation/flow-rate, triggering and cycling play a clinically relevant role in both the acute and chronic settings of NIV. As a consequence, the prescription of the optimal ventilator for NIV therapy requires the selection of the most appropriate device for each patient. Ideally, this would require the experimental comparison of how different devices perform with each individual patient. ■

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