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Non-invasive Ventilation – A century of experience

Frank van Rooyen, Krisztina Soltesz

Important note

Medical knowledge is subject to constant change due to research and clinical experience. The author of this booklet has taken great care to make certain that the views, opinions and assertions included, particularly those concerning applications and effects, correspond with the current state of knowledge. However, this does not absolve readers from their obligation to take clinical measures on their own responsibility.

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A century of experience**

Frank van Rooyen, Krisztina Soltesz

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Foreword

Since the first use of positive end-expiratory pressure ventilation in the late 1930's and early 1940's to treat cardiogenic pulmonary edema and other forms of non-hypercapnic respiratory failure, non-invasive ventilation (NIV) has come a very long way. Negative pressure NIV was used extensively during the major poliomyelitis epidemics of the 1950's, as well as later on in the chronic home care setting, but positive pressure NIV has become the accepted technique over the past twenty years [1].

The major evolution of NIV took place in the period ranging from the late 1980's and early 1990's to the present day in the fields of both chronic and acute respiratory failure.

Besides the accumulated evidence allowing an optimal strategy regarding clinical indications, long-term domiciliary NIV has been made much more efficient and user-friendly thanks to two important concomitant developments: the availability of dependable, powerful, compact and portable bilevel turbine-type ventilators, and major progress in NIV masks, in terms of materials used, adaptation to the patient's facial features, and overall comfort.

During that time, similar advances were made in the use of NIV to treat acute respiratory failure (ARF) [1]. The first studies were performed in patients with decompensated chronic obstructive pulmonary disease (COPD) [2]. Subsequently, evidence of the usefulness of the technique in avoiding endotracheal intubation in these patients accumulated, resulting in its acceptance as a standard of care in severely decompensated COPD [3, 4]. Studies performed in patients without COPD but with hypercapnic ARF yielded comparable results. In the setting of non-hypercapnic ARF, results of various studies have been somewhat contradictory and less convincing than in hypercapnic ARF [3, 4]. This is not surprising considering the large

heterogeneity of conditions manifested by non-hypercapnic ARF. However, both pathophysiological evidence and documented favorable outcomes point towards an increased recognition of the potential benefit derived from NIV in selected groups of patients [4, 5].

NIV is most often applied using a spontaneous-assisted mode such as pressure support (PS), proven to be equally efficient and more comfortable than controlled modes. However, to achieve an optimal interaction between the patient's respiratory activity and the intensity and timing of the ventilator's response can prove difficult and may result in patient-ventilator asynchrony, a situation which is worsened by the presence of leaks at the patient-mask interface [6]. Furthermore, leaks interfere with certain key ventilator functions such as triggering and cycling [7], which can worsen asynchrony. In turn, this leads to an increase in the work of breathing, discomfort and intolerance, the latter being associated with failure of NIV [8].

Therefore, successful and safe application of NIV in the setting of ARF requires minimization of leaks and their consequences on ventilator function, and optimization of patient-ventilator interaction.

The challenge involved is considerable. Indeed, having established that NIV is an indispensable tool in the treatment of several causes of ARF, we must now push the limits of our technology and know-how to provide NIV at its best to our patients. Several encouraging recent studies suggest some paths to follow in order to meet this challenge. Clinicians and researchers have gained better understanding of the pathophysiology of the control of ventilation and the mechanisms underlying patient-ventilator asynchrony, as well as the means to improve this problem [6, 9]. Some ventilator manufacturers have developed "NIV modes" which can, in many cases, attenuate the deleterious consequences of leaks on ventilator performance and asynchrony [7]. Finally, the automation of certain tasks such as titration of the level of ventilator support, detection of asynchrony and trigger and

cycling correction is being developed and the concept has already proved promising in clinical trials [10, 11].

The use of NIV is expected to increase considerably in the coming years, and clinicians, researchers and manufacturers will have to work closely to gain further knowledge and experience in dealing with its many challenges. It is of course beyond our reach to make NIV 100% successful, but we should strive to continue along the path of the considerable and impressive progress which has been made over just two decades to provide our patients with the highest possible level of care when using this technique.



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1.0 Introduction

In the past, patients suffering from acute respiratory failure were traditionally invasively ventilated via endotracheal intubation. In order to suppress spontaneous breathing and facilitate mechanical ventilation, sedation and sometimes muscle relaxation were used as well. Now, thanks to advances in our understanding of pulmonary mechanics and pathophysiology, the benefits of maintaining spontaneous breathing for as long as possible have become increasingly apparent.

It was in 1989 when Dräger introduced the Biphasic Positive Airway Pressure (BIPAP*) ventilation mode in the Evita ventilator. It was the first step toward a “Room to Breathe” concept which was later augmented with Dräger’s AutoFlow® and automatic tube compensation (ATC™) features. In 1995, as a response to new findings on lung protection during mechanical ventilation, Dräger introduced the innovative Evita 4. It was the first and only ventilator on the market that supported and stimulated spontaneous breathing during the entire respiration cycle in both volume and pressure controlled ventilation modes. Small tidal volumes and airway pressures below 35 cm H₂O were now broadly accepted goals in an effort to develop effective new protective ventilation strategies. Studies followed which demonstrated the benefits on gas exchange and lung recruitment with spontaneous breathing during BIPAP ventilation.

All the while, a different but similar form of BIPAP, known as BiPAP™, was being used with great success in the home care ventilation setting for the non-invasive treatment of OSA (Obstructive Sleep Apnea). Slowly, intensivists began to apply this non-invasive treatment to critically ill patients in order to avoid intubation or to offer non-invasive support after extubation.

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Several subsequent trials showed that NIV could reduce the length of stay on the ICU (Intensive Care Unit) as well as with intubation associated nosocomial pneumonia [12, 13, 14, 15].

This booklet will explain how the concept of NIV can be applied in hospitals in intensive care, medium care or emergency department in daily practice. It gives a clear overview of the different forms of respiratory failure which can be effectively treated with NIV. It will provide precise selection criteria for potential patients and describe in detail how NIV should be applied on the basis of those criteria. Because the psychological effects of mask ventilation and patient motivation are vital factors which, in many cases, can make the difference between success and failure, it will also take an in-depth look at the different types of masks, how to use them and what to watch for during therapy. Finally, the key characteristics of a modern ventilator and the potential benefits of NIV are described.

Initially, NIV may be somewhat more labor-intensive than conventional invasive ventilation, but benefits such as reduced length of stay on the ICU [16], shorter ventilation times [16] and the lower incidence of nosocomial pneumonia [17] and their subsequent positive effects in terms of both cost and outcome can make NIV well worth the effort.

The objective of this booklet is to provide the reader with a practical guideline for the use of non-invasive ventilation and is intended for personal study only. All medical statements and values in this handbook have been taken from the literature. It is beyond the scope of this booklet to validate the content and quality of these studies and no responsibility will be taken for errors or inaccuracies.



The therapy phases for a ventilated patient throughout the continuum from admission to discharge

2.0 NIV basics

WHAT IS NIV?

NIV – non-invasive ventilation is a broad term for any ventilation therapy applied in a non-invasive way, e.g. via a mask, nasal prongs or a helmet. Therefore, NIV, or NPPV (Non-invasive Positive Pressure Ventilation), is also very often referred to as “mask ventilation”. This is in contrast to “invasive ventilation”, where an endotracheal tube or a tracheal canula serves as an invasive interface between the patient and the ventilator.

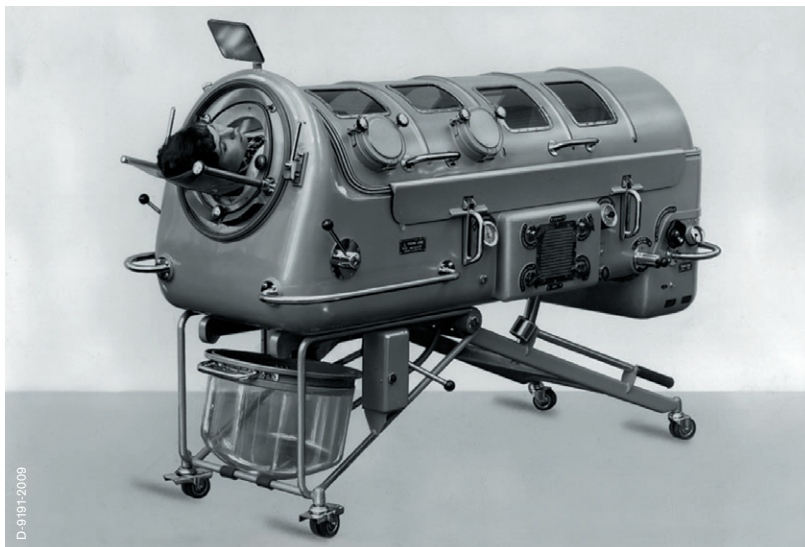
WHEN TO USE NIV?

NIV can be used either before intubation or following extubation. The classical use of NIV therapy in a hospital setting is following extubation, in particular in cases where spontaneous breathing is not sufficient for adequate gas exchange. Here, the goal of NIV is to promote the weaning process and avoid reintubation [18]. Increasingly, the early use of NIV on the ICU now serves as a first line interventional tool to prevent intubation [12]. Ideally, the entire spectrum of ventilation therapy (prevent – stabilize – wean – recover) can be adequately covered using NIV.

Another classical application of NIV therapy is in the home care environment, where it is primarily used to provide respiratory support in patients with OSA.

WHAT IS NEEDED FOR NIV?

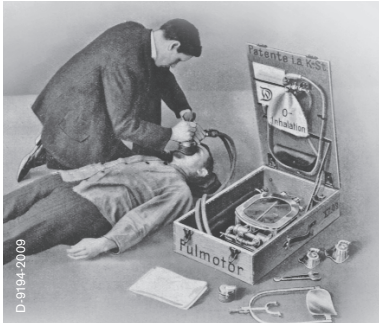
There are three prerequisites for NIV, the first and most important being a conscious, cooperative patient. The second is a NIV-capable ventilator equipped with leak compensation and smart measures to avoid auto-triggering. Thirdly, a well-fitting mask is vital for the success of NIV therapy. These prerequisites will be described in more detail later on in this booklet.



Dräger iron lung model E 52 with electric drive (1952)

3.0 History, trends and challenges of NIV

The first apparatus used for non-invasive ventilation was a whole body ventilator in which the patient was enclosed up to the neck in an airtight box. Invented by the Scottish physician John Dalziel (1838), this body ventilator relied on the cyclic application of positive and negative pressure to the body to support spontaneous breathing. Both huge and expensive, this manually operated ventilator did not come into widespread use. Based on this early work, Philip Drinker developed the first electrically-driven iron lung in 1929. This ventilator was later improved on by J.H. Emerson in Cambridge, Massachusetts in 1931, who made it lighter, less expensive and



The Dräger pulmotor in use.



NIV ventilation with Carina®.

added a manual backup drive system in case of a power failure. It was this type of ventilator which was predominantly used during the poliomyelitis epidemic of the 1950's, but a few were still in use all the way up to the beginning of this century.

As the need for a more portable model of the iron lung grew, R. Eisenmenger was inspired to develop the cuirass ventilator, which was patented in 1928. These chest shell ventilators were later improved on by Fairchild-Huxley and Monaghan and introduced in 1949. This type of non-invasive ventilation is still in use today in the home care setting.

In 1907, a pioneer in the field of developing ventilators, Heinrich Dräger, received a patent on the Pulmotor, a non-invasive ventilator. It was the birth of the mobile rescue ventilator. The first models had a fixed pressure cycling period and were powered by pressurized oxygen. Negative pressure was used to support exhalation. When measured against today's insights on protective ventilation, this ventilator was hopelessly inadequate, but it may have facilitated lung drainage and helped re-establish spontaneous breathing in its early applications in near-drowning victims. These prototypes were developed as single hose systems, which in turn caused CO₂ rebreathing

issues. When production started up in 1908, Heinrich Dräger's son Bernard changed the single hose to a dual hose system. Thirty-eight years later, Pulmotor number 12.000 left the production line in Lübeck.

Today, a wide variety of non-invasive ventilators are available which can be differentiated into two groups: sophisticated intensive care ventilators with a NIV option, and the less complicated NIV devices for use in the sub-acute and home care environment. The first group uses a high pressure gas inlet for both oxygen and air provided by a central gas supply, while the second group uses low and/or high pressure oxygen inlets only. For compressed air, these ventilators are equipped with either a blower or turbine technology. Turbine driven ventilators achieve higher inspiratory pressure and flow than blower operated devices, which are predominantly used for patients with OSA in a home care setting.

Current trends in hospitals show that NIV is being used more frequently and for a wider range of conditions than ever before. Patients with chronic obstructive pulmonary disease make up a large portion of the total population treated with NIV therapy on the ICU.

Following the introduction of better equipment and improved masks, interest in NIV has increased sharply. Enhanced leak management and a reduction in the incidence of facial lesions caused by poorly-fitting masks have served to further push the popularity of NIV.

4.0 Patient classification and categories of acute respiratory failure

In the past, the standard management for patients in the ICU suffering from severe acute respiratory failure included endotracheal intubation and mechanical ventilation. Today, it is becoming increasingly common to consider NIV as a first option. In order to decide whether therapy with NIV is indicated, a careful analysis of both the type and the underlying cause of respiratory failure is necessary. The success of NIV depends on several factors:

- Proper patient selection
- Correct classification of the respiratory failure type
- Knowledge of the underlying pathology
- Appropriate interface selection
- Skills and expertise of the care team
- Proper timing, i.e. when to start or stop NIV
- Ventilator capabilities with regard to leak management and auto-triggering

4.1 PATIENT SELECTION

Selecting the right patient, applying adequate ventilation support with an appropriate setting as well as the use of an optimal patient interface are all essential factors that can make the difference between failure and success.

A detailed understanding of the various causes of ARF and the underlying pathology are essential for the decision making process. A first set of selection criteria might be based primarily on clinical indicators, such as the severity of dyspnea, tachypnea, the recruitment of accessory muscles and the presence of paradoxical abdominal breathing.

COMPLY WITH THE FOLLOWING ENTRY CRITERIA BEFORE STARTING NIV

Indications for NIV*	Contra-indications NIV
moderate or severe dyspnea	respiratory arrest
respiratory rate ≥ 25 breath/min	impaired consciousness
use of accessory muscles	hemodynamic unstable
presence of paradoxical breathing	cardiac ischemia
$\text{PaCO}_2 > 45$ mm Hg / 6 kPa	arrythmias
$\text{PaO}_2/\text{FiO}_2 < 300$	hypotensive shock
$7.25 \leq \text{pH} < 7.35$	excessive secretions
	inability to clear airway
	agitated and not cooperative
	facial abnormalities that are affecting the acceptance and fit of the mask, e.g. burns, surgery, anatomic

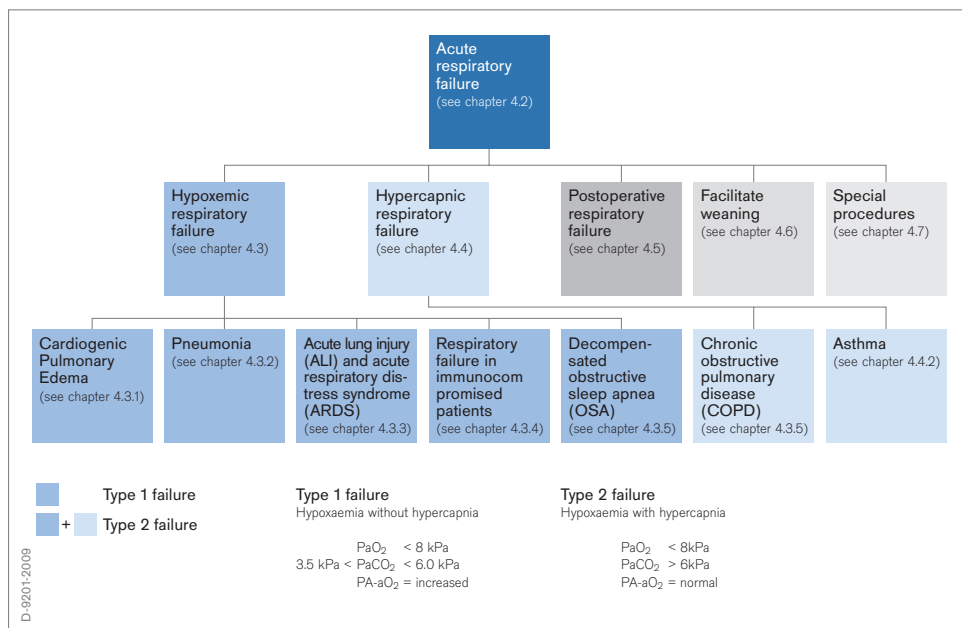
*NIV is indicated if two criteria are applicable

The type of ventilator accessible for therapy, its ventilation mode options and the available interfaces must also be taken into consideration, the later being of particular importance, as it has been shown that the patient interface often determines the success rate of NIV therapy.

4.2 DIFFERENTIATING ARF

Acute respiratory failure (ARF) is defined as the inability to maintain adequate pulmonary gas exchange and is characterized by abnormal levels of arterial PaO_2 and PaCO_2 blood gas tensions. The determination of arterial blood gases is important because it helps to differentiate between Type 1 and Type 2 failure.

A patient with Type 1 failure is hypoxemic and has a normal or low PaCO_2 . Oxygenation is affected by intrapulmonary venous admixture caused by pneumonia, emphysema or acquired respiratory distress syndrome (ARDS), which results in ventilation-perfusion mismatch. In most situations, oxygen therapy with or without CPAP (Continuous Positive Airway Pressure) therapy is sufficient to improve the situation.



Differentiating ARF

Patients suffering from Type 2 failure show a combination of hypoxemia and hypercapnia caused by airway obstruction, as in asthma and COPD, as well as a loss of diffusion area, as is the case with emphysema. These patients require ventilatory support, given as PS, BIPAP or even volume controlled ventilation (VCV) in order to restore acceptable arterial blood gas values.

Acute respiratory failure can be differentiated into 5 sub-classifications, each having one or more subgroups.

4.3 HYPOXEMIC RESPIRATORY FAILURE

Hypoxic respiratory failure is present in patients with resting dyspnea, a $\text{PaO}_2 / \text{FiO}_2 < 300$ mmHg and a respiratory rate $> 30/\text{min}$. A large, randomized study conducted by Antonelli et al. concluded that in 70% of the selected patients, intubation was avoided by using NIV therapy [19]. There are many conditions which are unrelated to COPD which can lead to hypoxic respiratory failure. Many subgroups can be defined, the most important of which are mentioned hereafter:

4.3.1 CARDIOGENIC PULMONARY EDEMA

Patients with cardiogenic pulmonary edema have a reduced functional residual capacity which can be effectively treated with non-invasive ventilation [20]. The use of continuous positive airway pressure (CPAP) with pressures between 10-13 cm H_2O will recruit collapsed alveoli and help reduce the work of breathing. Additional pressure support eases spontaneous breathing and helps reduce respiratory rate and alleviate dyspnea rapidly [21, 22].

4.3.2 PNEUMONIA

Pneumonia is an infection of the lung caused by bacteria, viruses, fungi or a combination of these pathogens. In adults, the most common form is bacterial streptococcal pneumonia, whereas in children, pneumonia caused by infections with *Mycoplasma* sp. is more frequent. In the elderly, patients suffering from dysphagia, often seen following a stroke or in Parkinson's disease, are affected most often.

Ventilator associated pneumonia (VAP) is often considered to be a greater potential threat because of the enhanced virulence observed in bacteria found in hospitals.

In addition to antibiotic therapy, NIV can be used in patients with pneumonia who are suffering from ARF. The often unpredictable course of pneumonia requires a carefully monitoring of the patient.

In the literature, there is some dispute as to the effects of NIV in patients with pneumonia. In some studies, NIV improves outcome, especially in patients with COPD [23, 24, 25]. On the other hand, several randomized, controlled trials demonstrated a higher failure rate for NIV, with more patients requiring intubation [19, 26]. In most situations, non-invasive CPAP therapy is sufficient and improves oxygenation, reduces the respiratory rate and alleviates dyspnea.

4.3.3 ACUTE LUNG INJURY (ALI) AND ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

ALI and ARDS are inflammatory disorders of the lung. ALI is caused by direct injury of the lung caused by pneumonia, aspiration or trauma and is characterized by:

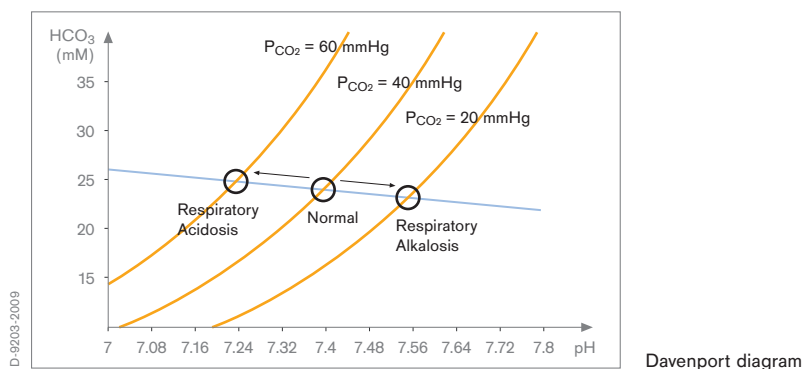
- bilateral pulmonary congestion (x-ray)
- pulmonary capillary wedge pressure ≤ 18 mmHg
- $\text{PaO}_2/\text{FiO}_2 < 300$ (ALI)
- $\text{PaO}_2/\text{FiO}_2 < 200$ (ARDS)

ARDS is a more severe form of ALI.

The success rate using NIV in this group of patients is about 50% [28]. In a recent prospective, multicenter study, it was found that NIV, used as a first line option, prevented intubation in 54% of the patients treated [27].

4.3.4 RESPIRATORY FAILURE IN PATIENTS WITH COMPROMISED IMMUNITY

In this group, patients develop hypoxemic respiratory failure as a response to organ or bone-marrow transplantation. The benefits of NIV versus intubation on patient outcome are mainly related to the reduced risk of septic shock, ventilator associated pneumonia (VAP) or nosocomial infections [28].



4.3.5 DECOMPENSATED OBSTRUCTIVE SLEEP APNEA (OSA)

Patients with obstructive sleep apnea (OSA) can develop ARF if the periods of hypoxemia and hypercapnia are getting longer and finally resulting into cardiopulmonary failure. Particularly obese patients with OSA can develop an ARF if breathing cost too much energy and if hypercapnia is associated with pulmonary hypertension. These patients are responding very well to a non-invasive CPAP therapy [26].

4.4 HYPERCAPNIC RESPIRATORY FAILURE

Hypercapnic respiratory failure is a Type 2 failure and is usually caused by hypoventilation. For reasons of clarity, this booklet will deal only with those forms of hypercapnic respiratory failure caused by tangible underlying pulmonary disease. Prolonged hypoventilation results in an acute respiratory acidosis with an increase of bicarbonate [HCO_3] ion concentration and a decrease in blood pH. It is important to differentiate between acute and chronic respiratory acidosis because treatment is different. In chronic respiratory acidosis, one can observe increased PaCO_2 but nearly normal pH (see page 17, Differentiating ARF).

This is possible because the kidneys can compensate the pH by stepping up acid excretion (renal compensation). The response time for this mechanism is slow ($> 48\text{h}$), and stands in contrast to the much faster respiratory mechanism which can react within minutes. Hypercapnic respiratory failure can be differentiated to the following subgroups:

4.4.1 CRONIC OBSTRUCTIVE PUMONARY DISEASE (COPD)

Chronic Pulmonary Obstructive Disease (COPD) is a preventable condition seen mainly in patients with a history of smoking. This subgroup represents the largest patient population to benefit from NPPV. The incidence of COPD increases with both age and severity of the smoking habit. Other, less frequent causes of COPD include viral or bacterial infections and allergic reactions to inhaled particles. The disease is characterized by inflammation of the bronchi, resulting in increased secretion production and airway narrowing. Symptoms include continuous coughing and dyspnea.

An allergic reaction can induce an exacerbation of COPD. Based on the results of several randomized trials it is recommended to consider NIV as a first option in patients with COPD suffering from acute hypercapnic respiratory failure with a $\text{PaCO}_2 > 6.0 \text{ kPa}$ and $\text{SpO}_2 \leq 88\%$ [29, 30]. For this group of patients, a large amount of evidence supports the idea that NIV can reduce intubation rates, length of hospital stay and the incidence of airway infections [13, 31].

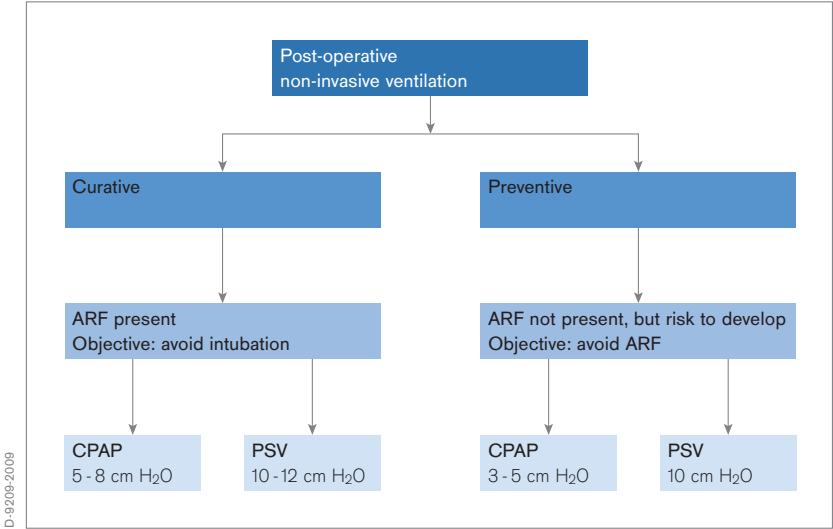
4.4.2 ASTHMA

Asthma is a chronic disease characterized by episodes of airway constriction and inflammation, sometimes accompanied by excessive mucus production. An asthma attack can be triggered by a wide variety of external stimuli such as cold air, sports, stress, smoke, and a large number of allergens. Inhalation therapy with bronchodilators is effective and alleviates airway constriction. Typical signs of an acute asthma attack include wheezing, prolonged expiration, increased heart rate and the extensive use of accessory muscles. The latter can be clearly recognized during inspiration by observing the sternocleidomastoid muscles, which are literally drawn in by the patient's greatly increased respiratory effort.

For patients with severe asthma suffering from acute respiratory failure, there is less evidence that NIV is always the best approach to begin with. However, several trials in patients with a status asthmaticus have demonstrated gas exchange improvement and a reduction of intubation rates [32, 33]. It is recommended to monitor these patients carefully and to intubate promptly if the situation deteriorates, or if there is no improvement after two hours of NIV therapy.

4.5 POSTOPERATIVE RESPIRATORY FAILURES

NIV is often used as a preventive therapy to restore a breathing pattern following surgery. Temporary upper airway obstruction due to swelling of the glottis is a frequent phenomenon and can cause ARF. For such patients, NIV with PSV (Pressure Support Ventilation) is a good alternative to reintubation, as it can rapidly improve lung mechanics and gas exchange [34, 35]. The literature shows predominantly positive results when NIV is used in postoperative patients. However, NIV should be discontinued in patients with ARF and concomitant surgical complications requiring major re-intervention. This group of patients will require intubation and controlled ventilation in any case.



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Cardiac surgery

Following cardiac surgery, patients frequently show altered breathing patterns. This is mainly due to pain and diaphragm dysfunction and leads to smaller tidal volumes and a higher respiratory rate in order to maintain adequate gas exchange. This in turn causes alveolar hypoventilation and the development of atelectasis. Preventive treatment with NIV is possible using CPAP therapy with 3-5 cm H₂O and, if necessary, additional pressure support ventilation PSV with a pressure of 10 cm H₂O.

Thoracic surgery

For patients who develop respiratory failure following lung transplantation, some studies show positive results with a significant reduction in the need for invasive ventilation from 50% to 21%. Prophylactic use of NIV following

lung resection have shown to result in a much lower incidence of atelectasis than in a control group [36].

Abdominal surgery

Patients who have undergone gastropasty, cholecystomy or thoracoabdominal surgery show significant improvement when treated with NIV during the first 24 hours after surgery with moderate PSV therapy (10-12 cm H₂O) [60]. Caution must be exercised when applying NIV at higher levels of PSV in the early postoperative phase in patients with new gastrointestinal anastomosis, since the accidental insufflation of air into the GI tract can leak through the sutures into the abdomen. In these patients, non-invasive CPAP therapy alone is preferred, and if PSV is deemed necessary, the pressure should be kept below 8 cm H₂O. In general, NIV used as a curative therapy shows very positive results, with a reduction of intubation rates of up to 70% [51, 52].

4.6 FACILITATION OF WEANING

Following extubation, non-invasive ventilation is being used increasingly as the next step in the weaning process. Outcomes of several randomized, controlled studies have shown that NIV reduces the time needed to successfully wean patients from the ventilator, thereby reducing the length of stay on the ICU, the duration of hospitalization as a whole as well as the risks and costs of infections associated with endotracheal intubation [2, 27, 30].

4.7 SPECIAL PROCEDURES

NIV is commonly used in critical ill patients before planned intubation. Here, NIV serves to pre-oxygenate the patient, helping to avoid hypoxic respiratory failure during the course of intubation.

Along these lines, NIV is often used in preparation for other short procedures such as endotracheal suctioning or bronchoscopy, where a drop in oxygen saturation is to be expected.

5.0 Prerequisites for NIV therapy – the first steps

THE PATIENT

After selecting the right patient for NIV, it is important to inform the patient as to what will happen next. Proper instruction, encouragement and motivation are essential factors for success. Before commencing NIV therapy, the patient should first be allowed to experience the feeling of the face mask. With the caregiver holding the mask, the patient should take 5-10 breaths, letting the patient become accustomed to the support of a ventilator. Start NIV with very low PEEP and PS levels to allow the patient to accept NIV. After a number of breathes slowly increase PEEP and PS to the desired settings, carefully monitoring patients response.

The patient should be very closely monitored for at least the next 30 minutes, and frequent checks should be performed to ensure that the patient is comfortable. If this is the case, observation intervals can be gradually increased. However, some patients may claim to be comfortable when the opposite is true. It is therefore important to correlate such statements with clinical observations. Highly motivated patients, doing their very best to breathe spontaneously, can sometimes exert themselves to the point of complete exhaustion. This is a potentially serious situation which may require conversion to a more invasive ventilation mode or even rapid intubation.

INTERFACE AND COMFORT

It is recommended to select a mask with a soft cushion (e.g. gel cushions are highly comfortable) of appropriate size. Preferably, the mask can be further molded to achieve a better fit, reducing leakage. With a well-fitting mask, the cushion provides equal pressure distribution over the face. This is less irritating for the patient and there is a reduced risk of skin lesions. Gentle tightening of the straps is usually all that is necessary; the need for excessive tightening is an indication that the mask is not of the appropriate size or shape to the face (for more information on masks, see the chapter 6.0 The interface).

MT-1188-2008



Evita Infinity® V500

MT-0495-2008



Evita XL

MT-1029-2008



Evita 4 edition

MT-766-99



Evita 2 dura

MT-0023-2008



Savina

MT-0514-2008 | 0513-2008



Carina® and Carina® home

MT-154-2001



Oxylog® 3000

MT-4300-2007

Oxylog® 2000 *plus*

MT-0472-2008

Babylog 8000 *plus*

THE VENTILATOR

Today, NIV on the ICU is being used increasingly as a first line intervention option to prevent respiratory function from deteriorating to the point where intubation becomes necessary [37, 38, 39, 40]. Nearly all current Dräger ventilators, such as the Evita Infinity® V500, Evita XL, Evita 4 edition, Evita 2 dura, Savina, Carina® as well as the transport ventilators Oxylog® 3000 and Oxylog 2000 plus are suitable for non-invasive ventilation. For the Savina, as well as the Evita and Oxylog® 2000, NIV requires an optional software upgrade. This upgrade provides leak compensation for leaks of up to 180 l/min (100 l/min for Oxylogs) and includes a smart algorithm for automatic adjustment of trigger sensitivity.



NovaStar® NIV full-face mask with standard elbow.



NovaStar® NIV full-face mask with anti-asphyxia valve and exhalation ports.

Furthermore, it allows enhanced alarm management, data and waveform monitoring. Automatic leak compensation and trigger adjustment ensure that patients can breathe spontaneously at the highest level of comfort while maintaining a degree of trigger sensitivity that would normally only be possible in a leak-free circuit.

The Evita Infinity® V500, Evita XL, Evita 4 edition, Evita 2 dura and Savina are used with a double limb system, i.e. an inspiratory hose and an expiratory hose connected with a y-piece to the mask. All mentioned ventilators using dual limb systems and with a built-in safety valve for ventilator failure require a NIV mask with so called standard elbow (SE). These masks are also known as non-vented NIV masks (see chapter 6.1 Choice of interface: vented versus non-vented systems).

The other category of NIV masks includes interfaces with integrated anti-asphyxia-valve (AAV) and exhalation ports (EP). These types of masks are usually used in combination with single limb systems and are named vented NIV masks.

If the single limb system has an integrated leakage valve and the ventilator has a built-in safety valve for ventilator failure, as it is the case for the Carina® system, a non-vented mask can be used in the hospital or institutional environment.

6.0 The interface

NIV represents a true advance in the management of both chronic and acute respiratory failure [41]. Apart from the choice of ventilator type, mode and settings, another crucial issue is the optimal interface. A broad range of patient interfaces is available, but until now, little attention has been focused on how to choose the right interface. Furthermore, there is no generally accepted consensus on interface management [42]. The following comments will focus on these five types of interfaces in a hospital or institutional setting.

In general, there are five different types of factory-made patient interfaces:



The full-face mask

The full-face mask covers nose and mouth. For this reason, this mask type is often called oronasal mask.



The nasal mask

The nasal mask covers the nose only, as its name indicates.



The nasal pillow

The nasal pillow – also called nasal prong – usually consist of silicone rubber and is introduced directly into the nostril.



The total-face mask

The total-face mask covers the entire face.



The helmet

The helmet is a transparent cylinder made of soft PVC which covers the entire head of the patient. Cushion-like elements ensure a nearly airtight seal at the neck and shoulder areas.

6.1 CHOICE OF INTERFACE: VENTED VERSUS NON-VENTED SYSTEMS

The choice of interface is influenced by numerous factors including the type of respiratory failure, patient condition, tolerance and type of ventilator. Once the interface (nasal, full-face, total-face etc.) is chosen, the type of interface system (non-vented or vented) must be selected. Technically, this is stipulated by the breathing system (incl. ventilator and breathing circuit) used. There are two major prerequisites for interfaces used in NIV:

- Sufficient CO₂ management (elimination)
- Adequate safety precautions in case of ventilator failure in order to avoid asphyxia / CO₂ narcosis.

Table 3 summarizes the most common combinations used with NIV in the hospital environment. However, always consult the instructions for use of the ventilator and its accessories before commencing therapy.

TABLE 3 – TYPES OF BREATHING SYSTEMS

System type	Built-in Safety valve in the ventilator	Type of circuit	Interface form	Interface type	Sufficient CO ₂ management	Adequate safety precautions in case of ventilator failure (Asphyxia / CO ₂ narcosis)
Active	Available	2 limb circuit system	non-vented	Interface (nasal, full-face, total-face masks) with standard elbow	Less relevant as inspiration / expiration take place separately	Built-in safety valve in the ventilator provides the patient access to room air in case of ventilator failure
	Not available	1 limb circuit system with "true" expiration valve	non-vented	Interface (nasal, full-face, total-face masks) with standard elbow	Maintained by expiration valve	Expiration Valve allows the patient to access room air in case of ventilator failure (pressure drop)
Passive	Not available	1 limb circuit system with leakage valve	non-vented	Nasal mask with standard elbow	Relevant to a lesser extent; CO ₂ elimination is maintained by leakage valve	Patient can breathe through his/her mouth in case of ventilator failure
	Not available	1 limb circuit system with leakage valve	non-vented	Full-face mask with standard elbow	Maintained by leakage valve	Only in hospital environment! Adequate alarm management must be available for ventilator failure! Medical stuff must immediately enable the patient to have access to room air in case of ventilator failure.
	Not available	1 limb circuit system with leakage valve	vented	Full-face mask with anti-asphyxia valve only (no exhalation port)	Maintained by leakage valve	Anti-asphyxia valve allows the patient for access to room air in case of ventilator failure (pressure < 3cm H ₂ O)
	Not available	1 limb "simple" circuit system	vented	Full-face / total-face masks with anti-asphyxia valve AND built-in exhalation ports in the masks	Maintained by exhalation ports incorporated in the mask	Anti-asphyxia valve allows the patient for access to room air in case of ventilator failure (pressure < 3cm H ₂ O)

One must differentiate between non-vented and vented NIV masks. Masks are usually called non-vented if they have a so called standard elbow. The mask elbow is usually colored blue to “warn” the user that it does not have an anti-asphyxia valve or exhalation ports.

Masks with anti-asphyxia valve and incorporated exhalation ports are usually called vented. The anti-asphyxia valve is a safety valve allowing the patient to breathe room air if the ventilator fails (pressure < 3 cm H₂O). The exhalation ports maintain CO₂ flush during NIV. The mask elbow is usually white / transparent so that the user can observe the position of the anti-asphyxia valve. Exhalation ports are usually incorporated into the mask body or mask elbow.

The breathing system (ventilator plus breathing circuit) is usually referred to as “active” if there is an (active) safety valve integrated in the ventilator or breathing circuit which allows the patient to breathe room air in case of ventilator failure (e. g. breathing circuits with true expiration valve, ventilators with built-in safety valve). If there is no active safety valve built in to the ventilator or the breathing circuit, the breathing system is usually referred to as “passive” (e. g. breathing circuit with a leakage valve only).

Although, there usually are sufficient alarm systems for ventilator failure and CO₂ monitoring during NIV ventilation in the hospital and institutional environment, the incorrect set up of the entire breathing system (incl. ventilator, breathing circuits, and NIV masks) can result in the clinical risk that the patient does not receive sufficient ventilation. Insufficient ventilation may lead to severe clinical consequences. For this reason, all product instructions for use must be consulted prior to use as well as the entire breathing system should only be installed by clinicians who have extensive experience in NIV ventilation.

The masks described above (non-vented or vented) are in widespread use in hospital settings. However, full-face masks equipped with an anti-asphyxia valve only (no exhalation ports) are also available. These masks are generally used with an additional leakage valve system placed within the breathing circuit or between the circuit and the interface. The CO₂ maintenance is carried out by the leakage valve, whilst the anti-asphyxia valve in the mask ensures the access to room air in case of ventilator failure. However, a more modern solution is a full-face mask with an anti-asphyxia valve and incorporated expiration ports and a simple single gas delivery circuit. This system is also associated with less dead space and more effective CO₂ reduction. Furthermore, a ventilator with a single limb circuit and a leakage valve is very often used in combination with nasal masks (e. g. chronic settings or weaning).

6.2 MAJOR CHALLENGES FOR PATIENT INTERFACES

The following sections discuss the major challenges faced in conjunction with NIV interfaces.

6.2.1 MINIMIZING LEAKS

Minimizing leakage is the most important challenge in NIV. Leaks result either from a poor seal between the mask and the skin or through the open mouth, reducing alveolar ventilation and synchrony between the patient and the ventilator [41]. The amount of leakage should be monitored and will influence the choice of mask type.

While using a nasal mask or nasal pillow, an open mouth can cause a loss of inspiratory volume. If mouth leakage is continued over long periods, it can lead to critical swelling of the nasal mucous membranes if high nasal airflow is present. In this case, a more suitable solution could be the use of a full-face mask.

If oxygen is being applied, leaks will of course cause a loss of oxygen in the airflow. Therefore, when oxygen is applied from an external source, given at a defined flow rate via a T-piece, care must be taken to ensure that the resultant oxygen concentration is sufficient for the patient. Correcting the problem may involve improving the seal of the mask, increasing the oxygen flow, or both.

In addition, it should be ensured that high-velocity airflow does not escape from the mask upwards into the patient's eyes, which can cause eye irritation and conjunctivitis [45].

6.2.2 MAXIMIZE COMFORT

The next major challenge is finding an interface which is comfortable, and free of unwanted side-effects. Although NIV is generally perceived as more comfortable for patients than invasive ventilation, mask intolerance remains a major cause of NIV failure. Failure rates range from below 10% to over 40%, despite the best efforts of skilled caregivers [46].

Mask-induced pressure sores, which typically occur over the nasal bridge, are usually caused by over-tightening the headgear straps. Pressure sores are an important disadvantage and may lead to reduced tolerance [41]. There are different types of skin lesions, ranging from slight redness over the nasal bridge to open ulcers. Although the nasal bridge is the most sensitive area, skin breakdown can also appear on the patient's face, in particular over the patient's zygomatic bone.

While the efficacy of short-term NIV therapy takes clear precedence over comfort, it is agreed that a well-fitting and comfortable mask is vital, both for therapeutic success as well as prevention of skin lesions.

Different dressings have been evaluated for their ability to prevent nasal bridge abrasion, especially in ARF. The fit and comfort of the mask can be improved by including mask cushions and seal/support rings. Variations include inflatable cushion masks, gel masks and customizable masks which can be molded to fit the patient's individual facial contours [42]. Newer, more compact masks and masks with gel seals are better tolerated by patients and are gaining popularity. Clinical studies have yet to evaluate their efficacy in NIV.

Regardless of the mask selected, proper fit is of paramount importance to optimize patients comfort. Sizing gauges should be used to facilitate proper sizing and minimize strap tension. Caregivers must be prepared to try different types and sizes of masks in an effort to enhance patient comfort [43].

6.2.3 MINIMIZE DEAD SPACE

The third challenge is the issue of dead space, which is an inherent problem of larger, non-invasive interfaces when directly compared with an endotracheal tube. Carbon dioxide rebreathing is seen in ventilators with a single gas delivery circuit and no true exhalation valve. For nasal masks or nasal pillow, CO₂ rebreathing is relevant, albeit to a lesser extent; the greatest effect is seen in full-face masks, total-face masks and the helmet.

CO₂ rebreathing can be reduced by taking a few key factors into consideration. It has been shown that continuous flow throughout the expiration phase reduces total dynamic dead space to almost physiological levels in most face masks. When positive pressure is not maintained throughout expiration, dynamic dead space was reduced during NIV, but to a lesser degree [47]. Furthermore, the position of the exhalation port has an influence on dynamic dead space: the exhalation port located within the full-face mask was more effective in eliminating CO₂ from the full-face mask and the circuit than the leakage valve exhalation port located within the circuit. Although, there have not been general data available addressing the effects of exhalation port position and mask inner volume on CO₂ rebreathing so far [44].

The clinical impact of mask-associated dead space in continuous flow circuits using an intentional leak to eliminate CO₂ versus systems with valves, where dead space may have a higher impact, has not yet been fully explored. Different types of full-face masks are now available e. g. masks with AAV and exhalation ports. Some of these masks have addressed the issue of dead space and have increased leak rates; which may improve the quality of NIV [42]. However, additional laboratory and clinical studies are necessary to confirm the above described observation.

6.2.4 PATIENT INTERFACES: CLASSICSTAR® AND NOVASTAR® NIV FULL-FACE MASKS

Fitting the mask to the patient rather than making the patient fit the mask was the goal of a new line of Dräger patient interfaces: The ClassicStar® and NovaStar® non-invasive ventilation full-face masks.

The ClassicStar® mask cushion can be inflated or deflated to match the patient's facial contours, resulting in an improved, anatomical fit. The NovaStar® mask has a fine silicone gel filled cushion which maximizes patient comfort built into the flexible, transparent mask shell. This pliable ring allows the NovaStar® mask to be shaped to match the individual patient's face, providing a truly customized fit.



ClassicStar® NIV full-face mask



NovaStar® NIV full-face mask

Additional features, e.g. access for nasogastric tube, adjustable forehead support etc. further improve the performance of the ClassicStar® and NovaStar® NIV full-face masks.

6.3 FULL-FACE MASK VERSUS NASAL MASK AND NASAL PILLOWS

Reviews of published studies show the breakdown of interfaces mostly used in acute settings: [41]

- | | |
|-------------------|-----|
| – Full-face masks | 63% |
| – Nasal masks | 31% |
| – Nasal pillows | 6% |

These results support the commonly held belief that in acute settings, the full-face mask is preferred over nasal masks. This may be due to the fact that dyspnoeic patients are predominantly mouth breathers and therefore predisposed to greater air leakage and reduced effectiveness during nasal mask ventilation [43]. Using a full-face mask usually offers improved alveolar ventilation. However, the nasal mask may be better tolerated by the patient [48].



Nasal mask



Nasal pillow

Nasal masks add less dead space and help minimize the feeling of claustrophobia. They also allow eating / drinking and expectoration. Sometimes, chin straps are used with nasal masks in order to reduce mouth leakage. However, this combination is rarely effective. The improvement in arterial blood gas tensions appears to be slower in some studies using nasal masks in comparison with full-face mask.

Nasal pillows or plugs are alternative types of nasal masks which use soft rubber or silicone pledgets that are inserted directly into the nostrils [43]. Though nasal pillows may cause less claustrophobia than nasal masks, they show similar advantages and disadvantages to nasal masks when compared with full-face masks.

The full-face mask allows delivering of higher ventilation pressures with less leakage. They also require less patient cooperation and permit mouth breathing. Compared to nasal masks, the more common application of full-face masks in ARF is a reflection of the higher quality of ventilation (at least during the initial phase of intervention) in terms of minute ventilation and improved blood gases [42].



Full-face mask NovaStar®



Total-face mask

6.4 TOTAL-FACE MASK

In an attempt to improve performance of the interface, the total-face mask was compared with the full-face and nasal masks [49]. Results showed that the total-face mask may improve ventilation – the reduction in PaCO_2 was greatest when NIV was delivered with total-face mask. In addition, patient discomfort, the level of mask / mouth leaks and dyspnea were most effectively reduced during NIV employing a total-face mask. Possible explanations could include:

- An unobstructed patient field of vision
- The ability to communicate verbally
- Less discomfort due to air flow directed into the eyes when leaks occur with a face mask
- The sensation of air flowing over the entire face (which relieves the sensation of dyspnea) [49].

The dead space volume of the total-face mask used in the study was approx. 1.500 ml, which is relatively large when compared to the nasal mask (105 ml)

and full-face mask (250 ml) (all masks in question were different from the above showed pictures) [51].*

Complications related to the increased dead space (e.g. increased sensation of dyspnea or adverse effects on blood gas tensions) were not observed. One would expect complications such as eye irritation and gastric distention to be more common during non-invasive ventilation with the total-face mask. This, however, was not observed [49].

Similar results were presented in another study [50]. Despite having a larger dead space volume than other masks (full-face and nasal), no patient demonstrated further increases in PaCO₂ or more labored breathing while using the total-face mask.

On the other hand side, the following should be taken into consideration: in order to minimize the potential adverse effects of increased dead space, all patients were treated with a continuous base flow of oxygen and air mixture (according to the patient's FiO₂ requirement), which served to wash out the dead space. Also, an ancillary flow of oxygen may have been delivered directly into the mask ports itself. In order to avoid further CO₂ rebreathing, all patients were placed on ventilators fitted with a dual-limb circuit (separate inspiratory and expiratory limbs) [50].

The results suggest that in patients with acute hypercapnic respiratory failure who did not tolerate NIV using nasal or full-face masks, the total-face mask might improve patient acceptance of NIV therapy, possibly enhancing gas exchange and respiratory mechanics, thereby avoiding the need for endotracheal intubation and mechanical ventilation. The total-face mask could be complementary to full-face masks which are used in the majority of cases in the hospital environment.

* Dead spaces of nasal, full-face, and total-face masks can vary depending on manufacturer, design, and sizes of the masks. Reduction in dead space by facial structures when wearing the mask was not taken into consideration.



Helmet

6.5 HELMET

The helmet is a new interface with a potential for increasing the success rate of non-invasive ventilation by improving tolerance.

Theoretically, the helmet has important advantages:

- Improved tolerance (satisfactory interaction of the patient with the environment)
- Fixation system (may reduce the risk of skin lesions)
- Universal fit (can be applied to any patient regardless of facial anatomy) [48].

The helmet was the subject of considerable enthusiasm after several publications reported the successful NPPV treatment of patients suffering from hypoxemic acute respiratory failure. In these studies, use of the helmet was associated with better tolerance and fewer complications than a full-face mask. In a pilot trial, it was reported that the helmet reduced the rate of skin lesions. It allows complete freedom of head movement, verbal communication, reading and normal alimentation. The helmet was better tolerated than the full-face mask and may even improve collaboration between patient and caregivers, and with that, the overall quality of care [51].

Results of a later study showed that both the helmet and the full-face mask improve $\text{PaO}_2/\text{FiO}_2$ ratios and can reduce PaCO_2 levels significantly. The reduction in PaCO_2 was less pronounced in the group of patients treated with the helmet than those treated with full-face mask. In the study, NPPV via helmet was less effective for hypercapnia than full-face NPPV. Two possible factors may have influenced this result: Firstly, carbon dioxide rebreathing and secondly, inspiratory effort [52].

A recent study reported similar results. Regardless of the interface used, non-invasive ventilation improved gas exchange and reduced inspiratory effort. The helmet, however, was less efficient than the full-face mask in reducing inspiratory effort and had a somewhat adverse effect on patient-ventilator synchrony, as indicated by the longer delays to trigger on and cycle off the mechanical assistance as well as the number in ineffective efforts [53].

No differences were seen between the two interfaces with regard to patient comfort. Helmet and full-face mask were tolerated equally well and both were effective in ameliorating gas exchange [53].

Despite all enthusiasm for the helmet, there are still reasons for caution.

- When NPPV is applied with the helmet, both the external and the middle ear are directly exposed to inspiratory positive pressure. This could theoretically expose the middle and inner ear to the risk of mechanical damage. Also, the noise level may be disturbing for some patients.
- Another major concern is the risk of rebreathing caused by the large dead space within the helmet.
- There are also potential ventilator triggering and cycling issues caused by the large compressible volume within the circuit.

Until these issues are resolved, the helmet should not be recommended for the treatment of hypercapnic respiratory failure with NPPV [39].

Although the use of the helmet has remained controversial and several studies have not come out with a clear recommendation for patients with acute hypercapnic respiratory failure, the positive achievements of this new interface in patients with acute hypoxic respiratory failure should be taken into consideration.

6.6 INTERFACE USE IN CHRONIC SETTINGS (HOME CARE ENVIRONMENT)

In contrast the breakdown of interfaces majorly used in chronic settings is:

- | | |
|-------------------|---------|
| - Full-face masks | 6% |
| - Nasal masks | 73% |
| - Nasal pillows | 11% |
| - Mouthpiece | 5% [41] |

The characteristics and advantages of each of these interfaces have been discussed previously. In general, patients rate nasal masks as more comfortable for long-term (chronic) applications [54].

6.7 NON-INVASIVE VENTILATION IN PEDIATRICS – THE INTERFACE

NIV in the pediatric environment has become an option in the last few years and its use is on the rise.

In contrast to studies in adults, nasal masks seem to be preferred, both in acute and chronic settings, this in spite of the fact that the children in these studies were often past the age of obligatory nose breathing. The use of a full-face masks carries the risk that the lower jaw will be pushed backwards, possibly resulting in airway obstruction. Furthermore, the risk of aspiration, issues with regard to proper fitting of full-face masks, problems with cooperation and increased dead space could serve to explain the more frequent choice of nasal masks [55]. In a newer study, continuous positive airway pressure was used with a modified helmet in 15 children with ARF. Results showed that the modified helmet was well tolerated and improved oxygenation in children (1 month to 5 years). This study was innovative and introduced a new NIV interface in the pediatric setting. However, as the study was a case series, several important points were not addressed [56].

Mask design should aim for the lowest skin contact pressure compatible with effective ventilation. Pressure marks should be looked for and adverse effects on the maxillary bone monitored. Changing mask position and/or shape can be options to minimize facial lesions. Tightening the mask straps to minimize leak to the extent that skin injury and cranial deformation occurs should be avoided. High priority should be given to choosing the smallest mask possible in order to minimize dead space and facilitate trigger function [55].

In spite of the crucial role they play, comparative data on non-invasive interfaces in the pediatric population is practically nonexistent. In addition, only a small number of interfaces are available for pediatric use (compared to the number available for adults). Further research and development are urgently needed in this area [55].

6.8 SUMMARY ON PATIENT INTERFACE

The choice of interface for NPPV has changed radical since the first custom-made masks appeared in the 1980s. Nowadays a wide range of sizes and styles are available. New and innovative interface are released frequently [57]. From the available evidence, it can not be said that any interface is clearly superior to any other in terms of important outcomes such as intubation rate or mortality.

The full-face interface may be more effective than the nasal interface for adult ARF patients [39]. In general, they seem to be the first choice approach. Results seem to give indication that on patients with acute hypercapnic respiratory failure, who could not tolerate NPPV using full-face or nasal masks, the total-face mask, could be used to improve patient acceptance. Though, the helmet as a relatively new patient interface it can not be recommended for NPPV treatment of patients with hypercapnic respiratory failure; its positive results should be taken into consideration in patients with acute hypoxic respiratory failure.

The mask design may affect the risk of facial skin breakdown. Based on anecdotal experience, using the correct size, not securing the headgear too tightly, and using wound-care tape on the bridge of the nose (full-face, nasal masks) are all important considerations to avoid facial skin breakdown [39]. Newer moldable masks with gel seals are well tolerated by patients and are gaining popularity. However, no clinical studies evaluated their efficacy in providing NPPV.

Numerous studies have compared the different aspects of interfaces. The research findings can be used as an indicator of which type of interface may be applicable, under what circumstances the interface would be changed and whether interfaces treat the breathing disorder in the same way [57].

All consulted studies have their strengths and limitations which are not subject to discussion. These studies should merely help to provide an insight into the use of patient interfaces during NPPV.

7.0 Humidification

Although NIV does not bypass the upper airway and humidification of inhaled air will take place naturally, it is still recommended to use a humidification system. Particularly in patients breathing through the mouth, artificial humidification is required. Depending on the amount and viscosity of secretions, an active humidifier or a heated moisture exchanger can be chosen.

7.1 ACTIVE HEATED HUMIDIFIERS

For patients with large leaks around the mask, high inspiratory flow and O₂ concentrations above 40%, an active humidifier is preferred because of their large capacity to produce heated and humidified air [58]. Many patients suffering from an ARF are dehydrated and have difficulty clearing secretions. Well humidified air at a temperature between 25-30 °C is an attributing factor for success in NIV therapy, as it improves both secretion clearance and the tolerance of the NIV therapy [20].

7.2 HEATED MOISTURE EXCHANGERS – (HME) FILTERS

An HME is a convenient solution for humidifying inhaled air. They are efficient and produce little resistance, but the necessary expansion of the breathing circuit increases dead space volume by 50-100 ml. This comes in addition to the dead space of the mask, which is usually about 200-300 ml for a full-face mask (see footnote page 40). When a dual-limb circuit is used, an additional 20-30 ml must be added to account for the short connection tube between the y-piece and mask. In a worst case scenario, the circuit dead space can double or even triple the physiologic dead space, which is equal to about 150 ml.

The patient will attempt to compensate for this additional dead space by increasing minute volume, subsequently resulting in an increase of the work of breathing (WOB) compared breathing with a heated humidifier at comparable PaCO_2 values [59, 60].

The detrimental effect of the increased dead space is ameliorated when a ventilator is used that requires vented masks (AAV) (see chapter 6.1 choice of interface).

The single-limb circuit makes the small connection tube to the mask redundant in most situations.

8.0 The medical team

Success with NIV therapy depends very much on the skills and experience of the medical team. A specialist physician generally decides which patients should be treated with NIV and is responsible for patient supervision. The specialist chooses which mode of support is needed and gives orders for ventilator settings. The physician should be assisted by trained nurses or respiratory therapists (RT) familiar with NIV therapy.

Training is required for all staff who will be working with NIV. ICU's are generally staffed by a multi-disciplinary team. The goal for the team is to reach the same advanced skill level.

In addition to a solid background in critical care ventilation, additional training is necessary in:

- selection criteria for NIV
- selection criteria for interfaces
- function, operation and NIV equipment settings
- assessing patient response to NIV and how to react if treatment fails
- understanding ventilator function with respect to leak compensation, triggering and free breathing

9.0 Monitoring NIV therapy

The level of monitoring necessary depends on several factors, including status of the patient, the severity of ARF and the treatment setting, e.g. ICU, emergency or intermediate care ward.

Standard monitoring

- ABG
- SpO₂
- Airway pressure
- Minute volume
- Apnoe time with back-up ventilation

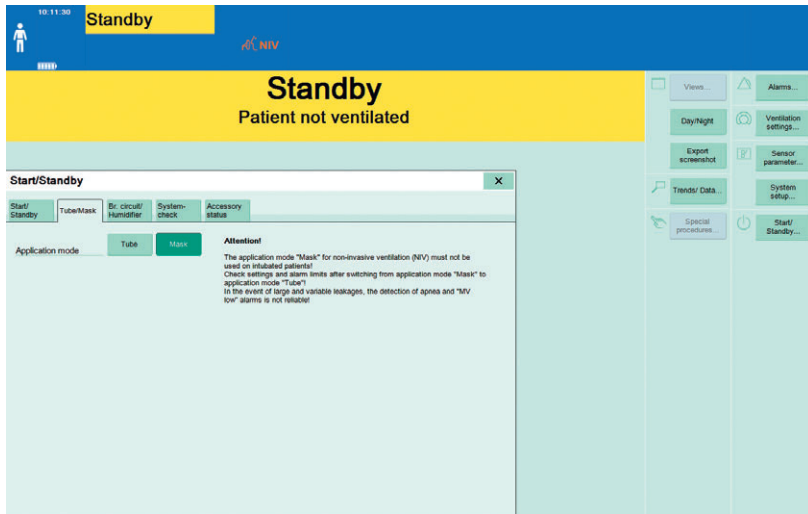
Extended monitoring

- ABG
- SpO₂
- Airway pressure
- Minute volume
- Apnoe time with back-up ventilation
- Frequency
- FiO₂
- Flow and pressure waveforms
- ECG
- NIBP
- Temperature

Target values for most adult patients are:

- SpO₂ ≥ 92%, for COPD SpO₂ ≥ 88%.
- $7.35 \leq \text{pH} \leq 7.45$
- $14 \leq \text{RR} \leq 25$ breaths/min
- $4.6 \text{ kPa} \leq \text{PaCO}_2 \leq 6.0 \text{ kPa}$
- $6 \text{ ml/kg} \leq \text{Vt} \leq 8 \text{ ml/kg}$

In cases where NIV failure is a possibility extended monitoring should be used, since the condition of patients with ARF can deteriorate very rapidly. A critical care ventilator should be on standby to facilitate a rapid switch to invasive ventilation.



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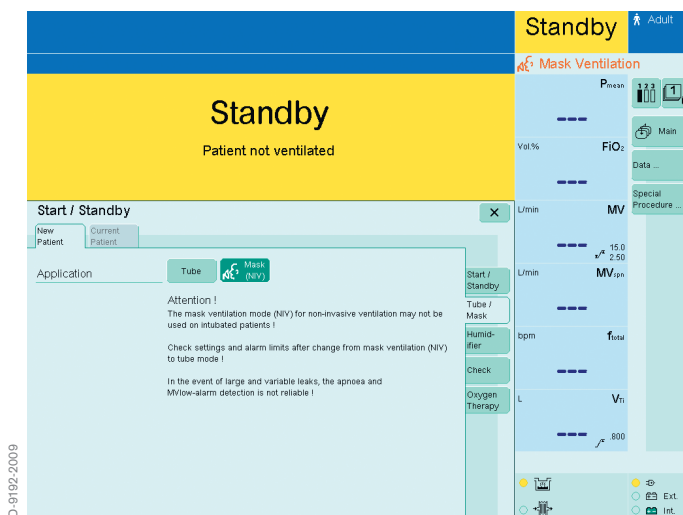
Evita Infinity® V500: select and confirm the NIV mode from the Standby menu

10.0 How to apply and set NIV

Once the patient has been selected (chapter 4) and informed as to what will take place, has practiced using the mask and is as comfortable as possible, it is time to switch on the ventilator.

SETTING UP THE VENTILATOR

For all Dräger ventilators, NIV is an option, with the exception of the Carina®, where it comes as a standard feature.

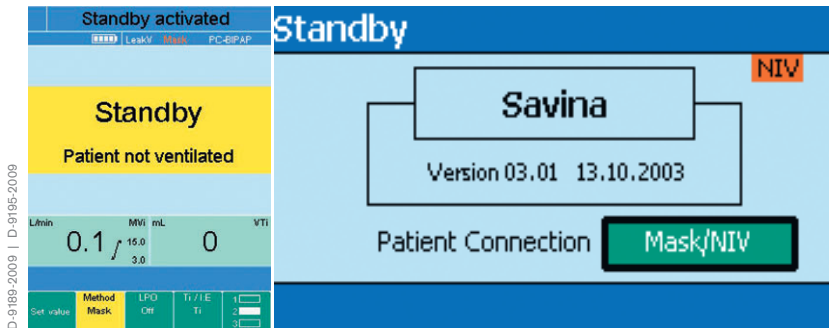


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Evita XL: select and confirm the NIV mode from the Standby menu

Set up and check the ventilator according to the instructions for use. When using Dräger Evita ventilators for NIV therapy select and confirm the NIV mode from the Standby menu. A switch from invasive to non-invasive ventilation and vice versa is possible only from here. Depending on the type of Evita ventilator an indicator representing a patient with a mask is a sign that NIV is switched on.

For the Dräger Savina ventilator, NIV is switched on via the Standby menu as well. From the menu Patient connection, then select Mask/NIV.



Carina®: select NIV from the Standby menu

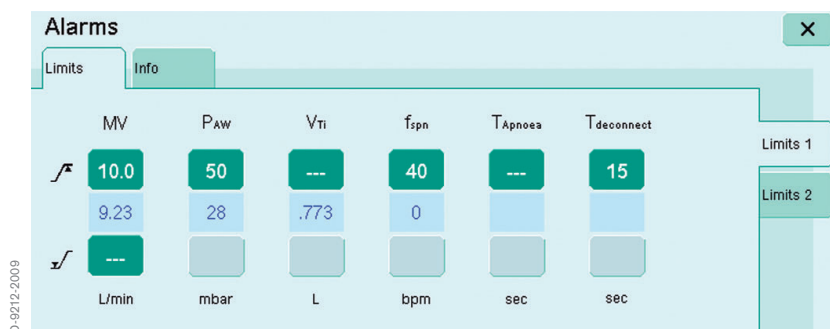
Savina: select and confirm the NIV mode from the Standby menu

With the Dräger Carina® ventilator, it is important to first verify that the selector for leakage valve or exhalation valve tubing systems at the bottom of the ventilator is in the position of leakage valve. Then NIV can be selected via the Standby menu. Using the Configuration and Method button, the NIV mode can be switched on.

Once on NIV Standby, the mode settings can be prepared and tested with a demonstration lung. After a check of the entire setup, the ventilator needs to be placed in Standby again; the device is now ready for use.

VOLUME CONTROLLED SETTINGS

Depending on the classification and the severity of acute respiratory failure, a volume or pressure controlled mode can be chosen. There is no clear evidence which mode is associated with better outcome. For both, it is important not to exceed a pressure above 20-25 cm H₂O; otherwise, there is a risk of gastric insufflation. Therefore, for a volume controlled strategy, total airway pressure including PEEP, should not exceed 25 cm H₂O. As in invasive ventilation, protective ventilation strategies should be applied with NIV therapy as well, with a target volume setting of 6-8 ml/kg for adult patients and 4-6 ml/kg for pediatric patients.



Alarm adjustment at the Evita XL

With the Evita, the body weight setting from the Standby menu can be used as a starting point for ventilation settings, which also includes an automatic adjustment of alarm limits.

In pressure controlled ventilation modes such as SIMVAutoFlow, PCV+, BIPAP or pressure support ventilation PS, the inspiratory pressure should not exceed 20-25 cm H₂O including PEEP. In pressure controlled ventilation, check that the resultant tidal volume is in accordance with the expectations. Begin with a PEEP or CPAP of 4-5 cm H₂O and a P_{insp} or P_{asb}/PS of 8-12 cm H₂O [61].

ALARM ADJUSTMENT

Set alarms for pressure, minute volume, tidal volume and frequency according to the ventilation settings and patient range. For Evita ventilators equipped with NIV plus, it is possible to turn off the alarms for MV low, Vt high and T_{apnea} in order to avoid nuisance alarms. Additionally, a delay time can be set for Paw low (airway pressure low), allowing short disconnections for skin care, alimentation or speaking without triggering a disconnect alarm.

BACKUP OR APNEA VENTILATION

Set the apnea time and the minimum minute volume setting V_t and frequency as a back up in case the patient stops breathing spontaneously.

POSITION OF THE PATIENT

The patient should be in a semi-recumbent position of about 45° . This position promotes spontaneous breathing as abdominal pressure is reduced and FRC is therefore increased. There is less risk of upper airway obstruction and coughing is facilitated, improving airway clearance.

MASK SELECTION

See chapter on interfaces. There are 5 types of factory-made interfaces available for NIV, most of them in different sizes:

- nasal pillow
- nasal mask
- full-face mask
- total-face
- helmet

For each type, there are advantages and disadvantages. The following criteria are important for the use of any interface:

- mask adapts well to the patient facial contours and thus, comfortable and well-tolerated
- optimal balance between leakage and headgear strap tension
- precautionary measures are taken against the development of pressure sores and skin breakdown
- adequate safety precautions in case of ventilator failure (e. g. built-in safety valve in the ventilator; anti-asphyxia valve in the mask) allowing the patient to breathe freely in case of ventilator failure
- Sufficient CO_2 management during NIV

If the Dräger NovaStar® NIV full-face mask is used, mask fit can be uniquely enhanced by modeling the mask to the shape of the patient's face. If the Dräger ClassicStar® NIV full-face mask is used, the mask cushion can be adjusted to the patient's face resulting in an improved, anatomical fit. When using Dräger ventilators, NIV masks (full-face) with standard elbow (non-vented) are to be used.

INSTALLATION - PREPARATION

Before each use:

Verify that the ventilator, including the alarms and safety systems, has been validated prior to use. Have the ventilator set up ready for use and in the Standby or Standby plus mode (Evita XL with NIV plus option). Inspect the mask prior to each use.

Appropriate mask fitting is essential for a successful non-invasive ventilation therapy. The Dräger Sizing Gauge (mask fitting template) helps you to choose the most suitable mask size for your patient.

Place the mask over the face of the patient and hold it in position. Evita Infinity® V500, Evita XL and Carina® with NIV plus will immediately support ventilation with the first inhalation (Auto wake up).

For all other ventilators activate the ventilator immediately after placing the mask over the face of the patient. A second person may be required to synchronize ventilator activation with the patient's first breath.



Mask ventilation with Carina® and NovaStar® NIV full-face mask



NovaStar® NIV full-face mask with standard elbow

Adjust the length of the strap to approximately the width of the face. Pull the upper strap over the head of the patient with your hand or swivel it around and snap it into its place. Then pull the second strap around the head and attach it to the mask while keeping the mask in position with the other hand.

Customizing the Dräger NovaStar® NIV full-face mask:

The pliable ring and the mask material allow for bending of the mask and re-shaping it according to the patient's face characteristics to provide the most comfortable fit.

Customizing the Dräger ClassicStar® NIV full-face mask:

In order to modify the cushion pressure, insert the Dräger pump ball (or a syringe) in the cushion valve, allowing the air volume in the cushion to be increased or decreased and thus, shape the mask to the patient's face contours.

If necessary, change the position of the forehead support and forehead pad to eliminate leaks at the bridge of the nose. Nose-bridge leaks must not be decreased by over-tightening the headgear straps.

Check the mask carefully for leaks and readjust the shape if necessary. Check the headgear straps for equal tension, making sure they are not too tight.

The same procedure can be used with nasal masks. Here, synchronization with the first breath is not critical as the patient can inhale through the mouth. Prerequisites for successful nasal mask therapy include breathing through its nose while keeping the mouth closed.

11.0 Practical aspects of NIV

MONITORING THE COURSE OF THERAPY

- Begin with a low pressure support level of about 4-6 cm H₂O and increase in steps of 2-3 cm H₂O until the desired support level is reached. This allows the patient to become accustomed to the ventilatory support.
- Start with a low PEEP of 2-3 cm H₂O and increase with steps of 1-2 cm H₂O at an interval time of about 10 minutes to get the patient accustomed. Increase PEEP till each breath is triggered and/or a appropriate level is achieved.
- Check the mask for leaks and reduce them if necessary by repositioning the mask, using supporting cushions or molding it to better fit the patient's facial contours (NovaStar® only).
- Motivate the patient to breathe quietly through the mask and provide feedback. Inform the patient that he/she is doing well and provide encouragement and praise. Due to the learning curve involved with assisted breathing, it is very important to communicate with the patient on his/her performance particularly during the first hour.
- In the initial phase, check the profile of breaths delivered by varying the Ti, ramp/rise time, termination criteria and trigger sensitivity. Ask the patient what is more comfortable following each change.
- If there are major tolerance problems which cannot be solved in the first 15-30 minutes, discontinue NIV and switch over to invasive ventilation.

Setting up NIV is somewhat more labor intensive, but maintaining NIV therapy requires the same amount of nursing time as invasive ventilation.

- Before beginning NIV, perform an arterial blood gas analysis and note the initial values for pH, PaO₂ and PaCO₂.
- Check oxygenation with SpO₂ monitoring and adjust % O₂ and/or PEEP to improve oxygenation.
- Observe how the patient is breathing and watch for the use of accessory muscles. If evident, apply faster insufflations or higher support levels, both within the normal safety boundaries for ventilation.
- Perform an arterial blood gas (ABG) analysis after 1 hour and monitor SpO₂, PaO₂, PaCO₂, and pH values. Repeat the ABG as needed or following major setting changes.
- Check to ensure that tidal volume and respiration rate are in accordance with your clinical expectations.
- Observe the flow waveform and check to ensure that expiratory flow returns smoothly back to zero before the next breath commences. If this is not the case, reduce rate, Ti, P_{ASB} or P_{insp}.

If expiratory flow does not return smoothly to zero, volume is trapped with each breath, resulting in the build-up of intrinsic PEEP. This can later cause trigger and synchronization problems. Without proper adjustment, it can result in NIV failure due to patient exhaustion.

It should be noted that in patients with severe COPD, a PEEPi of sometimes up to 10-15 cm H₂O can be observed. In such patients, work of breathing (WOB) can be reduced by increasing PEEP levels.

To increase patient tolerance

- Check to ensure that the mask is not too tight and is not leaking excessively (preferably M_{leak} < 20 l/min for adults, < 10 l/min for pediatrics, < 30% of minute volume for neonates). Find a compromise between leakage and headgear strap tension.
- Check the patients face for changes in skin color and pressure sores.

If an improvement of fit is not possible and the risk of developing a skin lesion appears unacceptably high, use support cushions, another type of mask and/or cushion, or discontinue non-invasive ventilation and change to invasive ventilation.

After 1 hour, if the patient has not responded to therapy and PaO_2 is still too low, consider the following:

1. Increase FiO_2
2. Increase PEEP
3. Increase Ti , Tpause or Flow for a longer Pplateau (BIPAP)

Options 2 and 3 will result in an increased mean airway pressure that should improve oxygenation but can effect haemodynamics.

If PaCO_2 is too high due to respiratory hypercapnia, increase minute ventilation by:

- Increasing the respiratory rate
and/or
- increasing Vt

Depending on the patient's condition, if there is no improvement at all after 1 hour of non-invasive ventilation, consider discontinuing NIV therapy and switch over to invasive ventilation.

Unfortunately, many patients do not have a standalone oxygenation or a ventilation problem. Usually, a combination of both can be observed. This is why it is important to have a good understanding of the cause of each of them, how they are related to each other and how to treat the condition most effectively.

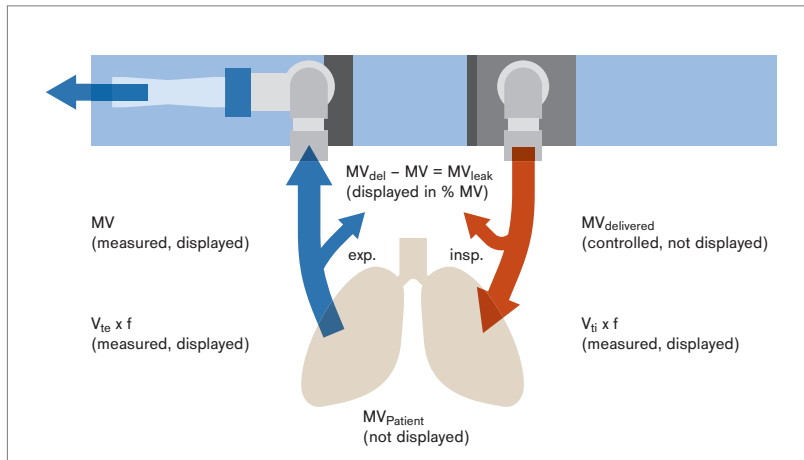
12.0 Leakage compensation and trigger adaptation

One of the technical challenges for any NIV ventilator is to involve strategies for dealing with leaks. Aside from the fact that leaks require some form of compensation in order to maintain PEEP, they are also responsible for monitoring and trigger problems. In particular, the ventilator's leak compensation mechanisms are tested during any form of volume controlled ventilation (CMVassist or A/C) [38].

COMPENSATING THE VOLUME

To solve these inherent problems, Dräger critical care ventilators utilize a smart algorithm which eliminates leak and triggering related problems. Like all other ventilators, Dräger ventilators measure volumes outside the lung. As a consequence, one may not assume that the difference between a set inspiratory volume (V_t) and a measured exhaled volume (V_{te}) corresponds to the leakage volume. Likewise, the measured exhaled volume cannot automatically be considered equal to the volume that has ventilated the lung (alveolar ventilation). These assumptions fail to take pressure and time effects into account. During inspiration, the pressure is usually higher than during expiration, resulting in increased leakage around the mask than during expiration. Time has a similar effect because the leak volume is the time (s) x the leakage flow (l/s).

The following example can serve to simplify the problem. A patient is ventilated with an inspiratory volume of (V_t) 700 ml with a certain amount of leakage around the mask. From this volume delivered by the ventilator, a certain amount has leaked away and is not reaching the lung. If the patient exhales, we measure a volume, e.g. $V_{te} = 500$ ml and one could erroneously assume that this is always the volume that was entered the lung. This is in fact the case when the leak is only present during inspiration. The volume entering the lung was actually higher, perhaps 550 ml, but a part has leaked away during expiration and did not pass the flow sensor. This explains why



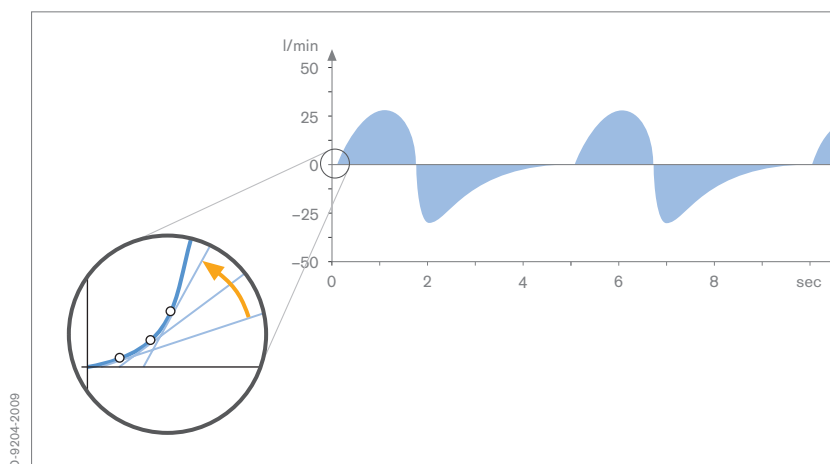
Automatic trigger adaptation to leakages

the leakage flow is not simply the difference between $f \times (V_t \text{ set} - V_{te})$. Thus, when applying volume controlled ventilation with 6-8 ml/kg strategy, the ventilator must make a number of measurements and corrections to ensure correct alveolar ventilation. The ventilator applies a higher volume (not visible) than was set in order to correct for inspiratory leaks. This is true for invasive as well as all non-invasive volume controlled ventilation modes.

A detailed explanation of the corrections made, compensating for humidity and temperature between V_{ti} , delivered by the ventilator and measured exhaled volume (V_{te}) from the patient, would be beyond the scope of this booklet.

COMPENSATING CPAP / PEEP

Leaks are not only a problem in volume controlled ventilation but also occur during pressure controlled ventilation, since in both types of ventilation, the leak has an effect on the set PEEP/CPAP levels, which should remain



SyncPlus®: Flow gradient triggering

constant. That means the ventilator needs to be equipped with an algorithm to compensate immediately a drop in CPAP/PEEP due to a leakage. When such a mechanism is not in place derecruitment can happen after each exhalation [38].

COMPENSATING AUTO-TRIGGERING

The challenge for all ventilators is to correctly differentiate between a drop in PEEP/CPAP caused by a leak or caused by an inspiratory effort. Because both generate a flow, this is immediately picked up by the flow sensor, triggering support from the ventilator.

In this situation, it is generally recommended to set the trigger sensitivity to a level lower than the leak flow in order to avoid auto-triggering. As long as the leak is constant, this would theoretically be sufficient. However, in daily practice, this is never the case. Instead, it can differ almost from breath to breath and requires adjustment each time without setting it at a value that

is below the expected maximum leakage; this would in turn increase the amount of effort required to trigger support to unacceptably high levels.

Currently, all Dräger ventilators feature a smart solution which makes manual re-adjustment of the flow trigger superfluous. Automatic leak and trigger adaptation makes use of the leak flow measurement and continuously adjusts the trigger sensitivity to a level which precisely cancels out the leak flow.

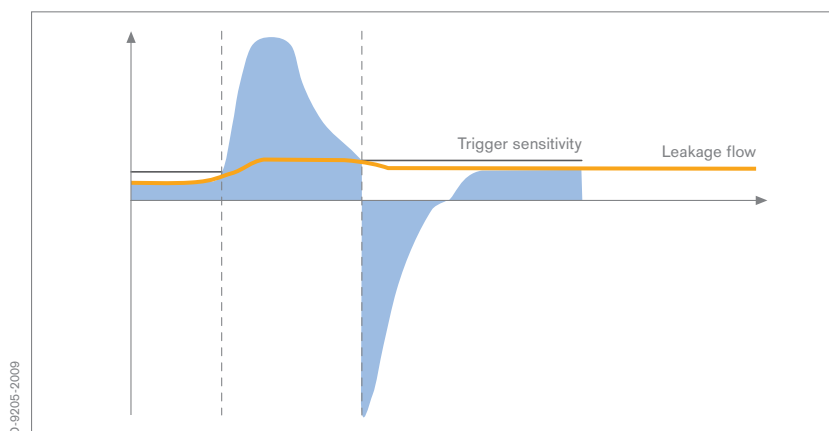
An example will explain what this means:

Let us assume to have a pressure support ventilation with a flow trigger set to 1 l/min. If there is no leakage, the patient must draw at least a flow of 1 l/min to trigger support.

Now a leak is detected, in this case it is measured to be 15 l/min, and the flow trigger sensitivity is automatically moved to a level of 16 l/min. The result eliminates auto-triggering and the patient feels the same trigger sensitivity as before.

In other words, if the leak increases or decreases, the trigger sensitivity will follow it at the same set distance.

The Carina® ventilator features a unique additional trigger algorithm SyncPlus® that works in parallel with the flow trigger system. This additional trigger algorithm was deemed necessary because the Carina® can be used with a leakage valve in a single hose system as well as with an exhalation valve. SyncPlus® combines a multitude of detection criteria and incorporates flow, pressure and flow gradient into a balanced trigger detection algorithm. This sophisticated algorithm adapts quickly to the needs of the patient and can differentiate between artefacts and even the smallest spontaneous breathing efforts. SyncPlus® helps to enhance therapy responsiveness, while the need for caregiver intervention is minimized.



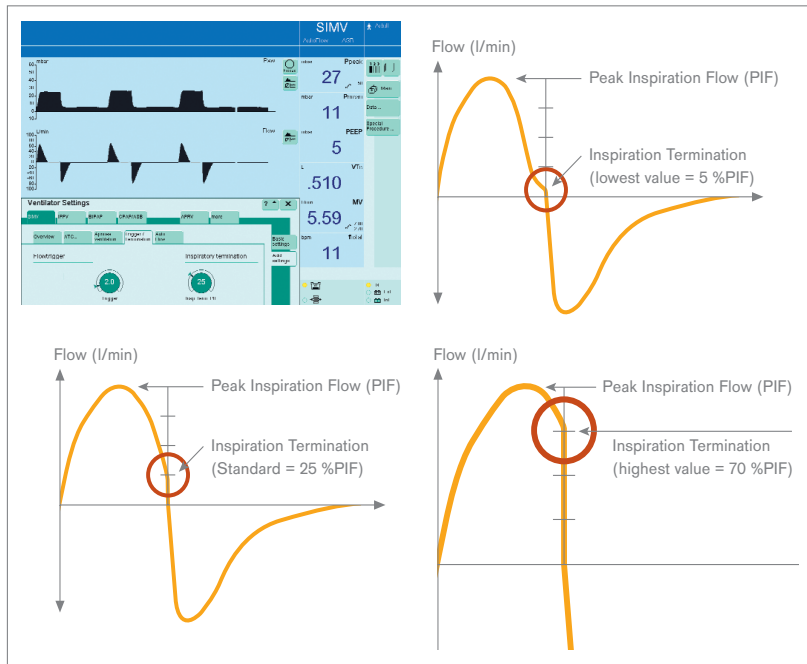
Automatic leakage and trigger sensitivity adaptation

INSPIRATION TERMINATION

Just as leaks cause problems during inspiration, they also interfere with the termination of PS breaths. It could happen, due to the leakage, that the flow termination criteria are never met and the ventilator remains in an insufflation phase.

For example, most ventilators terminate a PS breath when the inspiratory flow is reduced to 25% of initial peak flow. If the leak is larger than this, the ventilator continues to insufflate. Thus, an inspiratory termination trigger, adjustable from 5-70% of the maximal inspiratory flow, must be set.

In addition to its function in leak compensation, this inspiratory termination trigger is also required for pulmonary diseases such as asthma. These patients prefer fast and high flow support which is terminated at their natural expiration time, usually shorter than the standard termination criterion of 25% of peak flow. A prolonged inspiration shortens the natural expiration time, resulting in hyperinflation and increased patient work of breathing (WOB) [62].



Adjustable inspiration termination during pressure support

SMOOTH TRANSITION FROM INSPIRATION TO EXPIRATION

For more comfortable spontaneous breathing during non-invasive ventilation, flow acceleration during inspiration has to be adapted by the ramp setting to the patient's spontaneous breathing pattern. The transition from inhalation to exhalation is in the NIV plus option smoothed to increase the comfort of spontaneous breathing.

13.0 Summary: The benefits of NIV

NIV is used more and more at the ICU's as a first line treatment in case of an acute respiratory failure. From the literature there is much evidence that NIV can be used successfully on many patients with different types of respiratory failures as long as a proper selection has taken place and the underlying disease is known.

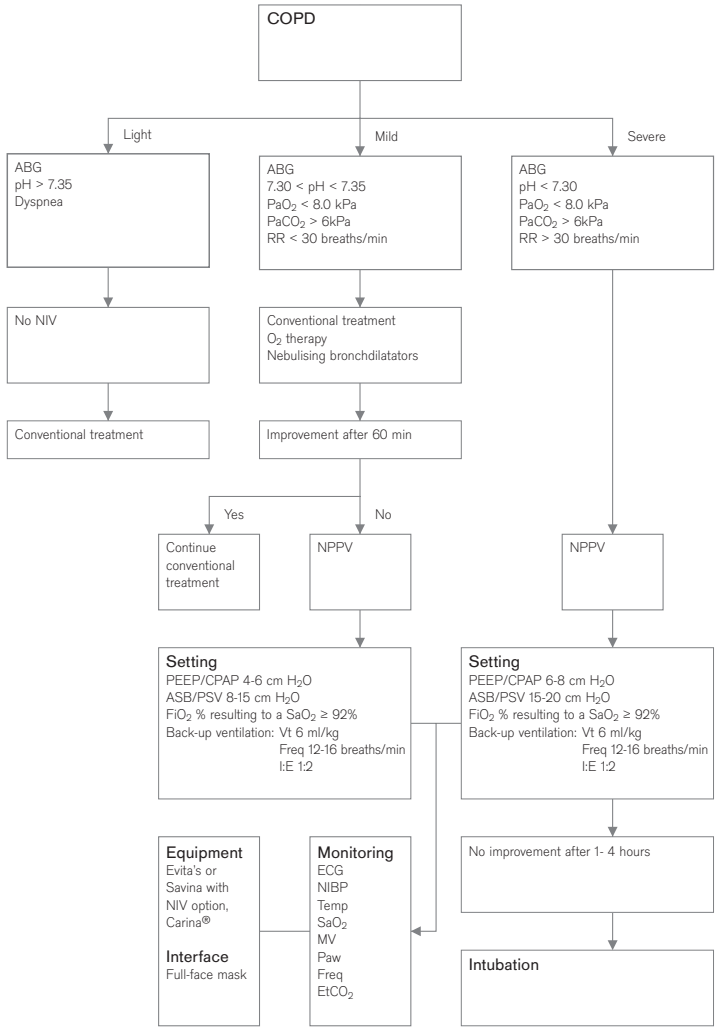
Important prerequisites for the success of a NIV therapy are a cooperative and well informed patient, a ventilator with a good leakage management in combination with an automatic adaptation of the trigger sensitivity and a trained medical team.

There is clear evidence for NIV that it result in to a reduction of infectious complications, reduced weaning time, reduced length of stay at the ICU and reduced intubation rates [16]. These benefits are going attendant with costs reductions.

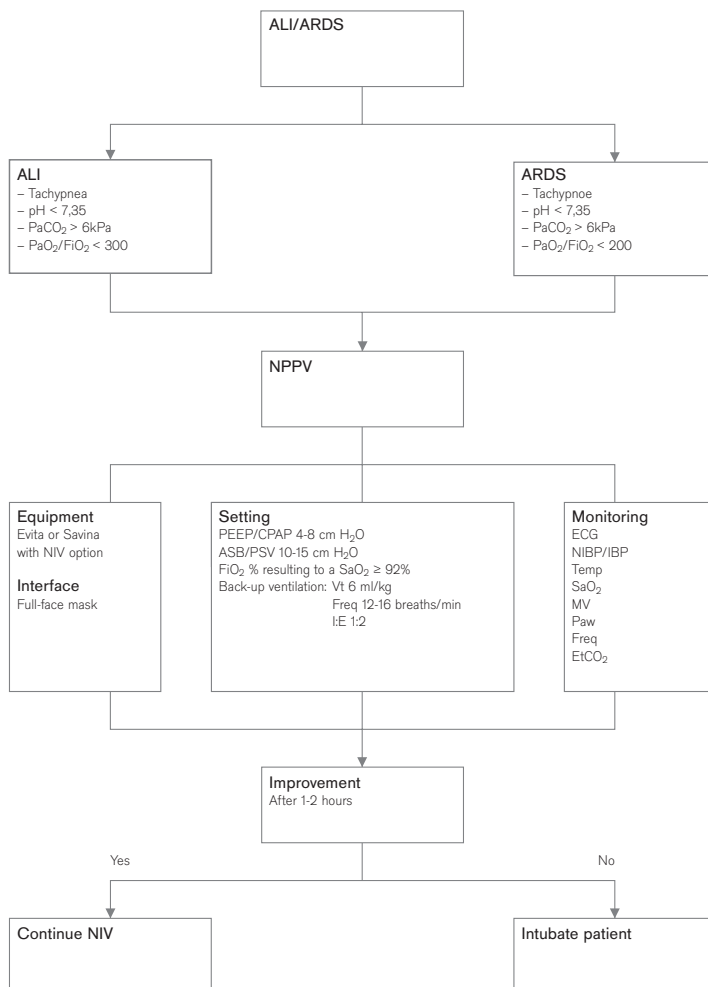
Selection of the interface is a critical point in NIV. There is no general recommendation about which type of interface has to be used for which type of respiratory failure or patient. Each type of interface has its place in the NIV therapy, with specific advantages and disadvantages. For all types of masks it is important to try different sizes in case you have problems with leakages or with tolerance by the patient. Use soft cushions (gel is preferred) and don't pull the headgear straps too tight. Be always alerted on rebreathing and additional death space. Make sure that you have chosen the right combination of mask (SE, AAV, vented or non-vented), breathing circuit and ventilator.

Last prerequisite for success is a ventilator that is able to ensure optimal synchronization under different leakage situations. The correct selection and setting of the ventilation mode and an adequate humidification are small things that can make a huge difference in the success rate of NIV.

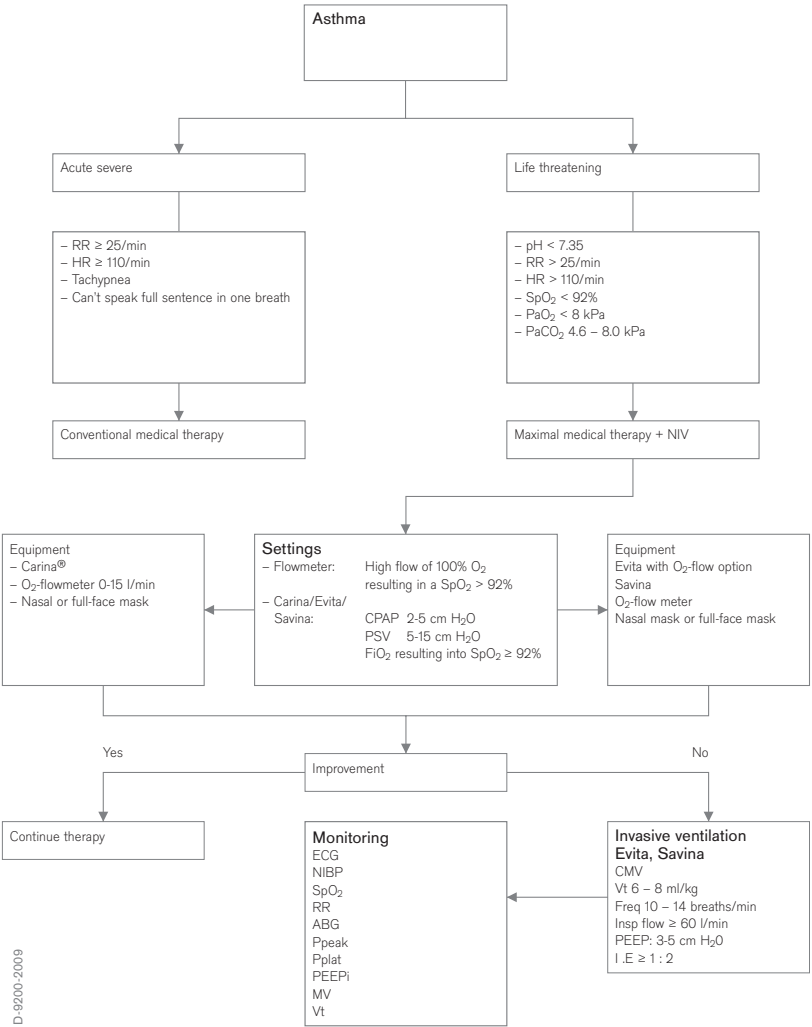
1. Appendix I – Hypercapnic respiratory failure



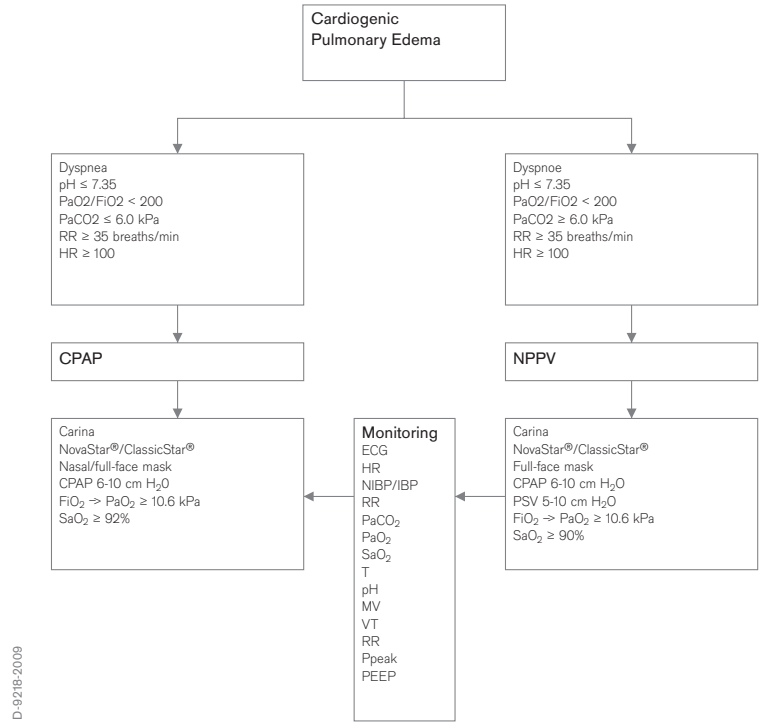
2. Appendix II – Hypoxemic respiratory failure



3. Appendix III – Hypercapnic respiratory failure



4. Appendix IV – Cardiogenic Pulmonary Edema



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16.0 Abbreviations

AAV	Anti-Asphyxia Valve
ALI	Acute Lung Injury
ARDS	Acute Respiratory Distress Syndrome
ARF	Acute Respiratory Failure
ATCTM	Automatic Tube Compensation
BIPAP	Biphasic Positive Airway Pressure Ventilation
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Pressure Ventilation
EP	Exhalation Ports
GI	Gastrointestinal anastomosis
HME	Heated Moisture Exchanger (Filter)
NIV	Non-invasive Ventilation
NPPV	Non-invasive Positive Pressure Ventilation
OSA	Obstructive Sleep Apnea
PSV	Pressure Support Ventilation

SE	Standard Elbow
VAP	Ventilator Associated Pneumonia
WOB	Work of breathing

HEADQUARTERS

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