# StarMed
## Study Portfolio

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## Background

Since the early 2000s several clinical studies have been published on the hood interface for Continuous Positive Airway Pressure (CPAP) and Noninvasive Ventilation (NIV). Initial works focused on high flow CPAP, which helped to establish the benefits of the new interface including patient comfort and the ability to provide uninterrupted therapy for longer periods.

Further research and technical papers then provided users with information on how to use the hood safely, these included indications relating to the minimal flow required to ensure optimal washout of the internal volume from a patient's expired $CO_2$.

Following on from this, more complex forms of mechanical ventilation support benefited from the introduction of the hood interface such as Pressure Support Ventilation (PSV) and Bilevel Positive Airway Pressure (BiPAP).

While the setting of a high flow CPAP system is relatively simple, requiring only the delivery of a constant gas flow and the use of a mechanical Positive End-Expiratory Pressure (PEEP) valve, the set up of Bilevel ventilation requires more fine tuning in order to be compatible with the patient's respiratory pattern.

Although the use of the hood has been proven to be clinically effective, several questions have been raised in relation to the mechanical performance, dead space and $CO_2$ rebreathing of this interface compared to NIV facemasks.

Therefore, a collection of studies/clinical evidence discussing these concerns is provided here, with clarifications and practical suggestions on how to best use the hood interface.

### Subjects of this study portfolio:

1. Optimal ventilator setting for hood NIV
2. $CO_2$ rebreathing during hood CPAP and NIV
3. Definitions of the hood dead space

# Supporting Research

## STUDY 1

### Helmet with specific settings versus facemask for noninvasive ventilation

Vargas F, Thille A, Lyazidi A, Campo FR, Brochard L. *Crit Care Med.* 2009 Jun;37(6):1921-8.

This study investigated the physiological effects of non-invasive pressure support ventilation (NPSV) delivered via facemask and hood interfaces with the same settings, compared to the use of the hood with specific settings. Outcomes measured included gas exchange, inspiratory muscle effort and synchrony.

To establish the performance of the hood interface when used with the facemask settings (Hsame) or with specific settings (Hspec), the pressure support (PS) and PEEP levels were increased by 50% using the shortest possible pressurisation time (pressure support range = 12 to 15 $cmH_2O$; PEEP range = 7 to 8 $cmH_2O$; pressurisation time = 0.05 seconds; flow triggering = 2 L/min).

Results showed no significant differences in the patient's breathing patterns or in hemodynamic parameters. On the other hand, the measurements of the indexes of inspiratory effort (Transdiaphragmatic pressure - Pdi and pressure-time product of transdiaphragmatic pressure per minute - PTPdi/min) demonstrated that Hsame reduced the inspiratory effort compared to spontaneous breathing, but to a lesser extent when compared to the facemask. However, when Hspec was used, the inspiratory effort was reduced to levels similar to the facemask.

Furthermore, for patient-ventilator synchronisation the inspiratory trigger delay was generally longer for the hood compared to the facemask, but this was significantly reduced for Hspec compared to Hsame. The expiratory synchronisation was not sufficiently improved by these specific settings, because the ventilator used for this test did not allow for increasing the expiratory cycling-off parameter, which was kept to 25% of the peak inspiratory flow for all experimental settings. Therefore, an increase in pressure support level and positive end-expiratory pressure using highest pressurisation rate may be recommended when providing NPSV via a hood.

Earlier research on hypercapnic patients demonstrated that the hood was associated with less inspiratory muscle unloading and with greater patient ventilator asynchronies compared to mask ventilation on stable COPD patients, when the hood was used with the same mask settings(1). Conversely, on acute exacerbations of COPD, circa 33% higher pressure support was required in order to eliminate accessory muscle activity and patient discomfort(2). In a clinical trial on hypoxic patients the hood allowed the use of 50% increased levels of end-expiratory pressure (PEEP), with positive results(3).

The authors of this study recognised that the compliance of the hood might have a large impact on the mechanical performance of the system due to its physical characteristics. It was shown that an increased level of PEEP can compensate for some of the compliance-related traits of the hood.

Better results may be achieved with hood-tailored settings (as proposed by Study 2 in this portfolio) or with different types of hood interfaces (i.e. the StarMed CaStar Next)(4) (5) (6) (7).

## Practical suggestions for ventilator settings for NIV:

- Increase the PEEP and PS levels by 50% in comparison to facemask ventilation, using the highest pressurisation rate
- Settings used on patients in this study:
    - Pressure support range = 12 to 15 $cmH_2O$
    - PEEP range = 7 to 8 $cmH_2O$
    - Pressurisation time = 0.05 seconds
    - Flow trigger = 2 L/min

## STUDY 2

### An optimized set-up for helmet noninvasive ventilation improves pressure support delivery and patient-ventilator interaction

Mojoli F, Iotti G, Currò I, Pozzi M, Via G, Venti A, Braschi A. *Intensive Care Med.* 2013 Jan;39(1):38-44.

The authors of this investigation stated that the high tolerability of the hood makes it the best NIV interface for patients with acute respiratory failure when prolonged and continuous assistance is needed. However, other studies have shown that the hood provides a reduced mechanical ventilatory support compared to a facemask. Therefore, this bench study set out to determine the effects of an optimised set-up of ventilator settings, ventilator breathing systems and the hood on mechanical performance. This work takes into consideration Study 1 for the proposed pressure settings resulting in reduced pressure-time product of transdiaphragmatic pressure (PTPdi) and suggests further adjustments to positively impact the patient-ventilator synchrony.

Hood NIV was applied to a polystyrene model simulating a passive patient in a pressure-controlled setting with maximum pressurisation rate. In addition, minute ventilation was measured under various conditions including pressure support and PEEP. Two levels of PEEP (5 and 10 cmH$_2$O) and two levels of PS (10 and 20 cmH$_2$O) were simulated as well as the inflation/deflation of the internal cuff of the hood and three different ventilator breathing systems offering increasing resistance to flow.

Findings obtained from this experimental protocol suggested that any action aimed at reducing the compliance of the hood interface and the resistance of the breathing system might have a beneficial impact on the mechanical performance of the hood at both PS levels. The best configuration for the hood to react to the patient triggers was: high PEEP, internal cuff well inflated, no respiratory filters at the hood inspiratory and expiratory ports and a breathing system with shorter limbs.

When the proposed new settings were tested on six patients the following pressure settings were used: PEEP = 10 cmH$_2$O; PS range = 13 to 20 cmH$_2$O. The internal cuff of the hood was inflated and low resistance breathing systems were used.

The optimal setup was associated both in the bench and the clinical study with major improvements in pressurisation rate, depressurisation rate as well as leakage occurrence. In addition, the occurrence of asynchronies and respiratory delay on the patient were both greatly reduced. The clinical application of the optimised set-up demonstrated that the rates of pressurisation and depressurisation approached 50% of the ideal values within the first 500 milliseconds from the onset of inspiration, moving close to the mechanical effectiveness of a well-managed NIV mask. Therefore, these settings that limit device compliance and ventilator breathing systems resistance are highly effective at improving pressure support delivery and patient-ventilator interaction.

In conclusion, this study confirms the importance of high PEEP settings in the hood for mechanical properties. Furthermore, these optimised settings have an effect in increasing the total hood minute volume (MV) and the patient minute volume, which are important elements that positively impacts on the $CO_2$ washout from the internal volume of the interface (this subject will be treated in more detail by Study 3 in this portfolio).

### Practical suggestions to ensure the hood is optimised for NIV ventilation:

- Set high PEEP levels, inflate the neck cushion of the hood and use low resistance breathing systems
- Settings used on patients in this study:
    - PEEP = 10 $cmH_2O$
    - Pressure support range = 13 to 20 $cmH_2O$

## STUDY 3

### Continuous positive airway pressure delivered with a “helmet”: effects on carbon dioxide rebreathing

Taccone P, Hess D, Caironi P, Bigatello LM. *Crit Care Med.* 2004 Oct;32(10):2090-6.

This study aimed to analyse the dynamics of the partial pressure of carbon dioxide ($\mathrm{PCO_2}$) within the hood interface during high flow CPAP therapy. The investigation was carried out in an American hospital both in bench settings and in healthy volunteers (n= 8). The human assessment was performed with a hood originally designed for hyperbaric medicine, as the StarMed product was not available in the US(8). Parameters including gas flow and $CO_2$ concentrations at the airway were measured continuously.

Here, the hood interface was described for the first time as a semi-closed environment, comparable to a closed room with an air exchange. This is an important difference compared to a facemask where the amount of $CO_2$ rebreathing is proportional to the mask internal volume in addition to anatomical dead space. The authors hypothesised that the $CO_2$ in the hood is evenly distributed and is dependent on the patient’s $CO_2$ production and the flow of fresh gases that flush the internal volume of the device, being independent from the size of the hood interface.

This research integrated previous investigations about hood CPAP that showed that the patient’s inspiratory $CO_2$ in the hood is not dependent on the PEEP pressure applied and is inversely correlated to fresh gas flow delivered through the interface(9). These findings were measured in the bench study, included in a mathematical model of the hood and were tested on healthy subjects.

This study also validated the behaviour of the semi-closed environment when CPAP is applied to the hood via a double-limb ICU ventilator. In this instance, the flow provided from the ventilator is only equal to the subject’s minute ventilation. In the absence of a leak this may be equivalent to an extremely low flow setting leading to increased rebreathing.

The authors have also found that the monitoring of the $CO_2$ concentration at the hood outlet was almost identical to those measured at the patient’s airways during the bench testing.

The authors concluded that the hood should not be used to deliver CPAP with a ventilator, as it does not behave as a simple dead space.

These results apply to the utilisation of continuous flow CPAP with the hood. However, a question in regards to the behavior of the system when non-invasive positive pressure ventilation (NPPV) is applied still remains unanswered (this question is addressed by Study 4 in this portfolio).

## Key notes from this paper:

- The $CO_2$ levels inside the hood are not related to the applied PEEP nor to the hood volume
- Hood CPAP should not be applied via a double-limb ICU ventilator but using high flow devices (i.e. Venturi equipments or air/oxygen blenders)

## STUDY 4

## Carbon dioxide rebreathing during non-invasive ventilation delivered by helmet: a bench study

Mojoli F, Iotti G, Gerletti M, Lucarini C, Braschi A. *Intensive Care Med.* 2008 Aug;34(8):1454-60.

This study set out to define how to monitor and limit $CO_2$ rebreathing during hood NIV ventilation. The Study 3 in this portfolio evaluated the rebreathing dynamics when continuous high flow CPAP is delivered to the interface, whilst this bench test simulates a patient being ventilated by a mechanical ventilator in Bilevel mode. The breathing system that was used consisted of two limbs connected to one side of the hood by a Y-piece, keeping the other side of the hood occluded by a blank cap. Hood NIV was applied to a polystyrene model simulating a passive patient in two series with varying ventilation conditions.

The main focus of this work was the simulation of the patient's production of increasing levels of $CO_2$ inside a hood, mechanically ventilated with a PEEP of 5 $cmH_2O$ and with inspiratory pressure of 10 $cmH_2O$ above PEEP. The $CO_2$ concentration was measured at different points inside the hood, at the patient's airway and at the Y-piece of the breathing system, while the quantity of carbon dioxide inspired by the mannequin was integrated from the readings of $CO_2$ and flows towards the lungs.

This protocol allowed the authors to identify the most reliable position to monitor $CO_2$ rebreathing even during clinical practice. The authors stated that if a 'quiet point' (that is not affected by the patient or ventilator flows) is located inside the hood, this might provide a precise measurement of the amount of $CO_2$ being re-breathed. This type of measurement inside the hood may not always be practical during clinical practice, but the experimental protocol showed that when $CO_2$ is monitored at the Y-piece (or at the expiratory connector of the hood) there is a linear correlation with inspired $CO_2$. Interestingly, the study also demonstrated that measuring $CO_2$ at the airways opening (as other studies about hood applications have previously proposed) might not give optimal results, particularly when performed on healthy subjects.

A second experimental protocol collected $CO_2$ readings in a number of conditions to investigate which of these could have an impact on the washout of the internal volume of the hood. Findings have shown that when a higher minute volume (MV) of fresh air is delivered to the patient-hood system, the inspired $CO_2$ is reduced. Using higher pressure support levels, activating leakages or controlling the ventilator bias flow (flow-by) might lead to an increase in MV.

In contrast to what happens during high flow CPAP, only a fraction of the volume delivered by the ventilator during positive-pressure ventilation reaches the patient respiratory system. The remaining volume is available to ventilate the hood itself and to reduce $CO_2$ rebreathing. Therefore, it has been proposed that if the ventilator is connected to the expiratory and inspiratory ports of the hood by two separate limbs, and a bias flow is continuously forced through the system (or at least during the whole expiratory phase), this might be very effective in removing $CO_2$. In addition, the rebreathing can be assessed by measuring $CO_2$ inside the hood or at the Y-piece connection, but not end-inspiratory at the airway opening.

In conclusion, this work provides practical suggestions supported by both empirical and mathematical evaluations, which are valuable tools that can help understand mechanical ventilation through the hood.

**Practical suggestions relating to $CO_2$:**

- When $CO_2$ is monitored at the Y-piece (or at the expiratory connector of the hood) there is a linear correlation with patient's inspired $CO_2$
- Using higher pressure support levels, activating leakages or controlling the ventilator bias flow (flow-by) might lead to an improvement of $CO_2$ washout

## STUDY 5

### Comparison of patient-ventilator interfaces based on their computerized effective dead space

Fodil R, Lellouche F, Mancebo J, Sbirlea-Apiou G, Isabey D, Brochard L, Louis B. *Intensive Care Med.* 2011Feb;37(2): 257–262.

This study aimed to characterise the issue of dead space associated with NIV interfaces, as it has often been considered equivalent to their internal volume. However, this concept can be challenged for an interface like the hood, as its internal volume is considerably higher than the patient's tidal volume. Earlier studies suggested that hood behavior is similar to a semi-closed environment (Studies 3 and 4), which strengthens the hypothesis of this study.

Here numerical simulations with computation fluid dynamics software allowed the authors to describe pressure, flow and gas concentration (for $O_2$ and $CO_2$) in four types of NIV interface commonly used in the ICU. Those interfaces included two oronasal masks (with different internal volume), one integral mask covering the patient's eyes, and a hood. The software was used to calculate the values of each parameter in every location within the interface (computational videos are available online as supplementary material to this study).

Findings have demonstrated that the efficacy of NIV treatment in clinical settings was not significantly different amongst all the interfaces with different physical properties. The author proposed that the actual dead space of an interface might be different to the interface gas region (volume of the interface which is surrounding the patient body within the interface itself). In addition, during every breath, the subjects inspire an amount of gas left in the interface by the previous respiratory cycle, as well as a volume of fresh gas that the ventilator delivers when triggered by the patient. Therefore, an adequate dead space (called 'effective dead space') is defined as the amount of re-breathed gas from the interface gas region.

The computer simulation has shown that the effective dead space for small NIV interfaces like oronasal masks, which possess a gas region comparable to the patient tidal volume, might be equivalent to their whole gas region volume. On the other hand, for a bigger interface like the hood, which has a gas region several times the patient tidal volume, the effective dead space is approximately 4% of the hood gas region and is limited to half of the patient's tidal volume.

Therefore it is interesting to note that for patients with smaller tidal volume, an interface with a bigger internal volume might protect from $CO_2$ rebreathing.

In essence, within the hood the flow of exhaled gas and fresh air are small in comparison to the large internal volume, and a single breath does not considerably modify the concentration of $CO_2$. In fact, within the hood the patient breathes in a tidal volume of gas containing a low fraction of $CO_2$, while in a mask some part of the tidal volume is made of higher $CO_2$ concentration re-breathed gas.

This paper provides practical clinical suggestions that are substantiated by the protocol used and further supports some concepts analysed in this portfolio(10).

## Key notes relating to dead space in the hood:

- The effective dead space of a big interface like the hood, which has a gas region several times the patient tidal volume, is approximately only 4% of the hood gas region
- For the hood the effective dead space is limited to half of the patient's tidal volume, whereas, for smaller interfaces it is close to the interface gas volume

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