REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

# Determina Dirigenziale N. 837 del 09/12/2020

**Proponente: Il Direttore UOC PROVVEDITORATO ED ECONOMATO**

**Oggetto: E-PROCUREMENT DELLA PUBBLICA AMMINISTRAZIONE-PROCEDURA TELEMATICA AI SENSI DELL'ART.58 DEL D.LGS N.50/2016 e smi. A MEZZO RDO N. 2662305 SU ME.PA. CONSIP PER L'AFFIDAMENTO, EX ART. 95 CO.4 DEL DECRETO CITATO,DELLA FORNITURA SEMESTRALE DI CPAP DI BOUSSIGNAC DA DESTINARE ALL'UOC FARMACIA- CIG ZA42F65EB3**

**PUBBLICAZIONE**
In pubblicazione dal 09/12/2020 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

**ESECUTIVITA'**
Atto immediatamente esecutivo

**TRASMISSIONE**
La trasmissione di copia della presente Deliberazione è effettuata al Collegio Sindacale e ai destinatari indicati nell'atto nelle modalità previste dalla normativa vigente. L'inoltro alle UU. OO. aziendali avverrà in forma digitale ai sensi degli artt. 22 e 45 D.gs. n° 82/2005 e s.m.i. e secondo il regolamento aziendale in materia.

**UOC AFFARI GENERALI**
**Direttore Eduardo Chianese**

**ELENCO FIRMATARI**

*Antonietta Costantini - UOC PROVVEDITORATO ED ECONOMATO*

*Eduardo Scarfiglieri - UOC GESTIONE ECONOMICO FINANZIARIA*

*Per delega del Direttore della UOC AFFARI GENERALI, il funzionario Pasquale Cecere*

**Oggetto:** E-PROCUREMENT DELLA PUBBLICA AMMINISTRAZIONE-PROCEDURA TELEMATICA AI SENSI DELL'ART.58 DEL D.LGS N.50/2016 e smi. A MEZZO RDO N. 2662305 SU ME.PA. CONSIP PER L'AFFIDAMENTO, EX ART. 95 CO.4 DEL DECRETO CITATO,DELLA FORNITURA SEMESTRALE DI CPAP DI BOUSSIGNAC DA DESTINARE ALL'UOC FARMACIA-CIG ZA42F65EB3

**Direttore UOC PROVVEDITORATO ED ECONOMATO**

**PREMESSO CHE**

- con nota protocollo n.32317/i dell'03/11/2020 (allegato n.1) il Direttore UOC Farmacia ha richiesto a questa Direzione l'acquisto urgente, considerato gli attuali numeri della pandemia Covid, pari ad un fabbisogno semestrale per l'UOC di Pneumologia e Fisiopatologia Respiratoria, di n.200 Cpap di Boussignac;

**RILEVATO CHE**

- pertanto con Determina dirigenziale n.775/2020, pubblicata sul sito istituzionale, è stata indetta gara telematica (RDO) per l'acquisto dei suindicati prodotti da aggiudicarsi secondo il criterio più basso;
- susseguentemente è stata avviata apposita RDO n. 2690143 del 12/11/2020 (allegato n.2) tramite l'utilizzo della piattaforma ME.PA. / Consip, invitando le Ditte iscritte al mercato elettronico nella categoria *"Beni/Forniture specifiche per la Sanità/Maschere per aerosolterapia"* a produrre offerta entro le ore 10.00 del 19/11/2020;
- entro il suddetto termine prescritto sono pervenute - le offerte delle Ditte B.R.S. CAPPUCCIO S.R.L. , DIMAR S.R.L. A SOCIO UNICO e SCOGNAMIGLIO SRL

**CONSIDERATO CHE**

- il Prof. Aantonio Ponticilello, Direttore l'UOC di Pneumologia e Fisiopatologia Respiratoria, ha esaminato le schede tecniche riferite alle offerte pervenute, come emerge dalle annotazioni dalla stessa apposte a margine della documentazione di interesse da cui risulta conforme la solo ditta Dimar srl (allegato 3);

- aperta l' offerta economica – sulla base dell'effettuata verifica di conformità – è risultato che la ditta Dimar srl offre n. 200 Cpap di Boussignac ad un prezzo cad. pari ad € 65,00, con costi per la sicurezza per una spesa complessiva pari ad € 13.097,50 iva esclusa al 22% (allegato 4) ;

**DETERMINA**

per i motivi espressi in narrativa di:

**I - PRENDERE ATTO** degli esiti della RDO n. 2690143 attivata su Mepa/Consip e, per l'effetto, di aggiudicare ex art. 95, comma 4, del D.Lgs. n.50/2016 e smi la fornitura semestrale sopra descritta per un importo complessivo di € 15.978,95 Iva inclusa c/o la ditta Dimar srl con sede legale in via G.Galilei,n.6- Medolla (MO),

**II - IMPUTARE** la spesa complessiva annuale pari ad € 15.978,95 Iva inclusa, come appresso dettagliato:

- per € 2.663,16 pari a 1/6 della fornitura, sul conto economico n. 5010107010 del bilancio 2020;
- per € 13.315,79 pari ai 5/6 della fornitura, al corrispondente conto economico di competenza del bilancio 2021;

**III – DI INSERIRE** nel contratto la clausola di recesso, ai sensi del combinato disposto degli artt. 92 e 100 del D.Lgs 159/2011 e smi, qualora vengano accertati elementi relativi a tentativi di infiltrazione mafiosa;

**IV – DI TRASMETTERE** copia della presente determinazione al Collegio Sindacale, come per legge ed alle UU.OO.CC Gestione Economica Finanziaria e Farmacia Ospedaliera;

**V - PUBBLICARE** integralmente la presente determinazione.

**Il Direttore UOC Provveditorato ed Economato**

**Dott.ssa Antonietta Costantini**

ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE
(per le proposte che determinano un costo per l'AORN – VEDI ALLEGATO)

ALLEGATO N. 1

Azienda Ospedaliera
di Caserta
Sant'Anna
e San Sebastiano
di rilievo nazionale
e di alta specializzazione

Al Direttore U.O.C. Provveditorato
E p.c. Al Direttore U.O.C. di Pneumologia

LORO SEDI

Oggetto: dispositivi per trattamento IR in pazienti Covid – Cpap di Boussignac.

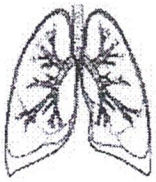
Si invia, in allegato, la richiesta del Direttore di U.O.C. di Pneumologia riferita ai dispositivi medici indicati in oggetto.
Si chiede di effettuare relativa RDO su piattaforma Mepa- Consip al fine di consentirne l'acquisto.
Il fabbisogno presunto è all'incirca per circa sei mesi.
Tanto per i successivi adempimenti consequenziali di competenza.

Il Direttore U.O.C. di Farmacia
Dott.ssa Anna Dello Stritto

*24/10/2020 10.48-20200031162*

AORN CASERTA

REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE
E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO" DI CASERTA




A.O.R.N. "Sant'Anna e San Sebastiano"
UOC di Pneumologia – Fisiopatologia Respiratoria
Direttore: Prof. A. Ponticiello
Email: pneumologia@ospedale.caserta.it


Caserta 24/10/2020

Richiesta **urgente** di dispositivo monouso per trattamento di IR in paziente Covid.

La CPAP di Boussignac è un dispositivo monouso per il paziente con insufficienza respiratoria o in fase di svezzamento dalla ventilazione meccanica. Il principale beneficio della terapia CPAP (Continuos Positive Airway Pressure) è di aumentare la capacità residua funzionale, ridurre il lavoro respiratorio (WOB) e migliorare l'ossigenazione del sangue arterioso.
E' un'alternativa compatta, economica ed efficace ai supporti ventilatori meccanici. Il dispositivo si compone di un generatore di pressione a forma di piccolo cilindro cavo aperto (dimensioni: lunghezza 5,5 cm; diametro 1,3 cm) e di un tubo connettore e si adatta a tutti i tipi di maschere facciali, di tubi endotracheali e cannule per tracheostomia.. Il tubo connettore in PVC è lungo 200 cm, è precollegato al generatore ed ha un attacco maschio per il rotametro. Quando l'aria immessa passa attraverso i piccoli canali del dispositivo per CPAP, crea una turbolenza. Questa, pur mantendendo la pervietà del dispositivo, crea un "diaframma virtuale", paragonabile ad una valvola PEEP, il cui valore può essere regolato aumentando o diminuendo la quantità di ossigeno o aria fornita al paziente. Il valore esatto della PEEP è monitorabile in ogni istante con l'aiuto del manometro dedicato.
Il dispositivo è presente su piattaforma MEPA.
Considerando gli attuali numeri della pandemia in Campania e il numero di posti letto della sola Pneumologia (18) e la possibilità di allargare l'uso del dispositivo anche ad altri reparti si stima un fabbisogno, al momento, di almeno 200 pezzi.

Prof. Antonio Ponticiello

Antonio Ponticiello

€ 80,00

Approvo!

A.O.R.N.
SANT'ANNA E SAN SEBASTIAN
CASERTA
Dipartimento di Scienze Mediche
Direttore Dott. Vincenzo Andreone
NA 22268

*TEAM MEDICO*

**Dr. Stefano Conte**
Tel. 0823/232399

**Dr.ssa Felice Di Perna**
*Tel. 0823/232399*

**Dr. Gaetano Ferrigno**
*0823/232630*

**Dr. Vincenzo Pezzella**
0823/232408

*COORDINATORE*

*INFERMIERISTICO*

**SIG. FRANCO PERRETTA**
TEL. 0823/232407

La copia di cartella clinica va richiesta alla fine del ricovero rivolgendosi all'Archivio

La data e l'ora, per la prima visita di controllo dopo la dimissione, verranno comunicati all'atto della stessa

Le visite successive con gli eventuali esami devono essere prenotate, dopo essersi forniti di impegnativa, al CUP
tel. 800 911818 (da telefono fisso) oppure tel 0823/1761547 (da cellulare)

acquistinretepa.it

ALLEGATO N. 1

## Dati generali della procedura

| | |
|---|---|
| **Numero RDO:** | 2690143 |
| **Descrizione RDO:** | Fornitura urgente CPAP di Boussignac per Covid 19 |
| **Criterio di aggiudicazione:** | Prezzo piu' basso |
| **Numero di Lotti:** | 1 |
| **Formulazione dell'offerta economica:** | Valore economico (Euro) |
| **Modalità di calcolo della soglia di anomalia:** | Il calcolo della soglia di anomalia delle offerte è effettuato secondo le prescrizioni dell'art. 97, comma 2, del Codice Appalti, in presenza di almeno 5 offerte ammesse. In caso di identico ribasso offerto, ai fini della determinazione della soglia di anomalia, le offerte identiche sono considerate come offerte uniche. La comparazione delle offerte ammesse alla soglia di anomalia determinata viene effettuata considerando le prime due cifre decimali delle offerte (troncamento alla seconda cifra decimale) |
| **Amministrazione titolare del procedimento** | AZIENDA OSPEDALIERA CASERTA<br>02201130610<br>Via Tescione CASERTA CE |
| **Punto Ordinante** | ANTONIETTA COSTANTINI |
| **Soggetto stipulante** | Nome: ANTONIETTA COSTANTINI<br>Amministrazione: AZIENDA OSPEDALIERA CASERTA |
| **Codice univoco ufficio - IPA** | 551B2G |
| **Inizio presentazione offerte:** | 12/11/2020 11:49 |
| **Termine ultimo presentazione offerte:** | 19/11/2020 10:00 |
| **Temine ultimo richieste di chiarimenti:** | 17/11/2020 23:00 |
| **Data Limite stipula contratto (Limite validità offerta del Fornitore)** | 12/12/2020 11:43 |
| **Giorni dopo la stipula per Consegna Beni / Decorrenza Servizi:** | 00 |

Data Creazione Documento: 12/11/2020 11:49

| | |
|---|---|
| **Misura delle eventuali penali:** | Indicate nelle Condizioni Generali di Fornitura allegate al Bando oggetto della RdO e/o nelle Condizioni Particolari definite dall'Amministrazione |
| **Bandi / Categorie oggetto della RdO:** | BENI/Forniture specifiche per la Sanità |
| **Numero fornitori invitati:** | Gara aperta a qualsiasi Fornitore del Mercato Elettronico (previa Abilitazione al Bando/Categoria della Richiesta di Offerta |

## Lotto 1 - Dettagli

| | |
|---|---|
| **Denominazione lotto** | Lotto unico |
| **CIG** | |
| **CUP** | |
| **Formula di calcolo del punteggio economico** | |
| **Oneri di sicurezza non soggetti a ribasso** | Non specificati |
| **Dati di consegna** | Via tescioneCaserta - 81100 (CE) |
| **Dati di fatturazione** | Codice IPA di Fatturazione Elettronica: 551B2G . Aliquote: secondo la normativa vigente |
| **Termini di pagamento** | 30 GG Data Ricevimento Fattura |
| **Importo dell'appalto oggetto di offerta (importo presunto)** | 40000,00000000 |

## Lotto 1 - Schede tecniche

| | |
|---|---|
| **Nome Scheda Tecnica** | CPAP di Boussignac |
| **Quantita'** | 500 |

I campi contrassegnati con * sono obbligatori

| Nr. | Caratteristica | Tipologia | Regola di Ammissione | Valori |
|---|---|---|---|---|
| 1 | * Marca | Tecnico | Nessuna regola | |
| 2 | * Codice articolo | Tecnico | Nessuna | |

| | | | | |
|---|---|---|---|---|
| | produttore | | regola | |
| 3 | * Nome commerciale della maschera per aerosolterapia | Tecnico | Nessuna regola | |
| 4 | * Unità di misura | Tecnico | Lista di scelte | • Pezzo |
| 5 | Descrizione tecnica | Tecnico | Valore massimo ammesso | n.500 pezzi di CPAP di Boussignac per aumentare la capacità residua funzionale, ridurre il lavoro respiratorio (WOB) e migliorare l'ossigenazione del sangue arterioso di cui n. 100 misura M, n.350 misura L e n.50 misura S |
| 6 | * Tipo contratto | Tecnico | Lista di scelte | • Acquisto |
| 7 | * Codice CND | Tecnico | Nessuna regola | |
| 8 | * Materiale | Tecnico | Nessuna regola | |
| 9 | * Luogo di produzione | Tecnico | Nessuna regola | |
| 10 | * Utilizzo | Tecnico | Nessuna regola | |
| 11 | * Tipo | Tecnico | Nessuna regola | |
| 12 | * Sterile | Tecnico | Nessuna regola | |
| 13 | * Modalità di risterilizzazione | Tecnico | Nessuna regola | |
| 14 | * Latex free | Tecnico | Nessuna regola | |
| 15 | * Fissagio | Tecnico | Nessuna regola | |
| 16 | * Misura | Tecnico | Nessuna regola | |
| 17 | * Connettore | Tecnico | Nessuna | |

| | | | | |
|---|---|---|---|---|
| | maschera [mm] | | regola | |
| 18 | * Tubo di collegamento | Tecnico | Nessuna regola | |
| 19 | * Materiale tubo | Tecnico | Nessuna regola | |
| 20 | * Lunghezza tubo [cm] | Tecnico | Nessuna regola | |
| 21 | * Connettore tubo [mm] | Tecnico | Nessuna regola | |
| 22 | * Prezzo | Economico | Nessuna regola | |

Nessun documento allegato alla Rdo

Richieste ai partecipanti

| Descrizione | Lotto | Tipo Richiesta | Modalita' risposta | Obbligatorio | Documento unico per operatori riuniti |
|---|---|---|---|---|---|
| TEMPI DI CONSEGNA IN FORMATO PDF | Lotto unico | Amministrativa | Invio telematico | Obbligatorio, ammessi più documenti | Si |
| scheda tecnica o depliants solo in formato pdf(PENA L'ESCLUSIONE) | Lotto unico | Tecnica | Invio telematico | Obbligatorio, ammessi più documenti | Si |
| INVIO RDM-CND E PREZZO SINGOLO PER SINGOLA MISURA | Lotto unico | Economica | Invio telematico | Obbligatorio, ammessi più documenti | Si |
| Offerta Economica (fac-simile di sistema) | Lotto unico | Economica | Invio telematico con firma digitale | Obbligatorio | Si |

In caso di accertamento del difetto del possesso dei requisiti di cui all'art. 80 del D.Lgs. 50/2016, l'Amministrazione potrà procedere alla risoluzione del contratto. In tal caso, il

pagamento del corrispettivo pattuito avverrà solo con riferimento alle prestazioni già eseguite e nei limiti dell'utilità ricevuta. L'amministrazione potrà altresì procedere all'incameramento della cauzione definitiva ove richiesta o, in alternativa, applicare una penale in misura non inferiore al 10 per cento del valore del contratto.

ALLEGATO N. 3

DIMAR

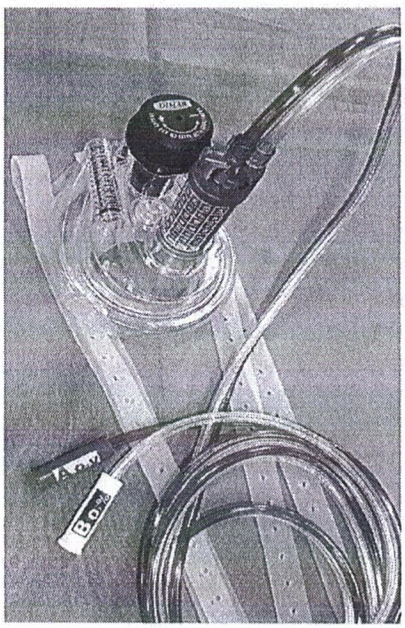
# SCHEDA TECNICA COMMERCIALE

# DimAir

## EASY VENT MASK

## SET per CPAP da Emergenza con Maschera formato da:

- Maschera facciale a doppio ingresso con cuscino anatomico gonfiabile completa di nucale reggi-maschera
- Valvola PEEP regolabile da 0 a 20 cm/$H_2O$ senza soluzione di continuità
- Manometro di controllo
- Generatore di flusso Venturi integrato
- Doppio tubo alimentazione antischiacciamento con raccordi di connessione collegabile anche ad una sola fonte di ossigeno




A.O.R.N. SANT'ANNA E SAN SEBASTIANO
CASERTA
U.O.C. Pneumologia
Fisiopatologia Respiratoria
Direttore Prof. Antonio Ponticiello
CE4263

CE 0425

**PRODUTTORE:** DIMAR s.r.l. – Medolla – (MO) Italia

DIMAR

# SCHEDA TECNICA COMMERCIALE

**MATERIALI:** PVC – PP – PCB di grado medicale. Acciaio Inox.
I materiali utilizzati sono certificati biocompatibili.

**LATEX E DEHP FREE**

**CONNESSIONE:** Connettori A/B ai flussimetri: raccordi morbidi conici 7÷11 mm

**DESTINAZIONE D'USO:**
Easy Vent Mask trova applicazione in ambulanza, mezzi di soccorso, nei reparti di Emergenza o di degenza Ospedaliera per il trattamento non invasivo in tecniche di C.P.A.P., dell'insufficienza respiratoria acuta di origine cardio-respiratoria o per lo svezzamento da respiratore di pazienti intubati e sottoposti a ventilazione meccanica.

**RENDIMENTI*:**

| PER OTTENERE | | IMPOSTARE | | OTTIENE |
|---|---|---|---|---|
| Conc. $O_2$ | Peep | flusso "A" Lt/min | flusso "B" Lt/min | flusso Tot. Lt/min |
| 30% | 5 | 10 | 0 | 60 |
| 35% | 5 | 7 | 0 | 60 |
| | 7,5 | 8 | 0 | 60 |
| | 10 | 9 | 0 | 60 |
| | 12,5 | 10 | 0 | 60 |
| | 15 | 11 | 0 | 60 |
| | 20 | 12 | 0 | 60 |
| 40% | 5 | 7 | 10 | 60 |
| | 7,5 | 8 | 9 | 60 |
| | 10 | 9 | 8 | 60 |
| | 12,5 | 10 | 7 | 60 |
| | 15 | 11 | 6 | 60 |
| | 20 | 12 | 5 | 60 |
| 50% | 5 | 6 | 18 | 60 |
| | 7,5 | 7 | 17 | 60 |
| | 10 | 8 | 16 | 60 |
| | 12,5 | 9 | 15 | 60 |
| | 15 | 10 | 14 | 60 |
| | 20 | 11 | 14 | 60 |
| 60% | 5 | 5 | 26 | 60 |
| | 7,5 | 6 | 26 | 60 |
| | 10 | 7 | 26 | 60 |
| | 12,5 | 8 | 26 | 60 |
| | 15 | 9 | 26 | 60 |
| | 20 | 10 | 24 | 58 |

| PER OTTENERE | | IMPOSTARE | | OTTIENE |
|---|---|---|---|---|
| Conc. $O_2$ | Peep | flusso "A" Lt/min | flusso "B" Lt/min | flusso Tot. Lt/min |
| 70% | 5 | 4 | 30 | 60 |
| | 7,5 | 5 | 30 | 60 |
| | 10 | 6 | 30 | 60 |
| | 12,5 | 7 | 30 | 60 |
| | 15 | 8 | 30 | 60 |
| | 20 | 9 | 30 | 60 |
| 80% | 5 | 3 | 30 | 50 |
| | 7,5 | 4 | 30 | 50 |
| | 10 | 5 | 30 | 50 |
| | 12,5 | 6 | 30 | 50 |
| | 15 | 7 | 30 | 50 |
| | 20 | 9 | 30 | 50 |
| 100%** | 5 | 30 | 30 | 60 |
| | 7,5 | 30 | 30 | 60 |
| | 10 | 30 | 30 | 60 |
| | 12,5 | 30 | 30 | 60 |
| | 15 | 30 | 30 | 60 |
| | 20 | 30 | 30 | 60 |

* Dati ottenuti con pressione di esercizio di 3,3 +/- 0,2 bar; data la variabilità delle pressioni negli impianti di distribuzione, i valori di flusso e FiO2 sono da considerarsi approssimativi.

** Valore ottenibile con l'utilizzo del tappo aggiuntivo.

RESPIRATORY CARE Paper in Press. Published on September 29, 2015 as DOI: 10.4187/respcare.04134

# CPAP Devices for Emergency Prehospital Use: A Bench Study

Claudia Brusasco MD, Francesco Corradi MD PhD, Alessandra De Ferrari MD, Lorenzo Ball MD, Robert M Kacmarek PhD RRT FAARC, and Paolo Pelosi MD

**BACKGROUND: CPAP is frequently used in prehospital and emergency settings. An air-flow output minimum of 60 L/min and a constant positive pressure are 2 important features for a successful CPAP device. Unlike hospital CPAP devices, which require electricity, CPAP devices for ambulance use need only an oxygen source to function. The aim of the study was to evaluate and compare on a bench model the performance of 3 orofacial mask devices (Ventumask, EasyVent, and Boussignac CPAP system) and 2 helmets (Ventukit and EVE Coulisse) used to apply CPAP in the prehospital setting. METHODS: A static test evaluated air-flow output, positive pressure applied, and $F_{IO_2}$ delivered by each device. A dynamic test assessed airway pressure stability during simulated ventilation. Efficiency of devices was compared based on oxygen flow needed to generate a minimum air flow of 60 L/min at each CPAP setting. RESULTS: The EasyVent and EVE Coulisse devices delivered significantly higher mean air-flow outputs compared with the Ventumask and Ventukit under all CPAP conditions tested. The Boussignac CPAP system never reached an air-flow output of 60 L/min. The EasyVent had significantly lower pressure excursion than the Ventumask at all CPAP levels, and the EVE Coulisse had lower pressure excursion than the Ventukit at 5, 15, and 20 cm $H_2O$, whereas at 10 cm $H_2O$, no significant difference was observed between the 2 devices. Estimated oxygen consumption was lower for the EasyVent and EVE Coulisse compared with the Ventumask and Ventukit. CONCLUSIONS: Air-flow output, pressure applied, $F_{IO_2}$ delivered, device oxygen consumption, and ability to maintain air flow at 60 L/min differed significantly among the CPAP devices tested. Only the EasyVent and EVE Coulisse achieved the required minimum level of air-flow output needed to ensure an effective therapy under all CPAP conditions.**
*Key words: noninvasive CPAP; emergency department; ambulance; cardiogenic pulmonary edema; helmet CPAP; Boussignac; acute respiratory failure.* [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

## Introduction

Noninvasive ventilation (NIV) reduces the need for endotracheal intubation, the occurrence of nosocomial infections, and both morbidity and mortality associated with respiratory failure.[1-5] The benefits of NIV are greater if started early, thus constituting the rationale for the increasing use of NIV in prehospital and emergency department settings.[6-8] Because of its ease of use and the small size of commercially available devices, CPAP is the most commonly used NIV technique in these settings.[5,9] The benefits of CPAP have been extensively described in the treatment of acute cardiogenic pulmonary edema[10-12] and acute

Drs Brusasco, De Ferrari, Ball, and Pelosi are affiliated with the Dipartimento di Scienze Chirurgiche e Diagnostiche Integrate, Sezione Anestesia e Rianimazione, Università degli Studi di Genova, Genova, Italy. Drs De Ferrari, Ball, and Pelosi are also affiliated with the Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS) Azienda Ospedaliera Universitaria San Martino-Istituto Scientifico Tumori, Genova, Italy. Dr Corradi is affiliated with the SC Anestesia e Rianimazione, EO Ospedali Galliera, Genova, Italy. Dr Kacmarek is affiliated with the Department of Anesthesiology and Critical Care and the Department of Respiratory Care, Massachusetts General Hospital, Boston, Massachusetts.

Dr Kacmarek has disclosed relationships with Covidien and Venner Medical. The other authors has disclosed no conflicts of interest.

Correspondence: Claudia Brusasco MD, Dipartimento di Scienze Chirurgiche e Diagnostiche Integrate, Sezione Anestesia e Rianimazione, Università degli Studi di Genova, Largo Rosanna Benzi 8, 16132 Genova, Italy. E-mail: claudia.brusasco@gmail.com.

DOI: 10.4187/respcare.04134

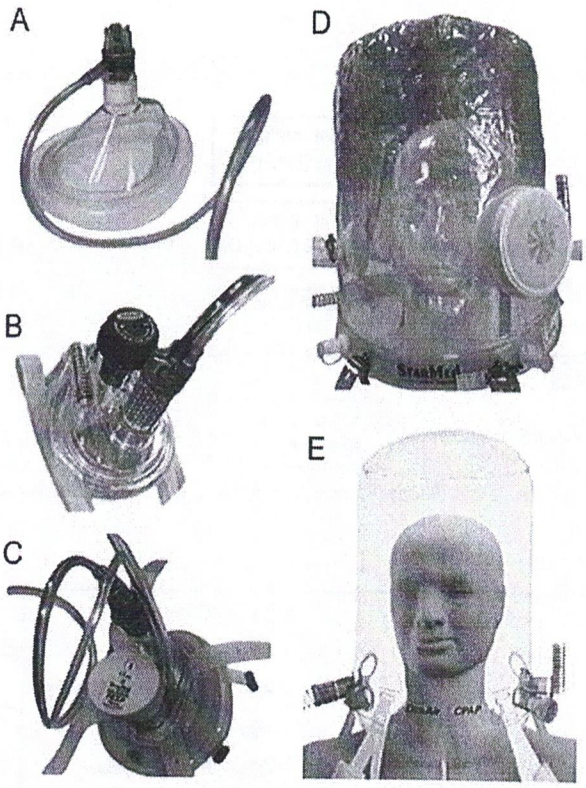



Fig. 1. The 5 tested devices. A: Boussignac CPAP system; B: EasyVent; C: Ventumask; D: Ventukit; E: EVE Coulisse.

Comparisons were performed between masks and between helmets because the devices from the same manufacturer (Ventumask/Ventukit and EasyVent/EVE Coulisse) use the same air-entrainment system and the difference between devices is the interfaces (mask or helmets). Moreover, the choice to use a mask or a helmet is strictly clinical, based on the patient's adherence or expected duration of needed assistance.

## Experimental Setting

Figure 2 shows the in vitro circuit used to evaluate the performance of each device in terms of flow, generated pressure, and delivered $F_{IO_2}$. A flow meter (ICU-Lab, KleisTEK, Bari, Italy) measuring air flow generated by the CPAP device was positioned downstream from each CPAP device's air-entrainment valve, as well as a rapid-response oxygen analyzer ($MaxO_2{}^+AE$, Maxtec, Salt Lake City, Utah) and a manometer.

The Ventumask, EasyVent, Ventukit, and EVE Coulisse devices were evaluated without CPAP and at 4 levels of CPAP (5, 10, 15, and 20 cm $H_2O$) set with each device's adjustable valve. For each CPAP valve level, the devices were tested at oxygen source flows of 5–15 L/min in 1 L/min increments, and generated pressure, air flow, and $F_{IO_2}$ were measured. The Boussignac CPAP system was evaluated for delivered air flow, $F_{IO_2}$, and pressure starting at 5 L/min oxygen up to 30 L/min, as recommended by the manufacturer, in 1 L/min increments from 5 to 15 L/min and then in 5 L/min steps to 30 L/min.

Each device was evaluated during simulated spontaneous breathing using a lung model. Airway pressure stability throughout the breathing cycle, estimated by calculating the mean of the pressure excursion inside the device chamber (maximum pressure-minimum pressure=excursion pressure), was used as an indirect index of work of breathing. As shown in Figure 2, a pneumatic lung simulator (Dimar) generating a mildly tachypneic sinusoidal flow pattern (tidal volume 500 mL, inspiratory time 0.8 s, expiratory time 1.6 s, breathing frequency 25 breaths/min) was directly connected to each device. A pneumotachograph and pressure transducer (ICU-Lab) were positioned between devices and the pneumatic lung simulator, and each device was tested during 60 s of uninterrupted simulated breathing. Air-entrainment devices were evaluated by delivering increasing levels of oxygen flow from 5 to 15 L/min in 1 L/min increments and then from 15 to 30 L/min in 5 L/min increments and at 4 different CPAP levels (5, 10, 15, and 20 cm $H_2O$), set with each device's adjustable CPAP valve. The Boussignac CPAP system was tested by delivering an increasing flow of oxygen from 5 to 30 L/min. For all devices, pressure excursion was calculated as mean of the pressure excursion over the 25 ventilatory cycles occurring during the recording time.

In addition, device oxygen consumption or rather oxygen inflow requirement was calculated from an oxygen tank (volume of 7 L) fully charged at 200 bar for a total 1,400 L of oxygen. The oxygen flow needed to generate a minimum air-flow output of 60 L/min was used to estimate efficiency in total minutes of run time. All experiments were carried out by the same researcher (CB).

## Statistical Analysis

Data are expressed as mean ± SD. All statistical analyses were performed using SPSS 21 (IBM, Armonk, New York), and significance was considered to be $P < .05$. All data were analyzed by averaging measurements on 3 different devices of each evaluated model.

## Gas Output Flow Generation Performances

The total gas output flow obtainable with the different devices was compared by 2-way analysis of variance, with input flow and device as factors. The relationship between oxygen input flow and generated air-flow outputs of each device was tested by linear regression analysis.

Table 1. Output Flow Generation Performance of Each Tested Device

| Device | Slope (95% CI) | Intercept (95% CI) | $r^2$ |
|---|---|---|---|
| Boussignac system | 0.7–0.9 | 0.8–3.1 | 0.97 |
| Ventumask | 5.9–6.4 | −14.5 to −9.8 | >0.99 |
| EasyVent | 4.8–11.0 | 7.3–8.8 | 0.98 |
| Ventukit | 4.2–5.3 | −18.7 to −5.3 | 0.99 |
| EVE Coulisse | 7.9–9.0 | −11.8 to −0.5 | >0.99 |

Results of linear regression of output flow versus input flow are reported.

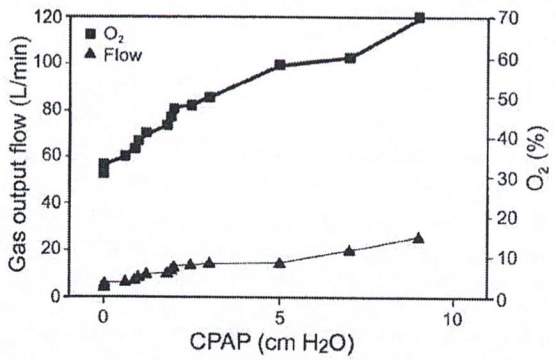



Fig. 4. Performances of the CPAP Boussignac system. The X axis represents CPAP values. The left Y axis represents air-flow outputs, and the right Y axis represents $F_{IO_2}$ generated at different oxygen flows from 5 to 30 L/min. Point labels are input flows (L/min). With the Boussignac CPAP system, output flows were slightly lower than input flows, possibly due to oxygen leakage through the virtual valve.

## Static Test

**Masks.** Considering the architectural differences between the Boussignac CPAP system and the other 4 devices (in particular, the inability to preset a positive pressure and $F_{IO_2}$), an initial separate characterization was performed (Fig. 4). The maximum positive pressure achieved with the Boussignac CPAP system was 9 cm $H_2O$ at an oxygen input flow of 30 L/min; therefore, no direct comparison with other mask devices could be performed at CPAP levels of 10, 15, and 20 cm $H_2O$.

At a CPAP of 5 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask and Boussignac (120, 75, and 15 L/min, respectively; $P < .001$ for all pairwise comparisons), with a lower $F_{IO_2}$ (31, 37, and 58%, $P < .001$ for all comparisons). At a CPAP of 10 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask (118 vs 70 L/min, $P < .001$), with a lower $F_{IO_2}$ (30% vs 40%, $P < .001$). At a CPAP of 15 cm $H_2O$, the EasyVent generated a higher output flow than Ventumask (100 vs 72 L/min, $P < .001$), with a lower $F_{IO_2}$ (33% vs 42%, $P < .001$). At a CPAP of 20 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask (90 vs 40 L/min, $P < .001$), with a lower $F_{IO_2}$ (35% vs 55%, $P < .001$).

**Helmets.** At a CPAP of 5 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (120 vs 60 L/min, $P < .001$), with a lower $F_{IO_2}$ (31% vs 41%, $P < .001$). At a CPAP of 10 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (112 vs 46 L/min, $P < .001$), with a lower $F_{IO_2}$ (30% vs 47%, $P < .001$). At a CPAP of 15 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (95 vs 35 L/min, $P < .001$), with a lower $F_{IO_2}$ (32% vs 54%, $P < .001$). At a CPAP of 20 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (80 vs 20 L/min, $P < .001$), with a lower $F_{IO_2}$ (34% vs 80%, $P < .001$).

A comparison of the overall efficiency of all devices with the static test is illustrated in Figures 4 and 5. All CPAP devices showed a reduction of air-flow output and an increase in $F_{IO_2}$ as the CPAP level was increased.

## Dynamic Test

Because the Boussignac CPAP system never reached a minimum air-flow output of 60 L/min, it was considered not to be comparable with the other devices and was not included in the dynamic bench test. Normality assumption for pressure excursion distribution was rejected for both masks and helmets, with $P < .001$. The dynamic bench test showed a significant negative correlation between the gas flow generated by the CPAP devices and the pressure excursion inside the device for both masks (rho = −0.86, $P = .01$) and helmets (rho = −0.79, $P = .03$). For both air-entrainment masks and helmets, a steep decrease in pressure excursion was observed when the delivered flow reached the threshold of 60 L/min (Fig. 6). Absolute values of pressure excursion were lower in helmets due to their high internal volume.

The EasyVent had significantly lower pressure excursion than the Ventumask at all CPAP levels ($P < .001$), and the EVE Coulisse had lower pressure excursion than the Ventukit at 5 cm $H_2O$ ($P < .001$), 15 cm $H_2O$ ($P = .02$), and 20 cm $H_2O$ ($P < .001$), whereas at 10 cm $H_2O$, no significant difference was observed between the 2 devices ($P > .99$). The results of the dynamic test are illustrated in Figure 7. The efficiency of devices in terms of oxygen consumption needed to achieve the output flow threshold of 60 L/min at a given CPAP level are reported in Table 2.

## Discussion

The major findings of this study are: (1) different devices for noninvasive CPAP varied significantly in their

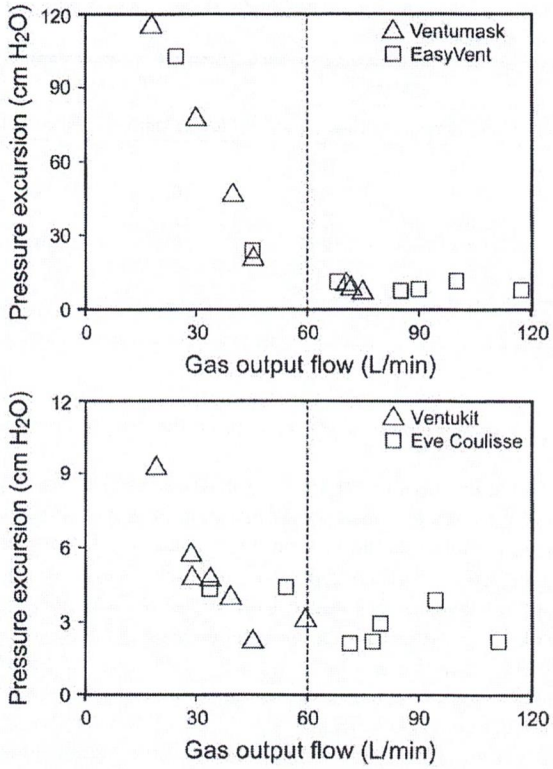
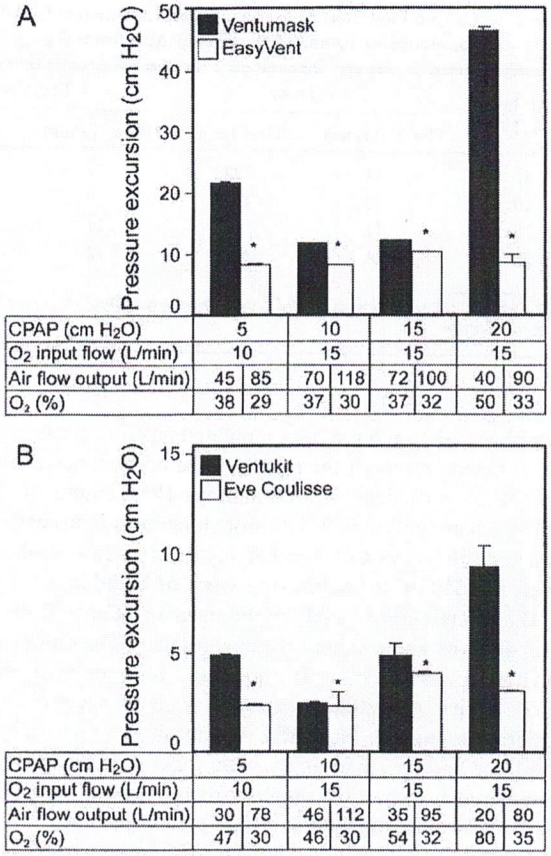



Fig. 6. Relation between pressure excursion and gas output flow in air-entrainment devices. A steep decrease in the first was observed above a threshold of 60 L/min.




| CPAP (cm $H_2O$) | 5 | | 10 | | 15 | | 20 | |
|---|---|---|---|---|---|---|---|---|
| $O_2$ input flow (L/min) | 10 | | 15 | | 15 | | 15 | |
| Air flow output (L/min) | 45 | 85 | 70 | 118 | 72 | 100 | 40 | 90 |
| $O_2$ (%) | 38 | 29 | 37 | 30 | 37 | 32 | 50 | 33 |

| CPAP (cm $H_2O$) | 5 | | 10 | | 15 | | 20 | |
|---|---|---|---|---|---|---|---|---|
| $O_2$ input flow (L/min) | 10 | | 15 | | 15 | | 15 | |
| Air flow output (L/min) | 30 | 78 | 46 | 112 | 35 | 95 | 20 | 80 |
| $O_2$ (%) | 47 | 30 | 46 | 30 | 54 | 32 | 80 | 35 |

Fig. 7. Pressure excursion (maximum pressure-minimum pressure=excursion pressure) of Ventumask and Easy Vent (panel A) and Ventukit and Eve Coulisse (panel B) during the dynamic bench test. Input flow, pressure, obtained output flow, and $F_{IO_2}$ are reported. * Significantly lower than the other device compared at the same pressure and input flow ($P < .001$). The Boussignac CPAP system was not included in this graph because its applied CPAP cannot be adjusted, and it does entrain ambient air.

air-flow output of 60 L/min at zero CPAP. The differences between these 2 devices in air-flow output may be due to the technical construction of the 2 jet entrainment systems. In fact, with the EasyVent, oxygen flow enters the system in parallel with air flow entrained from the external environment, generating laminar air flow, whereas with the Ventumask, oxygen flow enters at an acute angle to the ambient air flow and entrains less air, possibly due to the generation of turbulence.

Of the helmet devices, the EasyVent and EVE Coulisse were similar in effectiveness, and this result was expected because they both incorporate the same jet entrainment systems applied to 2 different interfaces (mask vs helmet). The Ventukit incorporates the same jet entrainment system as the Ventumask, but the total air-flow output differed between these 2 devices. Inside the helmet at the air-flow output point, the Ventukit includes a plug to reduce the noise generated by the jet entrainment system. This plug certainly reduces the noise inside the helmet, but adds a resistance, measured by the authors as 6 cm $H_2O$ per 50 L/min, significantly reducing the effectiveness of air entrainment. Unfortunately, this reduction in air entrainment limits the use of the Ventukit because the air-flow output was >60 L/min only at a CPAP of 5 cm $H_2O$, with an oxygen consumption of 14 L/min. An air-flow output >60 L/min is important in helmets not only to reduce the patient's work of breathing, as with masks, but also to avoid $CO_2$ rebreathing.[26,27] The EVE Coulisse maintained a total air-flow output well over 60 L/min with CPAP set from 5 to 20 cm $H_2O$ and consumed from only 8 L/min oxygen at a CPAP of 5 cm $H_2O$ to 13 L/min oxygen at a CPAP of 20 cm $H_2O$.

Our data also support the clinical relevance of an air-flow threshold of 60 L/min, which is recommended in CPAP guidelines.[20,21] We found increased pressure excursion and negative pressure spikes during the inspiratory phase whenever 60 L/min was not reached (see Fig. 6). Comparisons between devices systematically showed significantly larger pressure excursion for those devices that did not reach the 60 L/min threshold. In helmets, low total air flow also resulted in lower pressures during the inspira-

Langue Française. International Consensus Conferences in Intensive Care Med: noninvasive positive pressure ventilation in acute respiratory failure. Am J Respir Crit Care Med 2001;163(1):283-291.
3. Nourdine K, Combes P, Carton MJ, Beuret P, Cannamela A, Ducreux JC. Does noninvasive ventilation reduce the ICU nosocomial infection risk? A prospective clinical survey. Intensive Care Med 1999;25(6):567-573.
4. Carlucci A, Richard JC, Wysocki M, Lepage E, Brochard L, SRLF Collaborative Group on Mechanical Ventilation. Noninvasive versus conventional mechanical ventilation. An epidemiologic survey. Am J Respir Crit Care Med 2001;163(4):874-880.
5. Garuti G, Bandiera G, Cattaruzza MS, Gelati L, Osborn JF, Toscani S, et al. Out-of-hospital helmet CPAP in acute respiratory failure reduces mortality: a study led by nurses. Monaldi Arch Chest Dis 2010;73(4):145-151.
6. Kosowsky JM, Stephanides SL, Branson RD, Sayre MR. Prehospital use of continuous positive airway pressure (CPAP) for presumed pulmonary edema: a preliminary case series. Prehosp Emerg Care 2001;5(2):190-196.
7. Foti G, Sangalli F, Berra L, Sironi S, Cazzaniga M, Rossi GP, et al. Is helmet CPAP first line pre-hospital treatment of presumed severe acute pulmonary edema? Intensive Care Med 2009;35(4):656-662.
8. Ducros L, Logeart D, Vicaut E, Henry P, Plaisance P, Collet JP, et al. CPAP for acute cardiogenic pulmonary oedema from out-of-hospital to cardiac intensive care unit: a randomised multicentre study. Intensive Care Med 2011;37(9):1501-1509.
9. Kallio T, Kuisma M, Alaspää A, Rosenberg PH. The use of prehospital continuous positive airway pressure treatment in presumed acute severe pulmonary edema. Prehosp Emerg Care 2003;7(2):209-213.
10. Weng CL, Zhao YT, Liu QH, Fu CJ, Sun F, Ma YL, et al. Meta-analysis: noninvasive ventilation in acute cardiogenic pulmonary edema. Ann Int Med 2010;152(9):590-600.
11. Collins SP, Mielniczuk LM, Whittingham HA, Boseley ME, Schramm DR, Storrow AB. The use of noninvasive ventilation in emergency department patients with acute cardiogenic pulmonary edema: a systematic review. Ann Emerg Med 2006;48(3):260-269.
12. Vital FM, Ladeira MT, Atallah AN. Non-invasive positive pressure ventilation (CPAP or bilevel NPPV) for cardiogenic pulmonary oedema. Cochrane Database Syst Rev 2013;5:CD005351.
13. Ferrer M, Esquinas A, Leon M, Gonzalez G, Alarcon A, Torres A. Noninvasive ventilation in severe hypoxemic respiratory failure: a randomized clinical trial. Am J Respir Crit Care Med 2003;168(12):1438-1444.
14. Meduri GU, Abou-Shala N, Fox RC, Jones CB, Leeper KV, Wunderink RG. Noninvasive face mask mechanical ventilation in patients with acute hypercapnic respiratory failure. Chest 1991;100(2):445-454.
15. Cosentini R, Brambilla AM, Aliberti S, Bignamini A, Nava S, Maffei A, et al. Helmet continuous positive airway pressure vs oxygen therapy to improve oxygenation in community-acquired pneumonia: a randomized, controlled trial. Chest 2010;138(1):114-120.
16. Katz JA, Marks JD. Inspiratory work with and without continuous positive airway pressure in patients with acute respiratory failure. Anesthesiology 1985;63(6):598-607.
17. Bradley TD, Holloway RM, McLaughlin PR, Ross BL, Walters J, Liu PP. Cardiac output response to continuous positive airway pressure in congestive heart failure. Am Rev Respir Dis 1992;145(2 Pt 1):377-382.
18. Kaneko Y, Floras JS, Usui K, Plante J, Tkacova R, Kubo T, et al. Cardiovascular effects of continuous positive airway pressure in patients with heart failure and obstructive sleep apnea. N Engl J Med 2003;348(13):1233-1241.
19. Fessler HE, Brower RG, Wise RA, Permutt S. Mechanism of reduced LV afterload by systolic and diastolic positive pleural pressure. J Appl Physiol 1988;65(3):1244-1250.
20. British Thoracic Society Standards of Care Committee. Non-invasive ventilation in acute respiratory failure. Thorax 2002;57(3):192-211.
21. Glover GW, Fletcher SJ. Assessing the performance of the Whisperflow continuous positive airway pressure generator: a bench study. Br J Anaesth 2009;102(6):875-881.
22. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. Boussignac continuous positive airway pressure system: practical use in a prehospital medical care unit. Eur J Emerg Med 2003;10(2):87-93.
23. Wong DT, Tam AD, Van Zundert TC. The usage of the Boussignac continuous positive airway pressure system in acute respiratory failure. Minerva Anestesiol 2013;79(5):564-570.
24. Spijker EE, de Bont M, Bax M, Sandel M. Practical use, effects and complications of prehospital treatment of acute cardiogenic pulmonary edema using the Boussignac CPAP system. Int J Emerg Med 2013;6(1):8.
25. Sehlin M, Törnell SS, Öhberg F, Johansson G, Winsö O. Pneumatic performance of the Boussignac CPAP system in healthy humans. Respir Care 2011;56(6):818-826.
26. Taccone P, Hess D, Caironi P, Bigatello LM. Continuous positive airway pressure delivered with a "helmet": effects on carbon dioxide rebreathing. Crit Care Med 2004;32(10):2090-2096.
27. Foti G, Patroniti N, Pesenti A. Helmet CPAP in acute respiratory failure. In Vincent JL, editor. Yearbook of intensive care and emergency medicine. Berlin: Springer-Verlag; 2004;411-418.
28. Patroniti N, Foti G, Manfio A, Coppo A, Bellani G, Pesenti A. Head helmet versus face mask for non-invasive continuous positive airway pressure: a physiological study. Intensive Care Med 2003;29(10):1680-1687.
29. L'HerE, Moriconi M, Texier F, Bouquin V, Kaba L, Renault A, et al. Non-invasive continuous positive airway pressure in acute hypoxaemic respiratory failure—experience of an emergency department. Eur J Emerg Med 1998;5(3):313-318.
30. Simpson PM, Bendall JC. Prehospital non-invasive ventilation for acute cardiogenic pulmonary oedema: an evidence-based review. Emerg Med J 2011;28(7):609-612.
31. Williams B, Boyle M, Robertson N, Giddings C. When pressure is positive: a literature review of the prehospital use of continuous positive airway pressure. Prehosp Disaster Med 2013;28(1):52-60.
32. Williams TA, Finn J, Perkins GD, Jacobs IG. Prehospital continuous positive airway pressure for acute respiratory failure: a systematic review and meta-analysis. Prehosp Emerg Care 2013;17(2):261-273.
33. Cheskes S, Turner L, Thomson S, Aljerian N. The impact of prehospital continuous positive airway pressure on the rate of intubation and mortality from acute out-of-hospital respiratory emergencies. Prehosp Emerg Care 2013;17(4):435-441.
34. Aguilar SA, Lee J, Dunford JV, Castillo E, Lam B, Choy J, et al. Assessment of the addition of prehospital continuous positive airway pressure (CPAP) to an urban emergency medical services (EMS) system in persons with severe respiratory distress. J Emerg Med 2013;45(2):210-219.
35. Frontin P, Bounes V, Houzé-Cerfon CH, Charpentier S, Houzé-Cerfon V, Ducassé JL. Continuous positive airway pressure for cardiogenic pulmonary edema: a randomized study. Am J Emerg Med 2011;29(7):775-781.
36. Dib JE, Matin SA, Luckert A. Prehospital use of continuous positive airway pressure for acute severe congestive heart failure. J Emerg Med 2012;42(5):553-558.
37. Bledsoe BE, Anderson E, Hodnick R, Johnson L, Johnson S, Dievendorf E. Low-fractional oxygen concentration continuous positive airway pressure is effective in the prehospital setting. Prehosp Emerg Care 2012;16(2):217-221.

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Azienda Ospedaliera Caserta

Medolla, 18/11/2020

**Oggetto: RDO N. 2690143 Fornitura urgente CPAP di Boussignac per Covid 19**

**Dichiarazione di equivalenza**

Il sottoscritto Borsari Maurizio nato a Concordia sulla Secchia (MO) il 11/02/1962, C.F. BRSMRZ62B11C951Q, residente a 41037 Mirandola (MO) in Via San Martino Carano, 123 in qualità di Legale Rappresentante della ditta Dimar S.r.l. con sede in 41036 Medolla (MO), Via G. Galilei, 6, P.I. 02779340369, iscritta presso la Camera di Commercio di Modena al n. 02779340369 dal 21/03/2002

**DICHIARA**

con riferimento al prodotto "CPAP di Boussignac per COVID 19"

in base al Principio di Equivalenza previsto dall'art. 68 D. Lgs 50/2016, la Scrivente società offre un prodotto con caratteristiche tecniche e performances equivalenti e migliorative rispetto a quello da Voi richiesto.

Il prodotto offerto infatti, di facile applicazione ed utilizzo, permette la somministrazione di miscele gassose in tecniche di CPAP senza l'ausilio di tubi tracheali o cannule tracheostomiche, direttamente in regime di Emergenza o di Urgenza.

In Emergenza permette di ridurre i rischi di ipossiemia grave durante il trasporto grazie ad un approccio terapeutico precoce con conseguente miglioramento del quadro clinico, diminuzione dell'affaticamento muscolare, evitando il rischio di decesso durante il trasporto in autoambulanza.
In Urgenza in tutti i reparti per il trattamento delle insufficienze respiratorie di varia eziologia che si giovano di un approccio terapeutico in tecniche di CPAP o come coadiuvante della farmaco terapia.
Il precoce ed efficace trattamento riduce notevolmente il ricorso all'intubazione tracheale con conseguente necessità di trasferimento nei reparti di Rianimazione, riduzione dei tempi di degenza e risparmio dei costi di gestione ed eliminazione dei rischi di infezione correlate all'intubazione.

Il Dispositivo consiste in una maschera con nucale in silicone elastico completa di sistema venturi ad alta efficacia ed efficienza, una valvola PEEP regolabile senza soluzione di continuità da 0 a 20 cm/$H_2O$, un manometro a colonna per la verifica e gestione della pressione applicata alle vie respiratorie del paziente ed una valvola di sicurezza antisoffocamento.
Il particolare venturi applicato, di nuova concezione, consente di erogare miscele gassose variabili da 35% a 100% con flussi fino a 120 Lt/min e pressioni variabili fino a 20 cm/$H_2O$ (efficacia), con flussi di ossigeno impostato tra 5 e 9 litri/minuto max di consumo (risparmio dei costi - efficienza).

RESPIRATORY CARE Paper in Press. Published on September 29, 2015 as DOI: 10.4187/respcare.04134

# CPAP Devices for Emergency Prehospital Use: A Bench Study

Claudia Brusasco MD, Francesco Corradi MD PhD, Alessandra De Ferrari MD, Lorenzo Ball MD, Robert M Kacmarek PhD RRT FAARC, and Paolo Pelosi MD

**BACKGROUND: CPAP is frequently used in prehospital and emergency settings. An air-flow output minimum of 60 L/min and a constant positive pressure are 2 important features for a successful CPAP device. Unlike hospital CPAP devices, which require electricity, CPAP devices for ambulance use need only an oxygen source to function. The aim of the study was to evaluate and compare on a bench model the performance of 3 orofacial mask devices (Ventumask, EasyVent, and Boussignac CPAP system) and 2 helmets (Ventukit and EVE Coulisse) used to apply CPAP in the prehospital setting. METHODS: A static test evaluated air-flow output, positive pressure applied, and $F_{IO_2}$ delivered by each device. A dynamic test assessed airway pressure stability during simulated ventilation. Efficiency of devices was compared based on oxygen flow needed to generate a minimum air flow of 60 L/min at each CPAP setting. RESULTS: The EasyVent and EVE Coulisse devices delivered significantly higher mean air-flow outputs compared with the Ventumask and Ventukit under all CPAP conditions tested. The Boussignac CPAP system never reached an air-flow output of 60 L/min. The EasyVent had significantly lower pressure excursion than the Ventumask at all CPAP levels, and the EVE Coulisse had lower pressure excursion than the Ventukit at 5, 15, and 20 cm $H_2O$, whereas at 10 cm $H_2O$, no significant difference was observed between the 2 devices. Estimated oxygen consumption was lower for the EasyVent and EVE Coulisse compared with the Ventumask and Ventukit. CONCLUSIONS: Air-flow output, pressure applied, $F_{IO_2}$ delivered, device oxygen consumption, and ability to maintain air flow at 60 L/min differed significantly among the CPAP devices tested. Only the EasyVent and EVE Coulisse achieved the required minimum level of air-flow output needed to ensure an effective therapy under all CPAP conditions.**

*Key words: noninvasive CPAP; emergency department; ambulance; cardiogenic pulmonary edema; helmet CPAP; Boussignac; acute respiratory failure.* [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

## Introduction

Noninvasive ventilation (NIV) reduces the need for endotracheal intubation, the occurrence of nosocomial infections, and both morbidity and mortality associated with respiratory failure.[1-5] The benefits of NIV are greater if started early, thus constituting the rationale for the increasing use of NIV in prehospital and emergency department settings.[6-8] Because of its ease of use and the small size of commercially available devices, CPAP is the most commonly used NIV technique in these settings.[5,9] The benefits of CPAP have been extensively described in the treatment of acute cardiogenic pulmonary edema[10-12] and acute

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Dr Kacmarek has disclosed relationships with Covidien and Venner Medical. The other authors has disclosed no conflicts of interest.

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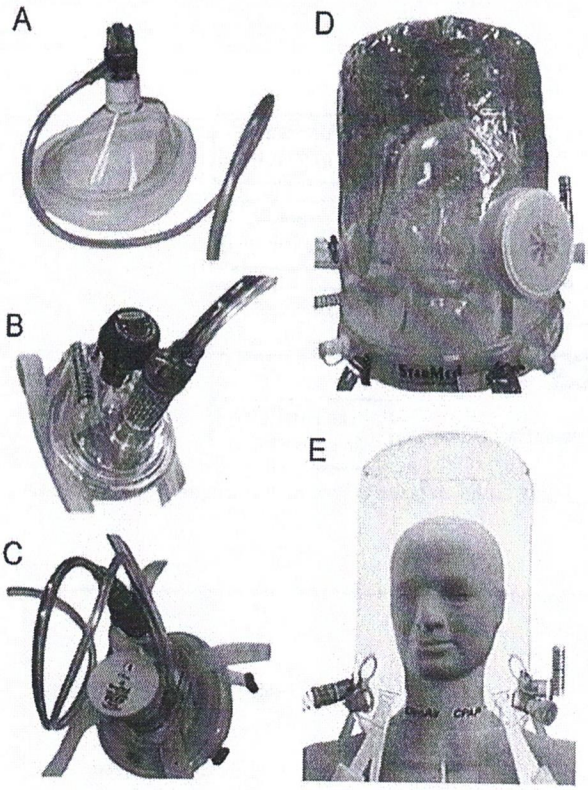



Fig. 1. The 5 tested devices. A: Boussignac CPAP system; B: EasyVent; C: Ventumask; D: Ventukit; E: EVE Coulisse.

Comparisons were performed between masks and between helmets because the devices from the same manufacturer (Ventumask/Ventukit and EasyVent/EVE Coulisse) use the same air-entrainment system and the difference between devices is the interfaces (mask or helmets). Moreover, the choice to use a mask or a helmet is strictly clinical, based on the patient's adherence or expected duration of needed assistance.

### Experimental Setting

Figure 2 shows the in vitro circuit used to evaluate the performance of each device in terms of flow, generated pressure, and delivered $F_{IO_2}$. A flow meter (ICU-Lab, KleisTEK, Bari, Italy) measuring air flow generated by the CPAP device was positioned downstream from each CPAP device's air-entrainment valve, as well as a rapid-response oxygen analyzer ($MaxO_2{}^+AE$, Maxtec, Salt Lake City, Utah) and a manometer.

The Ventumask, EasyVent, Ventukit, and EVE Coulisse devices were evaluated without CPAP and at 4 levels of CPAP (5, 10, 15, and 20 cm $H_2O$) set with each device's adjustable valve. For each CPAP valve level, the devices were tested at oxygen source flows of 5–15 L/min in 1 L/min increments, and generated pressure, air flow, and $F_{IO_2}$ were measured. The Boussignac CPAP system was evaluated for delivered air flow, $F_{IO_2}$, and pressure starting at 5 L/min oxygen up to 30 L/min, as recommended by the manufacturer, in 1 L/min increments from 5 to 15 L/min and then in 5 L/min steps to 30 L/min.

Each device was evaluated during simulated spontaneous breathing using a lung model. Airway pressure stability throughout the breathing cycle, estimated by calculating the mean of the pressure excursion inside the device chamber (maximum pressure-minimum pressure=excursion pressure), was used as an indirect index of work of breathing. As shown in Figure 2, a pneumatic lung simulator (Dimar) generating a mildly tachypneic sinusoidal flow pattern (tidal volume 500 mL, inspiratory time 0.8 s, expiratory time 1.6 s, breathing frequency 25 breaths/min) was directly connected to each device. A pneumotachograph and pressure transducer (ICU-Lab) were positioned between devices and the pneumatic lung simulator, and each device was tested during 60 s of uninterrupted simulated breathing. Air-entrainment devices were evaluated by delivering increasing levels of oxygen flow from 5 to 15 L/min in 1 L/min increments and then from 15 to 30 L/min in 5 L/min increments and at 4 different CPAP levels (5, 10, 15, and 20 cm $H_2O$), set with each device's adjustable CPAP valve. The Boussignac CPAP system was tested by delivering an increasing flow of oxygen from 5 to 30 L/min. For all devices, pressure excursion was calculated as mean of the pressure excursion over the 25 ventilatory cycles occurring during the recording time.

In addition, device oxygen consumption or rather oxygen inflow requirement was calculated from an oxygen tank (volume of 7 L) fully charged at 200 bar for a total 1,400 L of oxygen. The oxygen flow needed to generate a minimum air-flow output of 60 L/min was used to estimate efficiency in total minutes of run time. All experiments were carried out by the same researcher (CB).

### Statistical Analysis

Data are expressed as mean ± SD. All statistical analyses were performed using SPSS 21 (IBM, Armonk, New York), and significance was considered to be $P < .05$. All data were analyzed by averaging measurements on 3 different devices of each evaluated model.

### Gas Output Flow Generation Performances

The total gas output flow obtainable with the different devices was compared by 2-way analysis of variance, with input flow and device as factors. The relationship between oxygen input flow and generated air-flow outputs of each device was tested by linear regression analysis.

Table 1. Output Flow Generation Performance of Each Tested Device

| Device | Slope (95% CI) | Intercept (95% CI) | $r^2$ |
|---|---|---|---|
| Boussignac system | 0.7–0.9 | 0.8–3.1 | 0.97 |
| Ventumask | 5.9–6.4 | −14.5 to −9.8 | >0.99 |
| EasyVent | 4.8–11.0 | 7.3–8.8 | 0.98 |
| Ventukit | 4.2–5.3 | −18.7 to −5.3 | 0.99 |
| EVE Coulisse | 7.9–9.0 | −11.8 to −0.5 | >0.99 |

Results of linear regression of output flow versus input flow are reported.

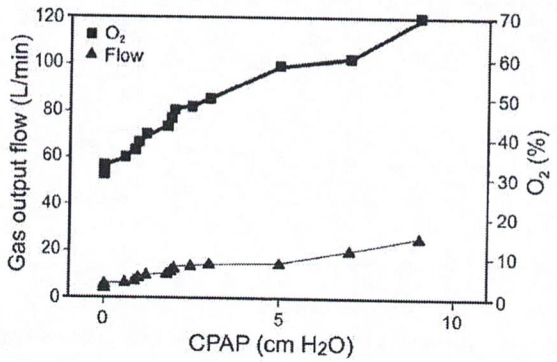



Fig. 4. Performances of the CPAP Boussignac system. The X axis represents CPAP values. The left Y axis represents air-flow outputs, and the right Y axis represents $F_{IO_2}$ generated at different oxygen flows from 5 to 30 L/min. Point labels are input flows (L/min). With the Boussignac CPAP system, output flows were slightly lower than input flows, possibly due to oxygen leakage through the virtual valve.

## Static Test

**Masks.** Considering the architectural differences between the Boussignac CPAP system and the other 4 devices (in particular, the inability to preset a positive pressure and $F_{IO_2}$), an initial separate characterization was performed (Fig. 4). The maximum positive pressure achieved with the Boussignac CPAP system was 9 cm $H_2O$ at an oxygen input flow of 30 L/min; therefore, no direct comparison with other mask devices could be performed at CPAP levels of 10, 15, and 20 cm $H_2O$.

At a CPAP of 5 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask and Boussignac (120, 75, and 15 L/min, respectively; $P < .001$ for all pairwise comparisons), with a lower $F_{IO_2}$ (31, 37, and 58%, $P < .001$ for all comparisons). At a CPAP of 10 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask (118 vs 70 L/min, $P < .001$), with a lower $F_{IO_2}$ (30% vs 40%, $P < .001$). At a CPAP of 15 cm $H_2O$, the EasyVent generated a higher output flow than Ventumask (100 vs 72 L/min, $P < .001$), with a lower $F_{IO_2}$ (33% vs 42%, $P < .001$). At a CPAP of 20 cm $H_2O$, the EasyVent generated a higher output flow than the Ventumask (90 vs 40 L/min, $P < .001$), with a lower $F_{IO_2}$ (35% vs 55%, $P < .001$).

**Helmets.** At a CPAP of 5 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (120 vs 60 L/min, $P < .001$), with a lower $F_{IO_2}$ (31% vs 41%, $P < .001$). At a CPAP of 10 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (112 vs 46 L/min, $P < .001$), with a lower $F_{IO_2}$ (30% vs 47%, $P < .001$). At a CPAP of 15 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (95 vs 35 L/min, $P < .001$), with a lower $F_{IO_2}$ (32% vs 54%, $P < .001$). At a CPAP of 20 cm $H_2O$, the EVE Coulisse generated a higher output flow than the Ventukit (80 vs 20 L/min, $P < .001$), with a lower $F_{IO_2}$ (34% vs 80%, $P < .001$).

A comparison of the overall efficiency of all devices with the static test is illustrated in Figures 4 and 5. All CPAP devices showed a reduction of air-flow output and an increase in $F_{IO_2}$ as the CPAP level was increased.

## Dynamic Test

Because the Boussignac CPAP system never reached a minimum air-flow output of 60 L/min, it was considered not to be comparable with the other devices and was not included in the dynamic bench test. Normality assumption for pressure excursion distribution was rejected for both masks and helmets, with $P < .001$. The dynamic bench test showed a significant negative correlation between the gas flow generated by the CPAP devices and the pressure excursion inside the device for both masks (rho = −0.86, $P = .01$) and helmets (rho = −0.79, $P = .03$). For both air-entrainment masks and helmets, a steep decrease in pressure excursion was observed when the delivered flow reached the threshold of 60 L/min (Fig. 6). Absolute values of pressure excursion were lower in helmets due to their high internal volume.

The EasyVent had significantly lower pressure excursion than the Ventumask at all CPAP levels ($P < .001$), and the EVE Coulisse had lower pressure excursion than the Ventukit at 5 cm $H_2O$ ($P < .001$), 15 cm $H_2O$ ($P = .02$), and 20 cm $H_2O$ ($P < .001$), whereas at 10 cm $H_2O$, no significant difference was observed between the 2 devices ($P > .99$). The results of the dynamic test are illustrated in Figure 7. The efficiency of devices in terms of oxygen consumption needed to achieve the output flow threshold of 60 L/min at a given CPAP level are reported in Table 2.

## Discussion

The major findings of this study are: (1) different devices for noninvasive CPAP varied significantly in their

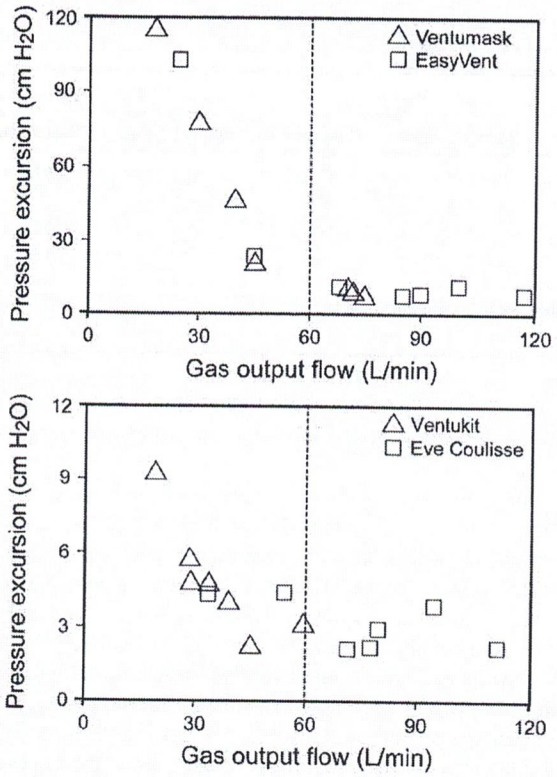
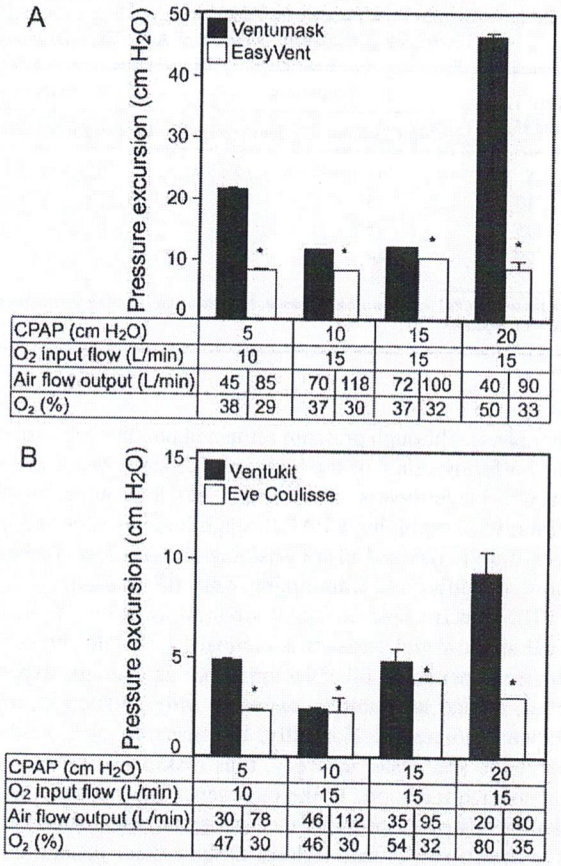



Fig. 6. Relation between pressure excursion and gas output flow in air-entrainment devices. A steep decrease in the first was observed above a threshold of 60 L/min.




| CPAP (cm $H_2O$) | 5 | | 10 | | 15 | | 20 | |
|---|---|---|---|---|---|---|---|---|
| $O_2$ input flow (L/min) | 10 | | 15 | | 15 | | 15 | |
| Air flow output (L/min) | 45 | 85 | 70 | 118 | 72 | 100 | 40 | 90 |
| $O_2$ (%) | 38 | 29 | 37 | 30 | 37 | 32 | 50 | 33 |

| CPAP (cm $H_2O$) | 5 | | 10 | | 15 | | 20 | |
|---|---|---|---|---|---|---|---|---|
| $O_2$ input flow (L/min) | 10 | | 15 | | 15 | | 15 | |
| Air flow output (L/min) | 30 | 78 | 46 | 112 | 35 | 95 | 20 | 80 |
| $O_2$ (%) | 47 | 30 | 46 | 30 | 54 | 32 | 80 | 35 |

Fig. 7. Pressure excursion (maximum pressure-minimum pressure=excursion pressure) of Ventumask and Easy Vent (panel A) and Ventukit and Eve Coulisse (panel B) during the dynamic bench test. Input flow, pressure, obtained output flow, and $F_{IO_2}$ are reported. * Significantly lower than the other device compared at the same pressure and input flow ($P < .001$). The Boussignac CPAP system was not included in this graph because its applied CPAP cannot be adjusted, and it does entrain ambient air.

air-flow output of 60 L/min at zero CPAP. The differences between these 2 devices in air-flow output may be due to the technical construction of the 2 jet entrainment systems. In fact, with the EasyVent, oxygen flow enters the system in parallel with air flow entrained from the external environment, generating laminar air flow, whereas with the Ventumask, oxygen flow enters at an acute angle to the ambient air flow and entrains less air, possibly due to the generation of turbulence.

Of the helmet devices, the EasyVent and EVE Coulisse were similar in effectiveness, and this result was expected because they both incorporate the same jet entrainment systems applied to 2 different interfaces (mask vs helmet). The Ventukit incorporates the same jet entrainment system as the Ventumask, but the total air-flow output differed between these 2 devices. Inside the helmet at the air-flow output point, the Ventukit includes a plug to reduce the noise generated by the jet entrainment system. This plug certainly reduces the noise inside the helmet, but adds a resistance, measured by the authors as 6 cm $H_2O$ per 50 L/min, significantly reducing the effectiveness of air entrainment. Unfortunately, this reduction in air entrainment limits the use of the Ventukit because the air-flow output was >60 L/min only at a CPAP of 5 cm $H_2O$, with an oxygen consumption of 14 L/min. An air-flow output >60 L/min is important in helmets not only to reduce the patient's work of breathing, as with masks, but also to avoid $CO_2$ rebreathing.[26,27] The EVE Coulisse maintained a total air-flow output well over 60 L/min with CPAP set from 5 to 20 cm $H_2O$ and consumed from only 8 L/min oxygen at a CPAP of 5 cm $H_2O$ to 13 L/min oxygen at a CPAP of 20 cm $H_2O$.

Our data also support the clinical relevance of an air-flow threshold of 60 L/min, which is recommended in CPAP guidelines.[20,21] We found increased pressure excursion and negative pressure spikes during the inspiratory phase whenever 60 L/min was not reached (see Fig. 6). Comparisons between devices systematically showed significantly larger pressure excursion for those devices that did not reach the 60 L/min threshold. In helmets, low total air flow also resulted in lower pressures during the inspira-

Langue Française. International Consensus Conferences in Intensive Care Med: noninvasive positive pressure ventilation in acute respiratory failure. Am J Respir Crit Care Med 2001;163(1):283-291.
3. Nourdine K, Combes P, Carton MJ, Beuret P, Cannamela A, Ducreux JC. Does noninvasive ventilation reduce the ICU nosocomial infection risk? A prospective clinical survey. Intensive Care Med 1999;25(6):567-573.
4. Carlucci A, Richard JC, Wysocki M, Lepage E, Brochard L, SRLF Collaborative Group on Mechanical Ventilation. Noninvasive versus conventional mechanical ventilation. An epidemiologic survey. Am J Respir Crit Care Med 2001;163(4):874-880.
5. Garuti G, Bandiera G, Cattaruzza MS, Gelati L, Osborn JF, Toscani S, et al. Out-of-hospital helmet CPAP in acute respiratory failure reduces mortality: a study led by nurses. Monaldi Arch Chest Dis 2010;73(4):145-151.
6. Kosowsky JM, Stephanides SL, Branson RD, Sayre MR. Prehospital use of continuous positive airway pressure (CPAP) for presumed pulmonary edema: a preliminary case series. Prehosp Emerg Care 2001;5(2):190-196.
7. Foti G, Sangalli F, Berra L, Sironi S, Cazzaniga M, Rossi GP, et al. Is helmet CPAP first line pre-hospital treatment of presumed severe acute pulmonary edema? Intensive Care Med 2009;35(4):656-662.
8. Ducros L, Logeart D, Vicaut E, Henry P, Plaisance P, Collet JP, et al. CPAP for acute cardiogenic pulmonary oedema from out-of-hospital to cardiac intensive care unit: a randomised multicentre study. Intensive Care Med 2011;37(9):1501-1509.
9. Kallio T, Kuisma M, Alaspää A, Rosenberg PH. The use of prehospital continuous positive airway pressure treatment in presumed acute severe pulmonary edema. Prehosp Emerg Care 2003;7(2):209-213.
10. Weng CL, Zhao YT, Liu QH, Fu CJ, Sun F, Ma YL, et al. Meta-analysis: noninvasive ventilation in acute cardiogenic pulmonary edema. Ann Int Med 2010;152(9):590-600.
11. Collins SP, Mielniczuk LM, Whittingham HA, Boseley ME, Schramm DR, Storrow AB. The use of noninvasive ventilation in emergency department patients with acute cardiogenic pulmonary edema: a systematic review. Ann Emerg Med 2006;48(3):260-269.
12. Vital FM, Ladeira MT, Atallah AN. Non-invasive positive pressure ventilation (CPAP or bilevel NPPV) for cardiogenic pulmonary oedema. Cochrane Database Syst Rev 2013;5:CD005351.
13. Ferrer M, Esquinas A, Leon M, Gonzalez G, Alarcon A, Torres A. Noninvasive ventilation in severe hypoxemic respiratory failure: a randomized clinical trial. Am J Respir Crit Care Med 2003;168(12):1438-1444.
14. Meduri GU, Abou-Shala N, Fox RC, Jones CB, Leeper KV, Wunderink RG. Noninvasive face mask mechanical ventilation in patients with acute hypercapnic respiratory failure. Chest 1991;100(2):445-454.
15. Cosentini R, Brambilla AM, Aliberti S, Bignamini A, Nava S, Maffei A, et al. Helmet continuous positive airway pressure vs oxygen therapy to improve oxygenation in community-acquired pneumonia: a randomized, controlled trial. Chest 2010;138(1):114-120.
16. Katz JA, Marks JD. Inspiratory work with and without continuous positive airway pressure in patients with acute respiratory failure. Anesthesiology 1985;63(6):598-607.
17. Bradley TD, Holloway RM, McLaughlin PR, Ross BL, Walters J, Liu PP. Cardiac output response to continuous positive airway pressure in congestive heart failure. Am Rev Respir Dis 1992;145(2 Pt 1):377-382.
18. Kaneko Y, Floras JS, Usui K, Plante J, Tkacova R, Kubo T, et al. Cardiovascular effects of continuous positive airway pressure in patients with heart failure and obstructive sleep apnea. N Engl J Med 2003;348(13):1233-1241.
19. Fessler HE, Brower RG, Wise RA, Permutt S. Mechanism of reduced LV afterload by systolic and diastolic positive pleural pressure. J Appl Physiol 1988;65(3):1244-1250.
20. British Thoracic Society Standards of Care Committee. Non-invasive ventilation in acute respiratory failure. Thorax 2002;57(3):192-211.
21. Glover GW, Fletcher SJ. Assessing the performance of the Whisperflow continuous positive airway pressure generator: a bench study. Br J Anaesth 2009;102(6):875-881.
22. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. Boussignac continuous positive airway pressure system: practical use in a prehospital medical care unit. Eur J Emerg Med 2003;10(2):87-93.
23. Wong DT, Tam AD, Van Zundert TC. The usage of the Boussignac continuous positive airway pressure system in acute respiratory failure. Minerva Anestesiol 2013;79(5):564-570.
24. Spijker EE, de Bont M, Bax M, Sandel M. Practical use, effects and complications of prehospital treatment of acute cardiogenic pulmonary edema using the Boussignac CPAP system. Int J Emerg Med 2013;6(1):8.
25. Sehlin M, Törnell SS, Öhberg F, Johansson G, Winsö O. Pneumatic performance of the Boussignac CPAP system in healthy humans. Respir Care 2011;56(6):818-826.
26. Taccone P, Hess D, Caironi P, Bigatello LM. Continuous positive airway pressure delivered with a "helmet": effects on carbon dioxide rebreathing. Crit Care Med 2004;32(10):2090-2096.
27. Foti G, Patroniti N, Pesenti A. Helmet CPAP in acute respiratory failure. In Vincent JL, editor. Yearbook of intensive care and emergency medicine. Berlin: Springer-Verlag; 2004;411-418.
28. Patroniti N, Foti G, Manfio A, Coppo A, Bellani G, Pesenti A. Head helmet versus face mask for non-invasive continuous positive airway pressure: a physiological study. Intensive Care Med 2003;29(10):1680-1687.
29. L'HerE, Moriconi M, Texier F, Bouquin V, Kaba L, Renault A, et al. Non-invasive continuous positive airway pressure in acute hypoxaemic respiratory failure—experience of an emergency department. Eur J Emerg Med 1998;5(3):313-318.
30. Simpson PM, Bendall JC. Prehospital non-invasive ventilation for acute cardiogenic pulmonary oedema: an evidence-based review. Emerg Med J 2011;28(7):609-612.
31. Williams B, Boyle M, Robertson N, Giddings C. When pressure is positive: a literature review of the prehospital use of continuous positive airway pressure. Prehosp Disaster Med 2013;28(1):52-60.
32. Williams TA, Finn J, Perkins GD, Jacobs IG. Prehospital continuous positive airway pressure for acute respiratory failure: a systematic review and meta-analysis. Prehosp Emerg Care 2013;17(2):261-273.
33. Cheskes S, Turner L, Thomson S, Aljerian N. The impact of prehospital continuous positive airway pressure on the rate of intubation and mortality from acute out-of-hospital respiratory emergencies. Prehosp Emerg Care 2013;17(4):435-441.
34. Aguilar SA, Lee J, Dunford JV, Castillo E, Lam B, Choy J, et al. Assessment of the addition of prehospital continuous positive airway pressure (CPAP) to an urban emergency medical services (EMS) system in persons with severe respiratory distress. J Emerg Med 2013;45(2):210-219.
35. Frontin P, Bounes V, Houzé-Cerfon CH, Charpentier S, Houzé-Cerfon V, Ducassé JL. Continuous positive airway pressure for cardiogenic pulmonary edema: a randomized study. Am J Emerg Med 2011;29(7):775-781.
36. Dib JE, Matin SA, Luckert A. Prehospital use of continuous positive airway pressure for acute severe congestive heart failure. J Emerg Med 2012;42(5):553-558.
37. Bledsoe BE, Anderson E, Hodnick R, Johnson L, Johnson S, Dievendorf E. Low-fractional oxygen concentration continuous positive airway pressure is effective in the prehospital setting. Prehosp Emerg Care 2012;16(2):217-221.

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Medolla, 18/11/2020

**Oggetto: RDO N. 2690143 Fornitura urgente CPAP di Boussignac per Covid 19**

**Offerta con indicazione di codici CND e RDM**

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# ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE

**relativa alla DETERMINA DIRIGENZIALE con oggetto:**

**E-PROCUREMENT DELLA PUBBLICA AMMINISTRAZIONE-PROCEDURA TELEMATICA AI SENSI DELL'ART.58 DEL D.LGS N.50/2016 e smi. A MEZZO RDO N. 2662305 SU ME.PA. CONSIP PER L'AFFIDAMENTO, EX ART. 95 CO.4 DEL DECRETO CITATO,DELLA FORNITURA SEMESTRALE DI CPAP DI BOUSSIGNAC DA DESTINARE ALL'UOC FARMACIA- CIG ZA42F65EB3**

**ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 1 (per le proposte che determinano un costo per l'AORN)**

Il costo derivante dal presente atto : €2.663,16

- è di competenza dell'esercizio 2020 , imputabile al conto economico 5010107010 - Dispositivi Medici
  da scomputare dal preventivo di spesa che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

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**ATTESTAZIONE DI VERIFICA E REGISTRAZIONE CONTABILE 2 (per le proposte che determinano un costo per l'AORN)**

Il costo derivante dal presente atto : €13.315,79

- è di competenza dell'esercizio 2021 , imputabile al conto economico 5010107010 - Dispositivi Medici
  da scomputare dal preventivo di spesa che presenta la necessaria disponibilità
- è relativo ad acquisizione cespiti di cui alla Fonte di Finanziamento

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Caserta li, 07/12/2020

**il Direttore**
**UOC GESTIONE ECONOMICO FINANZIARIA**
**Eduardo Scarfiglieri**