

Bubble CPAP SYSTEM



Fisher & Paykel
HEALTHCARE

Most respiratory diseases of the neonate occur as a result of the immaturity of the premature neonate's lungs. Despite stimulation, the normal process involved in the first breath does not occur. The respiratory system is underdeveloped and adequate gas exchange cannot take place. With this, there is a need for respiratory support.

Bubble CPAP with the combined effects of CPAP and pressure oscillations from the bubbles provides a lung protective, safe and effective method of respiratory support to spontaneously breathing neonates.

- ***Bubble CPAP effectively maintains Functional Residual Capacity (FRC)¹***

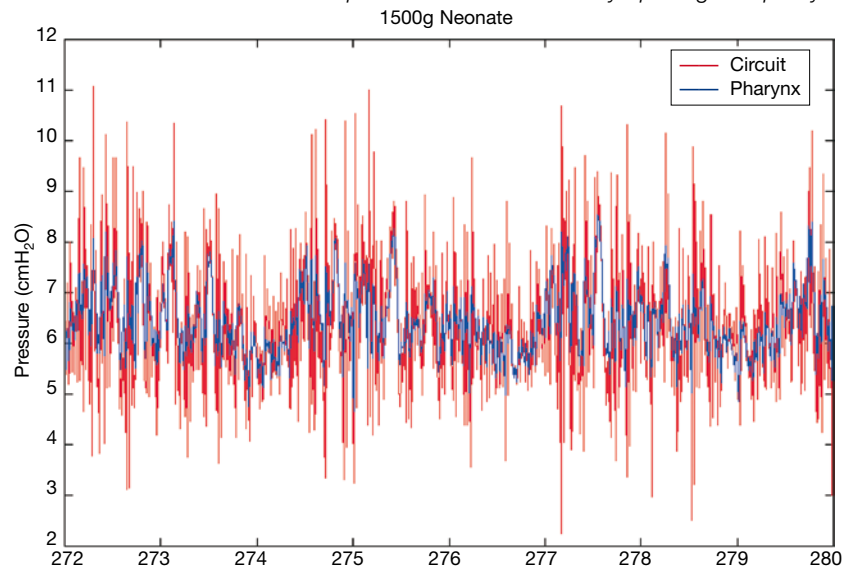
Most lung diseases that lead to respiratory failure are commonly associated with a reduced FRC. Maintaining FRC is very important to premature neonates who have a greater tendency of airway closure when FRC falls below closing volume.

- ***Bubble CPAP helps reduce the infant's Work of Breathing (WOB)²***

In a prospective randomized cross over trial performed by Lee, Dunn et.al. comparing bubble CPAP with ventilator-derived CPAP, results showed that there was a decrease in the infant's minute volume and respiratory rate with bubble CPAP. They observed chest vibrations caused by the pressure oscillations from the bubbling. These pressure oscillations, according to the study, are reverberated back into the infant's airway and may have provided an alternate form of gas exchange through the principle of facilitated diffusion. This physiologic effect of bubble CPAP may help improve gas exchange and reduce the infant's work of breathing ². Measurements done in vitro by Pillow and Travadi as well as in vivo measurements on a baby on bubble CPAP confirmed that the pressure oscillations from the bubbling are transmitted into the neonate's airway and lungs ^{3,4}.

Measurements from a 1500g neonate (2001)⁴

Note: Pressure oscillations are present at both the airway opening and pharynx.



• **Bubble CPAP may reduce the need for intubation and mechanical ventilation**^{5,6,7}

In the multi-center comparative study of Avery, et.al, it was noted that the use of bubble CPAP avoided the need for intubation reducing the possibility of airway injury, aspirations and secondary infection associated with the use of the ET tube^{5,7}. Results also showed significant reduction in the need for mechanical ventilation that may minimize the possible incidence of barotrauma^{5,1,2}.

A historical control study performed by AM De Klerk and RK De Klerk in the use of bubble CPAP further confirmed earlier results with data showing marked reduction in intubation and ventilation rates. There was also a decline in the number of days on oxygen and there were trends indicating less number of days on any respiratory support and to an earlier postnatal day of life when respiratory support is no longer needed⁶.

Faster recovery with less lung injury and better respiratory outcomes are possible using a cost-effective respiratory support system such as bubble CPAP.

• **Bubble CPAP tends to reduce the incidence of Chronic Lung Disease (CLD)**^{5,6,7}

Early treatment with bubble CPAP for infants with respiratory distress showed a change in the severity and duration of the disease. Significant reduction in the incidence of chronic lung disease which was defined as O₂ dependence at 28 days postnatal age or 36 weeks corrected gestation had been noted in some multi-center and comparative studies^{5,6}.

A case-cohort study of Linda Van Marter and colleagues suggested that barotrauma and oxygen toxicity were linked with CLD and that most of the increased risk of CLD was a result of the initiation of mechanical ventilation. Comparison of different respiratory care in 3 hospitals supported earlier results of reduced incidence of CLD with the use of bubble CPAP⁷.

Similar outcomes are being reproduced in hospitals that have used bubble CPAP. Below are some of the significant results from the historical control study done by AM de Klerk and RK de Klerk⁶.

Nasal Continuous Positive Airway Pressure and Outcomes of Preterm Infants⁶

	Period I Apr '93 – May '96 (n = 57)	Period II Jun '96 – Feb '98 (n = 59)	P
Ventilated Infants	65%	14%	0.0001
Receiving Surfactant	40%	12%	0.001
CLD at 28 days	11%	0%	0.02
Death or CLD at 28 days	16%	3%	0.046

Note: Period I - IMV / Conventional CPAP
Period II - Bubble CPAP

• **Bubble CPAP may improve non-pulmonary outcomes**

Improved non-pulmonary effects have also been observed in clinical trials such as the tendency to increase mean weight at 36 weeks corrected gestation, increase mean length and head circumference¹, reduction in time to reach full oral feeds and average length of stay⁶.

Fisher & Paykel's Bubble CPAP System has been developed based upon 30 years of proven clinical benefits as an effective method of providing respiratory support to neonates. The product is designed to provide a system that is safe, effective, lung-protective and easy to use.

The Delivery System

MR290 Chamber



- Easy to maintain
- Maintains constant CPAP
- Closed system ensures safety by minimizing the risk of contamination

Single-heated circuit



- Provides even heat distribution across the tube reducing heat loss and condensate build up
- Delivers optimal humidity to the neonate keeping a patent airway and allowing ease of suctioning

Pressure Manifold



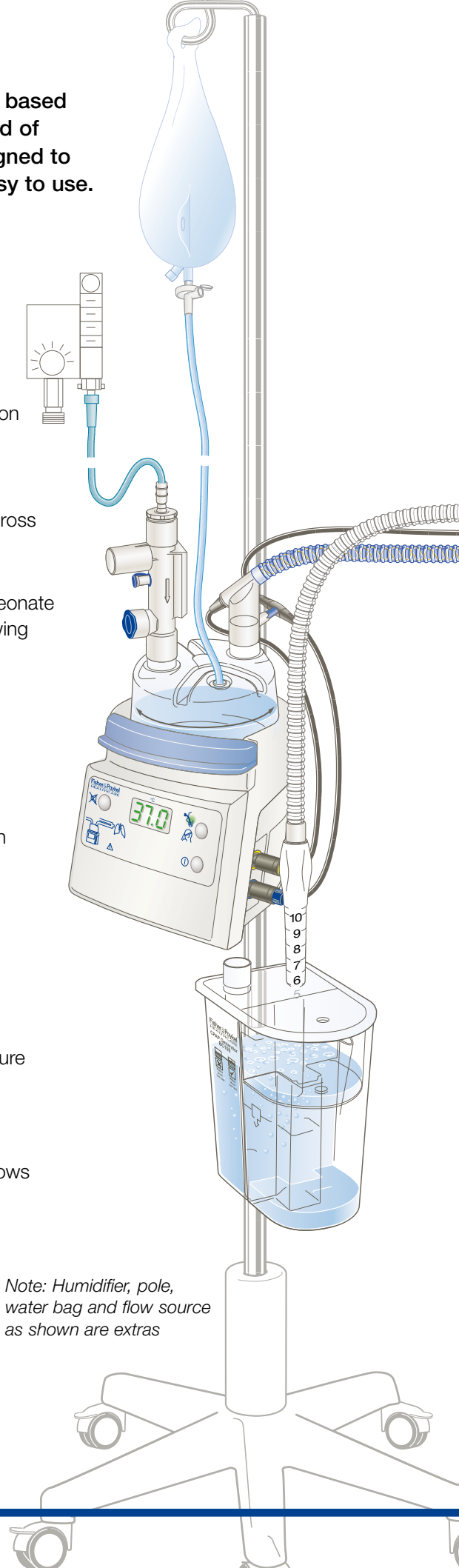
- Ensures patient safety by limiting the pressure delivered in an event of an occlusion
- Allows connection to a pressure monitoring device or an air/oxygen analyzer

CPAP Generator



- CPAP probe allows ease of pressure setting from 3 to 10cm H₂O
- Auto-level mechanism ensures constant mean CPAP pressure
- Detachable overflow container allows continuous CPAP while removing excess water from condensate
- Easy mounting using an F&P humidifier bracket

Note: Humidifier, pole, water bag and flow source as shown are extras

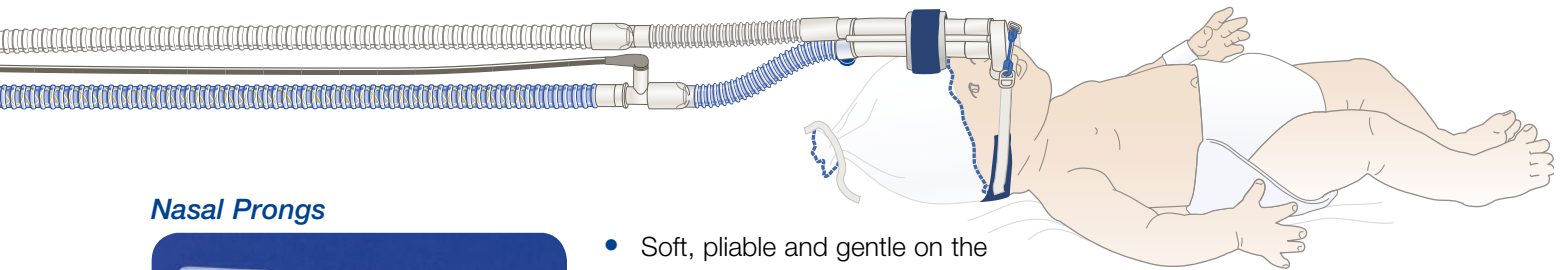


The Patient Interface

Nasal Tubing



- Low resistance to flow resulting in low Work of Breathing (WOB)
- Patented glider technology ensures proper fit preventing undue pressure-causing necrosis
- Supports various caring positions like prone, supine, lateral, etc.
- Collapsible extension tubing allows ease of circuit positioning and provides various length options to manage condensate
- With tear-off foam strip for adjustable height
- Available in 3 sizes Recommendation: 50mm ≤ 1.5kg
70mm ≤ 2.5kg
100mm > 2.5kg



Nasal Prongs



- Soft, pliable and gentle on the baby's nares
- Anatomically curved for a comfortable fit
- Available in 11 sizes based on prong diameter and width of septum
- Has the largest bore possible to reduce resistance to flow and Work of Breathing (WOB)
- Septum cut-away helps prevent septum necrosis

Infant Bonnet

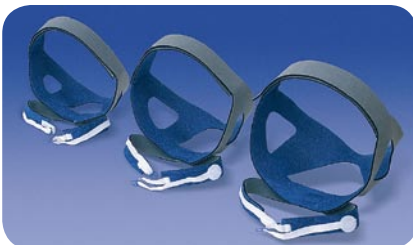


- Holds the nasal tubing in place for ease of setup
- Can open bonnet top to allow clinical procedures like ultrasound
- Available in 4 sizes that are designated by the head circumference
- Sizes are sewn on the bonnet for easy identification

Chin Strap

- Help optimize the effect of CPAP by preventing mouth leaks
- Soft, pliable material
- Split top design for better fixation
- Available in 4 sizes

Head Gear



- An alternative to the infant bonnet, the headgear is designed to suit larger infants of up to 45cm head circumference
- With 3-point fixation for a stable setup
- Soft, elastic material adapts to head contour
- Available in 3 sizes



Product Specification

Overall Infant Delivery System Specification

Delivery System Maximum Input Flow	15L/min
Maximum Mean CPAP	15cm H ₂ O

MR290 Humidification Chamber*

Inlet port	22mm Male
Outlet port	22mm Male
Compressible Volume	280ml
Compliance	0.4ml/cm H ₂ O
Maximum operating pressure	80cm H ₂ O
Maximum Peak Flow	180L/min

BC110 Pressure Manifold*

Maximum pressure Limit	17cm H ₂ O @ 8L/min
Inlet connector	O ₂ inlet adaptor
Outlet connector	22mm Female or 15mm Female
Luer port	Female Luer
Oxygen analyzer port	22mm Female or 15mm Female

BC060 Single Heated Breathing Circuit*

Circuit Length – Expiratory – Inspiratory	1.1m 1.2m
Compressible Volume Inspiratory Limb Expiratory Limb	149ml 101ml
Compliance Inspiratory Limb Expiratory Limb	0.19ml/cm H ₂ O 0.13ml/cm H ₂ O
Connectors	Manufactured to ISO 5356-1
Resistance to Flow	0.6cm H ₂ O @ 6L/min

CPAP Generator*

Inlet port	15mm Female
Exit port	22mm Male
CPAP pressure (mean)	3 - 10cm H ₂ O
Bubbler water container volume	Approx 500mls

Patient Interface Product Specification

Nasal Tubing*

Dead Space	nil
Length of nasal tubing <i>with collapsible extension</i>	
50mm (expanded) (collapsed)	224mm 163mm
70mm (expanded) (collapsed)	244mm 183mm
100mm (expanded) (collapsed)	274mm 213mm
Resistance to Flow <i>F&P Patient Interface with both inspiratory and expiratory collapsible extensions</i>	
50mm nasal tubing	0.49cm H ₂ O @ 6L/min
70mm nasal tubing	0.53cm H ₂ O @ 6L/min
100mm nasal tubing	0.55cm H ₂ O @ 6L/min

Nasal Prongs*

Material	Silicone (latex free)
Hardness	80 shore A
Resistance to Flow <i>Measured at the pressure port of the nasal tubing</i>	
BC3520 prongs	2.4cm H ₂ O @ 6L/min
BC4540 prongs	0.6cm H ₂ O @ 6L/min
BC6070 prongs	0.2cm H ₂ O @ 6L/min
Dead Space	
BC 3520 prongs	0.1ml
BC 6070 prongs	0.5ml

Infant Bonnet*

Bonnet tube material	Cotton/nylon blend (latex free)
----------------------	------------------------------------

Headgear*

Headgear material	Nylon/neoprene laminate (latex free)
-------------------	---

Chinstrap*

Chinstrap material	Nylon/polyurethane laminate (latex free)
--------------------	---

* single patient use

Reading References:

- 1 Vivek Narendran, Edward F Donovan, et.al. and Alan H Jobe. Comparison between Early Bubble CPAP and Conventional CPAP in Reducing the Incidence of Chronic Lung Disease. Presented at PAS Show in Baltimore. 2002
- 2 Lee KS, Dunn MS, et al. A Comparison of Underwater Bubble Continuous Positive Airway Pressure with Ventilator-Derived Continuous Positive Airway Pressure in Premature Neonates Ready for Extubation. Biol Neonate 73: 69-75. 1998
- 3 Travadi JN & Pillow JJ. Effect of Compliance and Flow on Pressure Waveform in the Lung During Bubble CPAP. An in Vitro study. Perinatal Society of Australia and New Zealand 5th Annual Congress
- 4 Fisher & Paykel Healthcare. Measurements on a baby. Middlemore Hospital, Auckland NZ. 2001
- 5 Avery, Mary Ellen, Tooley, William, et.al. Is Chronic Lung Disease in Low Birth Weight Infants Preventable? A Survey of Eight Centers. Pediatrics. Vol. 79 No. 1. 1987
- 6 AM de Klerk and RK de Klerk. Nasal continuous positive airway pressure and outcomes of preterm Infants. J Paediatr. Child Health (2001) 37, 161-167
- 7 Marter LJ, Pagano M, et al. Do Clinical Markers of Barotrauma and Oxygen Toxicity Explain Interhospital Variation in Rates of Chronic Lung Disease? Pediatrics. Vol 105 No.6: 1194-1201. Jun 2000
- 8 Verderer H, Albertsen P, et al. Nasal Continuous Positive Airway Pressure and Early Surfactant Therapy for Respiratory Distress Syndrome in Newborns of Less than 30 Weeks Gestation. Pediatrics. Vol 103 No.2 Feb 1999

WARNING: The use of the Bubble CPAP Delivery System with other than the recommended Fisher & Paykel Healthcare humidifier may impair performance or compromise safety

INTERNATIONAL Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland 2013; P O Box 14 348, Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.com Web Site: www.fphcare.com **AUSTRALIA** Tel:+61 3 9879 5022 Fax:+61 3 9879 5232 **AUSTRIA** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **BENELUX** Tel:+31 40 216 3555 Fax:+31 40 216 3554 **CHINA** Tel:+86 20 3205 3486 Fax:+86 20 3205 2132 **FRANCE** Tel:+33 1 6446 5201 Fax:+33 1 6446 5221 **GERMANY** Tel:+49 7182 93777 0 Fax:+49 7182 93777 99 **INDIA** Tel:+91 80 4123 6041 Fax:+91 80 4123 6044 **IRISH REPUBLIC** Tel: 1800 409 011 **ITALY** Tel:+39 06 7839 2939 Fax:+39 06 7814 7709 **JAPAN** Tel:+81 3 3661 7205 Fax:+81 3 3661 7206 **MIDDLE EAST** Tel: +9 71 4 360 0849 Fax: +9 71 4 368 8110 **NORTHERN IRELAND** Tel: 0800 132 189 **SPAIN** Tel:+34 902 013 346 Fax:+34 902 013 379 **SWEDEN** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **SWITZERLAND** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **UK (EU Authorised Representative)** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, United Kingdom Tel:+44 1628 626 136 Fax:+44 1628 626 146 **USA** Tel: +1 800 446 3908 or +1 949 453 4000 Fax:+1 949 453 4001