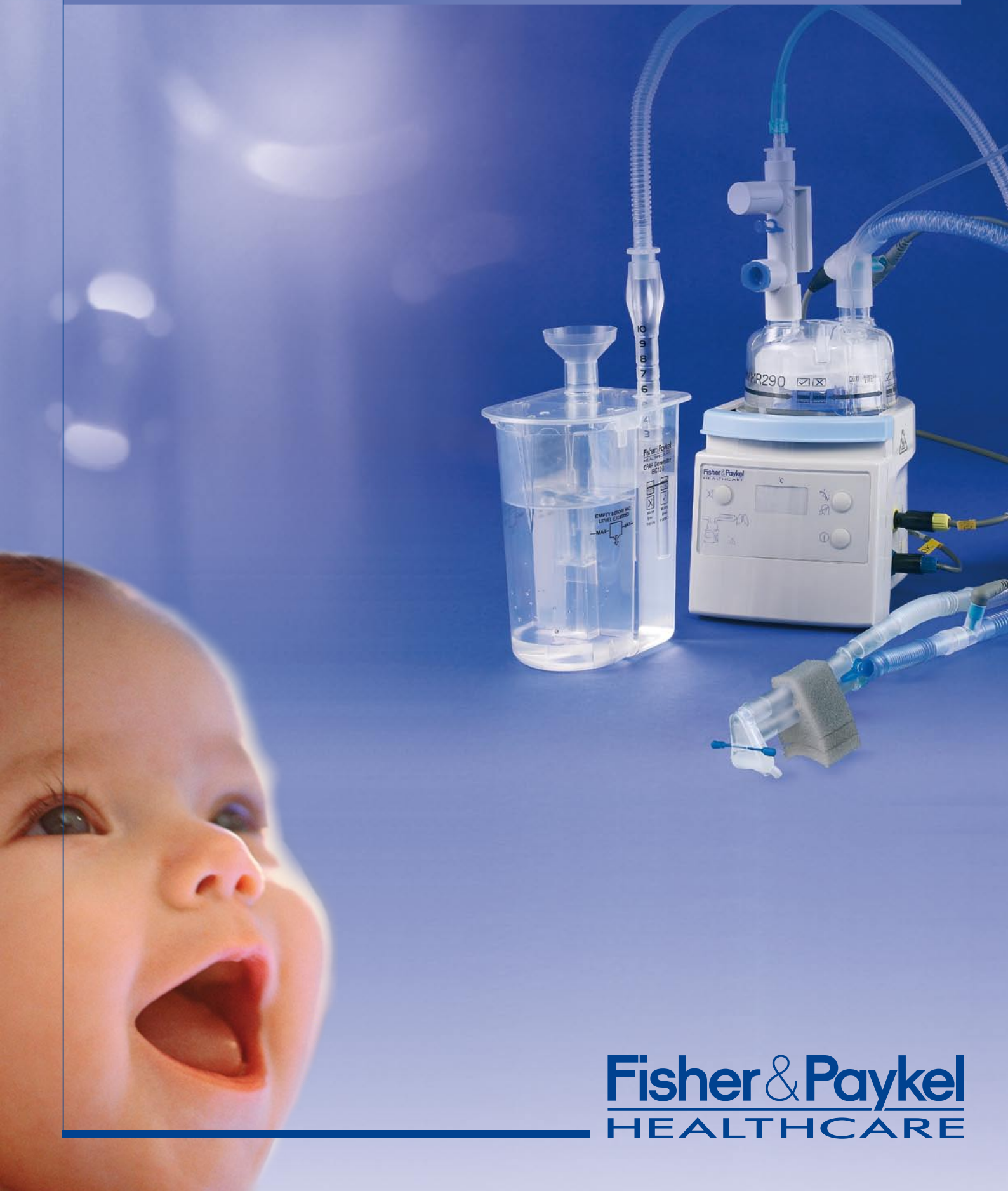
Neonatal

# Bubble CPAP SYSTEM

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**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]*

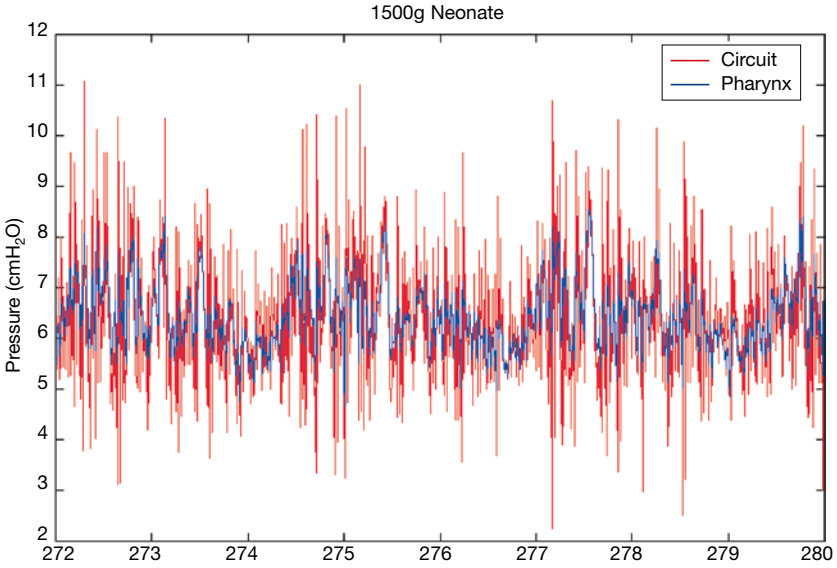
Most lung diseases that lead to respiratory failure are commonly associated with a reduced FRC. Maintaining FRC is very important to premature neonates who have a greater tendency of airway closure when FRC falls below closing volume.

## • *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 needed [6].

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 $O_2$ 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 CPAP[7].

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 Klerk [6].

*Nasal Continuous Positive Airway Pressure and Outcomes of Preterm Infants*[6]

| | Period I<br>Apr '93 – May '96<br>(n = 57) | Period II<br>Jun '96 – Feb '98<br>(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 circumference [1], reduction in time to reach full oral feeds and average length of stay [6].

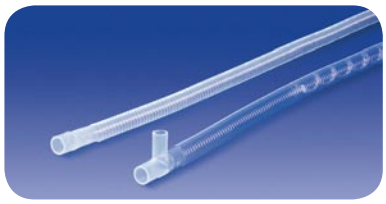
***Fisher & Paykel's Bubble CPAP System*** **has been developed based upon 30 years of proven clinical benefits as an effective method of providing respiratory support to neonates. The product is designed to provide a system that is safe, effective, lung-protective and easy to use.**

## *The Delivery System*

### *MR290 Chamber*

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

### *Single-heated circuit*



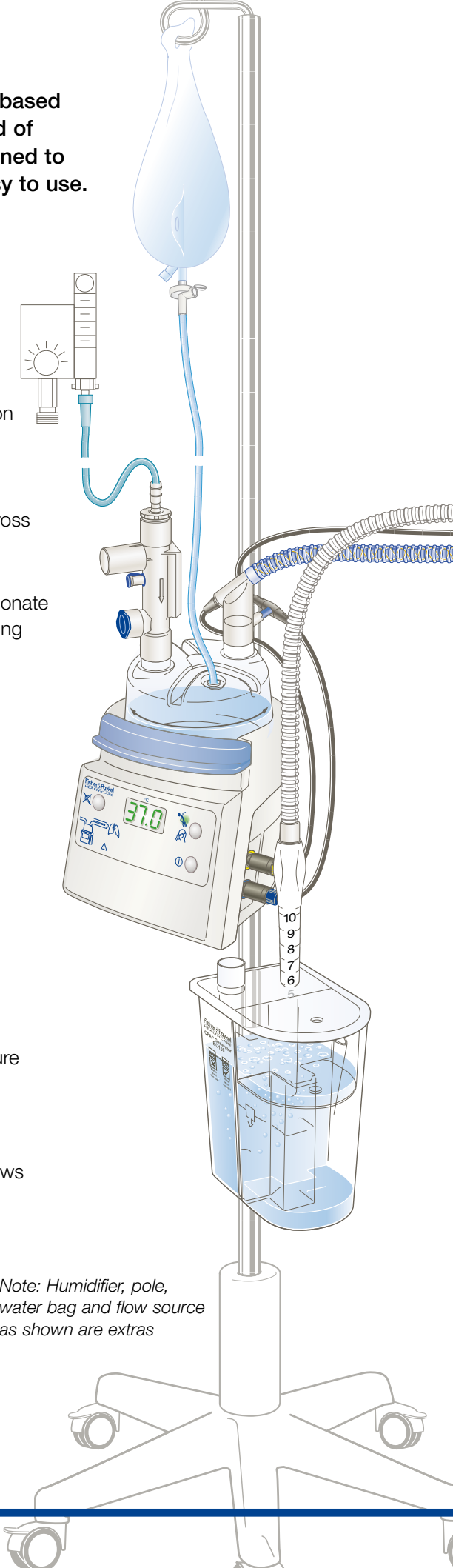
- Provides even heat distribution across the tube reducing heat loss and condensate build up
- Delivers optimal humidity to the neonate keeping a patent airway and allowing ease of suctioning

### *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 $H_2O$
- 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

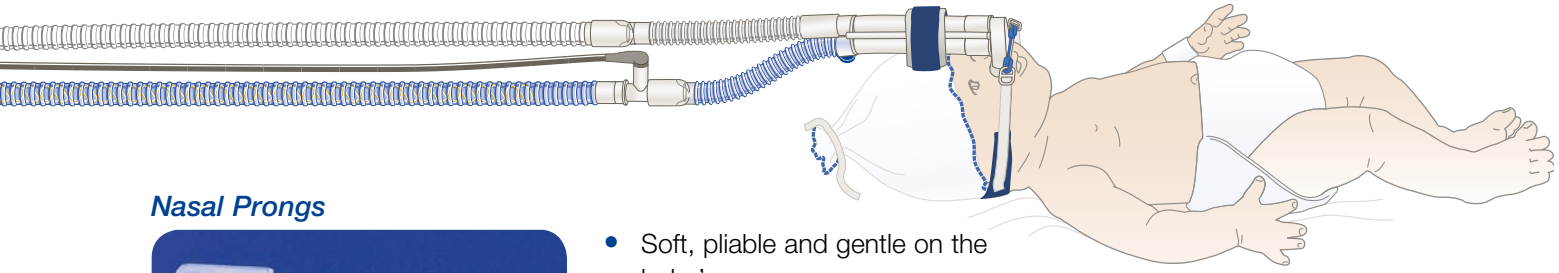



*Note: Humidifier, pole, water bag and flow source as shown are extras*

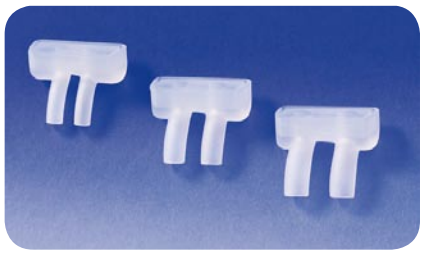
## The Patient Interface

### 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



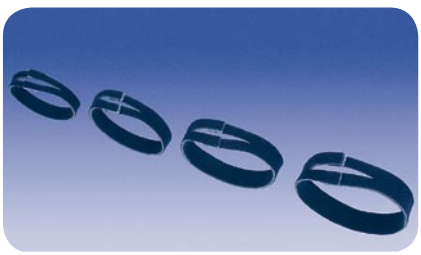
- Soft, pliable and gentle on the baby's nares
- Anatomically curved for a comfortable fit
- Available in 11 sizes based on prong diameter and width of septum
- Has the largest bore possible to reduce resistance to flow and Work of Breathing (WOB)
- Septum cut-away helps prevent septum necrosis

### Infant Bonnet

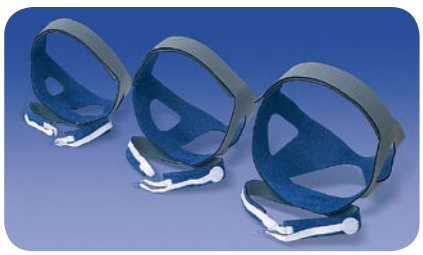
- Holds the nasal tubing in place for ease of setup
- Can open bonnet top to allow clinical procedures like ultrasound
- Available in 4 sizes that are designated by the head circumference
- Sizes are sewn on the bonnet for easy identification

### 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

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# Product Specification

## Overall Infant Delivery System Specification

| | |
|---|---|
| Delivery System Maximum Input Flow | 15L/min |
| Maximum Mean CPAP | 15cm $H_2O$ |

## MR290 Humidification Chamber*

| | |
|---|---|
| Inlet port | 22mm Male |
| Outlet port | 22mm Male |
| Compressible Volume | 280ml |
| Compliance | 0.4ml/cm $H_2O$ |
| Maximum operating pressure | 80cm $H_2O$ |
| Maximum Peak Flow | 180L/min |

## BC110 Pressure Manifold*

| | |
|---|---|
| Maximum pressure Limit | 17cm $H_2O$ @ 8L/min |
| Inlet connector | $O_2$ inlet adaptor |
| Outlet connector | 22mm Female or<br>15mm Female |
| Luer port | Female Luer |
| Oxygen analyzer port | 22mm Female or<br>15mm Female |

## BC060 Single Heated Breathing Circuit*

| | |
|---|---|
| Circuit Length – Expiratory<br>– Inspiratory | 1.1m<br>1.2m |
| Compressible Volume<br>Inspiratory Limb<br>Expiratory Limb | <br>149ml<br>101ml |
| Compliance<br>Inspiratory Limb<br>Expiratory Limb | <br>0.19ml/cm $H_2O$<br>0.13ml/cm $H_2O$ |
| Connectors | Manufactured to ISO 5356-1 |
| Resistance to Flow | 0.6cm $H_2O$ @ 6L/min |

## CPAP Generator*

| | |
|---|---|
| Inlet port | 15mm Female |
| Exit port | 22mm Male |
| CPAP pressure (mean) | 3 - 10cm $H_2O$ |
| Bubbler water container volume | Approx 500mls |

## Patient Interface Product Specification

### Nasal Tubing*

| | |
|---|---|
| Dead Space | nil |
| Length of nasal tubing<br>*with collapsible extension*<br>50mm (expanded)<br>(collapsed)<br>70mm (expanded)<br>(collapsed)<br>100mm (expanded)<br>(collapsed) | <br><br>224mm<br>163mm<br>244mm<br>183mm<br>274mm<br>213mm |
| Resistance to Flow<br>*F&P Patient Interface with both inspiratory and expiratory collapsible extensions*<br>50mm nasal tubing<br>70mm nasal tubing<br>100mm nasal tubing | <br><br>0.49cm $H_2O$ @ 6L/min<br>0.53cm $H_2O$ @ 6L/min<br>0.55cm $H_2O$ @ 6L/min |

### Nasal Prongs*

| | |
|---|---|
| Material | Silicone (latex free) |
| Hardness | 80 shore A |
| Resistance to Flow<br>*Measured at the pressure port of the nasal tubing*<br>BC3520 prongs<br>BC4540 prongs<br>BC6070 prongs | <br><br>2.4cm $H_2O$ @ 6L/min<br>0.6cm $H_2O$ @ 6L/min<br>0.2cm $H_2O$ @ 6L/min |
| Dead Space<br>BC 3520 prongs<br>BC 6070 prongs | <br>0.1ml<br>0.5ml |

### Infant Bonnet*

| | |
|---|---|
| Bonnet tube material | Cotton/nylon blend<br>(latex free) |

### Headgear*

| | |
|---|---|
| Headgear material | Nylon/neoprene laminate<br>(latex free) |

### Chinstrap*

| | |
|---|---|
| Chinstrap material | Nylon/polyurethane laminate<br>(latex free) |

** single patient use*

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**Reading References:**

1 Vivek Narenderan, 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

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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 Verder 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**

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