



Infant T-Piece Resuscitator

Clinical Paper Summaries





## **Humidified and heated air during stabilization at birth improves temperature in preterm infants**

### **AIM:**

To investigate the effect of using humidified and heated gas during respiratory support at birth on body temperature in very preterm infants admitted to the neonatal intensive care unit (NICU).

### **METHOD:**

This prospective observational study compared two cohorts of infants born at  $\leq 32$  weeks' gestation who required respiratory support in the delivery room. The first cohort was born from February to July 2008 (cold group; n=58) and the second was born from October 2008 to May 2009 after a change to hospital policy specified the use of humidified and heated gas (heat & humidification group; n=54). Humidification of inspired gases during respiratory support in the delivery room was provided using a heated humidifier [MR850; Fisher & Paykel Healthcare] set to 37°C. Respiratory support was provided using a T-piece ventilator [Neopuff infant resuscitator; Fisher & Paykel Healthcare]. After stabilization, infants were transferred to the NICU.

The primary endpoint of the study was rectal temperature which was taken on arrival at the NICU using a digital thermometer [Thermoal; Hartmann]. Secondary endpoints were requirement for mechanical ventilation and surfactant, oxygen treatment 28 days after birth, patent ductus arteriosus that required treatment, hypotension needing inotropic support,  $\geq$  grade 2 necrotising enterocolitis,  $\geq$  grade 2 intraventricular haemorrhage and/or cystic periventricular leukomalacia, and death during admission.

### **RESULTS:**

There were no significant differences in baseline characteristics between the two groups of infants. Data for the primary and secondary endpoints are reported in the table.

	<b>Cold group (n=58)</b>	<b>Heat and humidification group (n=54)</b>	<b>P value</b>
<b>Primary endpoint</b>			
Mean body temperature on arrival at the NICU (°C)	35.9	36.4	<0.001
Normothermia (patients)	12%	43%	<0.001
Mild hypothermia (patients)	33%	35%	NS
Moderate hypothermia (patients)	53%	19%	<0.001
Mild hyperthermia (patients)	2%	4%	NS
Moderate hyperthermia (patients)	0	0	NS

### Secondary endpoints (patients)

Surfactant treatment	31%	43%	0.24
Oxygen treatment at age 28 days	26%	15%	0.24
PDA needing treatment	12%	22%	0.11
Hypotension needing treatment	19%	7%	0.07
NEC $\geq$ grade 2	2%	4%	0.21
IVH $\geq$ grade 2 and/or cystic PVL	18%	15%	0.77
Death during admission	7%	6%	0.77

Normothermia = core body temperature 36.5-37.5°C; Mild hypothermia = core body temperature 36.0-36.4°C; Moderate hypothermia = core body temperature  $<$ 36.0°C; Mild hyperthermia = core body temperature 37.6-38.0°C; Moderate hyperthermia = core body temperature  $>$ 38.0°C; PDA = patent ductus arteriosus; NEC = necrotizing enterocolitis; IVH = intraventricular haemorrhage; PVL = periventricular leukomalacia; NS = not significant.

### DISCUSSION:

Delivery of dry, cold gases has a number of deleterious physiological effects. The use of humidified and heated gas has been defined as the standard of care during respiratory support for preterm infants in the NICU. However, there is no such recommendation for respiratory support provided in the delivery room. Preterm infants are at risk of heat loss after delivery, and can develop hypothermia, which is associated with increased morbidity and mortality. In this study, heating and humidifying respiratory gases given in the delivery room prevented the postnatal fall in body temperature and there was a significant reduction in the incidence of moderate hypothermia on admission to the NICU. There was no significant effect on morbidity and mortality, although this study was not adequately powered to assess these endpoints. More data are needed to determine whether reducing hypothermia in very preterm infants translates into a clinical benefit, and offsets the additional cost of providing heat and humidification (approximately €50 per patient in this study).

### CONCLUSION:

Adding heat and humidification to inspired gases during respiratory support in the delivery room appears to have a beneficial effect on body temperature at admission to NICU in very preterm infants. Further study of the effect of different gas conditions on lung physiology in preterm infants is required before the use of heated and humidified gas can be recommended as the standard of care in this setting.

### KEY POINTS:

- Use of heated and humidified gases for respiratory support of very preterm infants in the delivery room prevents the postnatal decrease in temperature.
- Morbidity and mortality rates are similar when either cold or heated and humidified gases are used for delivery room respiratory support in very preterm infants.

### DEFINITIONS:

Neonatal intensive care unit (NICU)

A hospital facility providing intensive nursing and medical care for critically ill newborn infants



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## Equipment and operator training denote manual ventilation performance in neonatal resuscitation

### AIM:

To investigate the effect of operator training in neonatal manual ventilation on the level of peak inspiratory pressure (PIP) and tidal volume (VT) during simulated neonatal resuscitation.

### METHOD:

Eighty-four health care professionals (10 paediatricians; 22 anaesthetists; 30 neonatal nurses; 22 midwives) were recruited in this prospective, crossover trial. Participants were defined by four levels of training: level 0 = no previous training; level 1 = training on manual ventilation in neonates; level 2 = level 1 plus history of tutorial on lung protective management; level 3 = level 2 plus specific manometer training.

Neonatal resuscitation was simulated using a leak-free neonatal mannequin resembling an infant with very low birth weight (VLBW; birth weight <1500 g), equivalent to a 1.0 kg infant lung with a compliance of 0.2 mL kPa<sup>-1</sup> [Fisher & Paykel Healthcare]. Two different manual resuscitation devices were used: a self-inflating (SI) bag consisting of a new 240 mL Laerdal®-bag [Laerdal] with a new Ambu®-10-PEEP-valve [Ambu] set at 5 cm H<sub>2</sub>O; and a T-piece resuscitator [Neopuff®; Fisher & Paykel Healthcare] with the positive end-expiratory pressure (PEEP) set at 5 cm H<sub>2</sub>O. A brief tutorial on the theoretical background and means of operation of the devices prior to testing was conducted to ensure that each participant had an equal understanding of the use of both devices.

Wall-mounted medical air provided a continuous gas flow of 8 L/min and participants were asked to manually ventilate to a target PIP of 20 cm H<sub>2</sub>O and a PEEP of 5 cm H<sub>2</sub>O with a rate of 60 breaths/min. Applied PIP and the resulting VT were measured using a pneumotachograph [CO2SMO+®; Novamatrix Inc.].

### RESULTS:

Operator training significantly affected the level of PIP and VT when using SI-bags for manual ventilation but not when using a T-piece device (see Table). The level of operator training also had a significant effect on inspiratory time when using an SI-bag (p=0.048).

	Training level	SI-bag	P value	T-piece device	P value
		Median (IQR)		Median (IQR)	
PIP (cm H <sub>2</sub> O)	0	34.5 (8)	<0.001	19.7 (0.43)	0.556
	1	32.9 (12.8)		19.6 (0.5)	
	2	24.7 (15.3)		19.6 (0.5)	
	3	18.3 (11.8)		19.7 (0.5)	
VT (mL)	0	7.3 (8)	<0.001	3.5 (0.8)	0.661
	1	6.4 (2.7)		3.5 (0.5)	
	2	4.8 (2.2)		3.4 (0.3)	
	3	3.8 (2.3)		3.5 (0.3)	

IQR = interquartile range; PIP = peak inspiratory pressure; SI = self-inflating; VT = tidal volume.

## DISCUSSION:

VLBW infants often require noninvasive respiratory support. However, excessive PIP and high VT during manual ventilation can cause volutrauma and barotrauma in the neonatal lung. In order to reduce neonatal lung injury, the avoidance of high PIP and VT is essential. The International Liaison Committee on Resuscitation (ILCOR) and European Resuscitation Council (ERC) guidelines equally recognize SI-bags and T-piece devices for manual neonatal resuscitation. While SI-bags are the most commonly used in neonatal resuscitation units worldwide (83%), most are used without pressure manometers or appropriate pressure control. In contrast, T-piece devices (used by 30-40% of units) used during manual ventilation deliver consistent predefined PIP compared with SI-bags. Data from this study indicate that the level and consistency of delivered PIP and VT depends on the resuscitation device and the level of operator training. There was large intersubject variability in levels of applied PIP and VT with the SI-bag for all training levels. However, the higher the operator's level of training, the better the adherence to the targeted PIP. In comparison, the use of a T-piece device provided consistent delivery of a defined PIP and VT in a simulated neonatal resuscitation scenario, irrespective of operator training level.

## CONCLUSION:

PIP and VT are strongly influenced by choice of manual ventilation device during simulated neonatal resuscitation. For operators with no specific training in manual ventilation, use of T-piece devices is advised to control for excessive PIP and VT application.

## KEY POINTS:

- PIP and VT are strongly influenced by choice of manual ventilation device during simulated neonatal resuscitation.
- T-piece devices provide more reliable and constant PIP and VT than SI-bags, irrespective of prior experience or level of profession of the operator.
- The higher the operator's level of training in manual neonatal resuscitation, the better the adherence to the targeted PIP and VT when using SI-bags, however larger inter-individual variation is still a problem at all training levels.

## DEFINITIONS:

Peak inspiratory pressure (PIP)	The pressure in the lungs at the end of inspiration
Positive end-expiratory pressure (PEEP)	The amount of pressure above atmospheric pressure present in the airway at the end of the expiratory cycle during mechanical ventilation
Tidal volume (VT)	The volume inspired or expired per breath



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## A randomized, controlled trial of delivery-room respiratory management in very preterm infants

### AIM:

To determine whether a sustained inflation followed by early nasal continuous positive airway pressure (CPAP) is more effective and less injurious than the conventional intervention with repeated manual inflations with a self-inflating bag and mask followed by nasal CPAP as a ventilatory strategy in very preterm infants.

### METHOD:

Two hundred and seven very preterm infants (25–32 weeks' gestation) were randomized to receive ventilation with an early functional residual capacity intervention (EFURCI) or a conventional intervention.

The EFURCI group received ventilation with a sustained pressure-controlled (20 cm H<sub>2</sub>O) inflation for 10 seconds using a nasopharyngeal tube and a T-piece ventilator (Neopuff Infant Resuscitator; Fisher & Paykel). This inflation was repeated with increased pressure (25 cm H<sub>2</sub>O) if breathing remained insufficient, the infant's heart rate was <100 beats/minute or the infant was cyanotic. After the inflation, early nasal CPAP was initiated at 5–6 cm H<sub>2</sub>O. Subsequently, if breathing remained insufficient, the infant's heart rate was <100 beats/minute, the infant was cyanotic, breathing was absent or marked dyspnoea occurred, endotracheal intubation and mechanical ventilation was initiated.

The conventional intervention group was treated with a self-inflating bag and mask with a built-in pressure limitation (Ambu Infant R Resuscitators; Ambu) and an oxygen reservoir. Initial inflation pressures of 30–40 cm H<sub>2</sub>O were used followed by pressures of ≤ 20 cm H<sub>2</sub>O. Early nasal CPAP was given on arrival to the neonatal intensive care unit (NICU) if needed. If breathing remained insufficient, the infant's heart rate was <100 beats/minute, the infant was cyanotic or inflation was not possible, endotracheal intubation and mechanical ventilation were performed.

The primary endpoint of the study was the proportion of infants intubated within 72 hours of age; secondary endpoints included intubation in the delivery room, the need for mechanical ventilation and surfactant treatment, death during admission or bronchopulmonary dysplasia (BPD) based on the National Institute of Child Health and Human Development definition and other neonatal morbidity outcomes.

### RESULTS:

Data for the primary and secondary endpoints are reported in the table.

	Type of ventilation		OR (95% CI)	P value
	EFURCI (n=104)	Conventional (n=103)		
Intubated within 72h of age, n (%)	38 (37)	52 (51)	0.57 (0.32–0.98)	0.04
Intubated in the delivery room, n (%)	18 (17)	37 (36)	0.37 (0.20–0.70)	0.002
Total period of mechanical ventilation of intubated infants <72h of age, days [median (IQR)]	2.5 (1–8.3)	4.5 (2–11.5)		0.2
Total period of NCPAP of total group, days [median (IQR)]	2 (0.3–8)	2 (0–11)		0.038
Surfactant doses, mean (SD)	0.4 (0.8)	0.6 (1.0)		0.3
Surfactant >1 dose, n (%)	10 (10)	22 (21)	0.39 (0.18–0.88)	0.02

Mortality, n (%)	2 (2)	4 (4)		0.4
BDP, n (%):				
total	22 (22)	34 (34)		0.05
moderate to severe	9 (9)	19 (19)	0.41 (0.18–0.96)	0.04
PDA needing treatment, n (%)	21 (20)	16 (16)		0.4
95% CI = 95% confidence interval; BDP = bronchopulmonary dysplasia; EFURCI = early functional residual capacity intervention; h = hours; IQR = interquartile range; n = number; NCPAP = nasal continuous positive airway pressure; OR = odds ratio; PDA = patent ductus arteriosus; SD = standard deviation;				

### DISCUSSION:

This is the first prospective, randomised trial in very preterm infants comparing an EFURCI ventilation strategy with conventional intervention using a bag and mask. The intubation rate, surfactant requirement and incidence of BPD were all reduced by the new strategy. Potential reasons for the beneficial effects of EFURCI include avoiding the use of potentially dangerous high inspiratory pressures, preservation of surfactant and allowing time to differentiate between RDS and transition problems. The latter reduces the number of infants undergoing unnecessary intubation. While this study shows the importance of early respiratory management for pulmonary outcome in very preterm infants, further randomised controlled trials are needed to develop an optimal strategy for these patients.

### CONCLUSION:

The EFURCI ventilation strategy, which consisted of a sustained inflation followed by early nasal CPAP delivered through a nasopharyngeal tube, is a more efficient strategy than the conventional intervention with repeated manual inflations with a self-inflating bag and mask followed by nasal CPAP in very preterm infants.

### KEY POINTS:

- Use of an EFURCI ventilation strategy in very preterm infants reduced the rate of intubation at <72 hours of age, surfactant usage and the incidence of BPD compared with a conventional ventilation strategy.
- Further randomised controlled trials are needed to develop an optimal strategy for these patients.

### DEFINITIONS:

95% confidence interval (CI)	A statistical measure showing that 95% of the results for that parameter lie within the range quoted
Bronchopulmonary dysplasia (BPD)	A chronic lung condition that affects newborn babies who were either put on a breathing machine after birth or were born prematurely. It involves the abnormal development of lung tissue and is characterized by inflammation and scarring of the lungs
Continuous positive airway pressure (CPAP)	A technique of respiratory therapy in which airway pressure is maintained above atmospheric pressure throughout the respiratory cycle by pressurisation of the ventilatory circuit
Dyspnoea	Laboured breathing or shortness of breath
Neonatal intensive care unit (NICU)	A hospital facility providing intensive nursing and medical care for critically ill neonatal patients



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## Ventilation of very preterm infants in the delivery room

### AIM:

To summarize current evidence on various elements of neonatal ventilation in the delivery room.

### DISCUSSION:

#### Peak Inspiratory Pressure (PIP)

Resuscitation guidelines recommend a PIP between 20-40 cmH<sub>2</sub>O for term and preterm infants. However these pressures, if maintained for 1 second, cannot establish adequate inflation volumes in asphyxiated neonates or preterm infants. This means that higher pressures are necessary in the first manual breaths to open the lungs. To overcome the problems presented with using potentially dangerous high pressures, prolonged inflation times (15-20 seconds) at 20-25 cmH<sub>2</sub>O may be used to overcome the long time constant of a fluid filled lung for preterm infants.

#### Positive End Expiratory Pressure (PEEP)

A 2001 survey showed that 59% of neonatologists in the USA use PEEP during resuscitation. The use of PEEP up to 12 cmH<sub>2</sub>O in ventilation and resuscitation of infants and lambs increases compliance, oxygenation and functional residual capacity (FRC). More randomized controlled clinical trials are needed.

#### Resuscitation Devices

Self-inflating bags are adequate to deliver the required tidal volumes but cannot deliver a constant PIP and an adequate PEEP. Flow-inflating bags are technically challenging so inexperience and improper techniques can lead to dangerously high pressures, sometimes 15 cmH<sub>2</sub>O above the target pressure. The Neopuff is a purpose-built mechanical device which is easy to use, even by inexperienced operators. Studies on an intubated mannequin revealed that whereas it is difficult to deliver sustained breaths with self and flow inflating bags, the Neopuff® delivers a more consistent and precise PIP and PEEP even during sustained inflation.

#### Oxygen Concentration

International guidelines recommend the use of 100% oxygen during resuscitation. There is mounting concern that high concentrations of oxygen may act as a lung irritant and trigger inflammatory responses and oxidative stress in the newborn. However, there is insufficient evidence from existing studies to recommend using room-air instead of 100% oxygen. Further trials are needed.

#### Nasal Continuous Positive Airway Pressure (nCPAP)

Using nCPAP directly after resuscitation is a gentle, non-invasive way to keep the lung open by maintaining lung volume, preventing atelectasis and stimulating respiration. NCPAP also reduces injury to the lung, the need for intubation in the delivery room, progression to mechanical ventilation and the amount of surfactant needed. Although the use of nCPAP is associated with a reduction in mortality of preterm infants there is still insufficient information to evaluate the effectiveness of prophylactic nCPAP in very preterm infants.

### TAKE HOME POINTS:

- During resuscitation, it is possible to open the lung using sustained inflations of 5 – 20 seconds.
- The best and easiest way to deliver a consistent and sustained PIP and adequate PEEP is a pressure-limited mechanical device with a T-piece i.e. the Neopuff® Infant Resuscitator.
- Using PEEP during resuscitation helps maintain FRC, and reduces lung injury, the need for intubation, mechanical ventilation and surfactant.
- 100% oxygen concentration is still recommended during resuscitation of preterm infants although there is increasing concern about oxygen toxicity. Further trials required.
- nCPAP is an efficient and gentle way to keep the lung open in the delivery room and may reduce lung injury and avoid intubation and mechanical ventilation of preterm infants.

## Comparison of three manual ventilation devices using an intubated mannequin

### AIM:

To compare three devices, the Fisher & Paykel Healthcare Neopuff™ Infant T-Piece Resuscitator, anesthesia bag with attached manometer (Intersurgical) and self inflating bag (Laerdal) for manual neonatal ventilation, using an intubated Fisher & Paykel Healthcare resuscitation doll.

### METHOD:

The 35 participants were neonatal health workers that ranged from neonatal nurses, consultant pediatricians and anesthetists, to an emergency medical technician, and a midwife. Participants were recruited at in-service training days throughout Ireland. The self inflating bag had a pop off valve set to activate at PIPs (Peak Inspiratory Pressures) in excess of 40 cmH<sub>2</sub>O, but no manometer to reflect current clinical use. The anesthetic bag did not incorporate a flow control valve, but the operator could control the volume and pressure of the bag by adjusting egress at the open end of the bag. The Neopuff PIP and PEEP (Positive End Expiratory Pressure) settings were preset by each participant before testing.

Each participant was asked to provide positive pressure ventilation to an intubated Fisher & Paykel Healthcare resuscitation doll for two minutes using each device, aiming to achieve a PIP of 20 cmH<sub>2</sub>O and a PEEP of 4 cmH<sub>2</sub>O and a breath rate of 40 breaths per minute. They were allowed to observe the manometer while using the anesthesia bag and Neopuff. They were not allowed to view a timer clock or their continuous recordings for any of the devices.


### RESULTS:

Significant differences were found between devices.

Response	Self Inflating bag	Anesthetic bag	Neopuff™	p Value
Max PIP	75.9	35.5	22.4	-
Mean Max PIP	44.7 (2.3)	22.6 (0.7)	20.4 (0.5)	< 0.001
Mean PIP	30.7(1.9)	18.1 (0.4)	20.1 (0.1)	< 0.001
Mean PEEP	0.15 (0.03)	2.83 (0.23)	4.41 (0.08)	< 0.001
Mean Airway Pressure	7.6 (0.8)*	8.5 (0.3)*	10.9 (0.3)	< 0.001
Mean rate	47.1 (3.0)*	47.3 (2.7)*	39.7 (1.8)	< 0.05
% total breaths ≤ 21 cm H <sub>2</sub> O PIP	39 (0.07)#	92 (0.02)* #	98 (0.02)* #	< 0.001
% total breaths ≥ 30 cm H <sub>2</sub> O PIP	45 (0.07) #	0*#	0*#	< 0.001

Values are mean cm of H<sub>2</sub>O (SEM – Standard Error of the Mean) except for # which are percentage (SEM)

\* Not significantly different within the same row (p > 0.05)



The performance of the Neopuff™ was more consistent and reliable when compared with the other two devices. There was a significant statistical difference between the Neopuff™ and both the anesthesia bag and self inflating bag with regard to PIP, PEEP, mean airway pressure and breath rate. The self inflating bag produced negligible PEEP, and greater mean and maximum PIP than the anesthetic bag and Neopuff™.

Using the Neopuff™:

- the mean and maximum PIP were more consistent and closer to the target value
- the mean PEEP values were significantly higher and closer to the target value
- the mean airway pressure was significantly greater
- the applied breath rate was more consistent, reliable and closer to the target rate.

There were no significant differences between the performance of the doctors and allied health professionals.

#### **DISCUSSION:**

The ability to provide consistent manual ventilation is dependent on the device. Self inflating devices without a manometer and a PEEP valve give excessively high PIP and minimal PEEP and should not be used with VLBW infants. Appropriate use of the anesthetic bag is dependent on adequate training and practice, otherwise the device is potentially dangerous. It is not mentioned that in order to provide a safe PIP and consistent PEEP when using the anesthesia bag, it is necessary to continuously watch the manometer, while when using the Neopuff™ one is free to watch the infant.

The PIP and PEEP values provided by the Neopuff™ are independent of user stress, fatigue level and skill.

#### **TAKE HOME POINTS:**

- The Neopuff was the most consistent and reliable device, providing statistically more consistent and appropriate PIP and PEEP, significantly greater mean airway pressure and a breath rate that was most consistent and closest to target.
- Self inflating devices without a manometer should not be used.
- This study concludes that the Neopuff™ should be incorporated into Neonatal resuscitation training programs to provide PEEP and controlled PIP.

## **Resuscitation of Premature Infants: What are we doing wrong and can we do better?**

### **AIM:**

To outline the principles and efficacy of current neonatal resuscitation devices and techniques and identify areas of further research. This will lead to better guidelines and international consensus statements on the appropriate methods used for resuscitation of premature infants.

### **DISCUSSION:**

#### **Role of PEEP**

Lamb studies by the authors showed that the use of PEEP during resuscitation improves oxygenation, respiratory compliance (by 25%) and maintains functional residual capacity (FRC), thereby reducing the progression to respiratory distress syndrome (RDS).

#### **Resuscitation Devices**

The greatest assets of the self-inflating bag are perceived to be the automatic re-expansion and ease of use. However, these may be falsely reassuring as a large proportion of the delivered breath may be unknowingly lost through leak around the mask. The self-inflating bag is unable to deliver a consistent PIP - which depends on the strength and speed of bag compression, the seal of the facemask and the respiratory compliance - or normally provide PEEP, or deliver prolonged inflations. Pressures produced by Flow-inflating bags can vary considerably because of difficulties with operator skill in controlling outlet gas flow and bag squeeze. Poor technique can produce inconsistent PIP and PEEP, and pressures may reach dangerously high levels. The Neopuff® is a T-piece resuscitation device with a variable PEEP valve, PIP control, and has a manometer to show delivered pressure. It can produce a constant PEEP for a given flow, PIP for every breath and can be adjusted according to clinical response. The Neopuff® is easy to use even by relatively inexperienced operators.

#### **Heat and Humidification during Neonatal Resuscitation**

In the NICU, care and attention are given to heat and humidify respiratory gas. It is therefore surprising that dry, cold gas is used for resuscitation in the delivery room

### **TAKE HOME POINTS:**

- Lamb studies show that PEEP during resuscitation improves respiratory outcomes.
- Re-expansion and ease of use are perceived assets of the self-inflating bag. These may be falsely reassuring as a large portion of the breath may be unknowingly lost through leak around the mask.
- Flow-inflating bags are difficult to use and therefore produce inconsistent PEEP and sometimes dangerous pressures.
- The Neopuff® is a T-piece resuscitation device with a variable PEEP valve, PIP control and a manometer. The Neopuff® is better than self and flow-inflating bags at providing safe consistent PIP, constant PEEP and delivering prolonged inflations.
- Heated and humidified gas - as opposed to cold and dry - should be considered for resuscitation of infants, following the preparation of respiratory gases used in the NICU.



For more information please contact  
your local Fisher & Paykel Healthcare representative

**Manufacturer** 

Fisher & Paykel Healthcare Ltd  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013

PO Box 14 348 Panmure  
Auckland 1741  
New Zealand

Tel: +64 9 574 0100  
Fax: +64 9 574 0158  
Email: [info@fphcare.com](mailto:info@fphcare.com)  
Web: [www.fphcare.com](http://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 7181 98599 0  
Fax: +49 7181 98599 66

**India**

Tel: +91 80 4284 4000  
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

**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

**Taiwan**

Tel: +886 2 8751 1739  
Fax: +886 2 8751 5625

**Turkey**

Tel: +90 312 354 34 12  
Fax: +90 312 354 31 01

**UK  (EU Authorised Representative)**

Fisher & Paykel Healthcare Ltd  
Unit 16, Cordwallis Park  
Clivemont Road, Maidenhead  
Berkshire SL6 7BU, UK

Tel: +44 1628 626 136  
Fax: +44 1628 626 146

**USA/Canada**

Tel: +1 800 446 3908  
or +1 949 453 4000  
Fax: +1 949 453 4001