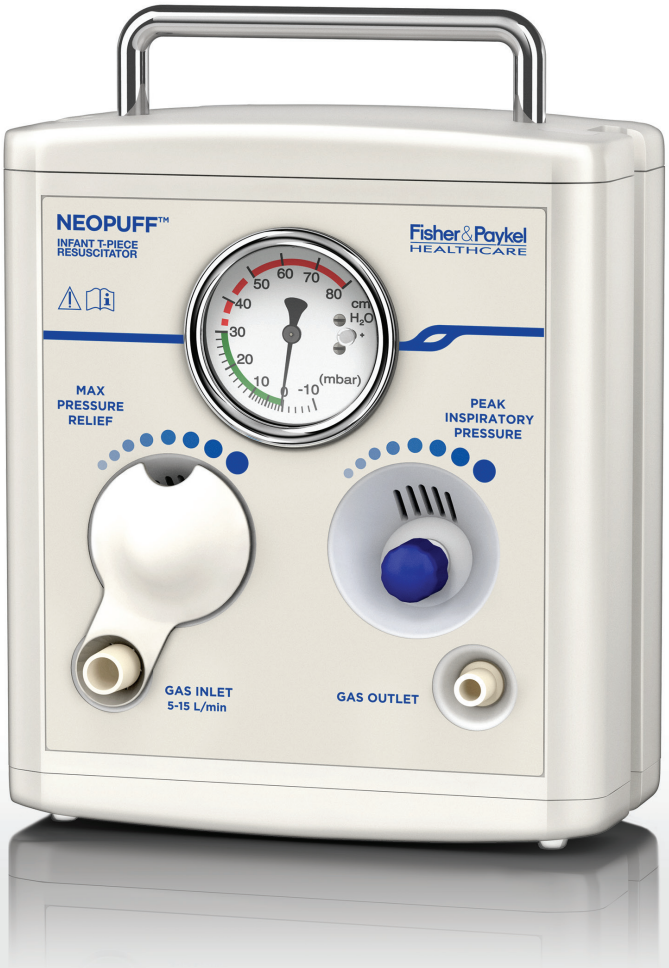
F&P Neopuff™ | F&P Perivent™

Infant Resuscitation | Technical Manual



Fisher&Paykel HEALTHCARE

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1. SPECIFICATIONS

1.1 Warnings

⚠ Input gas flow rate 5 to 15 L/min. **Recommended operating gas flow rate 8 L/min.** Input flow ranges are circuit specific, refer to circuit User Instructions.

⚠ **Do not attempt to use a higher gas flow rate than 15 L/min.**

⚠ Factory setting of pressure limit valve is at 40 cmH_2O. This setting is user adjustable up to 80 cmH_2O. **Do not attempt to set the pressure relief valve above 80 cmH_2O. Reset pressure relief valve to 40 cmH_2O after use (refer section 3.3.3 of this manual).**

⚠ Use only recommended F&P Neopuff™ / Perivent™ Infant Resuscitator accessories.

⚠ **Use only a F&P gas supply line or approved equivalent.**

⚠ Do not use oil, grease or other substances that are incompatible with oxygen on any part of the F&P Neopuff / Perivent T-Piece Circuit.

⚠ Incorrect use can be hazardous.

⚠ The device must not be used on unattended patients.

⚠ To be used for resuscitation only.

⚠ **The operation of the F&P Neopuff / Perivent must be checked prior to first use.**
Refer to section 3.3 "Testing of the F&P Neopuff / Perivent Performance".

1.2 Performance Specifications

Peak Inspiratory Pressure (PIP) Range	
@ 5 L/min	approx. 2 to 70 cmH_2O [mbar]
@ 8 L/min	approx. 3 to 72 cmH_2O [mbar]
@ 10 L/min	approx. 4 to 73 cmH_2O [mbar]
@ 15 L/min	approx. 8 to 75 cmH_2O [mbar]
Positive End Expiratory Pressure (PEEP) Range	
@ 5 L/min	approx. 1 to 6 cmH_2O [mbar]
@ 8 L/min	approx. 1 to 10 cmH_2O [mbar]
@ 10 L/min	approx. 2 to 15 cmH_2O [mbar]
@ 15 L/min	approx. 4 to 17 cmH_2O [mbar]
Input Gas Flow Range	
Minimum	5 L/min
Maximum	15 L/min
Operating Time (400 L Cylinder)	
5 L/min	80 minutes
10 L/min	40 minutes
15 L/min	26 minutes

NOTE: All performance figures listed above are representative only.
PEEP values stated are based on typical clinical PIP settings.
Higher PEEP values can be achieved if higher PIP values are set.

1.3 Technical Specifications

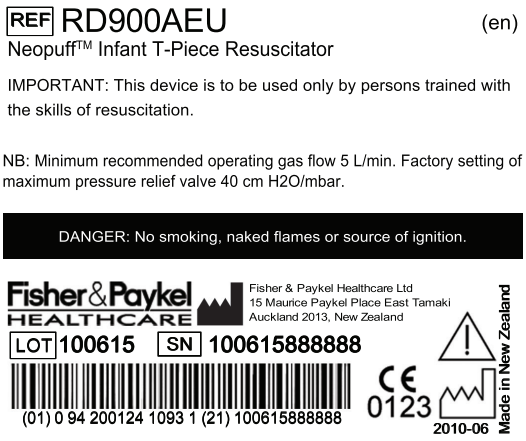
Height	250 mm (9.8")
Width	200 mm (7.9")
Depth	104 mm (4.1")
Weight	1.9 kg (4.2 lb)
Manometer Range	-10 to 80 cmH_2O [mbar]
Manometer Accuracy	+/-2.0% of Full Scale Deflection
Maximum Pressure Setting	65 to 80 cmH_2O [mbar] (dependent on flow rate)
900RD010 / 900RD110 Dead Space	6 ml
RD1300-10 Dead Space	3.3 ml
Storage Temperature Range	-10 to 50 °C (+14 to +122 °F), up to 95% humidity
Operating Temperature Ranges	
Humidified Circuit	+18 to 26 °C (+64 to +78 °F), 30 - 75% humidity
Non-Humidified Circuit	-18 to 50 °C (-0.4 to +122 °F), up to 95% humidity
Recommended Patient Body Weight	0 to 10 kg (22 lb)
Delivered Oxygen Concentration	Up to 100% depending on gas supply

1.4 Symbol Definitions

SYMBOL	DEFINITION
	Attention: Consult the Operating Instructions
	Sets the **Max Pressure Relief** that may be delivered to the patient (factory set at 40 cmH_2O)
	Controls the **Peak Inspiratory Pressure** delivered to the patient
	**Gas inlet** connection from gas supply (5 to 15 litres per minute)
	**Gas outlet** connection to patient

1.5 Label Identification

The label pictured is typical of the information contained on a F&P Neopuff™ / Perivent™ Infant Resuscitator.



REF - This details the product code which identifies the operating instruction language and fascia type

LOT - The production date: (10) = 2010, (06) = June, (15) = fifteenth day

SN - The serial number is specific to a particular F&P Neopuff / Perivent Infant Resuscitator. The first six digits match the LOT number and last six digits identify the specific product serial number.

The bar code consists of the following predefined application identifiers:

01 - Not used
0 - Sequence start
94 - Country of manufacture - New Zealand
200124 - Company Identifier - Fisher & Paykel Healthcare Ltd
1093 - Product Code
1 - Check Sum

REF - RD900XXX

RD900	XXX	Operating Instruction Language	Fascia Type
900 Series T-Piece Resuscitator	AEU	English	English Text
	ADU	Danish	Symbols Only
	AFU	French	
	ALU	Italian	
	AMU	Finnish	
	ANU	Dutch	
	ASU	Spanish	
	ATU	Portuguese	
	AVU	Norwegian	
	AWU	Swedish	
	AZU	Chinese	
	AGU	German (Perivent)	

- Comply with hospital, local and national guidelines for product cleaning frequencies.
- Ensure all oxygen and air supplies are turned off and disconnected from the F&P Neopuff™ / Perivent™ Infant Resuscitator before performing cleaning procedures. Explosion and fire hazards can exist when performing cleaning procedures in an oxygen-enriched environment.
- Cleaning shall be performed at ambient conditions.
- Before cleaning, remove and discard all used disposable products using the recommended method of disposal.
- Dust all surfaces with a clean damp soft cloth.
- Clean all plastic surfaces with detergent-based solution (maximum 2% in water) ensuring the manufacturer's directions for use of the cleaning agent are followed.
- The following proprietary chemical cleaning wipes are recommended if the F&P Neopuff / Perivent fascia requires cleaning for infection control purposes.

  Caviwipes (Metrex Research Corporation)
  Sani-cloth HB (Professional Disposables, Inc.)
  Asepti-Wipes II (Ecolab, Inc.)
  Spartan's TB-Cide Quat Wipes
  Vernacare Tuffie Wipes Alcohol Free
- Dry all surfaces after cleaning with a clean soft cloth or paper towel.

CAUTION: Ensure no part of the F&P Neopuff / Perivent Infant Resuscitator or related accessories is immersed in any cleaning liquid or cleaning solution. For Test Lung cleaning instructions, see section 2.2.2.

CAUTION: Do not clean the F&P Neopuff / Perivent Infant Resuscitator fascia with proprietary cleaning products containing either hydroxides, hypochlorites, peroxides, gluteraldehyde or cleaning products with a greater than 30% alcohol base.

NOTE: The recommended chemical cleaning wipes listed above have been checked for long-term compatibility with the IW900 Series Infant Warmers and the F&P Neopuff / Perivent Infant Resuscitator.

2.1 Cleaning Products to Avoid

CAUTION: The chemicals used in these proprietary cleaning products may lead to discoloration, crazing and eventual cracking of the fascia. Examples of proprietary cleaning products which contain such cleaning chemicals include but are not limited to:

Asepti-Wipes (Ecolab, Inc)
Clorox (The Clorox Company)
Endbac 256 (Johnson Wax Professional)
Quat (3M)
Sporiciden (Liberty Industries, Inc)
Sporox II (Sultan Healthcare)
Steris (Steris Corporation)
Terralin (Schülke & Mayr)
Virtek (A Virtek Company)
Virox (Virox Technologies)

CAUTION: Do not use abrasive cleaning solutions.
CAUTION: Ensure F&P Neopuff/ Perivent Infant Resuscitator and accessories are checked before returning the Infant Resuscitator to service.

2.2 Cleaning of the Test Lung

If required, the Test Lung can be disinfected. There are two different models of Test Lung and each has specific cleaning methods.

- The Test Lung is a consumable item. Irrespective of model, the Test Lung should regularly be inspected for signs of damage such as discoloration, perishing or cracking. Replace the Test Lung if damage is observed.

2.2.1 Latex (black) Test Lung (discontinued May 2007)

⚠ **WARNING** The Test Lung contains natural rubber latex that may cause allergic reactions.

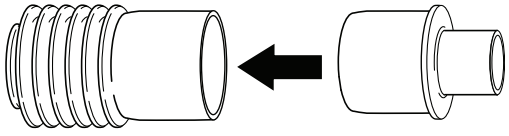
CAUTION: Latex is susceptible to attack by solvents. Ensure no solvents are used to clean the Test Lung.

This Test Lung consists of two parts, the flexible latex test lung and a rigid black plastic connector. The Test Lung can be disassembled for disinfection. It can be disinfected using ethylene oxide gas only. Some carrier gases can cause stress cracking and are not suitable. If in doubt, check with the chemical supplier.

2.2.2 Silicone (blue) Test Lung RD020-01

The Test Lung must be cleaned before every use or in accordance with hospital cleaning protocols. This test lung consists of two parts, the flexible silicone test lung and a rigid plastic connector. The two parts of the Test Lung may be disassembled for disinfection. It can be cleaned using disinfectants containing either peracetic acid (e.g. Perasafe®) or orthopthaldehyde (e.g. Cidex® OPA). Other disinfection methods can cause damage to the Test Lung and are not recommended.

Please follow the manufacturer's instructions for storage, handling and usage of these chemicals.

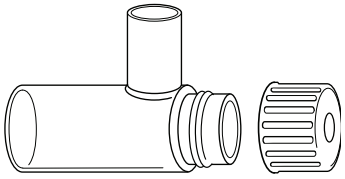


Silicone Test Lung Plastic Connector

⚠ **WARNING** Ensure the silicone Test Lung and plastic connector are both removed from the T-Piece before use on a patient.

2.3 Cleaning Reusable T-Piece (discontinued September 2008)

The reusable T-Piece 500RD104 consists of two parts and can be disassembled for disinfection (refer diagram). The T-Piece should be disinfected by autoclaving at up to 136 °C, 220 kPa for 4 minutes. Following reassembly, the T-Piece should be tested prior to use to ensure that it is functioning correctly. Refer to the F&P Neopuff™ / Perivent™ Operating Manual (Fisher & Paykel Healthcare Part No. 185041726) for set-up instructions.



Unscrew PEEP cap for disinfection

2.4 Sterilization

CAUTION:

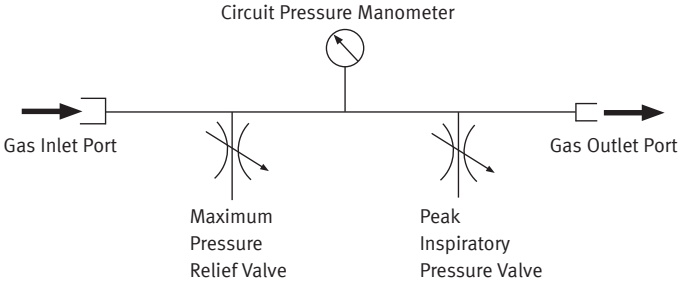
- Do not autoclave or gas-sterilize any part of the F&P Neopuff™ / Perivent™ Infant Resuscitator.
- Do not autoclave any of the Neopuff / Perivent accessories, e.g. Test Lung and Gas Supply Line.
- For cold sterilization: Ensure the cold sterilization agents are safe for use with the relevant surfaces.

2.5 After Cleaning

CAUTION:

- Ensure all F&P Neopuff / Perivent Infant Resuscitator parts and accessories are checked before returning the device to service.

3.1 Functional Schematic



3.2 Installation Checks and Preventative Maintenance

⚠ **WARNING** Dropping the F&P Neopuff™ / Perivent™ Infant Resuscitator or other similar forms of impact may cause damage resulting in incorrect operation of the unit. If you suspect damage to have occurred, please perform checks as outlined in section 3.3 before connection to a patient.

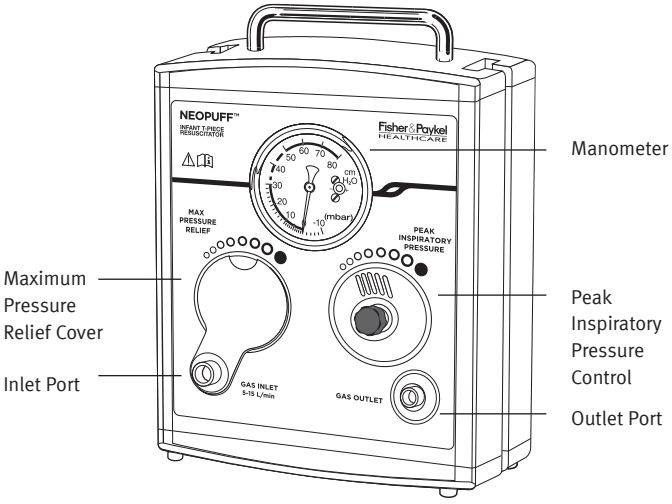
3.2.1 Installation Checks

Prior to first use:
– Remove manometer cover
– Complete Performance Testing (section 3.3)

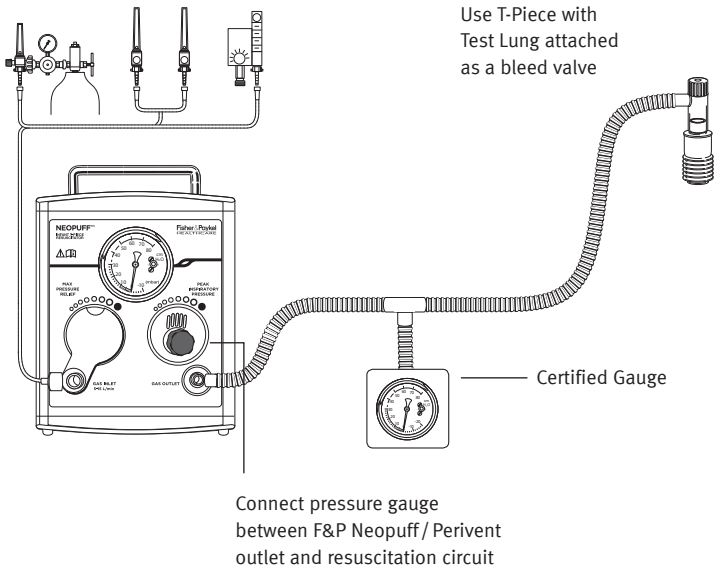
3.2.2 Preventative Maintenance

- The integrity of the system and manometer should be checked prior to first use, annually and after servicing, using the "Testing of the F&P Neopuff / Perivent Performance" procedure (section 3.3).
- The use of a mounting bracket to help prevent the F&P Neopuff / Perivent being damaged or dropped is recommended. Mounting solutions available can be found in section 5 of this manual.
- All maintenance and service procedures must be performed by qualified personnel using only Fisher & Paykel Healthcare parts.
- Always ensure gas passages are free from contaminants, especially hydrocarbons, oils and grease, prior to reassembly.
- Please contact an authorized Fisher & Paykel Healthcare representative for further assistance with any servicing or maintenance requirements.
- The Test Lung is a consumable item; it should be monitored for signs of wear and material degradation and replaced as required.

3.3 Testing of the F&P Neopuff™/Perivent™ Performance (Manometer and Valve System)



The integrity of the F&P Neopuff / Perivent manometer and valve system can be tested using the following guidelines. The inlet port must be connected to a gas supply capable of generating constant flow at 5, 10 and 15 L/min, and a certified gauge and bleed valve should be available to check the manometer accuracy. The F&P Neopuff / Perivent resuscitation circuit and T-Piece can be used in place of a bleed valve as shown below.



3.3.1 Testing of the Manometer

1. Lift the cover off the Max Pressure Relief Valve slightly and turn out of the way.
2. Disconnect all devices from the F&P Neopuff™ / Perivent™ outlet port. Check that the manometer needle is within +/-2 cmH_2O of zero on the manometer gauge. If the manometer does not read zero, the resetting of the manometer to zero procedure (section 3.3.4) should be followed.
3. Connect the outlet of the F&P Neopuff / Perivent Infant Resuscitator to a bleed valve and a certified gauge (e.g. Mensor Digital Pressure Gauge Series 2400). Set the gas supply to 10 L/min. Completely close the maximum pressure limit valve by turning the left-hand knob completely clockwise. With the bleed valve closed, adjust the Peak Inspiratory Pressure knob to set the pressure so that the certified gauge reads 10, 20 and 40 cmH_2O. Check that the manometer reads within +/-2 cmH_2O of these values at each set point.
4. With the pressure set to 40 cmH_2O, open and close the bleed valve three times and check the manometer needle rises and falls smoothly. **If the F&P Neopuff / Perivent Infant Resuscitator fails any of these tests, the manometer should be regarded as inaccurate and replaced with a new manometer (Part No. 043040841).**

   Follow the manometer replacement guidelines in section 3.3.5 of this manual, or contact your Fisher & Paykel Healthcare service representative for further guidance.

3.3.2 Testing of the Valve System

1. Set the gas supply to 5 L/min. Completely close the Peak Inspiratory Pressure control and the Max Pressure control by turning both knobs completely clockwise. Close the bleed valve and check that the gauge reads at least 60 cmH_2O.
2. Set the gas supply to 15 L/min. Close the bleed valve and check that the gauge reads no higher than 80 cmH_2O.
3. Set the gas supply to 10 L/min. Close the bleed valve and turn the Max Pressure Relief valve until the manometer reads 40 cmH_2O. Check that the manometer needle rises and falls smoothly. Gently rotate the Max Pressure Relief cover over the Max Pressure Relief knob.
4. Reset the peak inspiratory pressure to 20 cmH_2O and turn off the gas flow. Testing is now complete.

If the F&P Neopuff / Perivent Infant Resuscitator fails any of these tests, the valve assembly should be regarded as faulty and replaced with a new valve assembly (see the parts list (section 4.1.2) for part numbers). Follow the valve replacement guidelines in section 3.3.6 of this manual, or call your Fisher & Paykel Healthcare service representative for further information.

3.3.3 Setting Max Pressure Relief to 40 cmH_2O

This is required if the Max Pressure Relief has been changed. The factory setting for the Max Pressure Relief is 40 cmH_2O.

Alternative settings for the Max Pressure Relief should be made in accordance with hospital protocol.

1. Adjust gas flow to 10 L/min.
2. Close the Peak Inspiratory Pressure valve by turning the knob fully clockwise.
3. Adjust the Max Pressure Relief knob clockwise or counterclockwise until the manometer reads 40 cmH_2O.
4. Turn the Peak Inspiratory Pressure knob counterclockwise so the manometer reads 20 cmH_2O and shut off the gas flow.

3.3.4 Resetting the Manometer to Zero

To set the manometer to zero:

1. Disconnect the F&P Neopuff™ / Perivent™ Infant Resuscitator from any other equipment.
2. Remove the opaque plastic plug in the lens of the manometer.
3. Using a suitable slot screwdriver, carefully adjust the screw in the manometer face clockwise or counterclockwise to reset the manometer to zero. Care must be taken when doing this, as over-rotation of the screw can damage the manometer internals.
4. Replace the plastic plug in the lens of manometer.
5. Verify that the manometer needle is now within +/-2.0 cmH_2O of zero. If not, repeat the above procedure.

3.3.5 Manometer Replacement

The manometer is not a serviceable item and must be replaced by Manometer Kit 043040841.

1. Remove the back cover, fixed by four screws.
2. Disconnect the tube from the manometer.
3. Remove the manometer by unscrewing the two retaining nuts.
4. Fit the new manometer into the front panel, tighten the retaining nuts and reconnect the manometer tube.
5. Refit the front panel to the back cover with the four screws.
6. Carry out the manometer performance test as per section 3.3.1. It is recommended to record the lot number from the box label of the replacement manometer on the maintenance checklist.

3.3.6 Valve System Replacement

NOTE: The valves are an integral part of the valve, panel and manifold assembly and are not able to be serviced. Please specify the model number from the parts list (section 4.1.2) when ordering a replacement valve assembly.

1. Remove the back cover, fixed by four screws.
2. Disconnect the tube from manometer.
3. Remove the manometer by unscrewing the two retaining nuts.
4. Fit the existing manometer into the new valve assembly panel, tighten the retaining nuts and reconnect the manometer tube.
5. Refit the front panel to the back cover with the four screws from step 1.
6. Carry out the valve system performance test as per section 3.2.2. It is recommended to record the lot number of the new valve assembly onto the Set-up and Maintenance Checklist.

3.4 Set-up and Maintenance Checklist

The following table is provided to record the results of the performance tests described in section 3.3. Any components replaced should be recorded also, as appropriate. The table may be photocopied or otherwise reproduced as required.

Upon receipt of the product and prior to use on a patient, please complete the tests and fill in the table below.

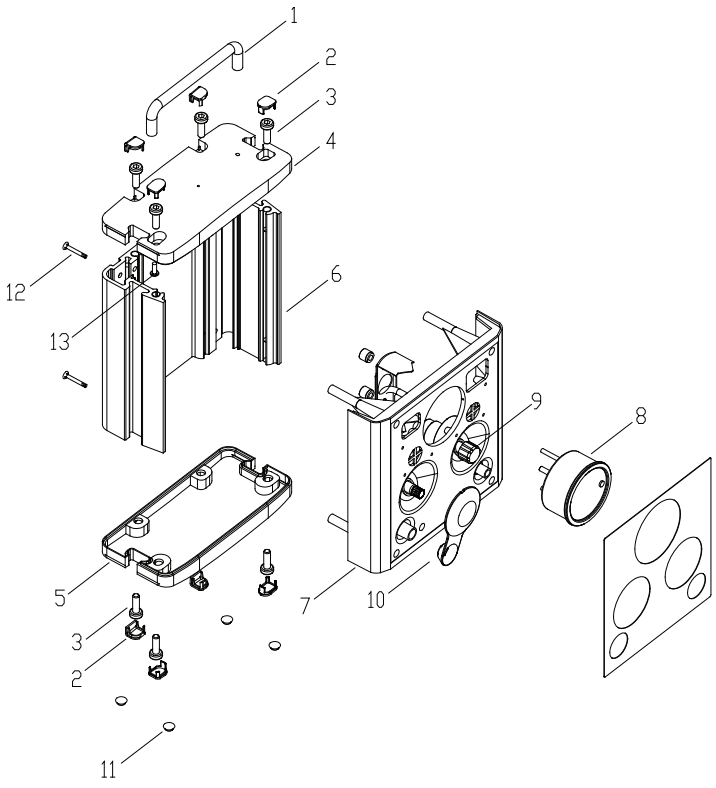
Customer Details	Name:	
	Address:	
	Country:	
	Phone Number:	
	Email:	
F&P Neopuff™/Perivent™ Performance Testing Record	Test Date:	
	Serial Number:	
	For 900IW130 only: Infant Warmer Serial Number:	
	Tested By:	
	Next Test Due Date:	

Check	Ref	✓ or X	Comments
Manometer Checks:			
Replacement Manometer Serial Number:			
Accuracy @ 0 cm (+/-2 cmH_2O)	3.3.1-2		
Accuracy @ 10 cm (+/-2 cmH_2O)	3.3.1-3		
Accuracy @ 20 cm (+/-2 cmH_2O)	3.3.1-3		
Accuracy @ 40 cm (+/-2 cmH_2O)	3.3.1-3		
Needle movement smooth?	3.3.1-4		
Valve System Checks:			
Pressure greater than 60 cmH_2O?	3.3.2-1		
Pressure less than 80 cmH_2O?	3.3.2-2		
Maximum pressure set to 40 cmH_2O	3.3.2-3		
PIP reset to 20 cmH_2O	3.3.2-4		
Additional Comments:			

4.1 F&P Neopuff™/Perivent™ Infant Resuscitator (Post June 2010)

This F&P Neopuff/Perivent module contains a sealed valve assembly that can not be serviced in the field. If a faulty valve occurs, the entire panel and valve assembly must be replaced.

4.1.1 Assembly Diagram



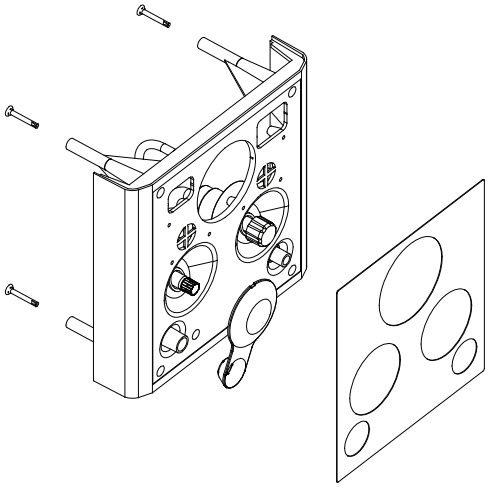
4.1.2 Parts List

UNITS MANUFACTURED POST JUNE 2010

#	Description	Part Number	Reqd
1	Handle Neopuff Spare	043043976	1
2	Plug (set of four)	693040706	2
3	Screw M8x20	614040309	8
4	End cap (upper)	043042565	1
5	End cap (lower)	043042564	1
6	Back cover	641040816	1
7	Model specific panel and valve assembly (see Spares Kit section 4.1.3)	(see table in section 4.1.3)	1
8	Manometer kit	043040841	1
9	Cap Valve Neopuff Spare (Blue)	043043977	1
10	Cover, maximum pressure relief valve	043041057	1
11	Foot	693041436	4
12	Screw #8x1” Csk	616050011	4
13	Screw M4x8 Pan hd (handle attachment)	614040117	2

NOTE: White valve cap (pre-June 2010) can be ordered using 043042345 (1 / bag).

4.1.3 Spares Kit



NOTE: All RD900 units manufactured from May 1999 can accommodate the above spares kit.

Model specific panel and valve assembly Blue (kit includes fascia)	
043043595	Fascia & Valve Assy Blue English
043043596	Fascia & Valve Assy Blue German
043043597	Fascia & Valve Assy Blue Italian
043043598	Fascia & Valve Assy Blue Spanish
043043599	Fascia & Valve Assy Blue French
043043600	Fascia & Valve Assy Blue Norwegian
043043601	Fascia & Valve Assy Blue Dutch
043043602	Fascia & Valve Assy Blue Swedish
043043603	Fascia & Valve Assy Blue Portuguese
043043604	Fascia & Valve Assy Blue Danish
043043605	Fascia & Valve Assy Blue Finnish
Model specific panel and valve assembly Purple (kit includes fascia)	
043042347	Fascia & Valve Assy English
043042348	Fascia & Valve Assy German
043042349	Fascia & Valve Assy Italian
043042350	Fascia & Valve Assy Spanish
043042351	Fascia & Valve Assy French
043042353	Fascia & Valve Assy Dutch
043042354	Fascia & Valve Assy Swedish
043042355	Fascia & Valve Assy Portuguese
043042356	Fascia & Valve Assy Danish
043042357	Fascia & Valve Assy Finnish
043042358	Fascia & Valve Assy Norwegian

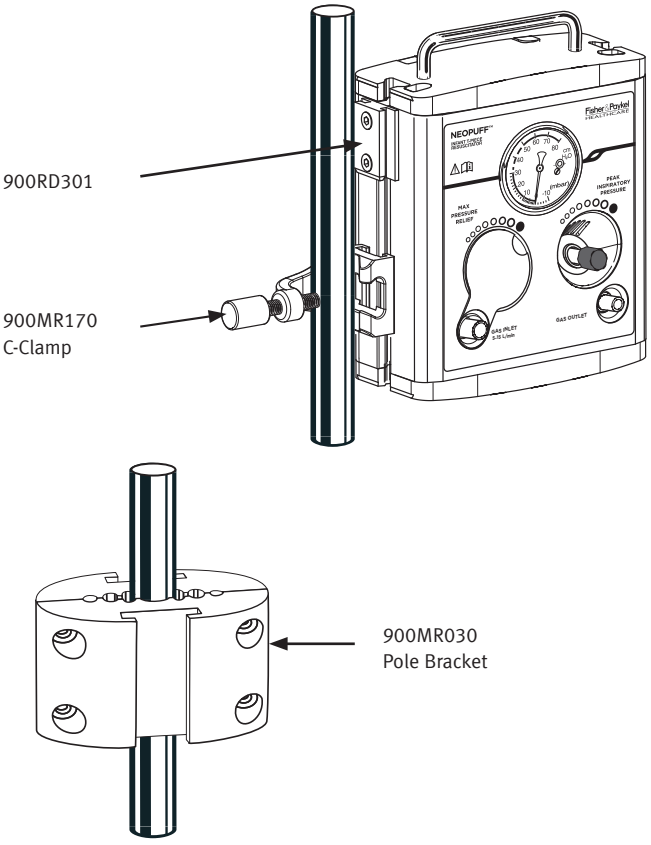
5. MOUNTING OPTIONS

Impact to the F&P Neopuff™ / Perivent™ Infant Resuscitator, caused by rough handling or the unit being dropped, can damage the valve system and produce irregular resuscitation pressures.
To help prevent any impact to the device, Fisher & Paykel Healthcare recommends the use of one of the mounting systems shown below.

5.1 900RD301 Side-Mounting Block, 900MR170 C-Clamp, 900MR030 Pole Bracket

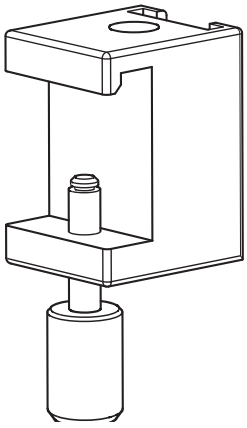
The 900RD301 Side Mounting Block fits into the dovetail slot on the side of the Infant Resuscitator. The 900RD301 may then be connected to a 17 to 40 mm pole using either the 900MR170 C-Clamp or 900MR030 Pole Bracket.

Mounting Option	Parts to order
Quick disconnect (C-Clamp)	900RD301 & 900MR170
Permanent Pole Bracket	900RD301 & 900MR030



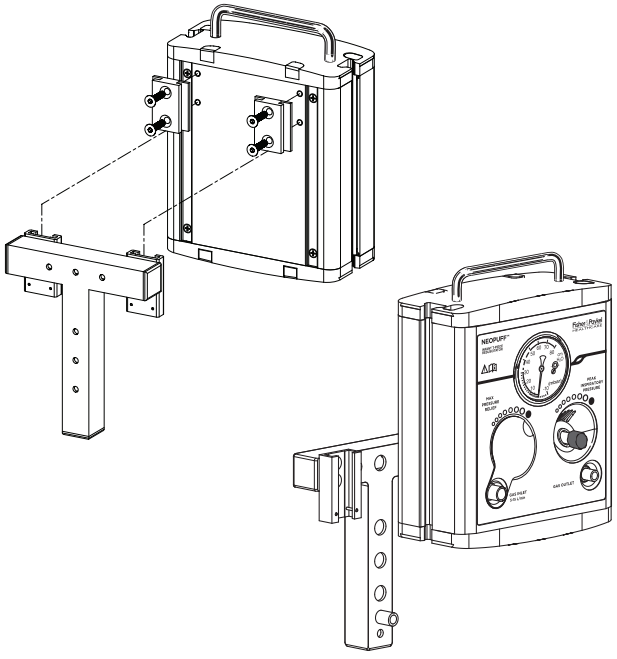
5.2 900MR088 Rail Bracket

For mounting the F&P Neopuff / Perivent Infant Resuscitator centrally on standard rails (2.5 to 5.5 cm x 1 cm / 0.98 to 2.17” x 0.39”).
Also requires RD050-01.



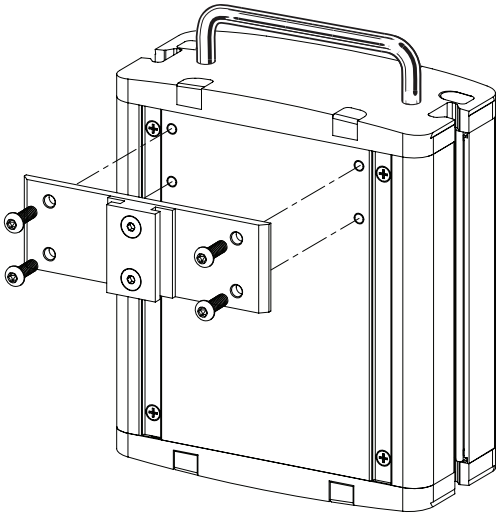
5.3 900RD302 Wall Mount Bracket

The 900RD302 Wall Mount Bracket has two tongue fittings that may be screwed to the back of the F&P Neopuff™ / Perivent™ Infant Resuscitator by removing the four plastic plugs from the rear panel, and a T-shaped bracket that should be screwed to the wall.
This allows the infant resuscitator to be quickly and easily removed from and replaced on the bracket as required.



5.4 RD050-01 Pole and Rail Central Mount

For mounting the F&P Neopuff™ / Perivent™ Infant Resuscitator centrally on a pole or on standard rails (2.5 to 5.5 cm x 1 cm / 0.98 to 2.17” x 0.39”), a central mounting block can be affixed to the back of the unit by removing the four plastic plugs from the rear panel. The unit will then fit the F&P bracket and clamps.



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

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