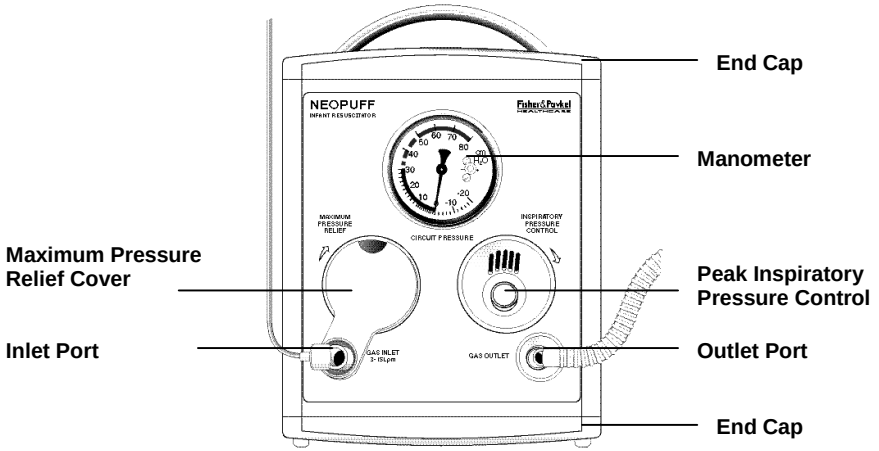
Neopuff™ Infant Resuscitator Technical Manual

This is a Technical Manual only, for instructions on how to operate the Neopuff™ Infant Resuscitator please refer to the Operating Manual.



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1.0 Performance Characteristics and Specifications

1.1 Caution

- Input gas flow rate 5-15 LPM, recommended operating gas flow rate 8 LPM. **Do not attempt to use a higher flow than 15 LPM.**
- Factory setting of pressure relief valve is at 40cm H_2O. This setting is user adjustable up to 80cm H_2O. **Do not attempt to set the pressure relief valve above 80-cm H_2O. Reset pressure relief valve to 40cm H_2O after use (refer 4.2.3 of this manual).**
- Use only recommended Fisher & Paykel Healthcare Neopuff™ Infant Resuscitator accessories.
- Do not use substances that are incompatible with O_2.

1.2 Typical Performance

Inspiratory pressure range		
@ 5 LPM	approx.	2-73cm H_2O [mbar]
@ 8 LPM	approx.	4-73 cm H_2O [mbar]
@ 10 LPM:	approx.	5-75 cm H_2O [mbar]
@ 15 LPM	approx.	10-77cm H_2O [mbar]
Input gas flow range:		
Minimum		5 LPM
Maximum		15 LPM
Peep range at:		
5 LPM		1-5 cm H_2O [mbar]
8 LPM	approx.	1-9 cm H_2O [mbar]
10 LPM		2-15 cm H_2O [mbar]
15 LPM		4-25 cm H_2O [mbar]

If the gas flow rate increases from 5 to 15 LPM, peak pressure values will increase by approximately 8 cm H_2O [mbar].

Operating time (400 litre cylinder):

5 LPM	80 minutes
10 LPM	40 minutes
15 LPM	26 minutes

PLEASE NOTE: The above figures are typical only.

1.3 Technical Specifications

Manometer range: -20 to 80cm H_2O [mbar]	
Manometer accuracy:	+/-2.0% of FSD
Maximum pressure setting:	65-80 cm H_2O [mbar] (dependant on flowrate)
Dimensions:	
Height	250mm (9.8”)
Width	200mm (7.9”)
Depth	100mm (3.9”)
Weight	2.1kg (4.6lb)
Operating and storage	0^0C to 50^0C, up to 90% humidity
Recommended body weight:	0-10kg (22lb)
Delivered oxygen concentration:	Up to 100%

4.2.3 Setting Maximum Pressure Relief to 40cm H_2O

This is required if the maximum pressure relief has been changed. The factory setting for he maximum pressure setting is 40cmH_2O. This should be adjusted in accordance with hospital protocol.

1. Adjust gas flow to 10 LPM.
2. Turn the peak inspiratory pressure knob fully clockwise
3. Adjust the maximum pressure relief valve clockwise or counter-clockwise until the manometer reads 40cm H_2O.
4. Turn the peak inspiratory pressure knob anticlockwise so the manometer reads 20cm H_2O and shut off the gas flow.

4.2.4 Manometer Replacement

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

1. Remove back cover, fixed by four screws
2. Disconnect tube from manometer.
3. Remove manometer by unscrewing the two retaining nuts
4. Fit the new manometer into front panel, tighten retaining nuts and re-connect manometer tube.
5. Record date code found on back of replacement manometer and serial number of Neopuff™ infant resuscitator from back cover and send copy to Fisher & Paykel Healthcare, Attention Neonatal Regulatory Affairs.
6. Re-fit front panel to back cover with four screws.
7. Complete Testing of Manometer (4.2.2)

4.2.5 Valve Replacement

Note: the valves are an integral part of the valve, fascia and manifold assembly and are not able to be serviced. Please specify model number from parts list (3.2.1) when ordering a replacement valve assembly.

1. Remove back cover, fixed by four screws
2. Remove plugs and remove end caps by unscrewing four cap screws per end.
3. Disconnect tube from manometer.
4. Remove manometer by unscrewing the two retaining nuts
5. Record valve assembly and Neopuff™ Infant Resuscitator serial numbers and send copy to Fisher & Paykel Healthcare, Attention Neonatal Regulatory Affairs.
6. Fit existing manometer into new valve assembly panel, tighten retaining nuts and re-connect manometer tube.
7. Re-fit front panel to back cover with four screws.
8. Re-fit ends caps with four cap screws per end and replace plugs.
9. Complete Testing of Manometer (4.2.2)

2.0 Cleaning of the RD900 Neopuff™ Infant Resuscitator

2.1 Cleaning

Clean the external surfaces of the Neopuff™ Infant Resuscitator either weekly or between patients using a damp cloth with dilute mineral acids, an acid-salt solution or correctly diluted disinfectant-detergent solution. Ensure that the manufacturer's directions for use of the cleaning agent are followed. Dry all surfaces after cleaning with a clean soft cloth or paper towel

2.2 Test Lung

If required the test lung can be sterilized using ethylene oxide gas only. Please note that the test lung is constructed of latex and is susceptible to attack by solvents. Ensure no solvents are used to clean the test lung.

2.3 WARNING

- Latex construction of the test lung may cause irritation.

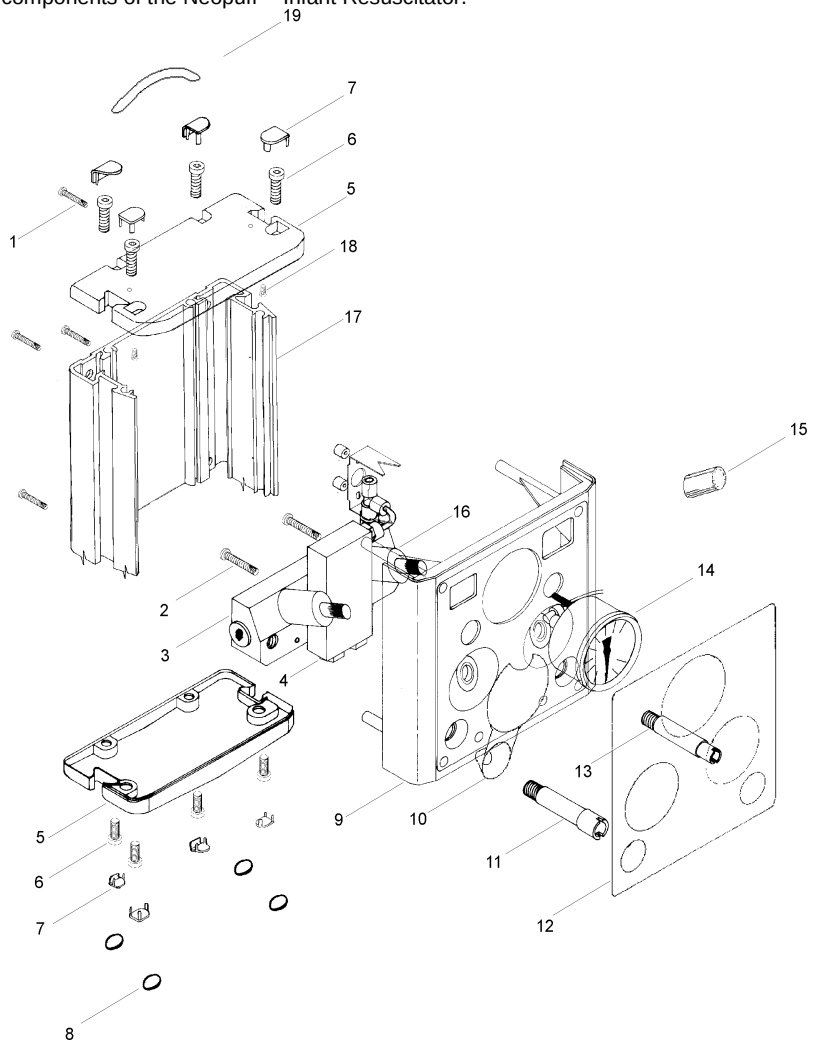
2.4 CAUTIONS

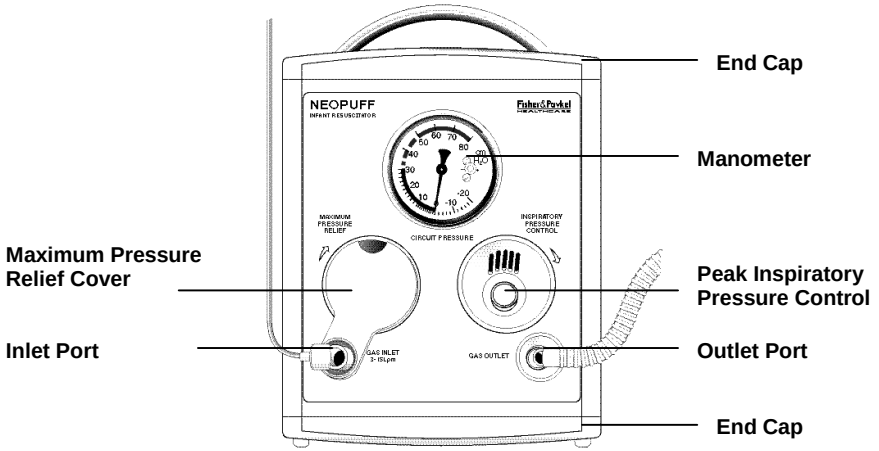
- DO NOT use any compounds containing aromatic hydrocarbons, ammonia, aqueous solutions or abrasive products. Use of alcohol based solutions may cause plastic surfaces to craze and crack.
- Ensure all oxygen and air supplies are turned off and disconnected from the Neopuff™ Infant Resuscitator before performing cleaning procedures. Explosion and fire hazards can exist when performing cleaning procedures in an oxygen-enriched environment.
- Before cleaning, remove and discard all used single use products using the recommended method of disposal.
- Do not attempt to clean single use products.
- The above methods of cleaning are suitable for the components, but the suitability of any method for a particular bacteriological situation is the responsibility of the user.
- Do not autoclave or gas sterilise the Neopuff™ Infant Resuscitator.
- Ensure all parts and accessories are checked before returning the device to service
- For ethylene oxide gases: Some carrier gases can cause stress cracking and are not suitable. If in doubt check with chemical supplier.
- Do not reuse single use Neopuff™ Infant Resuscitator products

3.0 Assembly Diagram

3.1 Serial Numbers before 99R9xxx083

For serial numbers predating 99R9___083, the diagram below represents the internal components of the Neopuff™ Infant Resuscitator.





4.2.2 Testing of Manometer

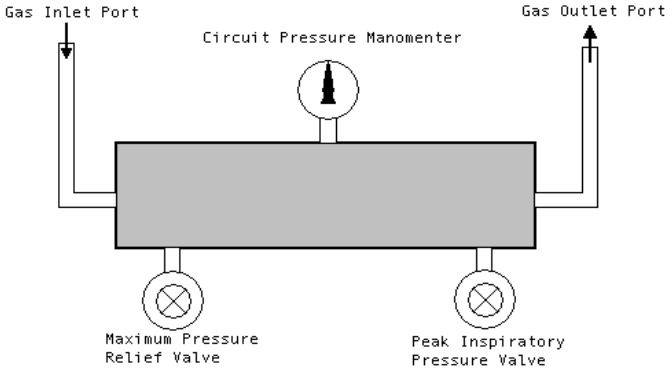
The manometer can be tested against a calibrated gauge using the following guidelines. The inlet port must be connected with a flow generator capable of generating constant flow at 5 and 10 LPM. The outlet port must be connected with a bleed valve and the certified gauge being used.

1. Lift the cover off the maximum pressure relief valve slightly and rotate out of the way.
2. Completely close the maximum pressure relief valve by turning fully clockwise.
3. At 10LPM the manometer should be within +/−2cm H_2O of the certified gauge at 10, 20 and 40cm H_2O
4. The manometer should have risen/fallen smoothly between the settings by using the peak inspiratory pressure control when the bleed valve is activated.
5. At 5 LPM set the manometer to 70cm H_2O, the certified gauge should read a minimum of 65cm H_2O.
6. At 10 LPM the unit should not generate pressures greater than 83cm H_2O.
7. Turning the maximum pressure relief valve counter-clockwise reset the maximum pressure to 40cm H_2O. (4.2.3)
8. Replace the maximum pressure valve cover by rotating the cover back into place and pressing it onto the valve stem.
9. Once testing is completed reset the peak inspiratory pressure to 20cm H_2O and turn off gas flow.

If the manometer fails on any of these settings then it should be regarded as inaccurate and replaced immediately with a replacement manometer 043040841. Follow manometer replacement guidelines in section 4.2.4 of this manual.

4.0 Service Information

4.1 Functional schematic



4.2 Preventative Maintenance

- The Neopuff™ Infant Resuscitator should receive annual servicing or maintenance when used under normal conditions. This should include Testing of the Manometer (4.2.2), Setting the Maximum Pressure Relief to 40cm H_2O (4.2.3) and if required Resetting the Manometer to Zero (4.2.1), Manometer Replacement (4.2.4) and Valve Replacement (4.2.5) of this manual.
- Both of the adjustment knobs should rotate easily without play, failure to do this may indicate damage to the valves and Valve Replacement (4.2.5) should be carried out.
- The integrity of the system and manometer should be checked annually and after servicing using include Testing of the Manometer (4.2.2).
- Qualified personnel using only Fisher & Paykel Healthcare parts must carry out all maintenance.
- Always ensure gas passages are free from contaminants, especially hydrocarbons, prior to re-assembly.
- Ensure only approved replacement parts are used during service and maintenance procedures.
- Please contact an authorised Fisher & Paykel Healthcare representative for further assistance with any servicing or maintenance requirements.
- The test lung should be replaced within three years of purchase.

4.2.1 Resetting the Manometer to Zero

To zero the manometer:

10. Disconnect Neopuff™ Infant Resuscitator from any other equipment.
11. Remove opaque plastic plug in lens of manometer
12. Using suitable slot screwdriver adjust clockwise (+) or counter-clockwise (-) to reset manometer to zero
13. Replace plastic plug in lens of manometer
14. Complete Testing of the Manometer (4.2.2)

3.1.1 Parts List

#	Description	Part Number	Reqd
1	Screw #8x1" CSK HD.	616050011	4
2	Screw #8x1" Pan HD.	614040153	2
3	Manifold block. Includes plug, T-piece, tube and 2 screws.	**See note**	
4	Reservoir. Includes 2 bungs, fitting and tube.	**See note**	
5	End cap	693040741	2
6	Screw M8x20.	614040309	
7	Plug set of 5.	693040706	1
8	Foot.	693041436	4
9	Plastic panel	See note	
10	Cover, max pressure relief, permanent and removable.	043041057	
11	Connector 10mm female gas inlet.	**500RD509**	
12	Model specific front fascia, please specify exact model		1

English	233201448	Dutch	233201518
German	233201467	Swedish	233201521
Italian	233201468	Portuguese	233201522
Spanish	233201469	Danish	233201523
French	233201470	Finnish	233201524
Japanese	233201471	Norwegian	233201525

13	Connector 10mm male gas outlet.	**500RD508**	**1**
14	Manometer kit	043040841	1
15	Cap, inspiratory pressure valve.	043042345	1
16	Valve assemblies, pair.	**See note**	
17	Column.	641040816	1
18	Screw M4x8 Pan HD.	614040117	2
19	Handle	641040809	1

Service kit, includes C-spanner and adapter for torque driver. 500RD521

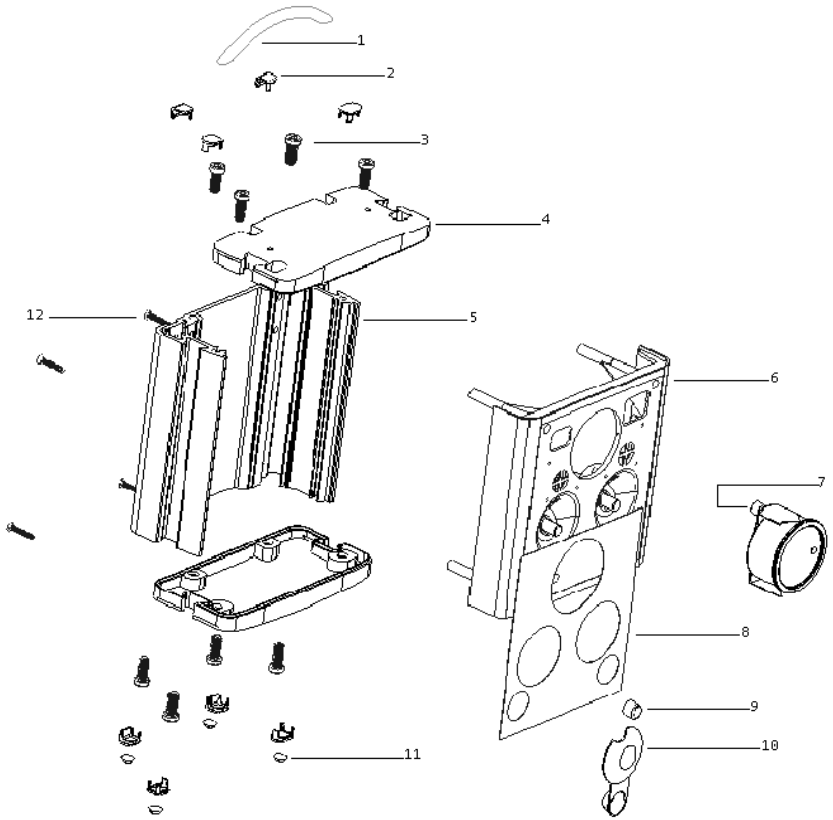
Note – Parts 3,4,9 and 16 are no longer available due to model update to that shown in 3.2. To replace any of these parts please order from the following language specific panel, fascia and valve assembly spare part:

Model specific panel and valve assembly (kit includes fascia)

English	043042347	Dutch	043042353
German	043042348	Swedish	043042354
Italian	043042349	Portuguese	043042355
Spanish	043042350	Danish	233201523
French	043042351	Finnish	233201524
Japanese	043042352		

3.2 Serial numbers after 99Rxxx083

On 29/03/01 serial numbers changed from the above format to the EAN format. The first number in the sequence was 010329000001. There was no change to the model itself.



3.2.1 Parts List

#	Description		Part Number	Reqd
1	Handle		641040809	1
2	Plug (set of four)		693040706	2
3	Screw M8x20		614040309	8
4	End cap		693040741	2
5	Back cover		641040816	1
6	Model specific panel and valve assembly (kit includes fascia)			1
		English	043042347	
		German	043042348	
		Italian	043042349	
		Spanish	043042350	
		French	043042351	
		Japanese	043042352	
		Dutch	043042353	
		Swedish	043042354	
		Portuguese	043042355	
		Danish	233201523	
		Finnish	233201524	
7	Manometer kit		043040841	1
8	Model specific front fascia, please specify exact model			1
		English	233201448	
		German	233201467	
		Italian	233201468	
		Spanish	233201469	
		French	233201470	
		Japanese	233201471	
		Dutch	233201518	
		Swedish	233201521	
		Portuguese	233201522	
		Danish	233201523	
		Finnish	233201524	
		Norwegian	233201525	
9	Cap, inspiratory pressure valve		043042345	2
10	Cover, maximum pressure relief		043041057	1
11	Foot		693041436	4
12	screw #8x1” Csk hd		616050011	4
---	Screw M4x8 Pan hd (not shown, handle attachment)		614040117	2
---	Test lung (not shown)		042040542	1