

Performance Test Report for Neonatal Resuscitation Circuit According to EN12342

Tested Device Name: Neonatal Resuscitation Circuit

Manufacturer : Marshall Products Limited

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Marshall Airway Products Limited declare that the following tests have been carried out to ensure the effectiveness and the safety of the device.

Test of resistance to flow

- a. The neonatal resuscitation circuit shall be conditioned at a temperature of $42\pm3^{\circ}\text{C}$ for at least 1h, and carry out the testing procedure at the temperature.
- b. The test is carried out according to the clause A4.3-A4.6 of EN12342:1998 *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

2. Test of leakage

- a. The neonatal resuscitation circuit shall be conditioned at a temperature of $42\pm3^{\circ}\text{C}$ for at least 1h, and carry out the testing procedure at the temperature.
- b. Occlude the patient opening of the 'T-Piece'.
- c. Apply an internal gas pressure of $(6\pm0.3)\text{kPa}$ [$(60\pm3)\text{cmH}_2\text{O}$] by introducing air to the breathing tube. Record the flow of air required to maintain the internal gas pressure.

3. Visual Inspection

- a. Implement an appearance defect inspection of the device for transparency, discolouration and damaging (cuts, holes, tears or scratches). Visually inspect each component, do not use if the construction changes or if there are any worn or brittle parts. Reject the device if any of these factors are apparent.
- b. Check the interior of the tube to ensure that it is free from blockages or loose particles. Any particles present in the tube, or on the exterior of the tube should be removed as they may be inhaled by the patient after insertion. Reject the device if the visible particles cannot be removed from the airway tube.
- c. Check the fit of the 15 mm connector onto the tube. Make sure the connector fits tightly into position and cannot be pulled off the tube by hand, using reasonable force.

Conclusion: We have completed the above tests for 30 NeoPEEP™ circuits. All the neonatal resuscitation circuit samples passed all the tests in excellent condition. Therefore, we concluded that the performance of the device is in accordance with the requirements of the related standards.

4. Test of Peep

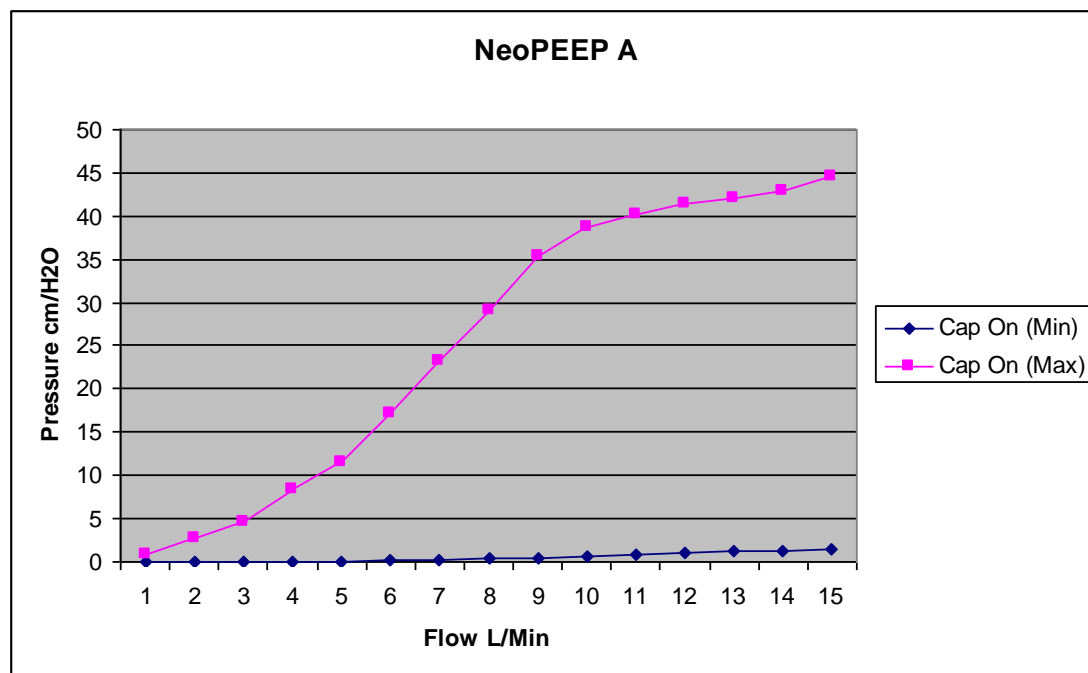
- a. Adjust gas supply (oxygen or blended oxygen/air) to required flow rate between 1 – 15 LPM respectively.
- b. Occlude the patient opening of the 'T-Piece' to secure an air tight seal.

- c. Adjust the PIP (Peak Inspiratory Pressure) on the Resuscitation device to the required setting.
- d. Adjust PEEP (Positive End Expiratory Pressure) setting by screwing/ unscrewing the PEEP control cap on the NeoPEEP™ Circuit to on or off , and record the manometer needle reading.
- e. Carry out this testing for two different NeoPEEP™ samples.

Result :

Sample A

Flow L/min	PEEP in mb			PEEP in cmH2O		
	Cap off	Cap on (min)	Cap on (max)	Cap off	Cap on (min)	Cap on (max)
1	0	0	0.9	0	0	0.91774459
2	0	0	2.6	0	0	2.65126215
3	0	0.1	4.6	0	0.10197162	4.69069458
4	0	0.1	8.2	0	0.10197162	8.36167295
5	0	0.1	11.2	0	0.10197162	11.4208216
6	0	0.2	16.9	0	0.20394324	17.233204
7	0	0.3	22.8	0	0.30591486	23.2495297
8	0	0.4	28.6	0	0.40788649	29.1638837
9	0	0.5	34.6	0	0.50985811	35.282181
10	0	0.7	38	0	0.71380135	38.7492161
11	0.1	0.9	39.4	0.1019716	0.91774459	40.1768188
12	0.1	1.1	40.7	0.1019716	1.12168783	41.5024499
13	0.1	1.2	41.2	0.1019716	1.22365946	42.012308
14	0.1	1.3	42.1	0.1019716	1.32563108	42.9300526
15	0.1	1.5	43.8	0.1019716	1.52957432	44.6635701



Sample B:

Flow L/min	PEEP in mb			PEEP in cmH2O		
	Cap off	Cap on (min)	Cap on (max)	Cap off	Cap on (min)	Cap on (max)
1	0	0	0.5	0	0	0.50985811
2	0	0	1.3	0	0	1.32563108
3	0	0.1	2.6	0	0.10197162	2.65126215
4	0	0.1	4.4	0	0.10197162	4.48675134
5	0	0.1	6.3	0	0.10197162	6.42421214
6	0	0.2	9.4	0	0.20394324	9.5853324
7	0	0.3	12.6	0	0.30591486	12.8484243
8	0	0.4	15.4	0	0.40788649	15.7036297
9	0	0.5	18.1	0	0.50985811	18.4568635
10	0	0.7	22.6	0	0.71380135	23.0455864
11	0.1	0.9	28.9	0.1019716	0.91774459	29.4697986
12	0.1	1.1	35.9	0.1019716	1.12168783	36.607812
13	0.1	1.2	37.8	0.1019716	1.22365946	38.5452729
14	0.1	1.3	38.6	0.1019716	1.32563108	39.3610458
15	0.1	1.5	40.3	0.1019716	1.52957432	41.0945634

