

## Second Clinical Evaluation Trial

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Rollins 7 Multitask Mask Study Primary Endpoint: Assessing Oxygen Saturation in clinical setting

Beginning Date: June 2010

Patient number: 11

Diagnoses: COPD. Pneumonia. Congestive Heart Failure, Lung Cancer

Evaluation design: patients selected for use were randomly selected, there were no exclusionary criteria except for primary physician or patient request not to use mask; no denials were requested.

Patient's ages were between 63 and 96. No patient had difficulty wearing or tolerating the mask.

**Patient JL:** 74 year old male with respiratory failure. Patient placed on Rollins7 and arterial blood gas obtained showing pH 7.45 pCO<sub>2</sub> 40.7 pO<sub>2</sub> 81. Showed efficacy of mask and no CO<sub>2</sub> retention

Oxygen saturation at 12 L flow per minute on standard mask: 98%

Oxygen saturation at 3 L flow per minute on Rollins 7 mask: 98%

**Patient FC:** 75-year-old male with hypoxic respiratory failure

Arterial blood gases on Rollins 7 on 10 L flow pH 7.436 pCO<sub>2</sub> 46.5 pO<sub>2</sub> 98.9

Showed efficacy of mask and no CO<sub>2</sub> retention

**Patient MR** 85 year old female with respiratory failure placed on Rollins 7 at 6 liters per minute flow with ABG showing 7.46 pCO<sub>2</sub> 47.4 pO<sub>2</sub> 160. Showed efficacy of mask and no CO<sub>2</sub> retention.

**Patient LS** 67 year old female with respiratory failure on 8 liters per minute flow on Rollins 7 with ABG 7.43 pCO<sub>2</sub> 42.4 pO<sub>2</sub> 72.6 ; Showed efficacy of mask and no CO<sub>2</sub> retention

Oxygen saturation on unknown liter flow before Rollins 7: 89%

Oxygen saturation on Rollins 7 at 6 L per minute flow: 95%

**Patient UV** 89-year-old female with hypoxic respiratory failure

ABG on 6 L flow with Rollins 7 pH 7.451 pCO<sub>2</sub> 50.6 pO<sub>2</sub> 60.5

Showed efficacy of mask and no CO<sub>2</sub> retention

**Patient BBJ** 84 year old female with hypoxic respiratory failure

ABG on 4 liters nasal cannula 7.55 pCO<sub>2</sub> 48.7 pO<sub>2</sub> 41.2

ABG on 6 liters Rollins 7 showed 7.52 pCO<sub>2</sub> 50.5 pO<sub>2</sub> 82.5

**Patient JS** with hypoxic respiratory failure

ABG on BiPAP 14/5 showed 7.46 pCO<sub>2</sub> 53.7 pO<sub>2</sub> 56.5

ABG on Rollins 7 on 15 L/min: pH 7.408 pCO<sub>2</sub> 64.9 pO<sub>2</sub> 67.3

**Patient GG** 69-year-old male with hypoxic respiratory failure

ABG on 15 L/min flow Venti mask pH 7.253 pCO<sub>2</sub> 68.9 pO<sub>2</sub> 73.7

ABG on 4 L/min Rollins 7 pH 7.246 pCO<sub>2</sub> 65.2 pO<sub>2</sub> 90.4

**Patient MV** 96-year-old female with hypoxic respiratory failure

ABG on 15 L non-rebreather mask pH 7.374 pCO<sub>2</sub> 42 pO<sub>2</sub> 48.3

ABG 15 liter/min flow Rollins 7 pH 7.406 pCO<sub>2</sub> 39.5 pO<sub>2</sub> 68

Conclusions:

1. Rollins 7 multitask mask administers adequate oxygenation
2. While on Rollins 7 Multitask mask patients received equal or more often superior oxygenation at lower flow rates
3. Rollins 7 multitask mask does not induce carbon dioxide retention
4. There is no patient discomfort with the mask
5. There is no requirement to change masks when transitioning from an  $\text{Fio}_2$  of 28% to 99%.