

CC = FRC - (volume from FRC to III-IV  
inflection expired nitrogen curve)

### RESULTS AND DISCUSSION

It proved easy to perform the ventilatory maneuvers with the 5-liter syringe, and the awake subjects tolerated the inflation and deflation maneuvers without complaint. Inspiratory and expiratory flow rates could be controlled at desired levels, and crisp III-IV nitrogen inflections were consistently observed. There was no significant difference in closing capacities determined by the three tests (table 1). This does not mean, however, that positive-pressure inflation might not affect the measurement of closing capacity. Our subjects were awake and tended to assist inspiration, which minimized pressure applied to their airways.

In the standard protocol for measurement of closing capacity subjects breathe room air and then inspire oxygen (test gas) from residual volume to total lung capacity.<sup>3</sup> We elected to have our subjects inhale the test gas, or have their lungs inflated, from FRC, considering that in patients whose ventilation is controlled FRC is an easily obtained and identified lung volume. Modification of the standard protocol, *i.e.*, starting at FRC not residual volume, was suggested by Mansell *et al.*,<sup>4</sup> who found that addition of an air-filled deadspace, expiratory reserve volume sharpened the III-IV point of nitrogen inflection.

In addition, we studied the results of using room air as the test gas, after the subject was denitrogenated by oxygen breathing. We considered that in comatose or anesthetized patients breathing high concentrations of oxygen, the use of room air as the test gas might be advantageous. The two test gases produced similar results (table 1).

We suggest that in using this method for measuring closing capacity in man suitable pressure valves be installed to prevent any unwanted pressure from being applied to the airway.

We have described a method for measuring closing capacity in unconscious subjects and in those unable to control their ventilatory patterns. There was no significant difference between closing capacities measured during conscious spontaneous breathing and during controlled positive-negative-pressure ventilation using this method.

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## Defective Disposable Oxygen Face Masks

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THIS COMMUNICATION reports three incidents in which manufacturing defects or poor design of disposable oxygen face masks led to potentially lethal problems when humidified,

oxygen-enriched gases were being administered to patients in the recovery room and intensive care unit.

### REPORT OF THREE CASES

**Patient 1.** A 69-year-old, edentulous man in good health underwent an inguinal herniorrhaphy. Anesthesia with thiopental, meperidine, and nitrous oxide was supplemented with pancuronium for muscle relaxation. At the conclusion of the operation, the patient was taken to the recovery room in a conscious but sedated state. A disposable,

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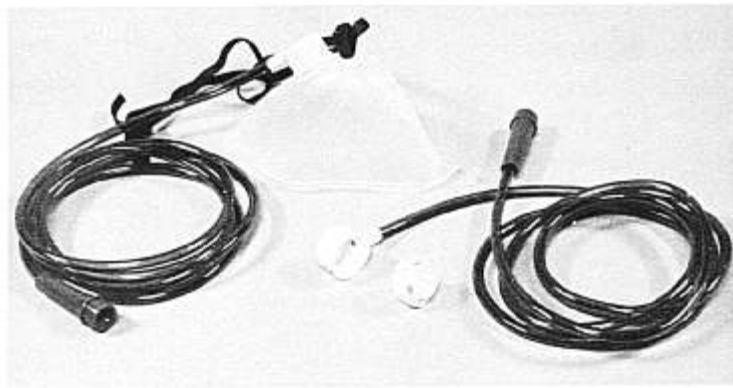


FIG. 1. The assembled Lif-O-Gen mask and the two parts of the swivel connector. The inner part projects through an opening in the mask from the patient's side; the outer part with the attached oxygen tubing slips over the projecting inner part.

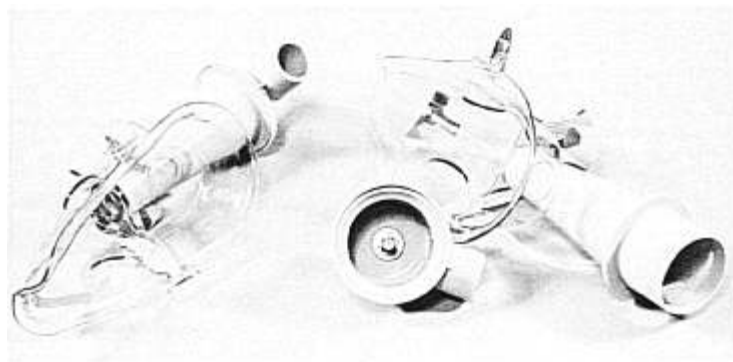


FIG. 2. The assembled and disassembled Vari-O-Mask. The disassembled mask is oriented to show the centrally located, oxygen orifice within the plastic body.

oronasal oxygen mask† (fig. 1) with a swivel connector was attached to the patient. Thirty minutes after admission to the recovery room, the patient was found choking. As the patient was turned onto his side, he coughed out of his pharynx the inner part of the swivel connector. This inner part of the connector had fallen into his mouth

† Lif-O-Gen Oxygen Mask, Model 260-5, Lif-O-Gen, Inc., Cambridge, Maryland.

as the connector spontaneously disassembled. It was later found that application of a slight force to the oxygen tubing dislodged the inner part of the connector from the outer part attached to the tubing.

**Patient 2.** A 75-year-old man with chronic obstructive pulmonary disease was admitted to the intensive care unit in acute respiratory failure. Arterial blood gases when the patient breathed room air were  $P_{O_2}$ , 34 torr,  $P_{CO_2}$ , 72 torr,

and pH 7.35. Due to a history of carbon dioxide retention, non-ventilatory therapy was employed initially. A disposable, variable-oxygen-concentration mask<sup>1</sup> (fig. 2) was connected to the patient, and the dial cap was set to deliver 35 per cent humidified oxygen. Thirty minutes later, arterial blood-gas values were  $P_{O_2}$  30.6 torr,  $P_{CO_2}$  79.3 torr, and pH 7.33. Because of the failure of the blood-gas values to change with oxygen therapy, the oxygen concentration under the mask was measured and found to be 20 per cent. Disassembling the mask disclosed that the oxygen orifice of the Venturi mechanism was occluded by a layer of clear plastic.

**Patient 3.** A 68-year-old man with chronic pulmonary disease was admitted to the hospital in acute respiratory failure. The patient's condition initially responded to therapy that included 30 per cent humidified oxygen delivered by a variable-oxygen-concentration mask<sup>1</sup> (fig. 2); arterial blood-gas values were  $P_{O_2}$  46 torr,  $P_{CO_2}$  55 torr, and pH 7.37. However, on the second night after admission, approximately 60 minutes after the mask had been replaced by a sterile one, the patient was confused. Measurement of the oxygen concentration under the face mask revealed an  $F_{I_{O_2}}$  of 100 per cent rather than 30 per cent. Inspection of the mask revealed that the indicator for the oxygen concentration dial was not marked clearly. This shortcoming in the design of the mask had led to the mistaken identification of a seam in the plastic body as the indicator and thereby to the error in administered concentration.

#### DISCUSSION

The cases presented document three unsuspected and dangerous complications resulting from the use of faulty disposable oxygen

masks. Complications of this type in patients who are dependent on oxygen-enriched gases could lead to hypoxia, cardiac arrhythmias and cardiac arrest.

Inspection of the stock of Lif-O-Gen face masks at our hospital revealed that many of the swivel connectors disassembled easily when a slight force was exerted on the oxygen tubing. In addition to the complication documented in the first case, this defect has caused disconnections of the oxygen tubing from the face mask on other patients during oxygen therapy. Because of the serious nature of this defect, I feel that the design of the connector should be modified by the manufacturer in order to prevent accidental disassembling.

Inspection of our stock of Vari-O-Masks revealed 15 masks with a plastic layer obstructing the oxygen orifice as in the second case; all the Vari-O-Masks in stock had oxygen concentration dials similar to that in the third case. This mask should be inspected before use to verify the patency of the oxygen orifice and to insure that the indicator for the oxygen concentration dial can be correctly identified.

In spite of its undeniable advantages, the era of disposable, mass-produced medical equipment may introduce added risks for the patient. The medical staff must be alert to these potential dangers and continue to inspect carefully equipment prior to and during its use. The findings discussed here have been reported to the respective manufacturers; it is hoped that appropriate corrective measures will be undertaken.

<sup>1</sup> Vari-O-Mask, No. D-6500, Dynacor, Northbrook, Illinois.