

# Comparação da FiO<sub>2</sub> Fornecida por Sete Modelos de Sistema Balão-Máscara Auto-inflável\*

## Comparison of the FiO<sub>2</sub> Delivered by Seven Models of the Self-Inflating Bag-Mask System

Armando Carlos Franco de Godoy<sup>1</sup>, Ronan José Vieira<sup>2</sup>

### RESUMO

Godoy ACF, Vieira RJ — Comparação da FiO<sub>2</sub> Fornecida por Sete Modelos de Sistema Balão-Máscara Auto-inflável.

**JUSTIFICATIVA E OBJETIVOS:** Devido ao fato dos reanimadores com sistema balão-máscara auto-infláveis fabricados e/ou comercializados no Brasil serem amplamente disponíveis e utilizados em serviços de saúde extra e intra-hospitalares, este estudo teve o objetivo de determinar as frações de O<sub>2</sub> oferecidas por sete reanimadores recebendo diferentes fluxo de O<sub>2</sub>.

**MÉTODO:** Sete reanimadores com sistema balão-máscara auto-infláveis foram testados na Unidade Respiratória do HC/UNICAMP. Um fluxômetro de O<sub>2</sub> de parede foi conectado ao reanimador que recebia fluxo de O<sub>2</sub> de 1, 5, 10 e 15 L.min<sup>-1</sup>, sendo estes conectados a um pulmão-teste. Os reanimadores que têm a capacidade de se conectar um reservatório de O<sub>2</sub> foram testados com e sem esse acessório. Foram efetuadas 20 medidas consecutivas e determinada a média.

**RESULTADOS:** Apenas um reanimador apresentou oferta de fração de O<sub>2</sub> pouco abaixo do limite mínimo preconizado (0,80), quando utilizado com o reservatório de O<sub>2</sub>. Sem esse dispositivo acoplado todos os reanimadores atingiram o limite mínimo de fração de O<sub>2</sub> preconizada (0,40). Os reanimadores que não apresentam a possibilidade de acoplar o reservatório de O<sub>2</sub> apresentaram maior oferta de O<sub>2</sub> em relação aos outros reanimadores.

**CONCLUSÕES:** Todos os reanimadores que possuem a opção de acoplarem o reservatório de O<sub>2</sub> forneceram maior concentração de O<sub>2</sub> com esse acessório. Os reanimadores que não têm possibilidade de acoplar o reservatório de O<sub>2</sub> apresentaram maior ofer-

ta de O<sub>2</sub> em relação aos outros que podem ser acoplados ao reservatório quando usados sem esse acessório.

**Unitermos:** EQUIPAMENTOS: Ventilador.

### SUMMARY

Godoy ACF, Vieira RJ — Comparison of the FiO<sub>2</sub> Provided by Seven Models of Self-Inflating Bag-Mask Systems.

**BACKGROUND AND OBJECTIVES:** Since resuscitators with self-inflating bag-mask systems manufactured and/or commercialized in Brazil are widely available and used in health services, both out- and intra-hospitals, the objective of this study was to determine the O<sub>2</sub> fractions delivered by seven resuscitators receiving different O<sub>2</sub> flows.

**METHODS:** Seven resuscitators with self-inflating bag-mask systems were tested at the Respiratory Unit of the HC/UNICAMP. A wall O<sub>2</sub> flowmeter was connected to the resuscitator that received an O<sub>2</sub> flow of 1, 5, 10, and 15 L.min<sup>-1</sup> and those were connected to a test lung. Resuscitators capable of being connected to an O<sub>2</sub> reservoir were tested with and without this accessory. Twenty consecutive measurements were performed and the mean determined.

**RESULTS:** Only one resuscitator delivered and O<sub>2</sub> fraction slightly below the accepted limit (0.80) when used with the O<sub>2</sub> reservoir. Without this device, all resuscitators achieved the minimal limit of O<sub>2</sub> fraction (0.40). Resuscitators not capable of being connected to an O<sub>2</sub> reservoir delivered a higher O<sub>2</sub>.

**CONCLUSIONS:** All resuscitators capable of being connected to an O<sub>2</sub> reservoir delivered a higher O<sub>2</sub> concentration when connected to this device. Resuscitators that do not have this capability delivered a higher O<sub>2</sub> concentration than the ones that could be connected to this device but are used without it.

**Key words:** EQUIPMENT: Ventilator.

### INTRODUÇÃO

Os reanimadores com sistema balão-máscara auto-infláveis (SBMAI) são aparelhos utilizados com a finalidade de ventilar pacientes com necessidade de suporte ventilatório em situações tais como transporte extra e intra-hospitalar e reanimação cardiopulmonar<sup>1</sup>. Os SBMAI podem ser divididos em duas partes: unidade compressível e conector ao paciente e em alguns modelos existe a opção de ser acoplar um reservatório de O<sub>2</sub> (Figura 1). A unidade compressível é a parte a ser comprimida pelo operador com a finalidade de

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apreensão das mãos do operador, presença ou não de válvulas que limitam pressão no conector ao paciente e do tipo de material, *design* e tamanho da unidade compressível<sup>2,5,16</sup>. Assim, nessa pesquisa cada aparelho ofertou livremente o volume corrente que seu *design* permitia.

Na pesquisa adaptou-se ao sistema do teste um tubo T com válvula direcional (Figura 2: 5, 6) com a finalidade de eliminar o ar ejetado do pulmão-teste para o ambiente, não permitindo o possível retorno do O<sub>2</sub> para o interior da unidade compressível, caso o SBMAI apresentasse falha de vedação na válvula do paciente. A ocorrência dessa falha de vedação poderia acarretar falso aumento da FiO<sub>2</sub> ofertada pelo SBMAI. Apesar de parecer pertinente a função desse mecanismo de vazão do ar ejetado, não se encontrou na literatura trabalhos que utilizaram esse artifício. Diversos autores utilizaram um orifício localizado entre o SBMAI e o pulmão-teste<sup>2,12-15</sup>. Assim, quando a unidade compressível era comprimida, concomitantemente esse furo era tapado com o dedo do pesquisador e quando a unidade compressível do SBMAI era descomprimida esse furo era destapado.

Durante a realização do teste de FiO<sub>2</sub> a frequência respiratória foi mantida em 12 incursões por minuto com uma ou duas mãos, por ser este o modo mais empregado com mais frequência durante as ventilações com SBMAI<sup>17</sup>.

A FiO<sub>2</sub> ofertada pelos SBMAI foi influenciada pelo fluxo de O<sub>2</sub> e a direção deste à unidade compressível, além da utilização ou não do reservatório de O<sub>2</sub>.

Todos os SBMAI têm a opção de acoplagem do reservatório de O<sub>2</sub>, Oxigel® modelo B, Missouri®, CE Reanimadores® e Protec® vinil forneceram maior FiO<sub>2</sub> quando esse acessório estava conectado a unidade compressível, e o CE Reanimadores® ofertou FiO<sub>2</sub> um pouco abaixo do limite mínimo de 0,80 preconizado pela ISO, 1997<sup>10</sup>, e ASTM, 1999<sup>11</sup>, isto é, 0,75 (0,6).

Todos os SBMAI que possuem acoplagem para o reservatório de O<sub>2</sub>, quando testados sem esse acessório, atingiram FiO<sub>2</sub> de 0,40 ou mais, quando recebiam fluxo de O<sub>2</sub> a partir de 10 L.min<sup>-1</sup>. Quando não se utilizou o reservatório de O<sub>2</sub> as FiO<sub>2</sub> ofertadas pelos SBMAI foram menores, pois o oxigênio ofertado ao reanimador é dissipado no ar ambiente próximo à unidade compressível (Figura 1), sendo parcialmente aspirado pelo reanimador. Os reanimadores que não têm a possibilidade de acoplar o reservatório de O<sub>2</sub> possuem maior oferta de O<sub>2</sub> em relação aos outros reanimadores em todos os fluxos de O<sub>2</sub>.

### **Comparison of The FiO<sub>2</sub> Delivered by Seven Models of the Self-Inflating Bag-Mask System**

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#### **INTRODUCTION**

Resuscitators with self-inflating bag-mask systems are used to ventilate patients who need ventilatory support in situations such as extra- and intra-hospital transportation and cardiopulmonary resuscitation<sup>1</sup>. Those devices can be divided in two parts: compressible unit and patient connector, but some models have the option to be connected to an O<sub>2</sub> reservoir (Figure 1). The compressible unit is the segment of the device that is supposed to be compressed by the operator to deliver a volume of air to the patient and, in the back, one

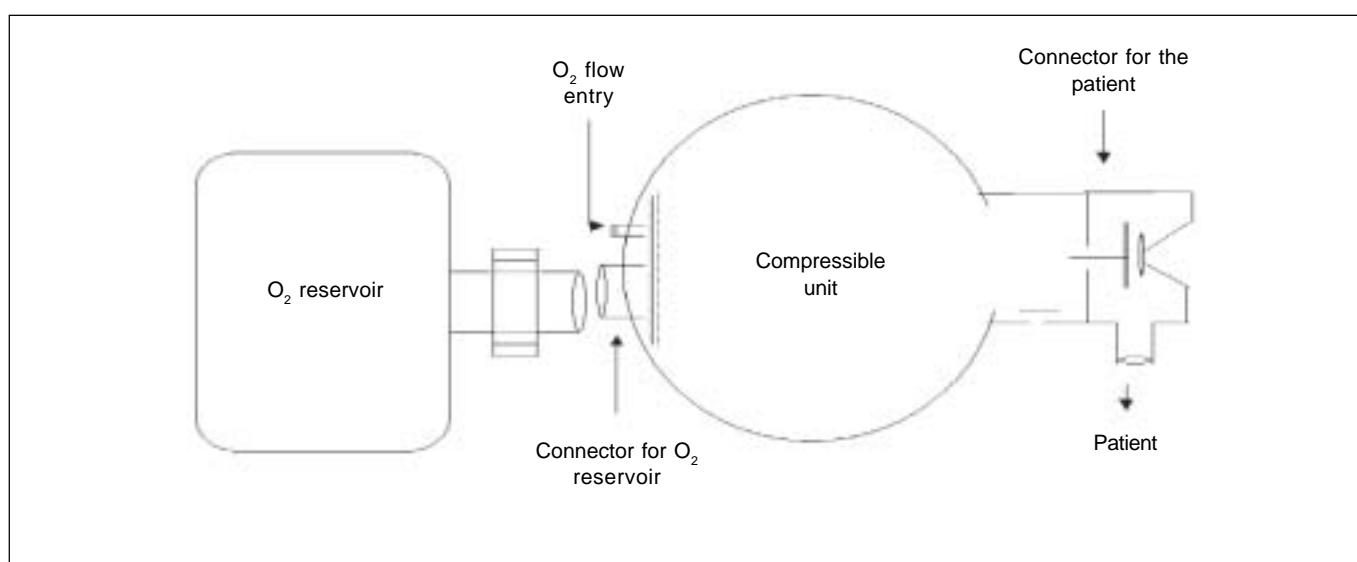


Figure 1 – Schematic Drawing of the Basic Components of Manual Resuscitators.

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might find the connection for the  $\text{O}_2$  reservoir and entrance of the  $\text{O}_2$  flow. The connector to the patient is where the face mask or endotracheal tube is attached.

Several studies have demonstrated that different models of self-inflating bag-mask systems<sup>1-3</sup> might show differences in the fraction of  $\text{O}_2$  delivered ( $\text{FiO}_2$ ), since it is influenced by the shape and type of material of the compressible unit<sup>4</sup>, tidal volume delivered<sup>3</sup>, the use or lack of the  $\text{O}_2$  reservoir<sup>1</sup>, and flow of  $\text{O}_2$  delivered to the compressible unit<sup>2-5</sup>, among others.

The objective of this study was to determine the  $\text{FiO}_2$  of seven different brands of self-inflating bag-mask systems manufactured or commercialized in Brazil when they received  $\text{O}_2$  at 1, 5, 10, and 15  $\text{L}\cdot\text{min}^{-1}$ , were manipulated with both hands at 12 breaths per minute with or without  $\text{O}_2$  reservoir.

### METHODS

The data was collected at the Respiratory Unit of the Hospital de Clínicas da Universidade Estadual de Campinas – Unicamp, from January to March 2007.

The material used in the study included: a Vent Aid TTL-49504 Michigan Instruments test lung, a Newport Medical Instruments OM-100  $\text{O}_2$  analyzer, a BD wall  $\text{O}_2$  flowmeter, an Oxigel 953 flowmeter, and a Bird T-tube with directional valve. The seven self-inflating bag-mask systems used could be classified into two groups, one group in which an  $\text{O}_2$  reservoir could be attached: Oxigel® model B, CE Reanimadores®, Protec® vinyl, and Missouri®; and those that could not be connected to an  $\text{O}_2$  reservoir: Oxigel model A®, Axmed®, and Narcosul®.

To test the  $\text{FiO}_2$  (Figure 2), the wall  $\text{O}_2$  flowmeter was connected to another flowmeter which was connected to the port

of  $\text{O}_2$  entry in the device. The connector to the patient was coupled to the  $\text{O}_2$  analyzer, which was connected to the T-tube with a directional valve leading the flow to the surrounding environment, and a T-tube was connected to the test lung. The test lung was ventilated by the device, with one or both hands, 12 incursions per minute, receiving flows of  $\text{O}_2$  of 1, 5, 10, and 15  $\text{L}\cdot\text{min}^{-1}$ . Systems that allowed the connection of  $\text{O}_2$  reservoirs were tested with and without it. After two minutes of ventilation with each flow, the  $\text{FiO}_2$  delivered by each device on the  $\text{O}_2$  flowmeter connected to the system was recorded. During the study, the test lung remained with a resistance of 20  $\text{cmH}_2\text{O}\cdot\text{L}^{-1}\cdot\text{sec}^{-1}$  and a complacency of 0.05  $\text{L}\cdot\text{cmH}_2\text{O}^{-1}$ , the self-inflating bag-mask systems were operated by the same person, and the flows of  $\text{O}_2$  delivered to the RAMI were measured and controlled by the devices of the system.

Twenty consecutive measurements of the  $\text{FiO}_2$  were recorded for each flow in each brand of the self-inflating bag-mask system and the person who recorded the data did not know the objective and methodological procedure of the study. The program BioEstat 3.0 for Windows was used for the statistical analysis using means and standard deviation.

### RESULTS

Figure 3 shows the  $\text{FiO}_2$  delivered by the seven different brands of systems manufactured or commercialized in Brazil when they received a flow of  $\text{O}_2$  1, 5, 10, and 15  $\text{L}\cdot\text{min}^{-1}$ , were manipulated with both hands with a frequency of 12 incursions per minute, and with and without an  $\text{O}_2$  reservoir.

### DISCUSSION

The Guidelines of the European Resuscitation Council 2000 on Advanced Adult Life Support, 2000<sup>6</sup> and the Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2000<sup>7</sup> emphasize that it is essential to administer oxygen at the highest concentration possible during resuscitation maneuvers, stating that high oxygen concentrations are toxic only when administered for a prolonged period. Some authors consider that the  $\text{FiO}_2$  delivered is the most important parameter to be considered regarding its performance.

Since most of the time hospitalized patients who need self-inflating bag-mask systems are already receiving supplemental oxygen, the ideal resuscitator should deliver  $\text{FiO}_2$  as closer to 1.0 as possible<sup>2,9</sup>.

ISO 1997<sup>10</sup> and ASTM 1999<sup>11</sup> recommend that those systems should deliver a  $\text{FiO}_2$  of at least 0.40 without an  $\text{O}_2$  reservoir and 0.80 with this accessory, receiving a maximal  $\text{O}_2$  flow of 15  $\text{L}\cdot\text{min}^{-1}$ <sup>2,8</sup>.

Contrary to other authors who stipulated a fixed tidal volume of 600 mL<sup>12-15</sup>, in the present study a fixed tidal volume was not stipulated because in daily practice one cannot maintain it unchanged since it depends on the size and compression force of the operator's hand, presence or absence of pres-

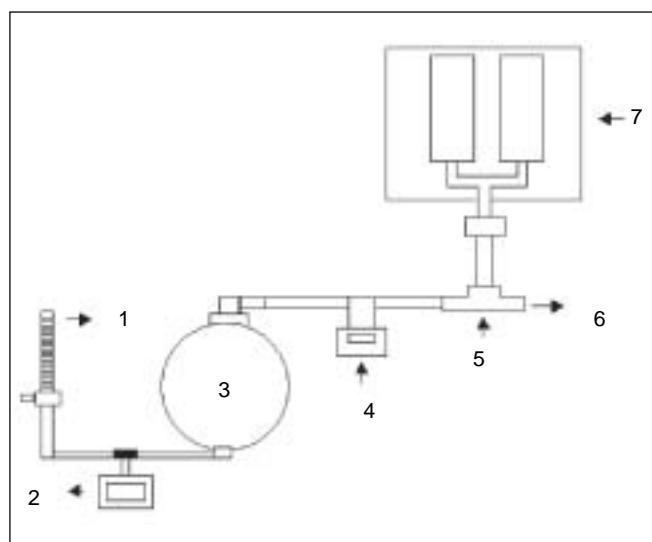


Figure 2 – Schematic Drawing of the  $\text{FiO}_2$  Test. 1) wall  $\text{O}_2$  flowmeter; 2) flowmeter; 3) self-inflating bag-mask system; 4)  $\text{FiO}_2$  analyzer; 5) T-tube with directional valve; 6) T-tube air exit; 7) test lung.

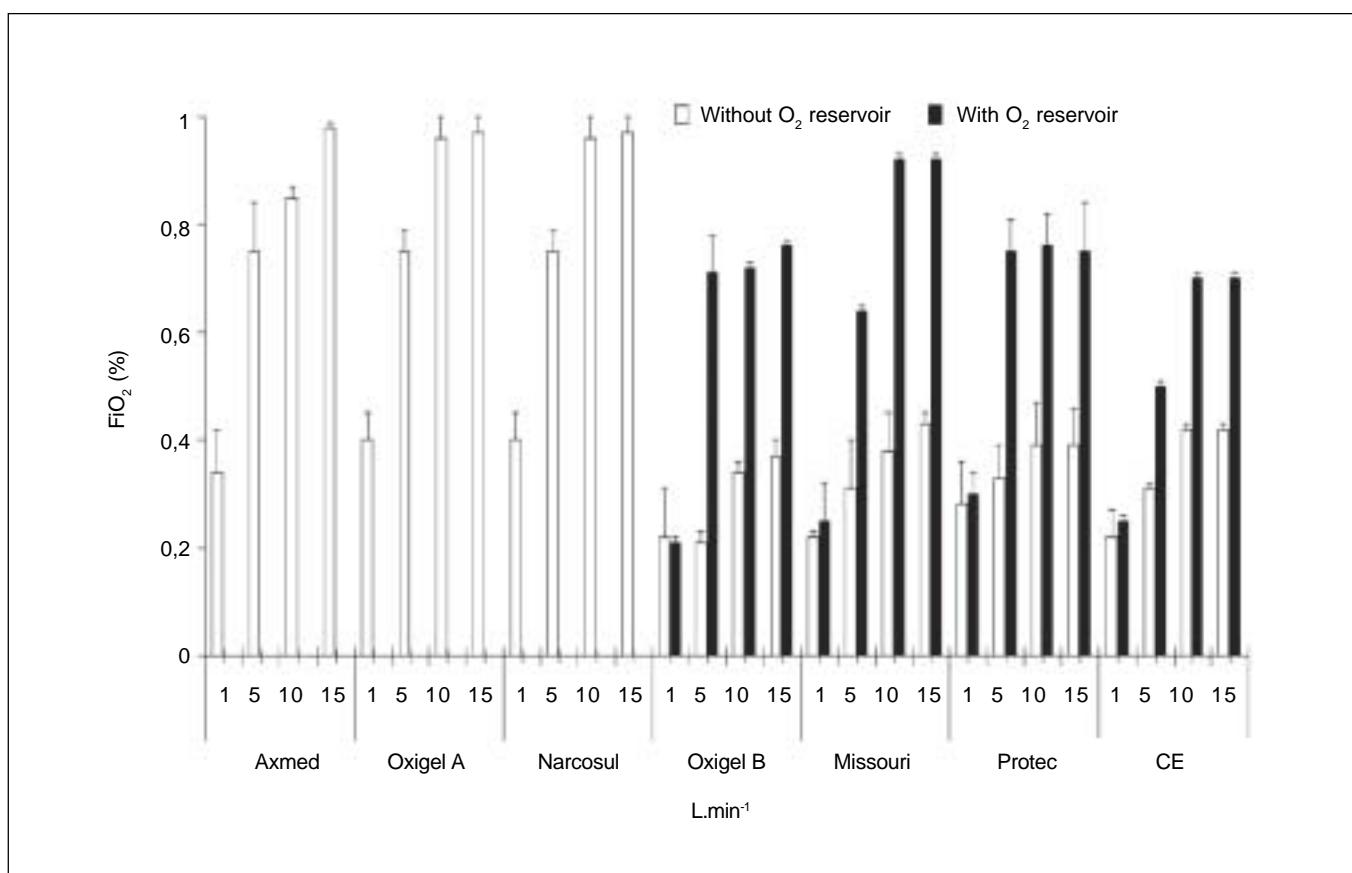


Figure 3 – Means and Standard Deviations of the  $\text{FiO}_2$  Delivered by the Self-Inflating Bag-Mask Systems with and without de  $\text{O}_2$  Reservoir.

sure-limiting valves at the connector to the patient, and the type of material, design, and size of the compressible unit<sup>2,5,16</sup>. Thus, each device delivered the tidal volume that its design allowed.

In the present study, the test system was adapted with a T-tube with directional valve (Figure 2: 5, 6) to eliminate the air ejected from the test lung to the environment preventing, therefore, return of the  $\text{O}_2$  to the compressible unit in case of failure of the seal of the patient's valve. Failure of the seal could lead to a false increase in the  $\text{FiO}_2$  delivered by the equipment. Although the function of this mechanism for ejection of the air is pertinent, we did not find studies using it in the literature. Several authors used a hole between the self-inflating bag-mask system and the test lung<sup>2,12-15</sup>; therefore, whenever the compressible unit was squeezed, this hole was simultaneously closed by the finger of the operator, and when the compressible unit returned to its normal size the hole was uncovered.

During the  $\text{FiO}_2$  test, the respiratory rate was maintained at 12 incursions per minute with one or both hands, since this is how ventilation with those devices is done more often<sup>17</sup>.

The  $\text{FiO}_2$  delivered was influenced by the flow of  $\text{O}_2$  and its dislocation to the compressible unit and the use, or lack, of the  $\text{O}_2$  reservoir.

All self-inflating bag-mask systems that could be connected to an  $\text{O}_2$  reservoir, Oxigel model B®, Missouri®, CE Reanimadores®, and Protec® vinyl, delivered a higher  $\text{FiO}_2$  when this accessory was connected to the compressible unit, but CE Reanimadores® delivered a  $\text{FiO}_2$  slightly below the minimal limit of 0,80 recommended by ISO, 1997<sup>10</sup> and ASTM, 1999<sup>11</sup>, i.e., 0,74 (0,6).

All self-inflating bag-mask systems that could be connected to an  $\text{O}_2$  reservoir delivered a  $\text{FiO}_2$  of 0,40 or more with an  $\text{O}_2$  flow of at least 10  $\text{L} \cdot \text{min}^{-1}$  when used without his accessory. When the  $\text{O}_2$  reservoir was not used, the  $\text{FiO}_2$  delivered was lower because the oxygen that reaches the resuscitator is dissolved in the room air near the compressible unit (Figure 1) and it is partially aspirated by the resuscitator. Devices in which an  $\text{O}_2$  reservoir could not be attached to, delivered higher amounts of  $\text{O}_2$  than the other resuscitators in all  $\text{O}_2$  flows.

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### RESUMEN

Godoy ACF, Vieira RJ — Comparación de la FiO<sub>2</sub> Suministrada por Siete Modelos de Sistema Balón-Máscara Autoinflable.

**JUSTIFICATIVA Y OBJETIVOS:** Debido al hecho de que los reanimadores con sistema balón -máscara autoinflables fabricados y/o comercializados en Brasil están ampliamente al alcance y que son utilizados en servicios de salud extra e intrahospitalarios, este estudio tuvo el objetivo de determinar las fracciones de O<sub>2</sub> ofertadas por siete reanimadores recibiendo diferentes flujos de O<sub>2</sub>.

**MÉTODO:** Siete reanimadores con sistema balón-máscara autoinflables fueron probados en la Unidad Respiratoria del HC/ UNICAMP. Un fluxómetro de O<sub>2</sub> de pared fue conectado al reanimador que recibía flujo de O<sub>2</sub> de 1, 5, 10 y 15 L.min<sup>-1</sup>, siendo que ellos se conectaron a un pulmón test. Los reanimadores que poseen la capacidad de conectarse a un reservorio de O<sub>2</sub> se probaron con y sin ese accesorio. Se efectuaron 20 medidas consecutivas y se determinó el promedio.

**RESULTADOS:** Apenas un reanimador presentó oferta de fracción de O<sub>2</sub> poco por debajo del límite mínimo preconizado (0,80), cuando se usó con el reservorio de O<sub>2</sub>. Sin ese dispositivo acoplado, todos los reanimadores alcanzaron el límite mínimo de fracción de O<sub>2</sub> preconizada (0,40). Los reanimadores que no presentaron la posibilidad de acoplar el reservorio de O<sub>2</sub> presentaron una mayor oferta de O<sub>2</sub> con relación a los otros reanimadores.

**CONCLUSIONES:** Todos los reanimadores que poseen la opción de acoplamiento del reservorio de O<sub>2</sub> suministraron una mayor concentración de O<sub>2</sub> con ese accesorio. Los reanimadores que no tienen la posibilidad de acoplar el reservorio de O<sub>2</sub> presentaron una mayor oferta de O<sub>2</sub> con relación a los otros que sí pueden ser acoplados al reservorio cuando se usan sin ese accesorio.