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INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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Medical endoscopes - Endoscope supply units - Insufflators

医用内窥镜 内窥镜功能供给装置 气腹机

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Foreword

This Standard is drafted according to the rules specified in GB/T 1.1-2009

Please note that some contents in this document may involve in patents. The issuing authority of this document will not be responsible to identify these patents.

This Standard was proposed by State Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Sub-committee (SAC/TC 103/ SC 1) on Medical Optical and Instrument of Standardization Administration of China.

Drafting organizations of this Standard: Hangzhou Medical Equipment Quality Supervision and Inspection Center of State Food and Drug Administration, and Zhejiang Medical Equipment Inspection Center.

The main drafting staffs of this standard: Yan Qinglai, Jia Xiaohang, He Tao, Zhang Qinyuan, and Mao Xinxin.

Medical endoscopes - Endoscope supply units - Insufflators

1 Scope

This Standard specifies the requirements and test methods of carbon dioxide insufflators for medical endoscope.

This Standard applies to the carbon dioxide insufflators that is used in the endoscopic surgery. The product is used to establish and maintain the pneumoperitoneum in minimally invasive endoscopic surgery.

2 Normative references

The articles contained in the following documents have become part of this document when they are quoted herein. For the dated documents so quoted, all the modifications (including all corrections) or revisions made thereafter shall be applicable to this document.

GB 9706.1-2007 Medical electrical equipment - Part 1: General requirements for safety

GB 9706.19-2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

3 Requirements

3.1 Interface specifications

The suction interface type and connection thread between the insufflator and external air source shall comply with requirements in GB 15383-1994.

3.2 Air-pressure

3.2.1 Adjustment range of setting air-pressure

The manufacturer shall provide the adjustment range of setting air-pressure. The adjustment range shall include 1999.5Pa (15mmHg); and it is consistent with the actual adjustment range of setting air-pressure of insufflators.

3.2.2 Accuracy of the air-pressure presetting

big enough. It shall not generate adverse effect to the ventilation capacity of the system under test.

4.2.2.1.2 Air-pressure gauge

Its accuracy shall be better than 79.9 Pa (0.6 mmHg). The measurement range shall be able to cover the actual maximum pressure range when measuring.

4.2.2.1.3 Connecting pipe for measurement

The cross section of ventilation pore that connects to the pipe for measurement shall be big enough with suitable length. It shall not generate adverse effect to the ventilation capacity of the system under test.

4.2.2.2 Steps

4.2.2.2.1 Preparatory work

The insufflators are connected with the air intake unit that comply with the air intake pressure specified in the attached information.

The insufflators shall be equipped with gas filter and aeroperitoneum pipe during test. The aeroperitoneum pipe shall be connected with deflated simulation abdominal cavity through the connection pipes for measurement.

Simulative abdominal cavity shall be connected with the air-pressure gauge through connecting pipe for measurement.

Control the power supply of the insufflator to maintain it stable at the nominal voltage. This voltage shall be monitored. The voltage stability shall be controlled within ± 2%.

After the completion of the starting self-check procedure of the irrigation pump, each component shall work normally.

4.2.2.2.2 Measurement procedure

Set the setting air-pressure on the insufflator, expressed as p_s. If the setting flow on the insufflator is adjustable, set its setting flow to the maximum value.

After establishing aeroperitoneum at the simulative abdominal cavity, adjust its gas switch to a tiny leakage state. In the process of keeping aeroperitoneum, measure the actual air-pressure p_r within the simulative abdominal cavity. The numerical value of p_r may be fluctuant. Record the Pr value when |Pr—Ps| is at miximum.

Adjust the setting air-pressure on the insufflator, so as to make p_s take at least 5 values. And it shall at least include the setting air-pressure's adjustment range's highest value; 1999.5 Pa (15mmHg); the lowest value [if the lowest value ≤666.5 Pa (5mmHg), then the lowest value of p_s shall be 666.5 Pa (5mmHg)]. Measure 3 times at each test point. Take

The result shall indicate the P_s, P_r, P_x and A_{px} values, when P_s is the 5 values set in 4.2.3.2.2 respectively.

4.2.4 Determination of overpressure alarm function

4.2.4.1 Device

Same as 4.2.2.1.

4.2.4.2 Steps

4.2.4.2.1 Preparatory work

Same as 4.2.2.2.1.

4.2.4.2.2 Measurement procedure

Set the setting air-pressure on the insufflators as P_{sg} = 1999.5 Pa (15mmHg). If the setting flow on the insufflator is adjustable, set its setting flow to the maximum value.

After establishing aeroperitoneum at simulative abdominal cavity, through the auxiliary methods, gradually increase the air-pressure within the simulative abdominal cavity until insufflator alarms due to overpressure. Meanwhile, measure the actual air-pressure within the simulative abdominal cavity, expressed as P_{rg}.

4.2.4.3 Results representation

The alarm air-pressure difference of overpressure alarm is expressed as P_{rg}-P_{sg}.

4.2.5 Determination of overpressure release function

4.2.5.1 Device

4.2.5.1.1 Simulative abdominal cavity

Same as 4.2.2.1.1.

4.2.5.1.2 Air-pressure gauge

Same as 4.2.2.1.2.

4.2.5.1.3 Connecting pipe for measurement

Same as 4.2.2.1.3.

4.2.5.1.4 Timing device

Accuracy shall be better than 0.01s.

4.2.6.3 Results representation

Under-pressure supplementary time is expressed as t_q.

P_{r1} and t_q values shall be indicated in the results.

4.3 Determination of flow

4.3.1 Inspection of adjustment range of setting flow

For operation inspection, adjust the button of setting flow on the insufflator; observe value display changes of setting flow on the panel of the insufflator, which shall be in consistent with adjustment range provided by the manufacturer.

4.3.2 Determination of accuracy on the set of flow

4.3.2.1 Device

4.3.2.1.1 Flow gauge

The accuracy shall be better than 0.5L/min (0.03m^3/h). The measurement range shall be able to cover the actual maximum flow when measuring.

4.3.2.1.2 Connecting pipe for measurement

The cross section of the ventilation pore of the connecting pipe for measurement shall be large enough with suitable length. It shall not generate adverse effect to the ventilation capacity of the system under test.

4.3.2.2 Steps

4.3.2.2.1 Preparatory work

The insufflators are connected with the air intake unit that complied with the air intake pressure specified in the attached information.

The insufflators shall be equipped with gas filter and aeroperitoneum pipe during test. The aeroperitoneum pipe shall be connected with flow gauge through connecting pipes for measurement. Control the power supply of the insufflator to maintaint it stable at the nominal voltage. This voltage shall be monitored. Its stability shall be controlled within ± 2%. After the completion of power-on self-check procedure of insufflators, all parts shall be in normal operation.

4.3.2.2.2 Measurement procedure

Set the setting air-pressure on the insufflator as P_s = 1999.5 Pa (15mmHg). Set the setting flow on the insufflator, expressed as L_s.

Measure the actual flow of insufflators in the inflating process, expressed as L_r.

The filtering rate of filter is given in Formula (1), expressed in %:

$$\left(1-\frac{n_1}{n_0}\right)\times 100\% \qquad \cdots\cdots(1)$$

where:

n_0 - Number of 0.5μm-and-above particles in the air;

n_1 - Number of 0.5μm-and-above particles in the air that has flown through the air filter.

4.6 Electrical safety test

The test shall be conducted in accordance with the requirements in GB 9706.1-2007 and GB 9706.19-2000.

4.7 Endurance test

Under the rated voltage of insufflators, running for 3h and stopping for 1h is deemed as 1 cycle. Run for 20 cycles. During running, inflate the simulative abdominal cavity to aeroperitnoeum maintaining state; and maintain the aeroperitnoeum in the tiny leakage state; set the air-pressure and flow to the maximum.

The test shall be conducted in accordance with the provisions in 4.2 and 4.3.

5 Inspection rules

The inspection rules shall be specified by the manufacturer according to the product features.

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