



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0843-2011

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

YY 0843 is the mandatory Chinese standard for insufflators, the units that fill the abdomen with carbon dioxide to create the working space for laparoscopic surgery. It sets the requirements such equipment has to meet and the test methods that verify them, covering the pressure delivered and the accuracy with which it is held, the flow rate, the overpressure protection, the gas heating and filtration, and the alarms. Intra-abdominal pressure is a physiological variable, not merely a mechanical setting: too much impairs venous return and ventilation, and a runaway insufflator can cause gas embolism. Laparoscopy is the default approach for most abdominal surgery in Chinese hospitals. Being a YY standard without the /T suffix, compliance is compulsory in China.

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

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 $\pm 2\%$. 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 P_r value when $|P_r - P_s|$ is at maximum. 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 (0.03m³/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 maintain it stable at the nominal voltage. This voltage shall be monitored. Its stability shall be controlled within $\pm 2\%$. 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 $P_s = 1999.5 \text{ Pa}$ (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 %. where. n_0 - Number of 0.5 μm -and-above particles in the air; n_1 - Number of 0.5 μm -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 aeroperitoneum maintaining state; and maintain the aeroperitoneum 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