Chinastandards.org

JJF

NATIONAL METROLOGY TECHNICAL SPECIFICATION OF THE

PEOPLE'S REPUBLIC OF CHINA

JJF 1892-2021

Calibration Specification for Insufflators

气腹机校准规范

(English Translation)

Issued on: February 23, 2021 **Implemented on: August 23, 2021**

Issued by: State Administration for Market Regulation

Preview: page 1 of 4 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1892-2021

Chinastandards.org

Table of Contents

Introduction (II)
1 Scope (1)
2 Reference documents (1)
3 Terms and units of measurement (1)
4 Overview (1)
5 Measurement characteristics (2)
5.1 Air pressure setting error (2)
5.2 Error of barometric pressure display value (2)
5.3 Overpressure alarm air pressure difference (2)
5.4 Error of flow setting value (2)
5.5 Error of flow display value (2)
6 Calibration conditions (2)
6.1 Environmental conditions (2)
6.2 Measurement standards and other equipment (2)
7 Calibration items and calibration methods (3)
7.1 Visual inspection (3)
7.2 Functional inspection and preparation before calibration (3)
7.3 Air pressure setting error (3)
7.4 Error of barometric pressure display value (3)
7.5 Overpressure alarm air pressure difference (4)
7.6 Error of flow setting value (4)
7.7 Error of flow display value (4)
8 Calibration result expression (5)
8.1 Calibration record (5)
8.2 Processing of calibration results (5)
9 Re-calibration interval (5)
Appendix A Insufflator calibration record format (6)
Appendix B. Internal page format of calibration certificate (8)
Appendix C Evaluation Example of Measurement Uncertainty (9)

Preview: page 2 of 4 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1892-2021

Chinastandards.org

9 Re-calibration interval (5)

Appendix A Insufflator calibration record format (6)

Appendix B. Internal page format of calibration certificate (8)

Appendix C Evaluation Example of Measurement Uncertainty (9)

Introduction

The compilation of this specification is based on JJF 1071-2010 "Rules for the Compilation of National Metrology and Calibration Specifications", JJF 1001-2011 "General Metrology Terms and Definitions", JJF 1059.1-2012 "Evaluation and Expression of Measurement Uncertainty" as the basis and in accordance with.

The formulation of this specification refers to YY0843-2011 "Medical Endoscope Endoscope Function Supply Device Pneumoperitoneum" machine".

This specification is released for the first time.

Insufflator calibration specification

1 Scope

This specification applies to the calibration of the measurement characteristics of the insufflator.

2 Reference documents the following documents are cited in this specification.

GB 9706.1 Medical electrical equipment Part 1: General requirements for basic safety and basic performance GB 9706.19 Medical electrical equipment Part 2: Special requirements for the safety of endoscopic equipment YY0843-2011 medical endoscope endoscopic function supply device pneumoperitoneum machine for dated reference documents, only the dated version applies to this specification; for all undated references the latest version (including all amendments) is applicable to this specification.

3 Terms and units of measurement

3.1 Gaspressureofover-pressurealarm Simulate the actual pressure value in the abdominal cavity when an overpressure alarm occurs in the insufflator, in Pa or mmHg (mmHg).

3.2 Gaspressuredifferenceofoverpressurealarm the difference between the overpressure alarm air pressure and the corresponding air pressure setting value, in Pa or millimeter mercury (mmHg).

3.3 Abdominal cavity simulator A device that can simulate the characteristics of the patient's abdominal cavity.

3.4 (gascharging) scalefactor Simulate the volume change per unit pressure in the

Preview: page 3 of 4 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1892-2021

abdominal cavity, in units of liters per pascal (L/Pa) or liters per millimeter of mercury Column (L/mmHg).

4 overview

Pneumoperitoneum machine is a special device used to establish and maintain pneumoperitoneum in abdominal endoscopic surgery. It is mainly in laparoscopy During the inspection and surgery, medical carbon dioxide gas is injected into the abdominal cavity, and the abdominal wall is separated from the abdominal internal organs with the gas to form Surgical operation and visual field space. When it reaches a predetermined pressure, it can automatically stop the air intake and maintain a certain amount of gas to make the abdominal cavity the inside has been in a predetermined pressure inflation state. When the air pressure in the abdominal cavity decreases during the operation, it can automatically inflate to maintain the hand Necessary operation and observation space required for surgical operation. The establishment of pneumoperitoneum is the basis of laparoscopic surgery, and the maintenance of pneumoperitoneum depends on the normal operation of the insufflator.

The insufflator is composed of an air intake tube, a main engine, a pneumoperitoneum tube, a filter, and a pneumoperitoneum needle. The main engine is mainly composed of decompression system System, solenoid valve, air pressure sensor, flow sensor, safety valve, power supply and display device.

Preview: page 4 of 4 shown, 10 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/jjf-1892-2021