

JIS

JAPANESE INDUSTRIAL STANDARD

**Direct Blood-Pressure Meters
for Clinical Use**

JIS T 1116—1985

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In the event of any doubt arising,
the original Standard in Japanese is to be final authority.

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J I S

Direct Blood-Pressure Meters
for Clinical Use

T 1116-1985

1. Scope

This Japanese Industrial Standard specifies the direct blood pressure meters which lead the internal pressure of heart and blood circulating system to the outside of body with using cardiac catheter, puncture needle etc. through mediation of liquid contacting directly with blood to convert the blood pressure into electric signal and indicate or record.

Remark: The units and numerical values given in { } in this Standard are in accordance with the International System of Units (SI) and are described together for informative reference.

2. Definitions

For the purpose of this Standard the following definitions apply. Other terms and definitions are given in JIS T 1001.

- (1) Direct Blood-Pressure Meter The blood-pressure measuring device using the method which connects the internal cavity of heart or blood vessel with the pressure converter outside the body by the duct system filled with filler and measures the internal pressure of that part (hereafter referred to as the "blood-pressure meter".).
- (2) Blood-Pressure ⁽¹⁾ The pressure generated in the internal cavity of heart or blood vessel.

Note ⁽¹⁾ The blood-pressure to be taken as object of measurement of this Standard means the pressure generated in the internal cavity of human heart or blood vessel and the blood pressure is divided into pulsating blood pressure and mean blood-pressure.

Applicable Standards:

JIS G 4305-Cold Rolled Stainless Steel Plates and Sheets

JIS T 1001-General Requirements for Safety of Medical Electrical Equipment

JIS T 1002-General Rules for Safety Testing Procedures of Medical Electrical Equipment

JIS T 1003-Testing Methods for Electrical Safety of Medical Electrical Equipment

JIS T 1004-Testing Methods for Mechanical Safety of Medical Electrical Equipment

JIS T 1005-Style Manual for Instruction Manuals

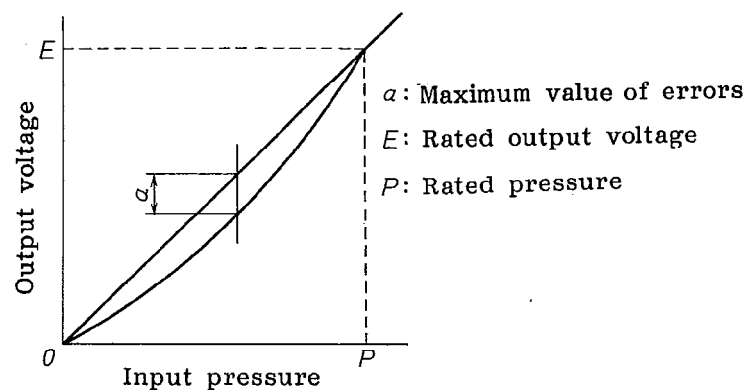
- (3) Pulsating Blood-Pressure The blood-pressure pulsating with passage of time by the pumping action of heart.
- (4) Mean Blood-Pressure The pressure of pulsating blood-pressure averaged by time.
- (5) Duct System ⁽²⁾ The fine tube system to reach directly the part to be measured by connecting the system with pressure converter outside of body and filling the system with filler for the purpose to measure the internal pressure.

Note ⁽²⁾ There are the cardiac catheter, cut-down tube, puncture needle, etc. and are used practically by combining these in different manners.
- (6) Filler ⁽³⁾ The liquid such as physiological saline solution, Ringer's solution, etc. based on the Japanese pharmacopoeia to fill the duct system.

Note ⁽³⁾ According to purpose, an antiblood-coagulation agent may be mixed.
- (7) Dome The vessel to be mounted on the pressure sensitive part of pressure converter and be connected with duct system to transfer the pressure.
- (8) Pressure Converter The converter with function to convert the pressure transferred through mediation of duct system to the electric signal proportional to this and including the dome (hereafter referred to as the "converter").
- (9) Insulation Type Converter The converter with pressure sensitive part in which the all outside covering except pressure sensing membrane are covered with insulating material. In the case where the joint connector of converter is esteemed as power supply primary circuit, that satisfying the electric safety of CF type and Class II equipment between this and applied part to patient.
- (10) Applied Part to Patient Connecting part of the duct system and converter. It designates concretely the duct system connecting part of converter.
- (11) Blood-Pressure Meter Main Equipment Device which supplies the energy required for working of converter and together outputs the electric signal proportional to the electric signal obtained by converter (hereafter referred to as the "main equipment").
- (12) Input Pressure Pressure applied to the converter.
- (13) Input Signal The electric signal to be the input of main equipment equivalent to input pressure.
- (14) Measuring Range of Converter The pressure range able to be measured by the converter.
- (15) Rated Pressure Upper limit value of measuring range.

- (16) Maximum Permissible Pressure The limit pressure able to satisfy the performance of converter even after the removal of pressure.
- (17) Burst Pressure The limit pressure applicable without mechanical breaking of converter. However, after the pressure removal, the performance may not be satisfied.
- (18) No Load Unbalancing The rate of output voltage at no loading at the normal mounting position to rated output voltage of converter.
- (19) Nonlinearity of Converter The ratio of maximum difference of the output voltage combining by a straight line between the output voltage at no loading and the real output voltage of converter to rated output voltage of converter (see Fig. 1).

Fig. 1. Nonlinearity



- (20) Hysteresis The ratio of maximum difference of output voltages in the same load at load increasing and load decreasing to the rated output voltage (see Fig. 2).
- (21) Reproducibility The ratio of maximum difference of output voltages at the same load (at repeating use) to the rated output voltage (see Fig. 3).

Fig. 2. Hysteresis

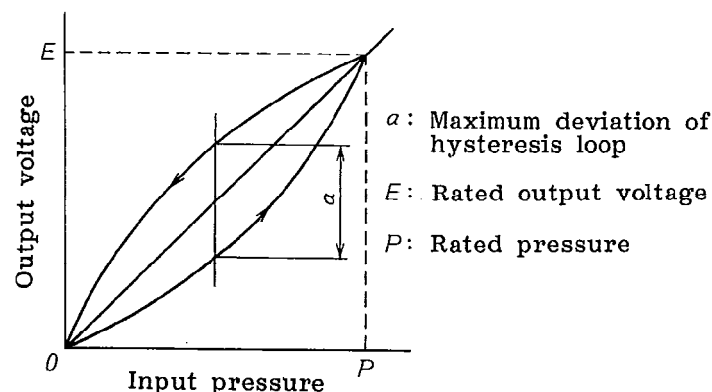
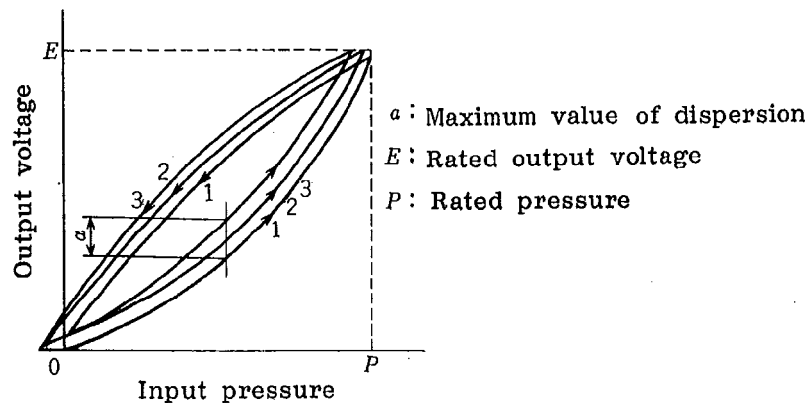


Fig. 3. Reproducibility



- (22) Temperature Sensitivity Change of Converter Change of pressure sensitivity by environmental temperature change.
- (23) Temperature Zero Point Change of Converter Change of no load unbalancing by environmental temperature change.
- (24) Withstand Voltage - 1 of Converter Withstand voltage between electric circuit in inside of converter and other conducting parts.
- (25) Withstand Voltage - 2 of Converter Withstand voltage between the part contactable with patient and the electric circuit in inside of converter.
- (26) Leakage Current of Converter The electric current flowing when the voltage has been applied between the part contactable with patient and the electric circuit in inside of converter.
- (27) Measuring Range of Main Equipment Pressure range measurable by the body.
- (28) Rated Output Voltage of Main Equipment Output voltage of auxiliary output terminal and terminal for test to the input signal same as the rated pressure.
- (29) Rated Output Sensitivity of Main Equipment Ratio of rated output voltage of body to input signal attaining the rated output voltage.
- (30) Nonlinearity of Main Equipment Ratio of maximum difference between output voltage combined by a straight line the output voltage at no input and the rated output voltage of body and real output voltage to the rated voltage of body (see Fig. 4)