

JIS

JAPANESE INDUSTRIAL STANDARD

Electronic Linear Scanning Ultrasonic Diagnostic Equipment

JIS T 1507—1989

Translated and Published

by

Japanese Standards Association

Printed in Japan

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

JAPANESE INDUSTRIAL STANDARD

J I S

Electronic Linear Scanning
Ultrasonic Diagnostic Equipment

T 1507-1989

1. Scope

This Japanese Industrial Standard specifies the B-mode linear scanning ultrasonic diagnostic equipment (briefly diagnostic equipment) to apply 1-MHz to 10-MHz ultrasound waves from the body surface for the purpose of clinical diagnosis, with the exception of Optic Organ diagnostic equipment and such other equipment which is difficult to cover by the this standard.

2. Definition

For the purpose of this standard, the following definitions apply. Other terms and definitions are given in the clause of "Definitions" of JIS T 1001 and JIS T 1501.

- (1) Electronic Linear Scanning An ultrasound beam scanning, where a large number of transducers (briefly elements) are arrayed in a probe so that their beam axis lies on a single plane, an array of elements being driven at a time by electrical pulses, and the adjacent array being driven sequentially by electronic circuits.
- (2) Frame Rate The number of probe scanings per second
- (3) Effective Frame Rate The number of frames per second of a complete B-mode image displayed on a display unit.

Remarks: For diagnostic equipment which displays one-frame B-mode image by one acoustic scan, the number of frame rates and the number of effective frame rates are identical. For diagnostic equipment which displays one-frame B-mode image by more than one acoustic scan, the effective frame rate is equal to an inverse of the acoustic scans required to generate one-frame B-mode image.

- (4) Number of Acoustic Scanning Lines A number of ultrasound beams required to display a more complete B-mode image on a display unit, scan positions being different.

Remarks: More than one acoustic scan shall be counted as one, if they follow the identical path. When the number of transmitting scanning lines is different from the number of receiving scanning lines, both numbers shall be specified as such. When they are equal, the number shall be designated as the number of transmitting/receiving scanning lines.

Applicable Standards: See page 32.

- (5) Transmitter/Receiver A composing unit which houses a probe, transmitting circuit, receiving circuit and parts with related functions, and where the received ultrasound high-frequency echoes are amplified, detected, and processed to output the signal suitable for display.
- (6) Display Unit A cathode-ray tube and a composing unit to meet the display function.

3. Test Condition

The test conditions shall conform to JIS T 1001, 3.

4. Classification

Classification shall be as shown in Table 1 according to display systems.

Table 1. Classification of Diagnostic Equipment
According to Display System

Classification system	Display system
Standard television display system	A system where, for example, a scan converter converts B-mode signals into NTSC signals ⁽¹⁾
Other display systems	A system where B-mode images are displayed by the methods other than those mentioned above.

Note (1) NTSC refers to a standard color television system.

5. Safety

The following safety requirements apply. Other requirements are given in JIS T 1001.

- (1) The type and grade of protection against electrical shock shall conform to classification specified in JIS T 1001, 4, respectively.
- (a) Classification according to Type of Protection against Electrical Shock, Class I equipment.
- (b) Classification according to Grade of Protection against Electrical Shock, Type B equipment or Type BF equipment.
- (2) The surface temperatures of probe shall conform to JIS T 1001, 8.1(1), provided that the ambient temperatures shall be kept at 36°C.

6. Performance

6.1 Maximum Overall Sensitivity When tested according to 8.3.2, the maximum overall sensitivity shall be 80 dB or over for ultrasound frequencies of 1 MHz and over to 7.5 MHz incl., and 60 dB or over for ultrasound frequencies of over 7.5 MHz to 10 MHz inclusive.

6.2 Resolution When tested according to 8.3.3, the resolution shall be specified as follows.

- (1) Depth Resolution 2 mm or under
- (2) Lateral Resolution 3 mm or under

6.3 Ultrasound Frequency When tested according to 8.3.4, the ultrasound frequency shall be kept within $\pm 20\%$ of the nominal value.

6.4 Ultrasound Output per Unit Area When tested according to 8.3.5, the ultrasound output per unit area shall be 10 mW/cm^2 for each probe at either aperture.

6.5 Preset Sound Velocity The preset sound velocity shall be 1530 m/s. However, when the preset sound velocity is selectable, the range shall include the value of 1530 m/s.

6.6 Distance Measurement Accuracy When equipment is provided with a scale and additionally with a function of measuring a distance between two points, the measurement accuracy shall be specified as follows.

- (1) When the distance to be measured (in vivo conversion) is 1 cm or over to 5 cm incl. $\pm 5\%$.
- (2) When the distance to be measured (in vivo conversion) is over 5 cm $\pm 2.5\%$.

Remarks: This standard shall not apply to the measurement of circumference, such as a trace. However, accompanying documents such as operation manuals should preferably describe principles for measurement and errors of measurement.

6.7 Grey Scale The displayed B-mode images shall have ten or more grey scales.

6.8 Effective Frame Rate In case of real time display, the effective frame rate shall be 15 or more frames per second.

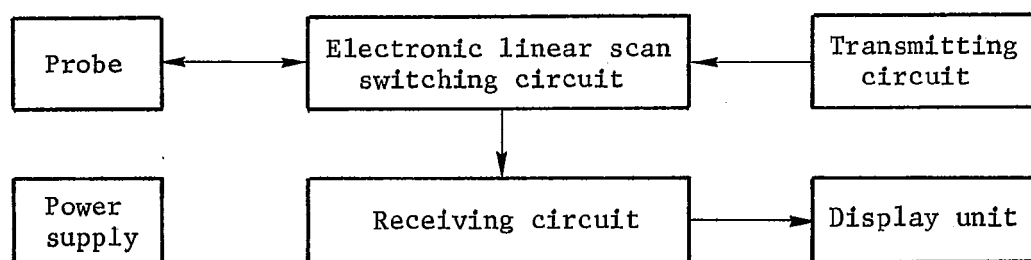
6.9 Interval of Acoustic Scanning Lines The interval of acoustic scanning lines shall not exceed 1.5 mm.

7. Configuration and Construction

7.1 Configuration Diagnostic equipment shall, as shown in Fig 1, consist of a probe having a great number of elements independently arrayed to transmit and receive ultrasound waves, an electronic linear scan switching circuit for electric switching of element groups, a circuit to generate electrical vibrations synchronously with an electronic linear scan switching circuit and to transmit them (briefly, transmitting circuit), a receiving circuit to amplify and detect echoes, a display unit to display B-mode images (2), a power supply unit to supply power to each component, and accompanying components to these circuits, units and components.

Note (2) A scan converter and its accompanying components shall be included in the display unit.

Fig. 1. Configuration Diagram



7.2 Construction The construction shall be specified as follows.

- (1) The display area of B-mode images shall be 8.5 cm or more wide and 18 cm or more deep in terms of in vivo conversion distances. However, when the display area is variable or selectable, the function and construction shall be designed to include this value in the range.
- (2) A sensitivity adjuster or other appropriate adjusters shall be provided in order to obtain proper B-mode images, depending upon the differences of characteristics of target regions of living bodies to be displayed.
- (3) A proper scale graduated in in-vivo conversion distance shall be provided in the width and depth directions of displayed images in order to facilitate measurement of B-mode images.
- (4) Surfaces, corners and edges of enclosures which a user can contact shall be processed to prevent injury to the user.
- (5) A probe shall use materials which are completely safe to the living body, and shall have a safe shape and construction.

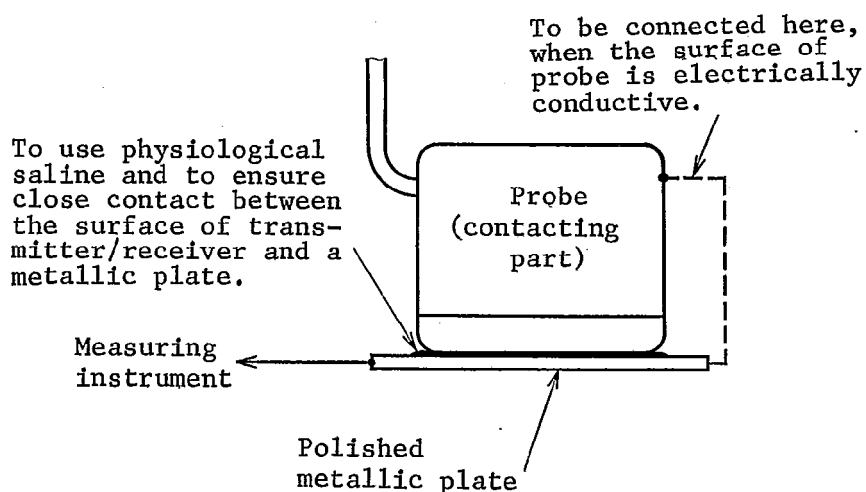
8. Test

8.1 Test Items The test items shall be specified as follows.

- (1) Safety Test
- (2) Performance Test
 - (2.1) Maximum Overall Sensitivity
 - (2.2) Resolution
 - (a) Depth Resolution
 - (b) Lateral Resolution
 - (2.3) Ultrasound Frequency
 - (2.4) Ultrasound Output per Unit Area
 - (2.5) Preset Sound Velocity and Distance Measurement Accuracy.
 - (2.6) Grey Scale
 - (2.7) Effective Frame Rate
 - (2.8) Interval of Acoustic Scanning Lines

8.2 Safety Test The safety test shall be made according to JIS T 1002, JIS T 1003 and JIS T 1004. However, the connection shall be as shown in Fig. 2, when "a contacting part (probe)" and "a measuring instrument" are connected for measurement according to JIS T 1003, 6.4 to 6.5.

Fig. 2. Measurement Circuit for Patient Leakage Current to Earth



8.3 Performance Test

8.3.1 Test Conditions The test conditions shall be specified as follows.

- (1) The test environment shall conform to JIS T 1002, 4.(1), with the exception of provisions in 8.3.3(2)(b) and 8.3.5(1)(a).
- (2) The testing power supply shall conform to JIS T 1003, 3.3.
- (3) The test shall start 10 minutes or more after the power is on, with the exception of provisions in 8.3.5(3), (a) to (c).

8.3.2 Maximum Overall Sensitivity The maximum overall sensitivity shall be specified as follows.

- (1) Test apparatus The following apparatus shall be used for this test.

- (1.1) Sensitivity Standard Tester A sensitivity standard tester shall consist of a "sensitivity standard testing box" made of transparent acrylic plastics with the shape and dimension as specified in Fig. 3, which incorporates as shown in Fig. 3 a "stainless steel ball reflector" (T-45 or T-48) (briefly, steel ball reflector) with the shape, dimension, and material as specified in Fig. 4. The sensitivity standard testers are classified into the following two types according to the steel ball reflectors used. The respective values of reflection loss shall be as shown in Table 2. When used, this sensitivity standard tester shall be filled with deaerated water ⁽³⁾.

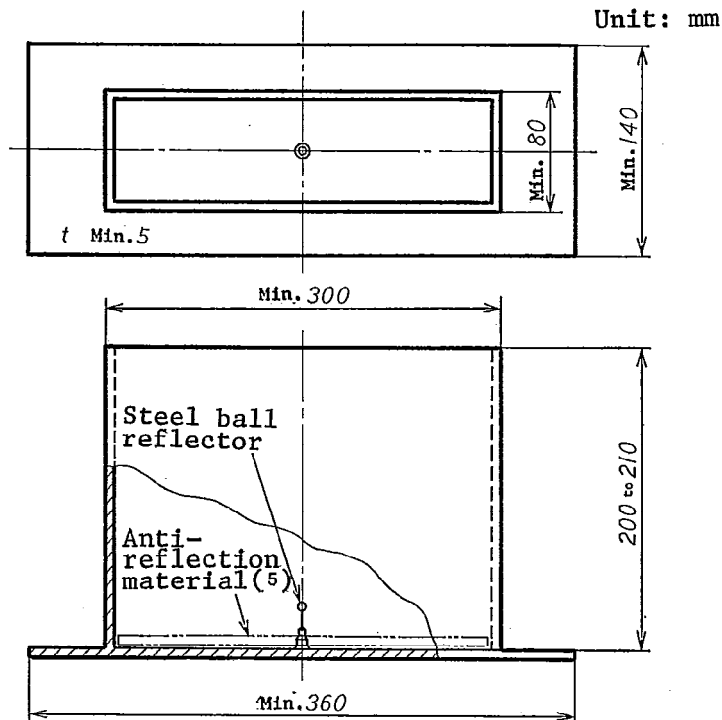
Note ⁽³⁾ Deaerated water shall be prepared by boiling pure water for 15 minutes or longer, and cooling it down to test temperatures without shaking. Deaerated water should preferably be used within 12 hours after preparation.

Table 2. Type and Value of Reflection Loss of Sensitivity Standard Tester

Type of steel ball reflector	Type of sensitivity standard tester	Value of reflection loss dB		
		Height of top of steel ball in water ⁽⁴⁾		
		150 mm	100 mm	50 mm
T-45	SST-2-45	42.0	38.5	32.5
T-48	SST-2-48	45.5	42.0	36.0

Note ⁽⁴⁾ According to ultrasound frequency ranges, the height in water shall be selected as shown in Table 4.

Fig. 3. Sensitivity Standard Testing Box (SST-2)



- (5) To reduce unwanted reflection from the bottom, anti-reflection material should preferably be a spongy mat with a rough surface, or similar material.

Fig. 4. Steel Ball Reflector

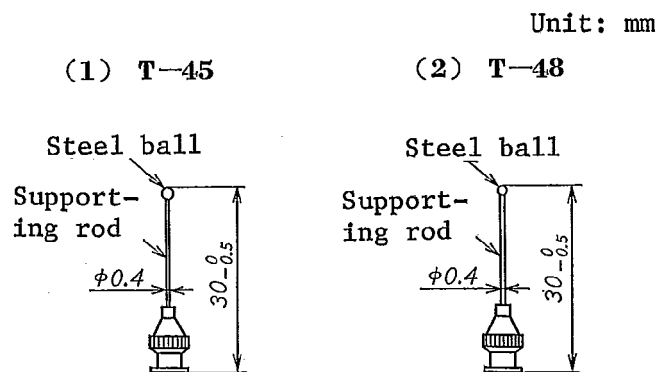


Table 3. Specifications of Steel Ball Reflector

	T-45	T-48
Dimension of steel ball mm (6)	2.381 2 ($\frac{3}{25}$)	1.587 5 ($\frac{1}{16}$)
Material of steel ball (7)	Martensite stainless steel	
Material of supporting rod	Stainless steel syringe	

Note (6) The values in parentheses are "nominal" according to JIS B 1501.

(7) The class of steel ball shall be the precision class in terms of size variation (max.) and sphericity (max.) according to JIS B 1501.

- (1.2) Attenuator An attenuator should preferably permit maximum attenuation of 60 dB or over with one step of 1 dB or under. The frequency range of attenuator shall be from DC to 20 MHz or over, and its allowance shall be within ± 0.5 dB for the display of less than 10 dB, and within ± 1 dB for the display of 10 dB or over. The sensitivity adjuster of diagnostic equipment calibrated to the above-mentioned accuracy at the time of the test may be deemed as the attenuator specified herein (with maximum sensitivity of 0 dB).
- (1.3) Oscilloscope The oscilloscope shall be provided with an external synchronous terminal, and have a frequency range of DC to 20 MHz or over, voltage sensitivity of 50 mV to 10 V, and calibration capability of voltage sensitivity and time axis sweep speed.
- (1.4) Effective Value Voltmeter The effective value voltmeter shall have a frequency range of 20 Hz to 10 MHz or over, and measure voltages of 1 mV to 10 V.
- (1.5) Signal Generator for Testing of Display Unit (8) The signal generator for testing of a display unit shall be specified as follows.
- (a) Voltage Waveform Generated The waveform shall be a stepped waveform as shown in Fig. 5. The maximum amplitude of waveform shall be sufficiently larger than the input of the display unit. The stepped wave should preferably have 8 steps or more, with one-step time axis of 5 to 26 μ s (equivalent to in vivo conversion distance of 0.4 to 2 cm).

Note (8) When diagnostic equipment incorporates an 8 stepped wave of generator or more, it may be used as a substitute.

The signal repetition frequency shall be approximately equal to the ultrasound pulse repetition frequency in actual use.

When the generated signal requires synchronization with the ultrasound pulse repetition signal, this signal should be generated by external synchronization.

- (b) Adjustor The adjustor shall be capable of the following adjustments.

Output voltage
amplification (E): Coarse adjustment in 3 steps

$\times 1$ range, max. 1

$\times 1/5$ range, max. 0.2

$\times 1/10$ range, max. 0.1

Fine adjustment 0 to Max. continuously variable

Voltage superimposing on zero potential (offset voltage):
 ± 4 V continuously variable at 1 range max.

- (c) Output Impedance

For testing of a display unit of 75Ω or less

For synchronous output for oscilloscopes of 200Ω or less.

Fig. 5. Waveform and Time Chart of Testing Signal for Display Unit

