

# Japanese Industrial Standards (Draft)

## Stabilometers

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## PREFACE

This standard belongs to Japanese Industrial Standards which has been revised by Minister of Health, Labor and Welfare and Minister of Economy, Trade and Industry in Japan preceded by the discussion of Japanese Industrial Standards Committee in accordance with the proposal by Japan Equilibrium Society to necessarily revise Japanese Industrial Standards from its original issue based on the rule of the clause 12, the section 1 followed by the clause 14 of Industrial Standardization Act.

According to this activity, JIS T 1190:1987 has been revised and replaced with this standard.

This standard is a book which is protected by the copy right regulation.

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## Stabilometers

### 1. Extent of Application

This standard stipulates Stabilometer which is to detect and indicate by upright weight sensors the position of center of foot pressure and motion (sway) with patients standing with upright posture.

### 2. Citation Standard

Standards described as below are to compose a part of the rule of this standard by means of citation to this standard. Among these cited standards, edition of the described year is applied for the one which has notification of the western calendar and revised edition (supplement is included) afterward is not applied. For the cited standard without notification of the western calendar, its latest edition (supplement is included) is applied.

JIS T 0601-1:1999

Electric Medical Devices - Part 1: General Requirement Items related to  
Safety

JIS T 0601-1-1:2005

Electric Medical Devices - Part 1: General Requirement Items related to  
Safety - Section 1: Subsidiary Notification  
- Safety Requirement Items of Electric  
Medical System

JIS T 0601-1-2: 2002

Electric Medical Devices – Part 1: General Requirement Items related to  
Safety - Section 2: Subsidiary Notification  
- Electro-Magnetic Compatibility -  
Requirement Items & Examination

JIS B 7516: Metallic Ruler

### 3. Terminologies & Principles

Terminologies and Principles used in this standard are deriving from JIS T 0601-1, JIS T 0601-1-1 and JIS T 0601-1-2 and are also based on the following items.

#### 3.1 Foot Pressure Detector

Detecting part of upright force by upright weight sensors against foot pressure at the time of upright standing with examinees.

#### 3.2 Upright Weight Sensors

Converter to exchange foot pressure to electric signal. Sensors consist of 3 or 4 pieces and support plate (hereinafter referred to as Upper Plate of Detector) contacting to foot bottom on foot pressure detector.

#### 3.3 Foot Pressure

Upright weight loaded onto upper plate of detector from foot bottom plane when examinees take upright standing on upper plate of detector.

#### 3.4 Center of Foot Pressure

Central position of foot pressure loaded onto upper plate of detector.

#### 3.5 X axis · Y axis

Coordinate axis to indicate center of foot pressure on upper plate of detector. X axis is left and right direction and Y axis is forward and backward direction at the time of examinees' upright standing.

#### 3.6 Regulated Center

Coordinate origin on upper plate of detector which is crossing point between X axis and Y axis.

#### 3.7 Regulated Center of Gravity Position

Setting definitive center of upper plate of detector as origin, circumference of 200mm diameter is divided by 3 equal portions to obtain each point and origin (4 locations).

### 3.8 AD Converter

Analog-Digital Converter to output digital value of sensor exchanging it from analog measurement value.

### 4. Types

Types of Stabilometer are as follows.

#### a) With or without indication part

Table 1 shows the types with or without indication part

Table 1 – Classification according to Stabilometers with or without indication part

With or without indicator	Classification	Content
Without	—	Stabilometer which has not indicator. Indicator is to be implemented by user's personal computer, recorder etc. Connection between Stabilometer and indicator is to be connected by cable etc. This regulation is not to be applied to indicator.
With	Separation Type	Indicator is to be equipped in the form of separation from detector and amplifier.
	Combined Type	Indicator is to be equipped together with foot pressure detector and/or amplifier.

#### b) Shield from electric shock

Table 2 shows the classification according to shielding types of electric shock. (refer to JIS T 0601-1)

Table 2 — Types of shield against electric shock

Type	Shield against electric shock
Class I Type	Other than basic insulation, anyone to be equipped with measure to connect with contacting line of fixed wiring.
Class II Type	Other than basic insulation, anyone to be equipped with additional safety measure like double insulation or reinforced insulation.
Internal Power Type	Anyone which can be motorized by internal power. In case the device is connected with power (commercial base), it conforms to Class I or Class II and if the device is not connected with power, it conforms to Internal Powered Device.

## 5. Composition

Stabilometer consists of foot pressure detector, amplifier and indication part which have the following functions.

Composition example is shown as Chart 1. It is good that each part is separated or assembled together.. However, Stabilometer without indicator does not include indicator.

### a) Foot Pressure Detector

Detect upright force of foot pressure at the time of upright standing with examinees by upright weight sensors.

### b) Amplifier

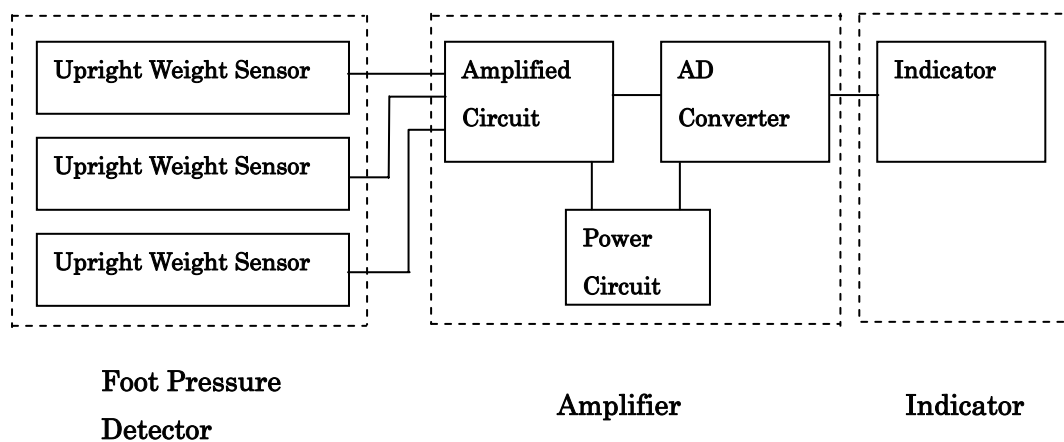
Amplify electric signal from each upright weight sensor of foot pressure detector.

### c) Indicator is to be in accordance with the following conditions.

Furthermore, it is not applied for Stabilometer equipped without indicator.

- 1) Anyone to indicate center of foot pressure which is calculated from foot pressure (for example, microcomputer, personal computer).
- 2) Indication of center of foot pressure and X-axis · Y axis has regulated center which comes from central position of foot pressure detector and X axis right direction to be +X, left direction to be -X, Y axis forward

direction to be +Y, backward direction to be -Y.



**【Chart 1 – Example of composition of Stabilometer】**

## 6. Using Condition

Using condition is to be in accordance with 10 of JIS T 0601-1 (Environment Condition) and also as per the following condition.

### — Placement of foot pressure detector

Placement location of foot pressure detector at the time of use is to be on leveled solid floor.

## 7. Performance

### 7.1 Measurement Available Weight

Measurement available weight is to be 10 to 150 kg.

### 7.2 Characteristic of Position of Center of Gravity

At the time of testing as per 10.3.1, deviation from regulated gravity position is to be within  $\pm 1\text{mm}$ .

### 7.3 Characteristic of Natural Oscillation Frequency

At the time of testing as per 10.3.2, natural oscillation frequency is to be more than 20Hz.



## 8. Structure

### 8.1 General

Stabilometer is to be easily handled and safe. Its characteristic is to be structured durable against temperature, humidity, sway, shock and also electric and chemical affect.

### 8.2 Structure of Foot Pressure Detector

Structure of foot pressure detector is as follows.

- a) Upper plate of foot pressure detector is to be supported by 3 or 4 pieces of weight sensor from floor contact.
- b) Largeness of upper plate of detector is to be diameter more than 350mm which has regulated center as origin.
- c) Measurement available range of center of foot pressure is to be diameter more than 200mm which has regulated center as origin.
- d) Height of upper plate of detector from floor is to be less than 50mm.
- e) Foot pressure detector is to be structured durable against the weight of  $200 \pm 20\text{kg}$  and also performance is not to change.
- f) Upper plate of detector has the following indications.
  - 1) X axis and Y axis on upper plate of detector.
  - 2) Position of regulated center of upper plate of detector.

## 9. Safety

As for the matter of Safety, it is to be in accordance with JIS T 0601-1 and JIS T 0601-1-1 (if applicable) and also as per the following conditions.

- a) Classification according to the level of shielding against electric shock is to be B type attachment.
- b) Resistant voltage of Stabilometer is to be in accordance with the state between (A-a), (A-f) of 20.1 (general required matters related to all types of device) of JIS T 0601-1 and (B—b) of 20.2 (required matters related to devices with attachments). However, (B-b) is to be in accordance with the state between the first circuit of power and plate contacting to foot bottom.
- c) Electro Magnetic Compatibility (EMC) is to be in accordance with JIS T 0601-1-2. However, in case of using indicator and/or amplifier for the purpose of non-patient environment<sup>1)</sup>, it needs to conform to

applicable JIS, technical standard of safety act of electric appliance etc. or it is also good with anyone having the equivalent safety measure.

Note <sup>1)</sup> Refer to JIS T 0601-1-1.

## 10. Test

### 10.1 Testing Environment Condition

It is in accordance 1.4 (environment condition) of JIS T 0601-1.

### 10.2 Device

Devices to be used for test are as follows.

a) Weighting Device: It belongs to either one of the following.

1) Weight for testing center of gravity position

Weight for testing center of gravity position (hereinafter referred to as “weight for loading”) is to be itemized with 3 types, one is mass  $10 \pm 0.10\text{kg}$  (call 10kg), another one is  $50 \pm 0.50\text{kg}$  (call 50kg) and still another one is  $100 \pm 1.00\text{kg}$  (call 100kg). These weights need to be traceable according to national measurement standards. Also, the above stated weights for loading are to be able to confirm center of gravity position on upper plate of detector. Furthermore, weight for loading is also good with some number of weight assembled together which is traceable with national measurement standards.

2) Weight charging device: It is to be the one that loading can be charged up to 1000 N which is traceable with national measurement standards.

b) Special Weight for Test: Weight to be used for 10.3.2 is to be mass  $50 \pm 0.5\text{kg}$  (call 50kg) which is traceable with national measurement standard. Furthermore, special weight for test is also good with some number of weight assembled together which is traceable with national measurement standards.

c) Ruler: It needs to be more than Class 2 or the one more than equivalent precision which is regulated in JIS B 7516 as metallic ruler.

### 10.3 Performance Test

#### 10.3.1 Characteristic of Center of Gravity Position

Test for characteristic of center of gravity position is either way as follows.

a) In case of using weight for loading

1) Place weight for loading on center of gravity position of foot pressure detector which position matches weight center of 10kg weight for loading and measure output signal. Implement this test for each regulated center of gravity position. Calculate center of gravity position from these measurement values and obtain deviation between measurement value and regulated center of gravity position. Reading of coordinate of regulated center of gravity position is limited with the digit of 0.1mm.

2) With regard to 50kg or 100kg weight for loading, testing procedure is the same as 1) and obtain deviation in each regulated center of gravity position.

b) In case of using weight charging device

1) Charge weight of  $98.1 \pm 0.98\text{N}$  on center of gravity position of foot pressure detector which position matches weight center and measure output signal. Implement this test for each regulated center of gravity position. Calculate center of gravity position from these measurement values and obtain deviation between measurement value and regulated center of gravity position. Reading of coordinate of regulated center of gravity position is limited with the digit of 0.1mm.

2) With regard to  $490 \pm 4.90\text{N}$  and  $981 \pm 9.81\text{N}$ , testing procedure is the same as 1) and obtain deviation in each regulated center of gravity position.

#### 10.3.2 Characteristic of Natural Oscillation Frequency

Place 50kg special testing weight on the position of regulated center of upper plate of detector and give some shock lightly to upright direction by hammer or the like. At this time, observe output signal of upright weight sensor and measure characteristic of natural oscillation frequency of stabilometer (foot pressure detector) from its oscillation wave.

### 10.4. Structure Test

10.4.1 Measurable range and largeness of upper plate of detector and also height from floor

Measurable range [8.2c)] and largeness of upper plate of detector and also height [8.2d)] from floor which are described by manufacturer is to be measured by the ruler [10.2c)] and read out up to 1mm.

#### 10.4.2 Indication

Support regulated in 8.2a) and indication regulated in 8.2e) are confirmed by eye sight inspection with healthy vision.

#### 10.5 Safety Test

Safety test is in accordance with JIS T 0601-1 and JIS T 0601-1-1 (if applicable). Electro magnetic compatibility is to be in accordance with JIS T 0601-1-2.

#### 11. Inspection

Inspection is to be implemented for each section of Clause 7 to Clause 9 by Clause 10 and eye sight inspection or the like with healthy vision and it needs to be conformed with the regulation of Clause 7 to Clause 9.

#### 12. Attachment Documents

Operation manual and inspection certificate or any equivalent need to be attached with Stabilometers. Operation manual is to be in accordance with JIS T 0601-1 and also the following matters are to be described.

- a) Matters related to composition, performance, specification, using condition etc.
- b) Matters related to safely used device
  - 1) Operating method.
  - 2) Warning matters and usage in order to keep safety against electric shock.
  - 3) Disinfecting method for upper plate of detector.
  - 4) Shielding method against impact weight of foot pressure detector.
  - 5) Necessary information in case of using users' own personal computer or the like as indicator.
- c) Matters related to maintenance inspection implemented by users.

### **13. Indication**

**6.1 (device or external indication of part of device) of JIS T 0601-1 or the like anywhere for easy looking on device and also indicate the following matters.**

- a) Name of manufacturer and distributor and address**
- b) Serial number of manufacture or signal of manufacture**
- c) Classification against electric shock**
- d) Matters of legally regulated indications other than the above matters**

**- following blank -**