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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee, as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Electronics and Information Technology Industries Association (JEITA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently JIS T 1303:1994 is replaced with this Standard.

The revision of this time is limited to reviewing the conformity to JIS T 0601-1 (*Medical electrical equipment—Part 1:General requirements for safety*), because no International Standard corresponding to JIS is developed.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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Fetal monitors

1 Scope This Japanese Industrial Standard specifies fetal monitors (hereafter referred to as “monitors”) that record continuously the ultrasonic doppler fetal heart rate curves and the external measurement labour curves on charts as fetal information and maternal information.

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0601-1 *Medical electrical equipment—Part 1: General requirements for safety*

JIS T 1031 *General rules for alarms of medical equipment*

IEC 61161 *Ultrasonic power measurement in liquids in the frequency range 0.5 MHz to 25 MHz*

3 Definitions For the purposes of this Standard, the definitions given in clause 2 (Definitions) of JIS T 0601-1 and the following definitions apply.

The terms defined in JIS T 0601-1 are bold-faced in this Standard.

- a) **ultrasonic doppler method** the method that uses the ultrasonic doppler effect
- b) **fetal heart rate** the heart rate per minute of a fetus. It is obtained by the following equation.

$$FHR = \frac{60}{T}$$

where, *FHR*: fetal heart rate (heart beats/min)

T: duration from any one heart beat to the next heart beat(s)

- c) **transvaginal direct induction fetal ECG signal** the fetal ECG signal that is acquired transvaginally via the fetal lower presentation, mother's vulva, or vaginal wall
- d) **abdominal wall induction fetal ECG signal** the fetal ECG signal that is acquired via the mother's abdominal wall
- e) **external measurement method** the method where measurement is made by placing externally a converter on the abdominal wall of pregnant woman
- f) **labour (labour pains)** a mechanical change that accompanies the uterine contractions and that occurs in the abdomen of pregnant woman

4 Safety The safety of monitors shall be as per the provisions of JIS T 0601-1 and the following.

- a) **Degree of protection against electric shock of the applied part** The fetal ECG measuring unit and the intrauterine pressure measuring unit shall be type CF applied part.
- b) **Surface temperature of applied part** When monitors are used at the ambient temperature of 36 °C, the surface temperature of applied part shall not exceed 41 °C.
- c) **Ultrasonic output** The ultrasonic output per unit area of ultrasonic probe shall be I_{SATA} (space average, time average strength) 10 mW/cm² or less, when monitors are tested by 9.2.1.

5 Classification Monitors shall be classified into two types: the basic monitors and the expanded monitors.

6 Configuration

6.1 Configuration of basic monitors The basic monitor shall, as shown in figure 1, consist of an ultrasonic probe, an ultrasonic doppler signal detection amplifier, a heart rate counter, a heart beat signal sound generator, a heart rate calibrator, an external measurement labour converter, a labour amplifier, a recorder, and a power supply unit. The basic monitor may be configured by providing an additional part as specified in 6.3, as long as it does not disturb the essential function of basic monitor.

The components of the basic monitor shall be as follows (see figure 1).

- a) **Ultrasonic probe** The ultrasonic probe emits ultrasonic waves through the abdominal wall into the body of pregnant woman, receives the reflected waves influenced by doppler effect due to the fetal heart beat, fetal movement etc., and converts them into electric signals.
- b) **Ultrasonic doppler signal detection amplifier** The ultrasonic doppler signal detection amplifier detects and amplifies the ultrasonic doppler signal, and provides the input signal (ultrasonic doppler heart beat signal) to the heart rate counter.
- c) **Heart rate counter** The heart rate counter measures the heart beat cycle from the heart beat signal, and converts this into the heart rate.
- d) **Heart beat signal sound generator** The heart beat signal sound generator makes the ultrasonic doppler sound, the heart sound, or the converted sound synchronized to the fetal heart beat audible.
- e) **Heart rate calibrator** The heart rate calibrator generates the heart rate calibration signal so that the heart rate calibrated value may be recorded at any time.

- f) **External measurement labour converter** The external measurement labour converter converts the labour into the electric signal (external measurement labour signal).
- g) **External measurement labour amplifier** The external measurement labour amplifier amplifies the external measurement labour signal.
- h) **Recorder** The recorder records the fetal heart rate curve and the labour curve in the same phase on the chart.
- i) **Power supply unit** The power supply unit provides the power required by each component.

6.2 Configuration of expanded monitors The expanded monitor shall, as shown in figure 2, consist of the basic monitor plus at least one of the five components: a direct induction fetal ECG measuring unit, an abdominal wall induction fetal ECG measuring unit, a fetal heart sound measuring unit, and an intrauterine pressure labour measuring unit. The expanded monitor may be configured by adding these units and plural components of basic monitor to the basic monitor. However, addition shall not disturb the essential function of the basic monitor. The expanded monitor may be configured by providing an additional part as specified in 6.3, as long as it does not disturb the essential function of basic monitor.

The components of the expanded monitor shall be as follows.

- a) **Direct induction fetal ECG measuring unit** The direct induction fetal ECG measuring unit consists of a direct induction fetal ECG electrode, an induction cord and a direct induction fetal ECG amplifier. The direct induction fetal ECG electrode and the induction cord detect the transvaginal direct induction fetal ECG signal. The direct induction fetal ECG amplifier amplifies this ECG signal and provides the input signal (direct induction fetal ECG heart beat signal) to the heart rate counter.
- b) **Abdominal wall induction fetal ECG measuring unit** The abdominal wall induction fetal ECG measuring unit consists of an abdominal wall induction fetal ECG electrode, an induction cord and an abdominal wall induction fetal ECG amplifier. The abdominal wall fetal ECG electrode and the induction cord detect the abdominal wall induction fetal ECG signal. The abdominal wall fetal ECG amplifier amplifies this ECG signal and provides the input signal (abdominal wall induction fetal ECG heart beat signal) to the heart rate counter.
- c) **Fetal heart sound measuring unit** The fetal heart sound measuring unit consists of a fetal heart sound converter and a fetal heart sound amplifier. The fetal heart sound converter converts the mechanical vibration on the abdominal wall of pregnant women due to the fetal heart sound into the electric signal. The fetal heart sound amplifier amplifies this electric signal and provides the input signal (heart sound heart beat signal) to the heart rate counter.

- d) **Intrauterine pressure labour measuring unit** The intrauterine pressure labour measuring unit consists of an intrauterine pressure converter and an intrauterine pressure labour amplifier. The intrauterine pressure converter converts the intrauterine pressure into the electric signal. The intrauterine pressure labour amplifier amplifies this electric signal (intrauterine pressure labour signal).

6.3 Additional parts The additional parts shall be as follows.

- a) **Alarm generator** When a monitor malfunctions, or when the preset condition has been detected, the alarm generator generates alarm.
- b) **Display unit** This unit displays the fetal heart rate, labour etc. and other measurement data, input data, etc.
- c) **Telemeter** The telemeter sends and receives via wireless transmission the maternal information and the fetal information. When the transmitter and the receiver are handled as a single unit respectively, it shall be handled as an expanded monitor irrespective of its configuration and function. The transmitter shall be as small and light as possible, and shall be operated, in principle, by built-in batteries.
- d) **Maternal heart rate counter** This counter measures the maternal heart rate.
- e) **Automatic pattern analyzer** This analyzer analyzes the fetal heart rate labour diagram, fetal movement diagram, etc.
- f) **Fetal movement measuring unit** This unit measures and records the fetal movement.
- g) **Memory unit** This unit memorizes the fetal heart rate, labour, etc. and other measurement data, input data, etc.
- h) **Other part** Communication function unit, multiple bed monitoring function unit, trend function unit, etc.

7 Construction The construction of monitors shall be as per section 10 (Constructional requirements) of JIS T 0601-1, and the following.

- a) **Ultrasonic probe** The ultrasonic probe shall be so constructed that the abdominal wall contact surface is impervious to water and oil, and that the enclosure is insulated electrically.
- b) **Fetal heart sound converter** The fetal heart sound converter shall be so constructed that it is impervious to perspiration, and that the enclosure is insulated electrically.
- c) **Fetal ECG signal electrode** The fetal ECG signal electrode shall be so constructed that handling is easy, that it can be applied to the skin easily and securely, that the material is resistant to the amniotic fluid, etc. and that it is sterilized or sterilizable.