### Essential Principles Checklist (Telemetry system, electrocardiograph etc)

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<th>Identity of Specific Documents</th>
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<td>Chapter 1   General Requirements</td>
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<td>Article1 Applied</td>
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<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
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<td>Article2 Applied</td>
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<td>Article4 Applied</td>
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<td>Article6 Applied</td>
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Equivalence to existing equipment shall be evaluated for the following items.

1) Wireless data sending function
   (1) Handling of Medical Telemeter Associated with the Revision of Regulations Related to Radio Act (PAB/ELD Notification No. 2-636 dated May 22, 1989)

2) For equipment with a wireless data receiving function
   (1) Handling of Medical Telemeter Associated with the Revision of Regulations Related to Radio Act (PAB/ELD Notification No. 2-636 dated May 22, 1989)

3) For equipment with an electrocardiogram measurement part
   (1) The following items shall be evaluated in accordance with IEC 60601-2-27:2005  Medical electrical equipment  Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
     50.102.1 Accuracy of signal reproduction
     50.102.2 Input dynamic range and differential offset voltage
     50.102.3 Input impedance
     50.102.10 Common mode rejection
     50.102.13 Rejection of pacemaker pulses
     50.102.15 Heart rate range, accuracy, and QRS detection range

4) For equipment with a respiration measurement part
   (1) Respiration detection sensitivity

5) For equipment with a body temperature measurement part
   (1) The following items shall be evaluated in accordance with EN 12470-4:2001  Clinical thermometers  Part 4: Performance of electrical thermometers for continuous measurement
   The following items shall be evaluated in accordance with the performance of electrical thermometers for continuous measurement.
   4 Unit
   6.2 Measuring Range
   6.3 a) indicating unit
   6.10.1 Digital increment
   6.10.2 Display (for equipment with this function)

6) For equipment with a non-invasive blood pressure measurement part
   The performance shall be stipulated as follows using the cuff intended to be connected to the product.
   (1) JIS T 1115:2005  Non-invasive Automated Sphygmomanometers
5.1 Error in cuff pressure indication
5.2 Error in blood pressure measurement by clinical performance tests
5.7.3 Quick exhaust

(2) IEC 60601-2-30:1999  Medical electrical equipment Part2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

"Maximum pressure (applicable only to equipment with automated repeating measurement function)

Cuff pressure under normal operation
300 mmHg for adults
150 mmHg for newborns

7) For equipment with an invasive blood pressure measurement part (including other physiological pressure)

(1) The following items shall be evaluated in accordance with JIS T 0601-2-34:2005  Medical electrical equipment Part2: Particular requirements for safety, including essential performance, of invasive blood pressure monitoring equipment.

51.102.1 Accuracy/sensitivity, reproducibility, non-linearity, drift, and hysteresis of pressure measurement
51.102.2 Accuracy of systolic blood pressure and diastolic blood pressure

If the transducer intended to be connected conforms to JIS T 3323, the evaluation may be performed only for the body.

8) For equipment with a pulse oximeter measurement part

Attach the optical system of the probe intended to be connected to the pulse oximeter tester, and perform the test for the probe and body, and evaluate the following items.

This pulse oximeter tester shall provide SpO2 (percutaneous arterial oxygen saturation) and pulse rate based on a specific correlation between the ratio of ripple factor of red relative to that of infrared (R) and arterial SaO2.

(1) SpO2 measurement precision
The following (a) or (b) shall be evaluated.

(a) ISO 9919:2005  Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use Annex FF

(b) ISO 9919:2005  Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

50.101.1 Specification
(2) Pulse rate measurement precision (applicable only to equipment with this function)

(a) ISO 9919:2005  Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

50.104 pulse rate accuracy

(3) SpO2 alarm function (applicable only to equipment with this function)

(a) ISO 9919:2005  Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

104 Alarm system
Pulse rate alarm function shall work as set.

The above test describes the way of optically connecting the pulse oximeter tester to probe. If the probe intended to be connected and the equipment are identical, the test may be performed by directly, electrically connecting the tester to the equipment.

For equipment with a brain wave measurement part

The following 1) or 2) shall be evaluated.

1) Equivalence shall be evaluated for the waveform linearity, noise, and interchannel interference.

2) The following items shall be evaluated in accordance with IEC 60601-2-26:2002 Medical electrical equipment Part 2-26: Particular requirements for the safety of electroencephalographs.
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*注: 引用した日本規格書類の詳細は省略。*