### Essential Principles Checklist (Electrode, foetal scalp etc)

#### Chapter 1   General Requirements

<table>
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<tr>
<th>Article</th>
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<td>1</td>
<td>Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
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<td>2</td>
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<td>3</td>
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**Application to JIS T 1303: Fetal monitors**

1. **Activation frequency of ultrasound probe**
   - Follow 8.1 Activation frequency of ultrasound probe.

2. **Heart rate measurement performance**
   - Follow 8.6.1 Heart rate measurement performance.

3. **External toco transducer performance**
   - Follow 8.8.1 Sensitivity.
   - Follow 8.8.2 Temperature drift.

4. **Intrauterine pressure transducer**
   - Follow 8.9.1 Sensitivity.
   - Follow 8.9.2 Temperature drift.

5. **Alarm function (for equipment with alarm function)**
   - Follow 8.13 Alarm function.

6. **Telemeter function (for equipment with a telemeter function)**
   - The system shall have FM-FM modulation or binary FSK modulation.

7. **Blood pressure measurement function (for equipment with a maternal blood pressure measurement function)**
   - 1) **Error in blood pressure measurement by clinical performance test**
     - Follow 5.2 of JIS T 1115 Non-invasive Automated Sphygmomanometers.
   - 2) **Error in cuff pressure indication**
     - Follow 5.1 of JIS T 1115 Non-invasive Automated Sphygmomanometers.
   - 3) **Quick exhaust**
     - Follow 5.7.3 of JIS T 1115 Non-invasive Automated Sphygmomanometers.
   - 4) **Maximum pressure (for equipment with automatic repetition measurement function)**
     - Cuff pressure under the normal operation: 300 mmHg
     - IEC 60601-2-30:

8. **SpO2 measurement function (for equipment with a maternal SpO2 measurement function)**
   - 1) **SpO2 measurement precision**
     - Follow Annex FF of ISO 9919: Medical electrical equipments for the basic…

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**Note:** The table continues with additional columns and rows, detailing specific performance aspects and standards for various components and functionalities of fetal monitoring equipment. Each entry includes references to applicable standards and specifications.
March 18, 2008

2) Pulse rate measurement precision (for equipment with this function)

Follow 50.104 Pulse rate precision of ISO9919: Medical electrical equipments for the basic safety and essential performance of pulse oximeter equipment for medical use.

3) SpO2 alarm function (for equipment with this function)

Follow 104 Alarm system of ISO9919: Medical electrical equipments for the basic safety and essential performance of pulse oximeter equipment for medical use.

4) Pulse rate alarm function (for equipment with this function)

Follow 104 Alarm system of ISO9919: Medical electrical equipments for the basic safety and essential performance of pulse oximeter equipment for medical use.

Chapter 2   Requirements for design and manufacture

Article 71

1 Applied JIS T 0601-1: JIS T 14971:

2 Applied JIS T 0993-1: JIS T 14971:

3 Applied JIS T 0601-1: JIS T 14971:

2 Applied JIS T 14971:

3 first Applied JIS T 14971:

second Not applied

4 Not applied

5 Applied JIS T 14971:

6 Applied JIS T 0601-1: JIS T 14971:

Article 81 Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004

1 Applied JIS T 0601-1:

2 Not applied

3 Applied JIS T 14971:

2 Not applied

3 Not applied

4 Not applied

5 Not applied

6 Partially applied

MHLW Ministerial Ordinance No. 169 dated December 17, 2004; PFSB/CND Notification No. 0330001 dated March 30, 2005

7 Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005

8 Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004

9 Not applied

10 Partially applied JIS T 14971:

Applied JIS T 14971: JIS T 0601-1: Package insert:

Article 9 1

1 Applied JIS T 14971:

2 Applied JIS T 0601-1: JIS T 0601-1-2: JIS T 1115:

3 Applied JIS T 14971:

4 Applied JIS T 0601-1:

5 Not applied

6 Applied JIS T 14971:

7 Not applied