Medical Devices In Legal Metrology Framework

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1. How accurate medical measurements are?
In addition to knowledge and experience of medical doctors, correct diagnosis and appropriate patient treatment largely depend on accuracy and functionality of medical devices. In a large number of serious medical situations proper functionality of medical devices is crucial for patients. Therefore it is necessary to carry out as strict and independent testing of functionalities of medical devices as possible and to obtain the most accurate and reliable diagnosis and patient treatment.

2. Medical device management
ISO/IEC and WHO recommendations adopted in healthcare institution

Preventive Maintenance; Corrective Maintenance; Clinical engineering divisions

Implementation of Directives of new approach for various groups of medical devices

3. Medical device in legal metrology framework

INSPECTION PROCEDURE

VISUAL INSPECTION
Detection of contamination of device, integrity and functionality, markings and other defined parameters.

SAFETY INSPECTION
Safety and performance inspections performed in accordance to IEC 60601 and IEC 62353.

PERFORMANCE INSPECTION
Inspection performed in accordance to ISO 17020 using etalons calibrated according to ISO 17025.

National Standard
National Institute of Metrology
Represents the SI units and ensure international comparability

Reference Standard
Calibration Laboratory
Calibration by National Institute of Metrology

Working Standard
Testing laboratory Calibration by accredited laboratory

Measuring equipment
Measurements and tests as part of quality assurance process

Medical Measurement traceability chain

4. Current research
Articles published in Indexed Journals and IEEE International Conferences
1. Measurement in medicine – Past, present, future
2. Medical devices in legal metrology
3. Opportunities and Challenges in BME for Growing Economies
4. Development and Perspectives of BME in South East European Countries
5. Testing of mechanical ventilators and infant incubators in healthcare institutions
6. Testing of therapeutic ultrasound in healthcare institutions in Bosnia and Herzegovina
7. Software Package for Tracking Status of Inspection Dates and Reports of Medical Devices in Healthcare Institutions of Bosnia and Herzegovina
8. Testing of dialysis machines in healthcare institutions in Bosnia and Herzegovina
9. Testing of infusion pumps in healthcare institutions in Bosnia and Herzegovina

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- ECG devices
- Patient monitors
- Defibrillators
- Mechanical ventilators
- Anesthesia machines
- Devices for measuring blood pressure
- Therapeutic ultrasounds
- Infant incubators
- Infusion pumps
- Perfusors
- Dialysis machines

Fig. 1. 2016/2015 Inspection results of dialysis machine and infusion pumps

Table 1. 2015/2016 Inspection results of incubators, therapeutic ultrasounds and mechanical ventilators

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Accurate</th>
<th>Faulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incubator</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Therapeutic ultrasound</td>
<td>70.94%</td>
<td>29.06%</td>
</tr>
<tr>
<td>Mechanical ventilator</td>
<td>52%</td>
<td>48%</td>
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Competing interests: The authors hereby declare they have no conflicts of interest.

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