OIML Webinar
Legal metrology and health

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June 30th 2021
Introduction

OIML → SDO

Medical Meas Instr
12 Recommendations

ISO → IEC

Medical Electrical Eqpt
(60601/80601 series)
Approx. 90 standards

How can Legal Metrology contribute to Health?
## Industrial revolution

<table>
<thead>
<tr>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanization, water power, steam power</td>
<td>Mass production, assembly line, electricity</td>
<td>Computer and automation</td>
<td>Cyber Physical Systems</td>
</tr>
</tbody>
</table>

### HEALTHCARE 4.0

- Use of innovative digital Technologies towards **real-time** customization of the healthcare provided to patients;

- Professional hospital care has gradually migrated to a **distributed**, patient-centered model as users and system operators have access to a structure capable of collecting and transmitting useful data for medical treatments.
Possible applications for Health 4.0

- Telemedicine
- Virtual home assistants
- Medical adherence tracking
- Emergency response system
- Automated patient care
# Health 4.0 Issues

## Impacts of Healthcare 4.0 digital technologies on the resilience of hospitals

Guilherme Luz Tortorella\textsuperscript{a,b, +}, Tarcísio Abreu Saurin\textsuperscript{c}, Flavio S. Fogliatto\textsuperscript{c}, Valentina M. Rosa\textsuperscript{c}, Leandro M Tonetto\textsuperscript{d}, Farah Magrabi\textsuperscript{e}

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### Summary of results.

<table>
<thead>
<tr>
<th>H4.0 digital technologies</th>
<th>Monitor</th>
<th>Anticipate</th>
<th>Respond</th>
<th>Learn</th>
<th>Overall impact on resilience abilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>t\textsubscript{1} - Remote consultations and development of plan of care in real time</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>High</td>
</tr>
<tr>
<td>t\textsubscript{2} - Digital non-invasive care</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>High</td>
</tr>
<tr>
<td>t\textsubscript{3} - Interconnected medical emergency support</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>High</td>
</tr>
<tr>
<td>t\textsubscript{4} - Digital platforms for collaborative sharing of patient data and information</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>High</td>
</tr>
<tr>
<td>t\textsubscript{5} - Augmented reality as clinical decision support</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Moderate</td>
</tr>
<tr>
<td>t\textsubscript{6} - Remotely assisted surgical and clinical procedures</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Moderate</td>
</tr>
<tr>
<td>t\textsubscript{7} - Remote nutrition and infusion management</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Moderate</td>
</tr>
<tr>
<td>t\textsubscript{8} - Synthetic medical information generation through cloud computing</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Moderate</td>
</tr>
<tr>
<td>t\textsubscript{9} - Medical devices' traceability system</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
</tr>
<tr>
<td>t\textsubscript{10} - Computer assisted design of customized and modular medical devices</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
</tr>
</tbody>
</table>
1st issue: Digital non-invasive care

Healthcare 4.0: A review of frontiers in digital health

Prem Prakash Jayaraman | Abdur Rahim Mohammad Forkan | Ahsan Morshed | Pari Delir Haghghi | Yong Bin Kang

How to assess measurement error in daily routine?
1st issue: Digital non-invasive care

Example: Legal Control of sphygmomanometers in Brazil

OIML R16-1 (R148)
OIML R16-2 (R149)

≈50%

Major causes of NC
- Clinical investigation
- Indication Error
- EMC

“Asymptomatic” defects
2nd Issue: treatment of patient data

Simple bibliometric analysis of Literature

- **Database**: Scopus
- **Search string**: “health 4.0” OR “healthcare 4.0”
- **Result**: 140 documents at 14/04/2021 (covering year 2011 to 2021)
- **Type of analysis**: Co-occurrence with Author Keywords
- **Software**: VOSviewer 1.6.15

How to ensure that data transmission and processing will not affect measurements?
2nd Issue: treatment of patient data

OIML Webinar about Digital Transformation in Legal Metrology

A framework for remote in-service metrological surveillance of energy meters

Žilvinas Nakutis, Paulius Kaškonas, Marius Saunoris, Vytautas Daunoras, Marko Jurčević

Field surveillance of fuel dispensers using IoT-based metering and blockchains

How can Legal Metrology contribute to Health?

• There should be no competition, but a complementarity;

• While the major focus of ISO/IEC standards are requirements for the design and manufacture of medical equipment, Legal Metrology should focus on surveillance the measurement error of medical instruments;

Primary Healthcare
Chronic diseases

Weight; Heart Rate; Body temperature; Blood pressure; Oxygen saturation; Blood glucose
Conclusion

Global trade contracts, while trade of medical equipment increases

Reliable results of medical laboratories conducting tests to detect the virus are essential. Quality control and product testing ensure that medical equipment is fit-for-purpose. Laboratories support the development of new medicines and vaccines through related scientific testing.

The number of infected people increases exponentially, while adequate medical equipment is scarce.

Quality infrastructure helps to mitigate the negative effects of the crisis and ensures the provision of essential services.

Quality infrastructure ensures the identification and dissemination of relevant standards, accurate measurement (metrology) and provides attestation (accreditation) of reliable test results.

Trade plays an important role in ensuring the availability and affordability of vital medicines, medical products, and protective gear.

Mutual recognition of accredited test results facilitate the trade of essential goods.

Global trade contracts, while trade of medical equipment increases.

Millions of people around the world depend on international trade for their food security and livelihoods.

Trade along global value chains needs to be ensured to sustain global supply of essential goods.

Hygiene practices and food safety standards are key to ensure global food supply.

Business continuity, risk and emergency management standards are key to ensure the uninterrupted production of essential goods.

Standards ensure that goods produced in response of COVID-19 (protective masks, gloves, etc.) are fit-for-purpose while workers are kept safe.

Additional medical and hazardous (infected) waste is generated.

Businesses worldwide struggle to keep up production of essential goods.

COVID-19 is a virus which has paralyzed human interaction worldwide. International cooperation is thus essential in order to mitigate the further spread of the corona virus and to reconstruct our societies once the present outbreak has been tamed.

Standards help to manage the increased hazardous waste.

Testing laboratories can detect pollution levels.

COVID-19 is a virus which has paralyzed human interaction worldwide. International cooperation is thus essential in order to mitigate the further spread of the corona virus and to reconstruct our societies once the present outbreak has been tamed.

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Thank you!

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