INMETRO

OIML Webinar
Legal metrology and health

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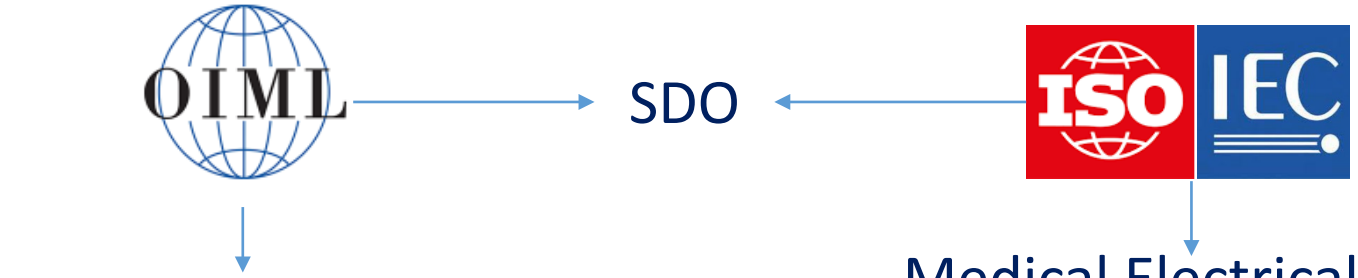
Introduction

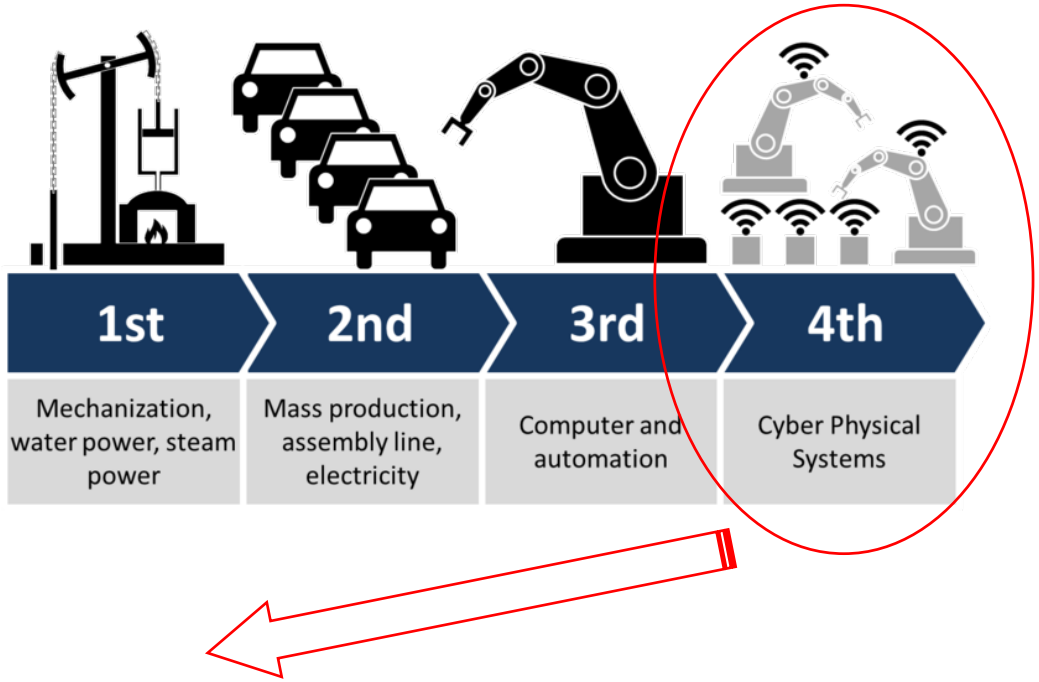


Medical Meas Instr
12 Recommendations

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

How can Legal Metrology contribute to Health?

Industrial revolution



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

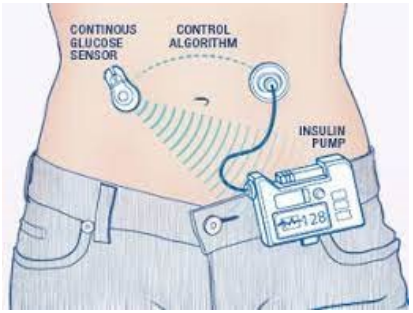
Telemedicine

Virtual home assistants

Medical adherence tracking

Emergency response system

Automated patient care



Health 4.0 Issues

Contents lists available at ScienceDirect

Technological Forecasting & Social Change

journal homepage: www.elsevier.com/locate/techfore

Impacts of Healthcare 4.0 digital technologies on the resilience of hospitals

Guilherme Luz Tortorella [a,b,*], Tarcísio Abreu Saurin [c], Flavio S. Fogliatto [c], Valentina M. Rosa [c], Leandro M Tonetto [d], Farah Magrabi [e]

Summary of results.

H4.0 digital technologies	Monitor		Anticipate		Respond		Learn		Overall impact on resilience abilities
	LMI	HMI	LAI	HAI	LRI	HRI	LLI	HLI	
t_2- Remote consultations and development of plan of care in real time		√		√		√		√	High
t_5- Digital non-invasive care		√		√		√		√	High
t_6- Interconnected medical emergency support		√		√		√		√	High
t_8- Digital platforms for collaborative sharing of patient data and information		√		√		√		√	High
t_1- Augmented reality as clinical decision support		√		√	√			√	Moderate
t_3- Remotely assisted surgical and clinical procedures	√		√			√		√	Moderate
t_4- Remote nutrition and infusion management		√	√			√	√		Moderate
t_9- Synthetic medical information generation through cloud computing	√			√	√			√	Moderate
t_7- Medical devices' traceability system	√		√		√		√		Low
t_{10}- Computer assisted design of customized and modular medical devices	√		√		√		√		Low

1st issue: Digital non-invasive care

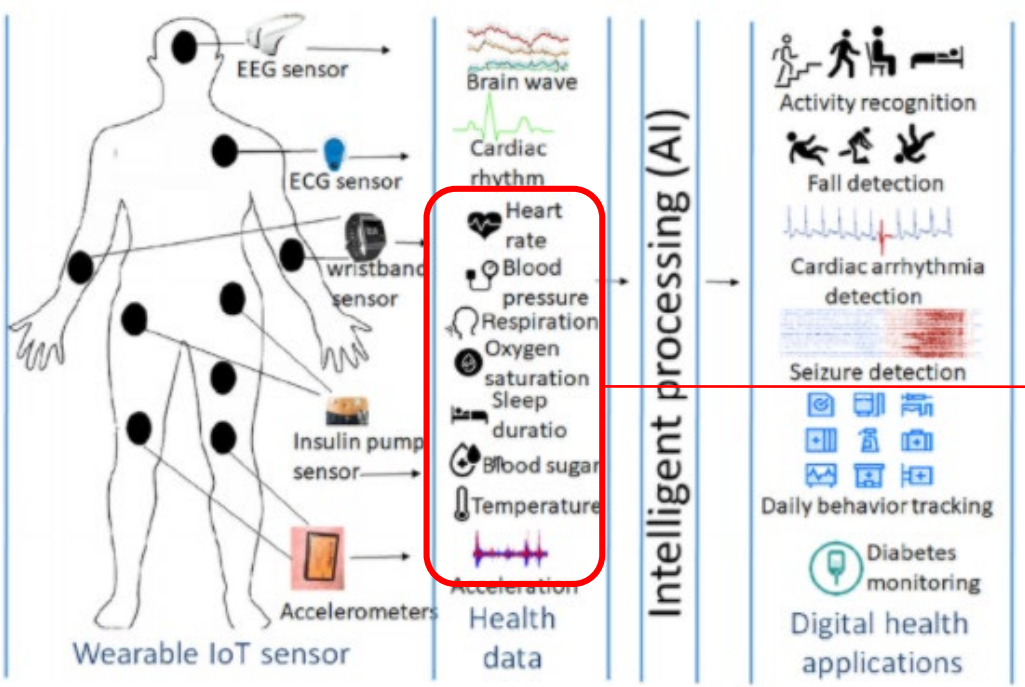
Received: 20 November 2018 | Revised: 20 November 2019 | Accepted: 21 November 2019
DOI: 10.1002/widm.1350

OVERVIEW

WIREs DATA MINING AND KNOWLEDGE DISCOVERY WILEY

Healthcare 4.0: A review of frontiers in digital health

Prem Prakash Jayaraman[1] | Abdur Rahim Mohammad Forkan[1] | Ahsan Morshed[2] | Pari Delir Haghighi[3] | Yong-Bin Kang[1]



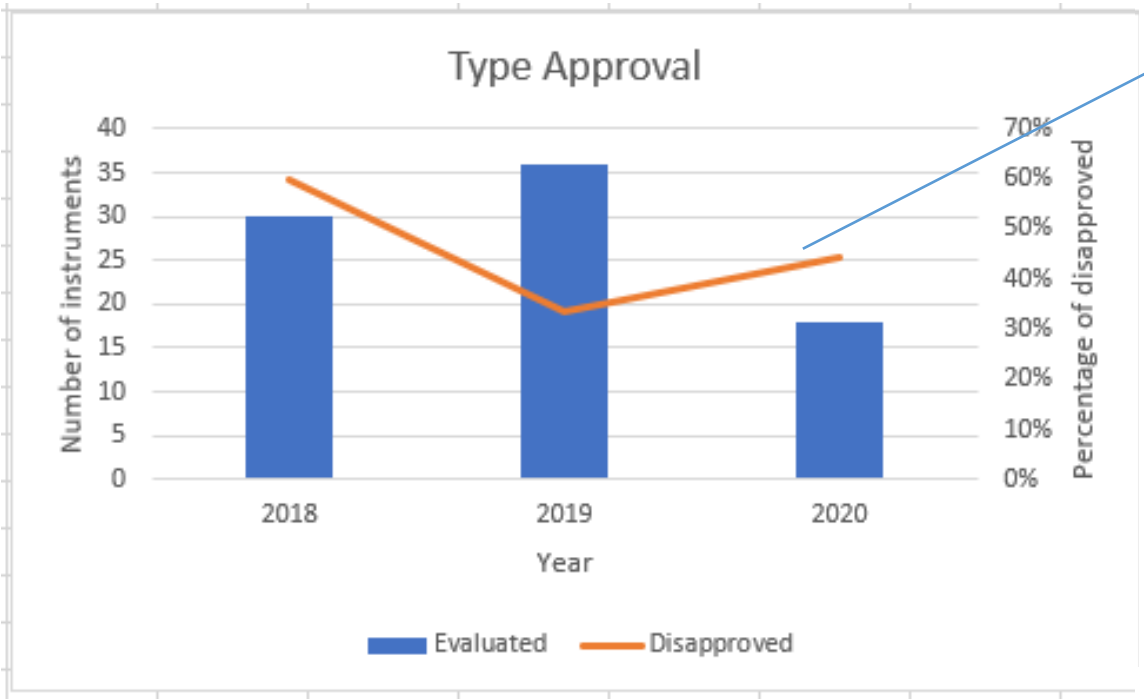
How to assess measurement error in daily routine?

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

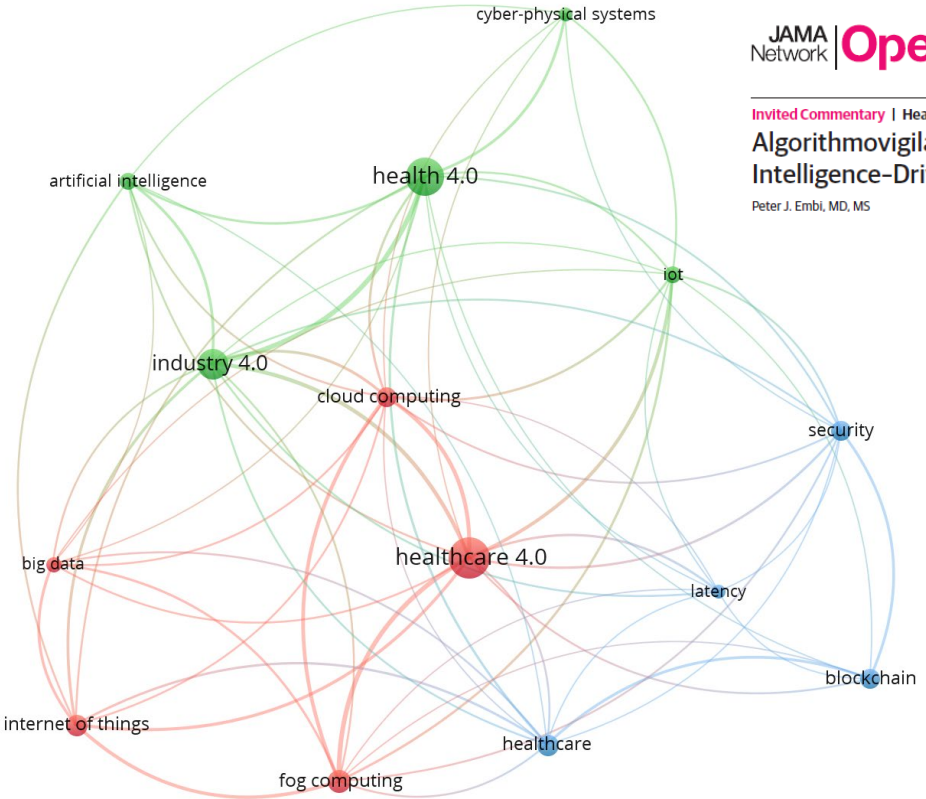
- Clinical investigation
- Indication Error
- EMC

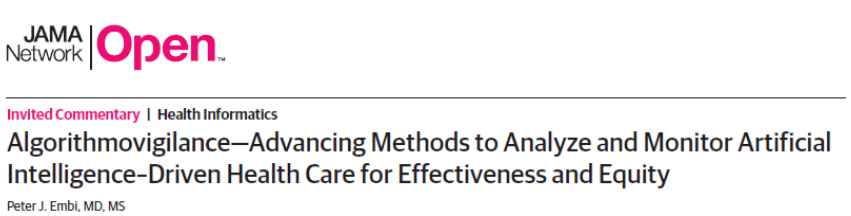
"Asymptomatic" defects

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-occurence with Author Keywords
- **Software:** VOSviewer 1.6.15




JAMA Network Open

Invited Commentary | Health Informatics

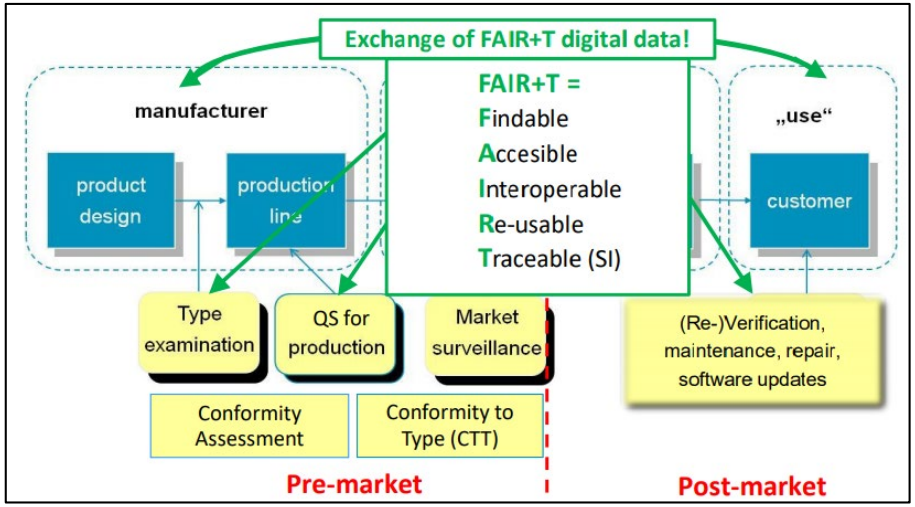
Algorithmovigilance—Advancing Methods to Analyze and Monitor Artificial Intelligence–Driven Health Care for Effectiveness and Equity

Peter J. Embi, MD, MS

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



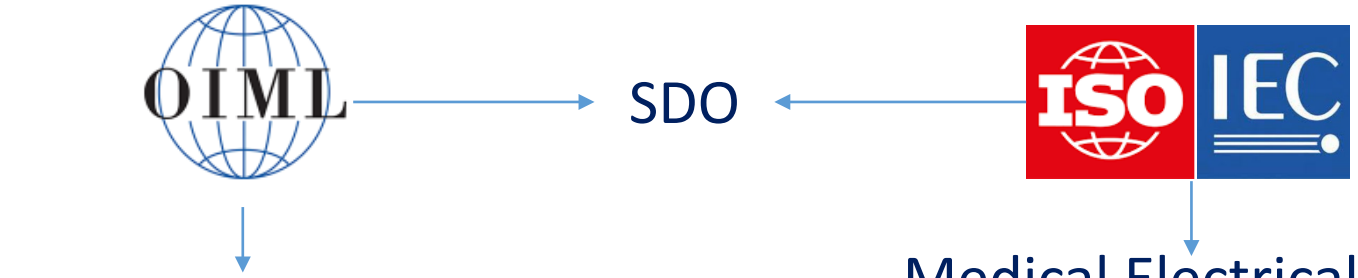
A framework for remote in-service metrological surveillance of energy meters

Žilvinas Nakutis [a,*], Paulius Kaškonas [a], Marius Saunoris [a], Vytautas Daunoras [a], Marko Jurčević [b]

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

Wilson S. Melo Jr. [a,*], Luiz V.G. Tarelho [a], Bruno A. Rodrigues Filho [a], Alysson N. Bessani [b], Luiz F.R.C. Carmo [a,c]

Analysis



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


COVID-19
The number of infected people increases exponentially, while adequate medical equipment is scarce
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
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
Standards ensure technologies used in mitigation of the crisis are safe, and that privacy and users are protected
Global trade contracts, while trade of medical equipment increases
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
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
Businesses worldwide struggle to keep up production of essential goods
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
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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