

Digital Metrology for Digital Health

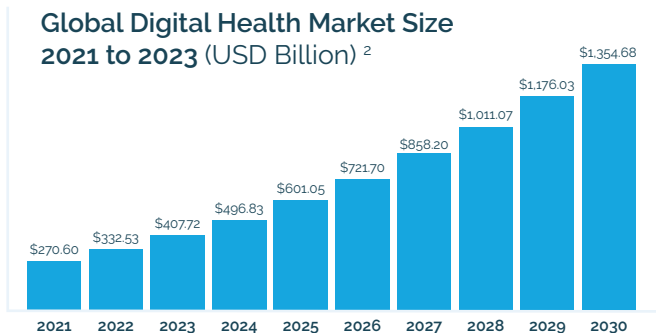


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Key messages

- The digital health market is booming and it is changing the way people access medical and health services.
- Digital metrology solutions enable continuous quality assurance and the safe operation of emerging digital health tools and technologies.
- Policies, regulations or legislation need to be put in place to recognise, regulate and support the development of these solutions, and their use in legal metrology.
- Governmental multi-year funding is recommended to support the development of digital metrology solutions for digital health.



What's the issue?

Digital health is transforming the healthcare sector and our lives, particularly in addressing the challenges of ageing populations, workforce shortages in healthcare, and pandemics. It combines sensors, software, smart algorithms including artificial intelligence (AI), computational platforms and connectivity, to provide a more holistic, efficient and personalised healthcare solution.

Digital health includes – but is not limited to – telehealth, telemedicine, mobile health, wearable devices, health information technologies, and personalised medicine ¹. Interest in digital health platforms, systems and technologies is growing at an unprecedented pace. The global digital health market is expected reach over US\$1354 billion by 2030, growing at a rate of 19.2% between 2022 and 2030 ².

Regulations in the Asia-Pacific region have shown initial support for digital health products ³. Further improvement is possible by using metrology to support product safety and to provide reliability assurance. Metrology has long played a key role in traditional healthcare instrumentation for benchmarking and calibration.

By providing traceability to the International System of Units (the SI), it brings confidence to clinical measurements and decision-making. Emerging digital metrology solutions, such as remote and data-driven calibrations, will strengthen the trust and quality in digital health, and in turn, facilitate the healthy growth of this sector.

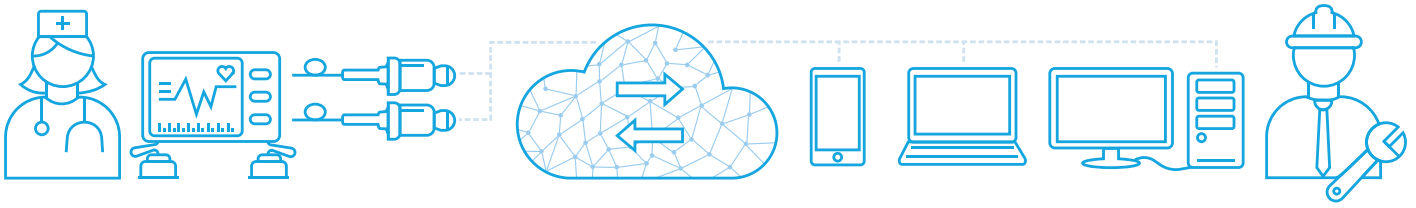
Why is this important?

Patient safety is of utmost importance. Medical and healthcare instruments used for diagnostics and treatments must be calibrated and validated frequently and periodically to catch any potential error as early as possible. Digital health products and services are no exception to this. It is vital to ensure that (1) their performance is evaluated regularly, (2) their quality achieves established standards, and (3) they provide measurement traceability.

With wearable or portable devices and sophisticated software becoming the norm in digital health, traditional hardware-oriented metrology, carried out through lab-based calibration and verification, is no longer suitable for meeting the needs of the industry.

Dedicated digital metrology solutions, such as remote and automated calibration, AI calibration and verification, and metrology big data techniques, are better suited to support this growing sector.

However, such digital metrology solutions may not yet be recognised by regulators, or fit within their domestic legal metrology framework. So, in order to support the growth of the digital health sector, it is important to revisit existing policies, and to develop new policies around new or revised digital metrology solutions.



The role of metrology

Accurate and fair data has been an important cornerstone of all digital developments in science and technology ⁴. Across the healthcare sector, dedicated digital metrology solutions are expected to improve data quality in disease diagnosis and treatment by providing efficient and reliable measurement methods and standards.

Currently, the calibration of medical devices and the type evaluation of legal metrology devices is carried out in person on-site ⁵. By virtue of IoT technology and innovative calibration techniques, it is becoming possible to provide digital calibration solutions and services remotely and automatically, to assure the accuracy and safety of medical and healthcare devices anywhere in the world. Just as with all medical devices, clear regulations will be a prerequisite ⁶.

Metrology will support this need directly by providing evaluation criteria for data quality, and ensuring the accuracy and reliability of health AI and big data algorithms. Additionally, driven by digital transformation, emerging metrology AI and big data techniques will also be utilized to support the manufacture of new digital health products, hospital management, and policy-making ⁷.

To ensure that digital metrology plays a core role in tomorrow's quality infrastructure for digital health, the metrology community needs to better cooperate with other participants in the health industry; agencies, standardization bodies, hospitals, accreditation organizations and product manufacturers. Open collaboration between regional task groups and focus groups on health and digital transformation, and global metrology bodies like the International Committee for Weights and Measures (CIPM), will be key to meeting this challenge.

What should policy makers do?

Digital transformation of the health system is a complex, costly and lengthy task and it requires governance that addresses rights, regulations, responsibilities and risks ⁸. Policies are needed to support the development and adoption of digital metrology for safe and trustworthy digitalization of the medical and healthcare sectors. Construction of digital metrology infrastructure should be incorporated and aligned to relevant national health strategies.

The digital transformation of metrology in the health sector should be prioritized at a national level, and supported by governmental multi-year funding plan. We should also pay attention to legal metrology's role in this emerging area, in order to protect the interest of all stakeholders ⁹.

Governance and regulation play a critical role in supporting the development and use of medical and health products.

To date, few international recommendations or national regulations exist to support the application of digital metrology to this critically-important sector. To change that, several steps need to be taken:

- 1) Clarify requirements for data quality and algorithm accuracy of digital health tools
- 2) Allow the use of digital metrology solutions and services for legal metrology medical products
- 3) Establish clear rules for quality, accessibility, interoperability and safety of data
- 4) Promote standardization to accelerate cooperation among the key players in digital health industry.

Leveraging the existing quality infrastructure will help to guide the development and recognition of emerging digital metrology services and solutions, such as standardization (IEC/ISO) and capability accreditation (ILAC MRA).

Local example: Singapore

Indoor air quality (IAQ) monitoring and fresh air ventilation are important for infectious disease control. A*STAR's National Metrology Centre in Singapore has conducted research to find out how digital metrology may improve the reliability of IAQ sensing, and to enable effective fresh air ventilation control using such sensors.

A data-driven calibration method – namely, self-diagnosis and self-healing – was developed to achieve autonomous calibration of sensing data without the need to interrupt the measurement process, nor an onsite reference device. The system has been successfully demonstrated in a Green Mark Platinum building, which is the most energy efficient building category currently in Singapore. It has achieved a 20% energy saving in ventilation while maintaining the IAQ target.

Early recognition and approval would aid in the deployment of this type of digital metrology solution in the healthcare sector. Regulators and policymakers may not need to establish new processes but instead leverage the existing metrology frameworks. One way of achieving such recognition and acceptance could be through CIPM's Mutual Recognition Arrangement (MRA) or the laboratory accreditation scheme under the International Laboratory Accreditation Cooperation MRA (ILAC MRA).



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