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**ISO/IEEE
11073-10700**

**Health informatics — Device
interoperability —**

**Part 10700:
Point-of-care medical device
communication — Standard for
base requirements for participants
in a Service-oriented Device
Connectivity (SDC) system**

Informatique de santé — Interopérabilité des dispositifs —

*Partie 10700: Communication entre dispositifs médicaux sur le
site des soins — Norme relative aux exigences de base pour les
participants à un système de connectivité de dispositifs orientée
services (SDC)*

**First edition
2024-09**



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Published in Switzerland

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Medicine and Biology Society (as IEEE Std 11073-10700) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

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Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html. **Abstract:** Medical devices that offer a communication interface as specified by the IEEE 11073 Service-oriented Device Connectivity (SDC) standards can be integrated into a health IT system to jointly execute system functions. However, implementing the IEEE 11073 SDC communication protocol is not sufficient to demonstrate safety, effectiveness, and security of system functions resulting from the combination of system function contributions from two or more medical devices. SDC participant key purposes (PKPs) are sets of requirements that allow for manufacturers to have certain expectations about BICEPS participants from other manufacturers. This common understanding enables the manufacturers to perform risk management, verification, validation, and usability engineering for the safe use of system functions. This standard specifies requirements for the allocation of responsibilities to SDC base participants.

Keywords: base PKP; BICEPS; communication protocol specification; documentation and process responsibilities; dynamic medical device interoperability; IEEE 11073-10700™; integrated clinical environment; participant key purpose; point-of-care medical device communication; risk management; SDC; service-oriented device connectivity; safety, effectiveness, and security; system function; system function contribution; usability engineering

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PDF: ISBN 978-1-5044-9848-7 STD26263
Print: ISBN 978-1-5044-9849-4 STDPD26263

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This introduction is not part of IEEE Std 11073-10700-2022, Health Informatics—Device Interoperability—Part 10700: Point-of-Care Medical Device Communication—Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System.

The IEEE 11073 Point-of-Care Medical Device Communication Standards enable communication between health IT elements in a HEALTH IT SYSTEM including MEDICAL DEVICES. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

- Provide real-time plug-and-play interoperability for MEDICAL DEVICES. “Real-time” means that data from multiple MEDICAL DEVICES can be retrieved, temporally correlated, displayed, and processed in fractions of a second. “Plug-and-play” means that there are no recurring configuration steps necessary to enable data exchange between MEDICAL DEVICES.
- Facilitate the efficient and effective exchange of vital signs and MEDICAL DEVICE data acquired at the PoC in all health care environments. “Efficient and effective exchange of MEDICAL DEVICE data” means that data captured at the PoC, e.g., patient vital signs, can be received, parsed, and interpreted by different types of applications without the loss of safety-critical information.

The IEEE 11073 Point-of-Care Medical Device Communication Standards are targeted at surgical as well as acute and continuous care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, endoscopic camera systems, insufflators, dissectors, etc. They build a family of standards that can be bound to one another to provide optimized connectivity for devices at the PoC.

Within the context of the ISO/IEEE 11073 family of standards for Point-of-Care Medical Device Communication, this standard defines the requirements for SDC BASE PARTICIPANTS in an SDC SYSTEM that comprises an IT NETWORK of MEDICAL DEVICES to enable safe and secure contribution to SYSTEM FUNCTIONS.

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