Board Report: IHE Devices (DEV) Domain – October 2025

Sponsors:

- OR.NET – DPI Program & joint IHE-HL7 Gemini MDI Program

Leadership (dev@ihe.net):

Devices Secretariat:	Resource needed – Domain Technical Management Hagan Horn, IHE – Domain Administration
IHE Board Representative:	Kurt Elliason, ICU Medical (kurt.elliason@icumed.com)
Planning Cmte Co-chairs:	PCD - Kurt Elliason, ICU Medical (kurt.elliason@icumed.com) PCH - Open DPI - Ken Fuchs, Red*Fox Consulting (KFuchs@ihe.net)
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NOTE: Each DEV program group has a representative („Rep“) on the domain Planning & Technical Committees; however, within the domain program groups, the leadership may reflect that of the overall domain (with additional co-chairs), or may be simpler (e.g., flat) based on the needs of the program participants.

Membership Rosters:

- **(IHE Google Drive) IHE Documents/DEV Domain/Roster** :
  https://drive.google.com/drive/folders/1AWuSbQ5H9gxM_6fmalPoo90Z6fxUjcoN?usp=sharing

  DEV Ballot Roster 2024.xlsx

  Note: With the transition from PCD to DEV, the domain TPM & administrator “secretariat” changes, and moving to Google Meet and a centralized IHE meeting calendar, domain rosters, Google email groups, wiki pages are actively being updated.

Activity:

- Domain Scope: **IHE Devices** advances device interoperability from home to hospital, supporting the integration of device informatics into all health-related information technologies, and laying the foundation for innovation and furthering health knowledge and state-of-the-art healthcare.

  NOTE: “Devices” include regulated and non-regulated, purpose-built hardware and Software as a

Medical Device (SAMD) “apps”. Excluded are devices that are in the scope of other IHE domains such as radiology and laboratory.

- Background: IHE PCD was established in 2005 by HIMSS & ACCE; domain reorganized as IHE DEV in 2019.
- Domain activities are organized around three core work ***programs***, each covering distinct application contexts:
    - ***Patient Care Device (PCD) Work Program (Enterprise Integration)*** is concerned with use cases in which at least one actor is a patient-centric point-of-care medical device or information system that communicates with at least one other actor such as a medical device or information system (e.g., device gateway to an enterprise electronic medical record).
    - ***Personal Connected Health (PCH) Work Program (Home & Mobile Integration)*** supports those device-related harmonization activities that are required for seamless integration between the clinical and consumer environments (e.g., from a person-worn sensor to a home “hub” to a monitoring service)
    - ***Device Point-of-care Interoperability (DPI) Work Program (High-acuity Point-of-Care Integration)*** focuses on the peer-to-peer plug-and-trust integration of medical technology at high-acuity points-of-care (e.g., around an OR table or ICU bed)

Summary of Major Changes 2024-2025:

- Completed 4 years of CP’s and name change (PCD to DEV) edits to release an updated Devices Technical Framework in November 2024.
- Loss of the HIMSS-funded Domain TPM has continued to impact processing of change proposals and updates to the Devices Technical Framework.
- IHE published several SDPi Supplement updates: SDPi 1.4 in October 2024, SDPi 2.1 in May 2025. SDPi 2.2 is in the publication approval pipeline and is also in the HL7 pipeline to become the first-ever HL7 publication of SPDi, as an STU Edition 1, on an ANSI accredited standard path.
- SDPi and PCIM development is fully integrated with the IHE Github (repo, issues, PRs, actions, etc.) and now generate HTML + PDF documents, and support rich embedded metadata (e.g., formal requirements automatically exported and published as a JSON file) with the use of AsciiDoc.
- Joint balloting of the SDPi specification in IHE and HL7 continued, including tight comment resolution and tooling coupling.

Significant Profiles:

Title	Work Program	# vendor (Cthon 2025)	# product (Registry)	Description	Significance
Device Enterprise Communication (DEC)	PCD	9 (12 systems)		Supports publication of consistent messaging format and device semantic content acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems.	Expected to be included in future IHE certification programs. Over 1000 Production installations using the DEC profile globally.
Alert Communication Management (ACM)	PCD	10 (13 systems)		Enables remote communication of point-of-care medical device and system alert conditions ensuring the right alert (alarm or advisory) with the right priority to the right individuals with the right content (e.g., evidentiary data) and is supportive of alert escalation or confirmation based on dissemination status, and recipient response.	Expected to be included in future IHE certification programs. Over 500 Production installations using the ACM profile globally
Point of care Infusion Verification (PIV)	PCD	5		Supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop."	Expected to be included in future IHE certification programs. Over 500 Production installations using the PIV profile globally
Infusion Pump Event Communication (IPEC)	PCD	6 (7 systems)		Provides a means for an infusion system to report events in the course of an infusion to allow the pump to report a detailed event flow to another system.	Expected to be included in future IHE certification programs. Over 500 Production installations using the IPEC profile globally
Implantable Device Cardiac Observation (IDCO)	PCD	0	0	Specifies the creation, transmission, and processing of discrete data elements and report attachments	

				associated with cardiac device interrogations (observations) or messages.	
MEMLS	PCD	2		This profile provides detailed device and people location identification which can be sourced by embedded location sensing components or through location sensing tags external to equipment and these tags can also provide additional information such as button presses and environmental information such as temperature and humidity It is a combination of profile types as it defines workflow through use case specification and transport through its described use of the HL7 and IEEE 11073 standards for information communication.	Expected to reach final text within 1-2 years. Actively working with IEEE P1847 location services in healthcare. Some work done to synchronize with IEEE P11073-10471 for nomenclature. Some work done to synchronize with FHIR location resource. Less than 10 Production installations using the MEMDMC profile globally
MEMDMC	PCD	4	0	MEMDMC is focused with sending equipment identification observations whether or not there is a patient associated with the device to equipment management systems, such as CMMS. Equipment identification, configuration, and status information needs to be recorded for effective management of the equipment, whether or not there is a patient currently associated with the equipment.	Expected to reach final text within 1-2 years. Less than 10 Production installations using the MEMDMC profile globally
Personal health device Observation Upload (POU)	PCH	0		Describes a standardized means of representing personal healthcare device (PHD) data as FHIR resources. PHDs are typically used by patients at home. The POU Profile is anticipated to supplement any IHE profile or	Enables any compliant device to automatically connect to any compliant gateway and any compliant health record system, and upload observations using the FHIR standard.

				activity requiring a patient to use PHDs	
Point of Care Identity Management (PCIM)	PCD	4	0	Describes a standardized means of reporting and communicating device patient association events and status at the point of care. Accurate device patient (and optionally location) association data enhances the value of other IHE PCD profiles such as ACM and DEC. Both snapshot status and real-time publish models are supported.	Healthcare organizations and device manufacturers benefit from patient device interoperability as knowing which patient is associated with each device at any moment of time improves safety, efficacy and efficiency. There can be many devices at the point of care, some of which come with small screens and/or limited input mechanisms and enabling any compliant device to automatically receive association status and events from a medical record or RTLS system allows them to transmit outbound data that includes accurate patient identification in a more natural and time-saving workflow.
Service-oriented Device Point-of-care Interoperability (SDPi)	DPI	4 (PAT track)	0	Provides for device-to-device plug-and-trust interoperability, especially in acute care contexts (OR, ICU, Emergency, etc.). SDPi comprises four profiles: SDPi-P for seamless connectivity; SDPi-R for medical data reporting; SDPi-A for medical alerting; SDPi-xC for device-external control. Gateway specifications for the PCD DEV and ACM profiles ensure seamless integration with these enterprise-focused specifications.	SDPi addresses a 40 year effort to bring plug-and-trust interoperability to the medical technology around a patient at the point-of-care. SDPi interoperability not only realizes significant improvements in safety, security, clinical effectiveness and workflow efficiency, it also opens the door to an entire new generation of medical technology applications, such as clinical algorithms (e.g., delirium management) and use cases such as silent ICU.

Significant Content Modules and Value Sets:

Title	# vendor (Cthon)	# product (Registry)	Description	Significance
Rosetta Terminology Mapping (RTM)	10	N/A	Establishes a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation	RTMMS managed by NIST is at http://rtmms.nist.gov Conformance to RTM is required for DEV profiles. The number of vendors

			using ISO/IEEE 11073 semantics and UCUM units of measurement and additionally, the Rosetta tables capture parameter co-constraints, specifying the set of units of measurement, body sites, and enumerated values that may be associated with a given parameter, thus enabling even more rigorous validation of exchanged medical device semantic content.	making implementing RTM is a union of the DEV profile vendor Connectathon results.
Device Specialization – Infusion Pump – LVP/Syringe/PCA (DS-IP-X)	N/A	N/A	A set of profiles that combine core profiles (e.g., DEC and ACM) with pump-specific content modules	
Pulse Oximetry Integration (POI)	N/A	N/A	A transaction profile which provides specific guidance on transactions to be used by pulse oximetry devices	Included in IHE-USA ICSA Labs Certification program for provisional certification at 2014 North America Connectathon.
Waveform Content Module (WCM)	N/A	N/A	Extends DEC and ACM profiles to pass near real-time waveform data using HL7 v2 messages. Extends ACM to pass ECG waveform snippets in alert messages. (As an option to the DEC and ACM profiles, it isn't identified in Connectathon results.)	Several Production installations globally.

Significant Deployment Activity:

- Point-of-Care Identity Management (PCIM) foundational CP was added to the IHE DEV TF PCIM TI

Demonstrations and Other Events:

- HIMSS 2025– Interoperability Showcase, vendor participation
- DMEA (Berlin) 2025 featured SDC/SDPi demonstrations.
- North America Connectathon was held Feb. 3-7, 2025 in Toronto. Numbers were up from the previous year, of the 34 participating vendors, the Devices Domain PCD program had 9 vendors representing 12 different systems. A new SDPi Plugathon Track was held.
- IHE Europe Connectathon was held in June 2025 in Vienna, including a second SDPi Plugathon Track.
- IHE Devices fall 2025 face to face meeting was held jointly with IEEE 11073 PoCD and PHD WGs at FDA headquarters in Silver Spring MD Sept. 9-11, 2023. Plans are in place to hold another joint meeting in Sept. 2026. A Spring F2F for the Devices Domain was held in April 2024 at BD's office in

San Diego.

- SDC/SDPi Plugathon testing events have been conducted (virtual and in person) in Germany since late 2019; the latest was #21 in October 2025.
- SDPi Developers (& Testers) Workshops conducted in Germany in June 2024, November 2024 and October 2025, with one scheduled for June 2026.

New/Updated Profiles: 2024 – 2025 Cycles

- Plan to submit a proposal for a new profile, Point-of-Care Monitored Communication (PCMC)
- Point of Care Identity Management (PCIM) was included at Connectathon for the third time. 4 vendors tested revision 2.2.
- Gemini SDPi profiles are updated 2-4 times per year, both with new capabilities and incremental updates and fixes. These frequent updates will continue for the foreseeable future.

Trends:

- Domain continues to work to include PCD profile items in updates to IEEE 11073.
- Domain leadership utilizes opportunities to provide comments to federal standards directives.
- Domain working to make use of FHIR with existing PCD profiles (PCIM).
- Interest in plug-and-trust device interoperability has continually gained momentum, especially with an increasing number of vendors participating in the bi-monthly plugathons, products coming to market or announced, public statements, public demonstrations and the formation of the Gemini Devices Accelerator in late 2025.
- Devices on FHIR and the integration of FHIR-enabled specifications continued to grow. Three “Devices Tracks” have been held at HL7 FHIR Connectathon events in 2025, with prototypes by several vendors tested. Although FHIR adoption has been relatively slow in the device interoperability ecosystem; it is anticipated that this area will continue to grow in 2026 with vendors increasingly participating in FHIR-based testing and demonstration events.
- Active regulatory engagement, especially with the EU Notified Bodies and the U.S. FDA, continued in 2024 and 2025; this bodes well for the medical device interoperability industry.

Summary of Future Plans:

- Transition to the use of AsciiDoc and the Github tooling that is also being used in the PCIM and SDPi profiles, leading to HTML publication + PDF generation, and easing the integration of the supplements when they are ready to become Final Text.
- Increase interactions with end user communities (clinicians and CE).
- Minor updates to MEM DMC and MEMLS TI in progress to prepare it to move to final text.
- The PCH Program is currently in semi-hibernation mode while keeping alignment with the development work at IEEE 11073, Bluetooth SIG and HL7 Devices, as well as planning for an overhaul of the Personal Health Device Observation Upload (POU) Profile in 2026 (pending sufficient resourcing)..

- SDPi releases continue with a 2-4 times a year cadence, with a major release planned annually; this technical specification roadmap is closely aligned with vendor product plans + available resources and priorities
- SDC/SDPi bi-monthly plugathon testing has been a huge success for fostering an implementation community; in 2026 the community will be transitioning to IHE Connectathon testing as well.
- SDPi Conformity Assessment (CA) program is required for this ecosystem, and is being actively considered by the emerging roadmap, with certification and integration with security infrastructure key success factors.
- FDA & EU Notified Body engagement across all aspects of the SDPi will continue to be advanced, from specification development to testing to regulatory market clearance & TPLC management.
- Gemini Accelerator Program in conjunction with HL7 is in the final stages of creation
    - The accelerator program will provide a governance and funding model for the Gemini roadmap discussed above.
    - This funding would include support for IHE related aspects of the roadmap, including IHE Catalyst Connectathon and tooling development and support.
    - Launch is in late 2025