Committee Approval Date:

2021-05-29

Publishing Lead:

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Contributing or Reviewing Work Groups:

HL7 Devices WG

FHIR Development Project Insight ID:

Scope of coverage:

Way of representing physiological and technical data communicated by point-of-care (acute care) regulated medical devices for near-real-time reporting, archiving, analytics, and related use models, in FHIR. Includes representation of structure of the device and the state of device subsystems according to the ISO/IEEE 11073-10201 Domain Information Model. Future scope extension to cover near-real-time event reporting for physiological and technical alerts and alarms conforming to IEC 60101-1-8 and related standards.

Content location:

https://github.com/hl7/uv-pocd

Proposed IG Title:

HL7 FHIR Point-of-Care Device Implementation Guide

Proposed IG realm and code:

uv
FHIR Core version(s):

4.01

Maintenance Plan:

HL7 Devices Work Group

Short Description:

This Implementation Guide supports in-depth reporting device observations, configuration and state information communicated by complex point-of-care medical devices. It is based on a widely used hierarchical domain information model (ISO/IEEE 11073-10201).

Long Description:

This Implementation Guide shows methods for providing information communicated by complex point-of-care medical devices such as multi-parameter monitors, ventilators, anesthesia workstations with additional discoverable structural and current configuration information backing up the measurement information carried in the Observation resource. It can be thought of as "rich metadata" for the observations which includes a view into the arrangement and state of device systems and subsystems.

It leverages standards in the ISO/IEEE 11073 Medical Device Communications standards series, widely used by device manufacturers, which is also used in the IHE Patient Care Device Program's current HL7 V2-based profiles for device data observation reporters (such as device interfaces and device data gateways), and device observation consumers (for example, electronic medical record systems and archiving systems). It allows receiving systems to discover the basic arrangement and state of of hierarchy of device, device subsystems (Virtual Medical Devices in the ISO/IEEE Domain Information Model), their logical channels grouping the measurements, and the individual measurement capabilities (called Metrics in the models).

This information provides traceability if the Observation to its specific instrumental source in the device, which can be of high importance in, for example, research uses and adverse event analysis.

Involved parties:

None

Expected implementations:

Dräger, Philips, other prototyping and test activities in progress. Note that the DeviceMetric resource has not yet had sufficient testing to advance its FHIR Maturity Level - this is a principal goal of this release of the IG which is proposed to advance that goal.

Content sources:

ISO/IEEE 11073-10201 Medical Device Communications Domain Information Model
ISO/IEEE 11073-10101 Medical Device Communications Nomenclature
ISO/IEEE 11073-10207 Medical Device Communications Service-Oriented Domain Information and Service Model
IHE Patient Care Device Program Device Enterprise Communications Profile
LOINC
Example Scenarios:

Device or device gateway reports configuration (hierarchical device model) and state of system and subsystems to EMR or archiving system
Device or device gateway reports periodic and aperiodic measurements and internal device configuration and state updates to EMR or archiving system
Receiving systems queries persistent hierarchical device model from resources held by FHIR server

IG Relationships:

Planned future IGs for added use cases enabled by developing IEEE 11073 service-oriented device communications capabilities expected to rely on this IG

Timelines:

FMG Notes