IHE-HL7 Gemini SES+MDI – Device Alerting & Reducing Clinician Alert Fatigue

2022.07.25
Gemini SES+MDI Device Alerting & Reducing Clinician Alert Fatigue

What is a medical device “alert” or “alarm”?  
Overview of Standards and Technologies for Device Alerting 
Introducing: FHIR DeviceAlert Resource 
Understanding & Addressing Alert Fatigue
Gemini SES+MDI – Reducing Alert Fatigue –

What is a device “alert” or “alarm”?

Where do device alerts or alarms come from? Why are they the source of so much NOISE and exasperation and ... clinician fatigue?!
What is a device “alert” or “alarm”?

Start with: What is a medical device?

3.34 medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer (3.33) to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Note 1 to entry: Products (3.39) which can be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproductive technologies.


See current Gemini discussion @ Paper: What is a device?
What is a device “alert” or “alarm”?  

Lot’s-o-definitions ...

**ALERT:** Synonym for the combination of patient-related physiological alarms, technical alarms, and equipment user advisory signals.

Non-technical / legal ...

An alarm is a risk mitigation where the underlying “root cause” of potential HARM cannot be designed out and a clinician must be notified.
Gemini SES+MDI – Reducing Alert Fatigue –

**Overview of Standards & Technologies**

A rich ecosystem of standards and technologies has been established over the decades ... all targeted to improve patient safety. Understanding this landscape is necessary to understand how it might evolve and be better utilized to address clinician alert fatigue.
So many SDOs ... so many standards!!!

“Gemini” is an HL7-IHE collaboration for joint projects

To keep things sorted ... we have models of standards ... yikes!
So many SDOs ... so many standards!!!

Device Alert Standards & IGs/Profiles are core ...

ISO/IEEE 11073 –
- 10101  Alert & Event Nomenclature
- 1020x  Information & Service Models
- 1070x  PKP Risk Assessment Stds.
- 2070x  WS-based Specifications

IHE Devices Profiles:
- ACM  Alert Communication Mgmt.
- IPEC  Infusion Pump Event Comm.

ISO/IEC Standards
- 60601-1-8 MedDev Alarm Systems
- 14972  MedDev Risk Management
- 80001-1 Safe, Effective & Secure (SES) Risk Management
So many SDOs ... so many standards!!!

And have consistent / harmonized semantic elements:

Source: ISO/IEEE 11073-10207
Gemini SES MDI – IHE Catalyst Study Project

ISO/IEEE 11073 SDC + Gemini SDC/SDPi+FHIR
Alert Signal Distribution
Combining IEEE 11073 SDC & IHE PCD ACM

IEEE 11073 SDC
- Patient Monitoring
- Ventilation

IHE PCD ACM
- PCD-04/05
- PCD-06/07

Gateway
- Alert Consumer
- Alert Reporter
- Alert Manager
- Alert Communicator

HL7 V2 Messaging w/ ISO/IEEE 11073 Semantics

Distributed Alarm “Information” System (DIS)
SDC & Silent ICU Use Case Narrative ...

SILENT ICU BY ALARM SIGNAL DELEGATION

Today

Tomorrow

Reduction of alarms

Alarm Distribution

~ 80 - 95 % clinically irrelevant

up to 40 min. to alarm confirmation

50 % are not noticed

~ 40 different sounds in one ICU

road to
1 alarming device per patient

Gemini SES MDI – IHE Catalyst Study Project

HIMSS ‘20
1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.

2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.

3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.

4. The alarm producer has to be able to observe that the **alert is generated correctly**.

*Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC“, Kasparick et al.*
Integration of Device Alarm Systems

Gemini program pushing from “quiet” hospital solutions to Silent ICU & Smart Alarm Systems

For more background see: Topic: DAS + Smart Alerting Challenges
Gemini SES+MDI – Reducing Alert Fatigue –

Introducing: FHIR DeviceAlert

FHIR brings some excellent out-of-the-box capabilities to enable insightful improvements in the environment of care and reduce clinician fatigue, but it has to build on top of the pre-existing rich ecosystem of device alerting standards and technologies. Enter: FHIR DeviceAlert resource project ...
What about HL7 FHIR & Device Alerting?

HL7 Project PSS-2005 recently approved to craft a new purpose-built FHIR Resource: DeviceAlert

Resource will be …
✓ Consistent with existing device alert informatics standards and technologies
✓ Focus will be on alert information logging vs. real-time communication (DIS/DAS)
✓ Enabler of analysis, analytics, environment of care re-engineering, ...

Improving patient safety, quality of care and ... reducing clinician alarm fatigue!

See Draft Proposed FHIR Resource: DeviceAlert
See also Devices on FHIR confluence site
Gemini SES+MDI – Reducing Alert Fatigue –

Understanding & Addressing Fatigue

Informatics standards and technology is needed, but too often what is delivered is either off target, not helpful or useful, too complicated, too simplistic … what is the “sweet spot” between the bare minimum and comprehensive “kitchen sink” alert information? What will enable genuine improvements in quality of care and reduction of clinician alert fatigue?
Acute Care MDI – *Today’s Reality!*

The Value of MDI?

THE VALUE OF MEDICAL DEVICE INTEROPERABILITY:

Improving patient care with more than $30 billion in annual health care savings

@westhealth | #interoperability  westhealth.org
Updated Value of MDI Study

### USE CASES

| Isolation Room | 65% | 1 |
| Digital Charting | 47% | 2 |
| Ward Round Pol | 44% | 3 |
| Quiet ICU Ward | 41% | 4 |
| Integrated UI | 41% | 5 |
| Surgical Display | 31% | 6 |
| Spotcheck Monitoring | 27% | 7 |
| Automated OR Setup | 22% | 8 |
| Service – Predictive Maintenance | 18% | 9 |
| Physiological Closed Loop Control | 17% | 10 |
| Central Patient Watch | 15% | 11 |
| Intra Hospital Transport Monitor | 12% | 12 |
| Service – Biomed Notification | 9% | 13 |
| Treatment Recommendation | 6% | 14 |
| Augmented Surgical Display | 3% | 15 |
| Personal Health Integration | 0% | 16 |
| Safety Interlock | 4% | 17 |
| Dual Bedside Display & Control | -11% | 18 |
| Benchmark Therapy | -18% | 19 |

### USE CASES

- Maintain your value products
- Create a product

### THE REAL VALUE OF MEDICAL DEVICE INTEROPERABILITY IN HOSPITALS

Medical Device Interoperability (MDI) is one of the most relevant technology trends in the development of medical devices. As the result of a study conducted with more than 230 participants from the main areas of patient care in hospitals, we summarize which MDI use cases are valued most by both medical technology manufacturers and especially the previously neglected perspective of healthcare professionals. We also provide valuable recommendations for the future direction of MDI development.
Getting “Reducing Alarm Fatigue” … right!

Standards and technology abound and are evolving … hopefully progressing!

But some major questions remain, including:

What should be included in a FHIR server-based alert/alarm log beyond

Basic minimum data
and

Kitchen Sink “full disclosure”

What else should be considered and supported by informatics standards & technologies?
IHE-HL7 Gemini SES+MDI – Device Alerting & Reducing Clinician Alert Fatigue

2022.07.25