U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Common Device Connectivity

AHIC Extension/Gap

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1.0   Preface and Introduction

1.1   Background

In April and June of 2008, the American Health Information Community (AHIC) approved a recommendation to develop documents that address extensions/gaps from the use cases published between 2006 and 2008. One of the extensions/gaps prioritized for subsequent processing in the national health agenda activities in 2009 was Common Device Connectivity. AHIC specifically requested that the 2009 Common Device Connectivity Extension/Gap address the electronic exchange of information from high-acuity and inpatient diagnostic/therapeutic medical devices (e.g., physiological monitors, infusion pumps, ventilators, glucometers, blood pressure cuffs, and other devices) into Electronic Health Records (EHRs) and other systems.

This extension/gap document is being developed by the Office of the National Coordinator for Health Information Technology (ONC) to represent AHIC priorities and provide context for the national health agenda activities, beginning with the selection of harmonized standards by the Healthcare Information Technology Standards Panel (HITSP). Components that need to be considered during the standards identification and harmonization activities include standardized vocabulary, data elements, datasets, and technical standards that support the information needs and processes of the consulting clinicians and clinicians receiving patients from other care settings or organizations. This document is the Final AHIC Extension/Gap. Feedback received on the AHIC Extension/Gap has been considered and incorporated into this document where applicable. HITSP has the opportunity to reuse standards, where applicable, from those previously recognized by the Secretary of Health and Human Services, to specify and constrain how they are to be used to advance interoperability and to work with standards development organizations to see that gaps in standards are filled.

1.2   Progress to Date

To date, the national health agenda, including AHIC and HITSP activities, has not formally addressed the interoperability considerations for connectivity between medical devices and EHRs.

Previously published AHIC use cases incorporate several concepts that have been evaluated by HITSP and could be leveraged during standards harmonization for this extension/gap.

- The 2008 Remote Monitoring Use Case includes the need for communicating remote monitoring information from an ambulatory setting, including physiological, diagnostic, medication tracking, and activities of daily living (ADL) measurements, to a clinician's EHR or a patient's Personal Health Record (PHR) for management of chronic health problems, new conditions, or maintaining wellness.

2.0   Overview and Scope

2.1   Document/Request Overview

This extension/gap document is focused on information needs to facilitate the electronic exchange of clinical device information. The 2009 Common Device Connectivity Extension/Gap document is divided into the following sections:

- Section 1.0, Preface and Introduction, describes the progress to date, the additional priorities identified by the AHIC, the resulting extensions/gaps, and their purpose;

- Section 2.0, Overview and Scope, describes the sections of an extension/gap document, the request being made to HITSP, and the scope of that request;

- Section 3.0, Functional Needs, describes the combination of end-user needs and system behaviors which support interoperability and information exchange;

- Section 4.0, Stakeholder Communities, describes individuals and organizations that participate in activities described in this extension/gap;

- Section 5.0, Issues and Obstacles, describes issues and obstacles that may need to be planned for, addressed, or resolved to achieve the capabilities described in the extension/gap;

- Section 6.0, References to Use Case Scenarios, describes various scenarios and information exchanges that assist in the communication of information. Scenarios may re-used from previously published 2006 – 2008 Use Cases and/or new scenarios may be described;

- Section 7.0, Information Exchange, describes information exchange capabilities that are needed to support the scenarios and the high-level role of information exchange;

- Section 8.0, Dataset Considerations, identifies specific information opportunities relevant to this extension/gap document that may support future identification, development, and harmonization of standards;

- Appendix A, Glossary, provides contextual descriptions of key concepts and terms introduced in this extension/gap document; and

- Appendix B, Analysis and Examples, identifies specific data types, datasets, data elements, vocabularies, naming conventions, capabilities, and technical standards which may support future industry efforts in the identification, development, and harmonization of standards.

2.2 Scope

Common device connectivity is the means by which high-acuity and inpatient clinical device information such as settings, measurements, and monitoring values are communicated to and from EHR and other specialized clinical information systems. Examples of devices include hemodynamic monitors, ventilators, anesthesia monitors, and infusion pumps. Radiological devices are not considered in scope for this extension/gap.

Therefore, the requirements for 2009 Common Device Connectivity Extension/Gap can be summarized as:

- The ability to communicate high-acuity and inpatient multi and single parameter device information to and from an EHR and other specialized clinical information systems via direct network connections and wireless networking within an organization.

The identification, development, and harmonization of standards to support the interoperability associated with communication of device information to EHRs is progressing but will require additional work with standards and professional organizations, care delivery organizations, and organizations providing information technology services and products to the healthcare industry. As mentioned in Section 1.0, the needs expressed here have not yet been fully addressed by the national health agenda's standardization efforts. Examples of gaps in industry standards are outlined in the upcoming sections of this extension/gap document.

3.0   Functional Needs

This section describes a combination of end-user needs and system behaviors to support the exchange of information between medical devices and EHRs. Support for this exchange includes the development of interoperability standards for vocabularies, data elements, datasets, and other technical components that are implicit in these functional needs. Rather than an all-inclusive list of functional requirements, key capabilities are outlined below. The descriptions in this section are not intended to prescribe policy nor propose architectures required to implement capabilities.

A. The ability to configure and register a device to communicate with an EHR or other system.

   i. When a device is set up within an organization to communicate measurement information, the device is configured and registered within the organization's electronic health record to uniquely identify the device and enable connectivity between the device and system.

B. The ability to associate patient identification and device information within an EHR.

   i. Patient registration, location, and identification information available within the EHR is uniquely associated with the patient's monitoring device using standardized mechanisms for admission, transfer, and discharge from beds, units, wards, and entities within the facility.

   ii. In the event patient identification information is associated with a device in error, the device can be disassociated with the current patient within the EHR and associated with the correct patient.

   iii. A patient may be placed on a monitoring device prior to the completion of patient registration or the availability of patient identification information within the EHR, especially in emergent or critical situations. The measurement information is available in the EHR upon initiation of the monitoring function or medical device initiation, and can be reconciled with patient registration or patient identification information within the EHR when available. Data collected prior to patient registration should be buffered and retained for a reasonable period of time sufficient to complete the registration process.

   iv. Organizational policies and procedures may require medical device measurement values within a patient's record to be validated by a licensed clinician prior to being stored within a patient's record. This function may prevent the charting of erroneous values within a patient's permanent medical record.

C. The ability to communicate detailed measurement information to the EHR for effective patient monitoring and management.

    i.   Measurement and device information generated by the medical device is communicated to the EHR. Measurement information such as device settings, parameters, values, and units may be utilized by the EHR and/or clinical decision support (CDS) systems to support patient management.

    ii.   The devices should communicate state, error conditions, and user selections to support the analysis of adverse events.

D. The ability to support point-of-care integration to uniquely identify a device and related components, communicate device setting and detailed device information, associated with each measurement value, to the EHR.

    i.   When a patient device is replaced by another device of the same type, measurement information may seamlessly populate the EHR. The devices may be from different manufacturers, but communicate the same information to the EHR. The EHR recognizes the measurement parameters and is able to represent the measurement values consistently within the EHR. Device information, settings, and metadata specific to each device is associated with each measurement value and is accessible within the EHR. This is accomplished via a standards-based first communication link interface between the point-of-care device and the EHR, device intermediary, or device gateway."

    ii.   A patient may be placed on multiple monitoring and patient care devices that need to be associated with the patient within the EHR. When multiple devices are capturing the same measurement or monitoring parameter, the information available within the EHR enables clinicians to distinguish between the measurements and determine the measurements that are captured from each device.

    iii.   Device data should be uniquely associated with the device, the patient, and the date and time the data was acquired, sent, and received.

E. The ability to communicate measurement intervals and device setting information within the EHR.

    i.   When a patient is placed on a medical device, the clinician's order details may specify measurement intervals for patient information to be communicated to the EHR.

    ii.   Depending upon patient acuity and monitoring needs, measurement intervals may need to be modified during the course of patient care. A clinician may

modify the measurement parameters and intervals via the EHR or by modifying the device directly. Measurement interval information is communicated from the device to the EHR so the clinician may access this information.

iii. Inbound device settings and controls from the EHR may be subject to clinical oversight, validation and verification at the point of care prior to execution on the instrument itself.

iv. Measurement intervals are reconciled against the system time available from the EHR to ensure consistent and accurate identification of time intervals and absolute time.

v. The communication of multiple interval types should be supported (e.g. episodic, regular, quasi-continuous, sampled waveform, continuous waveform).

F. The ability to query the device or device intermediary for additional information captured by the device that may not have been communicated to the EHR.

i. A clinician may request certain intervals for viewing device measurements or information within the EHR. If a patient event occurs that requires further investigation, the clinician may utilize the EHR to query for additional retrospective device information or measurement details that were not initially communicated to the EHR based upon the data intervals set for the patient.

G. The ability to communicate device and measurement information to the EHR when there is a lapse in EHR connectivity.

i. If a break in network connectivity occurs, or other factors prevent device communication to the EHR, device and measurement information is communicated to the EHR when connectivity is restored. Upon establishing or re-establishing this connectivity, there is no loss of measurement information in the EHR. In addition, details associated with measurement or device settings are communicated with the appropriate timestamp and patient parameters (e.g., identification, device settings) present at the time of information capture at the device.

ii. A notification may be sent to the EHR notifying of the event in which data transmission or communications are lost between the EHR and medical device. This notification consists of a standard health and status message that confirms device connectivity and general operation.

H. The ability to communicate standardized alarm types and alarm violation types to the EHR in near real-time.

    i.   If a medical device generates an alarm, the alarm information and details are communicated to the EHR in time to support clinician life support efforts and critical care activities. Both text-based and audible alarm information should be communicated. For example, when a clinician or patient modifies device settings such as patient-controlled analgesics that are out of range and generates an alarm, the alarm and associated device details are communicated to the EHR.

I.   The ability to set and communicate limits and safeguards for device settings from the EHR to a device.

    i.   Evidence-based guidelines or clinician preferences for device parameters or alarms may be communicated from the EHR or other systems to the device. For example, this would enable an infusion pump to be interrupted or paused based upon EHR information or decision-support information. Interrupts and pauses are not intended to be or imply closed loop control.

J.   The ability to wirelessly communicate point of care device information from the device to a device intermediary or EHR.

    i.   Wireless communication of high-acuity and inpatient medical device information may require specifications for wireless networking that supports the critical nature of this information and can co-exist with other medical devices and wireless applications.

4.0   Stakeholder Communities

Examples of stakeholders who may be directly or indirectly involved in the exchange of clinical device information have been listed below. Specific descriptions of each type of stakeholder can be found in the previous 2006 – 2008 AHIC Use Cases.

Stakeholders that may be directly involved in the exchange of clinical device information may include: Clinical Support Staff, Clinicians, and Patients.

Stakeholders that may assist in clinical device information communication may include: Decision Support Tool Suppliers, Device Data Intermediary Suppliers, Device Manufacturers, EHR System Suppliers, Organizational Support Staff (such as Biomedical Engineering, Clinical Engineering or Information Technology staff), and organizations managing devices, EHRs, and clinical information systems for or within a high-acuity or inpatient facility.

Stakeholders that may be sources or recipients of clinical device information may include: Clinicians, Clinical Support Staff, Patients, Consumers, and Regulatory Agencies.

5.0   Issues and Obstacles

A number of issues in today's health information technology environment are obstacles to achieving the healthcare data standardization and interoperability to promote patient safety, reduce healthcare costs, and increase the value of electronic health information exchange. Some general issues were described within the 2006 – 2008 AHIC Use Cases. Examples of specific issues and obstacles related to Common Device Connectivity are outlined below.

    A. Regulated Medical Devices:

       i. Software, device intermediaries, and devices described in this extension/gap may at times be considered regulated medical devices.

          a. Electronic health record system suppliers, device manufacturers, software intermediaries, and other providers of Medical Device Data Systems (MDDS) may need to consider Food and Drug Administration (FDA) regulations to provide common device connectivity.

          b. Capabilities that include, but are not limited to, providing decision support functions, modifying device settings, and providing real-time, active, or online patient monitoring functions may need to follow regulations for Class III regulated medical devices.

    B. Patient Identification:

       i. In order to effectively exchange medical device information, systems need to be capable of uniquely associating a medical device with an organization's patient identification information.

    C. Device Data Storage:

       i. Some devices do not currently archive information in a format, or for a length of time, that will permit captured or retrospective device information to be queried or forwarded if that data was not originally communicated.

       ii. Devices are capable of generating significant information in excess of the information that may be reviewed for routine clinical activities. Organizational policies regarding the retention of information communicated by a device that is not validated/documented by a clinician in the patient's chart need to be considered.

          a. Without organizational policies for storage of device information, data storage needs may exceed device, EHR, or other organizational data storage capabilities, or be purged prematurely.

D. Device Data Standardization:

i. Currently, a standardized nomenclature for describing devices and data has not been harmonized. Additional standards activities are needed to support common device connectivity for high-acuity and inpatient environments that support a nomenclature for both device classes and individual devices.

   a. Devices of a similar class may not have comparable data models. Reconciliation between data models across similar classes of devices is needed prior to transmission.

   b. Data outputs from devices should also be standardized so widespread use of devices and their data streams is possible with minimal customization of supporting systems.

   c. Nomenclature standardization may occur through existing instrument gateways to provide an intermediate and standardized function of translating proprietary data into a standardized format.

ii. Standards development efforts are needed to develop uniform mechanisms to communicate device-generated information. Device information from various manufacturers and intermediaries need to utilize interoperable data, including the terminology for device types, measurement parameters, and units of measure to prevent inaccurate or conflicting clinical results.

   a. Without standardization of device information, common device connectivity to EHRs may be limited because of the segmentation among technology suppliers (brands) and safety risks of errors resulting from different terminologies or standards.

   b. Without standardization of device information, EHRs and clinical decision support capabilities may be limited due to varying terminologies for measurement parameters and/or values.

iii. Device information may need to adhere to device reporting requirements that enable the communication of device identification information to the clinician for complete disclosure.

   a. Without standardization of device identification, the ability to adhere to device reporting requirements may be limited.

iv. Device information could be utilized by EHRs and other applications for secondary uses such as research, device safety, and recall needs. This secondary use of

information should be managed to allow for appropriate approvals. Standards for these secondary uses do not exist.

    a. Without harmonized standards for unique device identification, secondary uses of remote monitoring information may be limited.

v. Specific patient populations may need technical and standards considerations to support the need of the population.

    a. There are a variety of technical considerations for common device connectivity to support neonatal or pediatric care, shock/trauma, care of morbidly obese adults, and frail elderly populations.

    b. It may be difficult to develop standards to support some small segments of the patient population with information needs that apply specifically to their populations and are not universally applicable.

E. Device Interface Standardization:

i. Additional standard activities are needed to identify interface specifications for communicating information from common device types.

    a. A standardized device connectivity interface for commonly used devices with determinations regarding the detail, structure, and quantity of patient information to be stored may not exist between devices and EHRs, limiting widespread adoption due to the complexity and costs of device to EHR integration.

    b. Legacy devices may require the use of device intermediaries or may not capture the detailed information contained within interoperability specifications. The ability for legacy medical devices to communicate standardized information to EHRs and other systems may be limited.

F. Legal Medical Record:

i. Regulatory and process considerations regarding device information that may be communicated from the device to the EHR, but has not been validated by a clinician need to be considered.

    a. Without clarity about the scope of the medical/legal liabilities and the legal medical record associated with common device connectivity, particularly as it relates to measurements and device information that is not accompanied by a validation or attestation step by a medical professional, adoption of common device connectivity by clinicians may be limited.

b. Clinicians may want to receive notification and choose whether to chart or document device-generated information within the medical record. Examples include alarms or incorrect readings that may routinely occur such as monitors detaching or loosening from the patient where measurement values may be out of range but may not require clinical documentation associated with the value, as the measurement may not be a validated value.

G. Information Integrity, Interoperability, and Exchange:

i. Incomplete, inaccurate, or proprietarily-formatted information prevents efficient device connectivity and utilization of electronic health information.

a. Without data standards that promote compatibility and interoperability, information reported to patient medical records may be inaccurate and / or incomplete.

H. Wireless Communications:

i. Additional standards activities may be required to support wireless communication of medical device information in a reliable and effective manner.

a. Interoperability specifications for wireless communication of device information and measurements may require privacy and security considerations.

b. Without standards that support the communication of information regarding signal interruptions, clinicians may experience loss of data or be unaware of loss of data received from a medical device.

c. Wireless communications mechanisms for medical device information must support the co-existence of multiple wireless devices and other applications without electrical interference.

6.0   References to Prior Use Case Scenarios

The 2009 Common Device Connectivity Extension/Gap Document focuses on the communication of device information to EHRs. Specific events and information exchanges have been selected from previous use cases for contextual purposes.
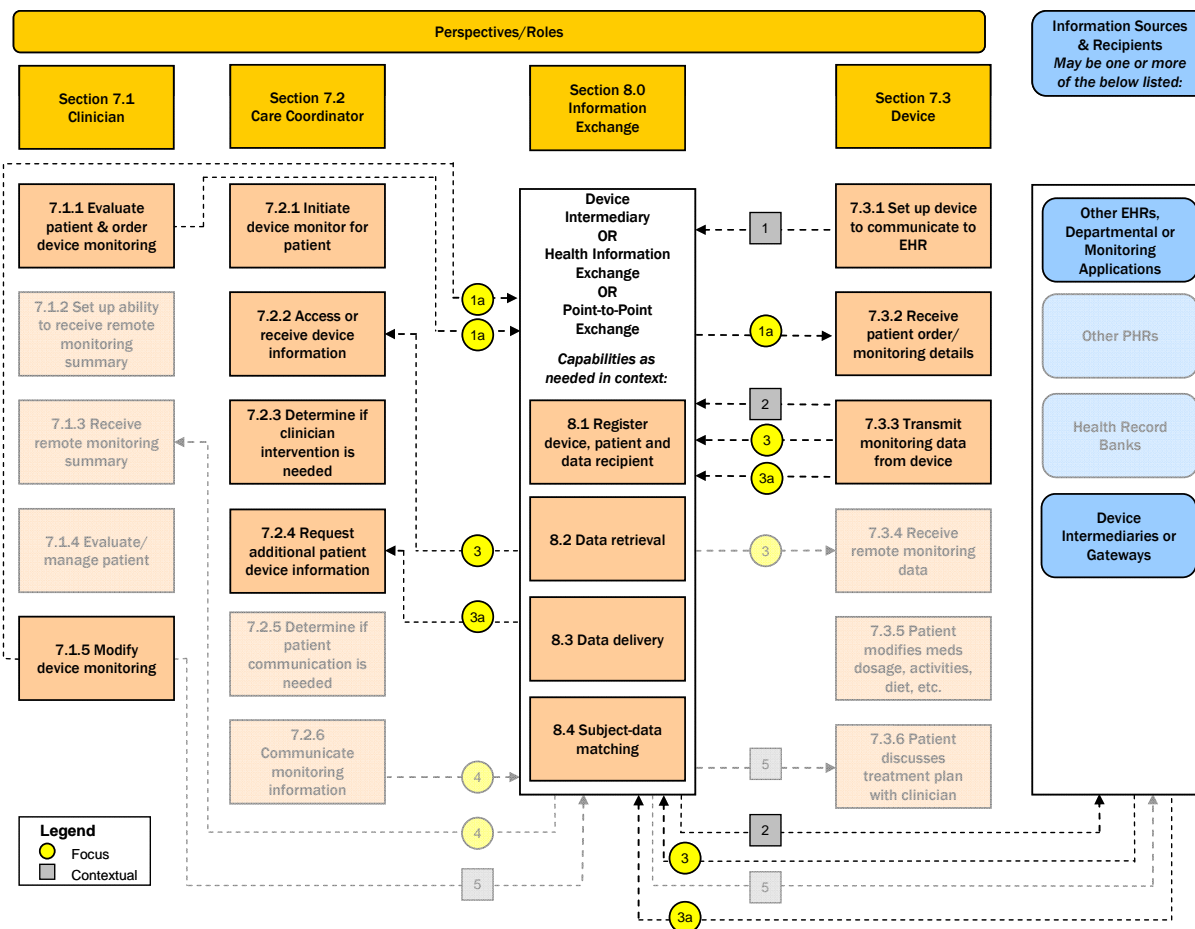
The 2008 Remote Monitoring Use Case describes the communication of remote monitoring information to EHRs and PHRs.

The events and information flows which are pertinent to the 2009 Common Device Connectivity Extension/Gap are shown in bold. All other events and information flows have been faded out.

6.1 Reference to Prior Use Case: 2008 Remote Monitoring

Figure 6-1. Communication of Remote Monitoring Information to EHR or PHR

In 2008 Remote Monitoring Use Case Event 7.3.1, the event to obtain and set up the device is conducted by the patient. When addressing common device connectivity, device registration may be initiated by Biomedical Engineering, IT staff, or other staff, and the initiation of a patient device is completed by a care coordinator. Therefore, information flow 1 should be referenced and considered an in focus information flow when addressing Common Device Connectivity.

Events 7.1.1, 7.1.5, and 7.3.2 represent the clinician order or device setting details to the device for communication of measurement intervals and device setting information. This information may also include the communication of limits and safeguards for device settings. Information flow 1a should be considered an in focus information flow when addressing common device connectivity.

As expressed in Events 7.3.3 and 7.2.2, the device information, such as monitoring data or alarms, is transmitted and communicated from the patient device to the care coordinator.

Therefore, Information flows 2 and 3 should be referenced and considered an in focus information flow when addressing common device connectivity.

Event 7.2.4 represents the request and communication of additional device information that may have been captured by the device, but not communicated to the care coordinator in the previous events. Information flow 3a should be considered an in focus information flow when addressing common device connectivity.

7.0   Information Exchange

The information exchange requirements for the effective selection and communication of common device information may comprise:

- The ability to communicate and associate device and patient information to an electronic health record (EHR);

- The ability to communicate device setting and measurement information to the EHR for effective patient monitoring and management;

- The ability to communicate and manage measurement intervals and device setting information within the EHR;

- The ability to query for additional device information captured by the device that may not have been communicated to the EHR;

- The ability to communicate measurement information to the EHR when there is a lapse in EHR connectivity;

- The ability to communicate standardized alarm types and alarm violation types to the EHR;

- The ability to set and communicate limits and safeguards for device settings from the EHR to a device; and

- The ability to wirelessly communicate point of care device information from the device to a device intermediary or EHR.

Examples of information exchange capabilities described above and in Section 3.0 may include: Registration of a Device, Patient, and Data Recipient; Data Retrieval; Data Delivery; and Subject Data Matching. Descriptions of each of these are in the previous 2006 – 2008 AHIC Use Cases.

The functional capabilities may be provided fully or partially provided by a variety of organizations including: health information exchange organizations, integrated care delivery networks, provider organizations, health record banks, specialty networks, and others.

While not described in this section, device intermediary, Health Information Exchange (HIE), Point-to-Point exchanges, or specialty network exchanges may assist in the completion of the processes described in this extension/gap. Examples of these exchanges can be found in the previous 2006 – 2008 AHIC Use Cases.

8.0   Common Device Connectivity Dataset Considerations

The following non-exhaustive information categories and limited examples illustrate some of the information needs from this extension/gap document. Examples of common device information are included in Appendix B.

To date, there is no harmonized dataset associated with the communication of common device information to EHRs. Device information communicated to EHRs could include raw data, intervals of raw data, alert information, device setting information, device identification information, device summary information, and device intermediary or interface information.

A. **Device Identification/Registration Data —** Information that assists in the communication and registration of a device within an EHR. This may include: unique device identification, device type, brand, serial number, manufacturer, and device intermediary information.

B. **Patient Identification and Device Association Data —** Information that assists in the communication and coordination of patient and device identifying information within an EHR. This may include patient identification information, patient location, device identification information, and clinician information.

C. **Device Types and Modules —** Information that assists in the identification of clinical devices, components, and associated management interfaces. Standards harmonization is needed to identify device types, particularly where multiple device types may be capturing the same measurement value or parameter. Device types may include: anesthesia monitors, hemodynamic monitors, therapeutic devices (e.g. infusion pumps, dialysis machines, heart lung bypass machines), ventilators, and vital signs monitors.

D. **Measurement/Monitoring Parameters —** Information that assists in the identification of measurement, monitoring, or setting parameters that may be generated by a clinical device. Standards harmonization is needed to identify measurement parameters that may enable use of device information in EHRs and clinical decision support applications. Examples of parameters include blood glucose, blood pressure, heart rate, and temperature.

E. **Measurement Details —** Information that may accompany a device parameter or measurement that includes patient identification, clinician identification, device setting, user-interaction, measurement interval, units, and error/calibration details.

F. **Alarm and Alert Types —** Details indicating alarms as well as alert types (alert levels) that may be generated by a device when a device setting or measurement value is out of range or identifies a change in trend.

Appendix A: Glossary

The 2006 – 2008 AHIC Use Cases contained general terms and their contextual descriptions. Listed below are the new terms that are specific to this extension/gap.

Clinical Support Staff: Individuals who support the workflow of clinicians.

Clinicians: Clinicians are healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, psychologists, pharmacists, dentists, oral surgeons, therapists, and other licensed and credentialed personnel involved in treating patients

Device Module: A device that may be associated and used in conjunction with another device to enable operation. Examples of device modules are the multiple modules that can be used within anesthesia carts for patient monitoring, such as anesthetic gas, pulse oximetry (SpO2), spirometry, and others.

Device Parameter: A measurement type generated by a device that may be communicated to an EHR, such as peripheral oxygen saturation (SpO2), venous oxygen saturation (SvO2), non-invasive blood pressure (NIBP), and others.

Patients: Members of the public who receive healthcare services.

Appendix B: Analysis and Examples

Multiple industry efforts are currently in progress to identify integration specifications and datasets to communicate common device information. An analysis of the dataset and examples of dataset considerations is included here. The information, datasets, and examples are intended to serve as examples and do not constitute a comprehensive set of common device connectivity information. These examples are not intended to be inclusive of all activities in this area.

Device connectivity standardization efforts have been initiated or are in progress among organizations such as Integrating the Healthcare Enterprise's (IHE) Patient Care Devices (PCD) Technical Committee and the Continua Health Alliance. The Healthcare Information Technology Standards Panel (HITSP) has initiated activities for remote monitoring associated with the 2008 AHIC Remote Monitoring Use Case that may have applicability to this extension/gap.

A coordinated effort that facilitates collaboration and participation from the private and public sectors, including healthcare organizations, clinical stakeholders, and standards development organizations (SDOs) is needed to select standards, identify gaps, and drive standards development and selection for gap areas. Standards and implementation guides identified in relation to common device connectivity include SNOMED, ISO/IEEE 11073 (MDC), LOINC, and the IHE PCD Technical Framework.

The following non-exhaustive information categories and limited examples are provided as background information for future standards efforts to provide direction on information needs for common device connectivity:

Device Identification/Registration Data– Information that assists in the communication and registration of a device within an EHR.	
A.1.	Device Identifier (Device Type, Brand, Serial Number, Date of Manufacture, Location of Assembly)
A.2.	Other Identifying Information – Device Manufacturer or Intermediary
Patient Identification and Device Association Data – Information that assists in the communication and coordination of patient and device identifying information within an EHR.	
B.1.	Patient Identification Information
B.2.	Patient Location
B.3.	Clinician Identification

Device Types and Modules — Information that assists in the identification of clinical devices, components, and associated interfaces.   Standards harmonization is needed to identify device types, particularly where multiple device types may be capturing the same measurement value or parameter.

C.1.	Airway
C.2.	Anesthesia Machine
C.3.	Hemodynamic Monitor
C.4.	Intracardiac Monitor
C.5.	Medication Infusion Device
C.6.	Modules for Anesthesia Machine (Various)
C.7.	Pulmonary Artery (PA) Catheter
C.8.	Patient Controlled Analgesia (PCA) Pump
C.9.	Suction
C.10.	Ventilator
C.11.	Vital Signs Monitors (Various)

Measurement/Monitoring Parameters — Information that assists in the identification of measurement, monitoring, or settings parameters that may be generated by a clinical device. Standards harmonization is needed to identify measurement parameters that may enable use of device information in EHRs and clinical decision support applications. Examples are provided below.

D.1.	Vital Signs
	
	    o Blood Gas
	
	    o Blood Pressure – Diastolic, Systolic, Mean, Wedge
	
	        o Unspecified
	
	        o Non-invasive
	
	        o Invasive
	
	            o Arterial

		- Central Venous - Left Atrial - Pulmonary Arterial - Pulmonary Capillary Systemic - Right Atrial - Umbilical Venous ○ Pulse Oximetry Peripheral Heart Rate ○ Respiratory Rate ○ Temperature (Temp) - Airway Temp - Arterial Temp - Core (Body) Temp - Esophageal Temp - Injectate Temp - Nasopharyngial Temp - Rectal Temp - Skin Temp - Unspecified Temp - Venous Temp
D.2.		Pulmonary Artery (PA) Catheter ○ Cardiac Output ○ Pulmonary Artery Systolic Pressure ○ Pulmonary Artery Diastolic Pressure

		o Mean Arterial Pressure (MAP)
D.3.	Hemodynamic Monitoring	
		o Arterial Oxygen Content (CaO2)
		o Arterial Oxygen Pressure (PaO2)
		o Arterial Oxygen Saturation (SaO2)
		o Arterial Oxygen Saturation (SpO2)
		o Arterial-Venous Oxygen Difference (a-vO2)
		o Body Surface Area (BSA)
		o Cardiac Index (CI)
		o Cardiac Output (C)
		o Cardiac Output Average
		o Continuous Cardiac Output
		o Coronary Perfusion Pressure (CPP)
		o Ejection Fraction (EF)
		o End Diastolic Volume
		o End Diastolic Volume Index
		o End Systolic Volume
		o End Systolic Volume Index
		o End Tidal CO2
		o Heart Rate
		o Mean Arterial Pressure (MAP)
		o Mixed Venous Oxygen Pressure (PvO2)
		o Mixed Venous Oxygen Saturation (SvO2)

		o Oxygen Consumption (VO2)
		o Partial Carbon Dioxide Venous (PvCO2)
		o Partial Pressure Carbon Dioxide (pCO2)
		o Partial Pressure Oxygen (pO2)
		o Pulmonary Capillary Wedge Pressure (PCWP)
		o Regional Oxygen Saturation
		o Stroke Volume
		o Stroke Volume Indexed
		o Systemic Vascular Resistance
		o Systemic Vascular Resistance Indexed
		o Total Pulmonary Resistance
		o Venous Oxygen Content (CvO2)
D.4.		Ventilator Modes o Assist-Control Ventilation (A/C) o Constant Positive Airway Pressure (CPAP) o Control Ventilation (CV) o High Frequency Ventilation (HFV) o Independent Lung Ventilation (ILV) o Inverse Ratio Ventilation (IRV) o Positive End Expiratory Pressure (PEEP) o Pressure Support Ventilation (PSV) o Synchronous Intermittent Mandatory Ventilation (SIMV) Ventilator Settings and Parameters

- o   Flow Rate

- o   Flow Trigger

- o   Fractional Inspired Oxygen (Fi02)

- o   Inspiratory to Expiratory Time Ration (I:E Ratio)

- o   Measured Tidal Volume

- o   Peak Pressure

- o   Positive End Expiratory Pressure (PEEP) Pressure

- o   Preset Tidal Volume

- o   Pressure Support

- o   Sensitivity/Trigger

- o   Sigh

Measurement Details – Information that may accompany a device parameter or measurement that includes patient identification, clinician identification, device setting, user-interaction, measurement interval, units, and error/calibration details.

E.1.	Device Identification Information
E.2.	Patient Identification Data
E.3.	Device Type
E.4.	Device Setting Information (May vary across device types)
E.5.	Device Setting Changes or User Interaction ("Keystroke") Information
E.6.	Date/Time of Measurement
E.7.	Measurement Interval
E.8.	Measurement Scale/Units
E.9.	Device Calibration/Programming Data
E.10.	Error Details:

		o Device Malfunction
		o Device not Functioning within Specifications
		o Operator Error During Measurement
		o Measurement Cancelled (Stopped measurement process or marked measurement as invalid)

Alarm and Alert Types – Details indicating alarms as well as alert types (alert levels) that may be generated by a device when a device setting or measurement value is out of range or identifies a change in trend.

F.1.	Ventilator Alarms (safety, warning, caution)
	o Apnea Interval
	o High Oxygen
	o High Peak Inspiratory Pressure (PIP)
	o High Pressure Limit
	o High Respiratory Rate
	o Low CPAP
	o Low Exhaled Minimum Volume
	o Low Exhaled Tidal Volume
	o Low Oxygen
	o Low Peak Inspiratory Pressure (PIP)
	o Low PEEP
	o Low Pressure Limit
	o Maximum Airway Pressure (Paw) Exceeded
	o Minimum Airway Pressure (Paw) Exceeded
	o Minute Volume High
	o Minute Volume Low
	o Minimum Minute Ventilation

F.2.	Other Alert Types:

> o   Hemodynamic Monitoring Alarms
>
> o   Electorcardiographic Alarms (e.g. ST segment changes)
>
> o   Infusion Pump Alarms
>
> o   Mechanical Ventilation Alarms

Other Sample Alarm Types for Device Function:

> o   Air in Line
>
> o   Bag Empty
>
> o   Device Malfunction
>
> o   Door Open
>
> o   Low Battery
>
> o   Low Flow
>
> o   Occlusion
>
> o   Programming Error
>
> o   Pump on Hold
>
> o   Set Loading Error