U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Common Device Connectivity

Draft 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 Common Device Connectivity Extension/Gap address the electronic exchange of information from 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 Office of the National Coordinator for Health Information Technology (ONC) to represent the AHIC priorities and provide context for the national health agenda activities, beginning with the selection of harmonized standards by the Health Information Technology Standards Panel (HITSP) for harmonized standards. Components that need to be considered during the standards identification and harmonization activities include standardized datasets, data elements, vocabularies, naming conventions, capabilities, and technical standards which support the information needs and processes of the consulting clinicians and clinicians receiving patients from other care settings or organizations. During the development of this document, there will be an opportunity for review and feedback by interested stakeholders within both the private and public sectors.

1.2 Progress to Date

To date, the national health agenda, including AHIC and HITSP activities, has not fully addressed the interoperability requirements for connectivity between 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 describes 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 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 clinical device information such as settings, measurements, and monitoring values are communicated to an EHR. Examples of devices include hemodynamic monitors, ventilators, anesthesia monitors, and infusion pumps. Therefore, requirements for common device connectivity can be summarized as:

- The ability to communicate clinical device information to an EHR.

The identification, development, and harmonization of standards to support communication of device information to EHRs still requires additional work. As mentioned in Section 1.0, these needs 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 needed to support the users during the communication of device measurement information to EHRs. Rather than an all-inclusive list of functional requirements, key capabilities are outlined below with associated functionality. 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 for communicating with an EHR.

   i. When a device is first obtained within an organization, organization-specific device identifiers may be assigned for device management and tracking. The device is configured and registered within the organization's electronic health record to enable unique identification and connectivity between the device and the EHR.

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 associated with the monitoring device to enable capture of measurement information uniquely identified with the patient and medical device. 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.

   ii. 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.

C. The ability to communicate 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. The measurement parameters, values, and units may be utilized by the EHR and/or clinical decision support (CDS) systems to support patient management.

D. The ability 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 associated with each measurement value is accessible within the EHR.

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.

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

i. When a patient is placed on patient monitoring or 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. If device settings or measurement parameters are modified directly on the device, the associated information is communicated to the EHR so the clinician may access this information.

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

i. A clinician may request certain intervals for viewing device 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 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 communication of measurement information 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.

H. The ability to communicate standardized alarm types and alarm violation types to the EHR.

   i. If a medical device generates an alarm, the alarm information and details are communicated to the EHR. 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.

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, and EHR System Suppliers.

Stakeholders that may be sources or recipients of clinical device information may include: Clinicians, Patients, and Consumers.

5.0 Issues and Obstacles

A number of issues in today's health information technology environment are obstacles to achieving the full potential of electronic health information exchange (HIE). 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. Device Data Storage:

i. 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 and duration of storage of device information communicated by a device that are 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.

B. Device Data Standardization:

i. Currently, a standardized nomenclature for describing devices and data has not been harmonized.

   a. 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.

ii. Standards development efforts are needed to develop uniform mechanisms to communicate device-generated information. Device information from various manufacturers and exchanges 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 would entail the ability of the device and information intermediaries to communicate 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 use of secondary 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.

C. 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.

D. 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 needs 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.

6.0 References to Prior Use Case Scenarios

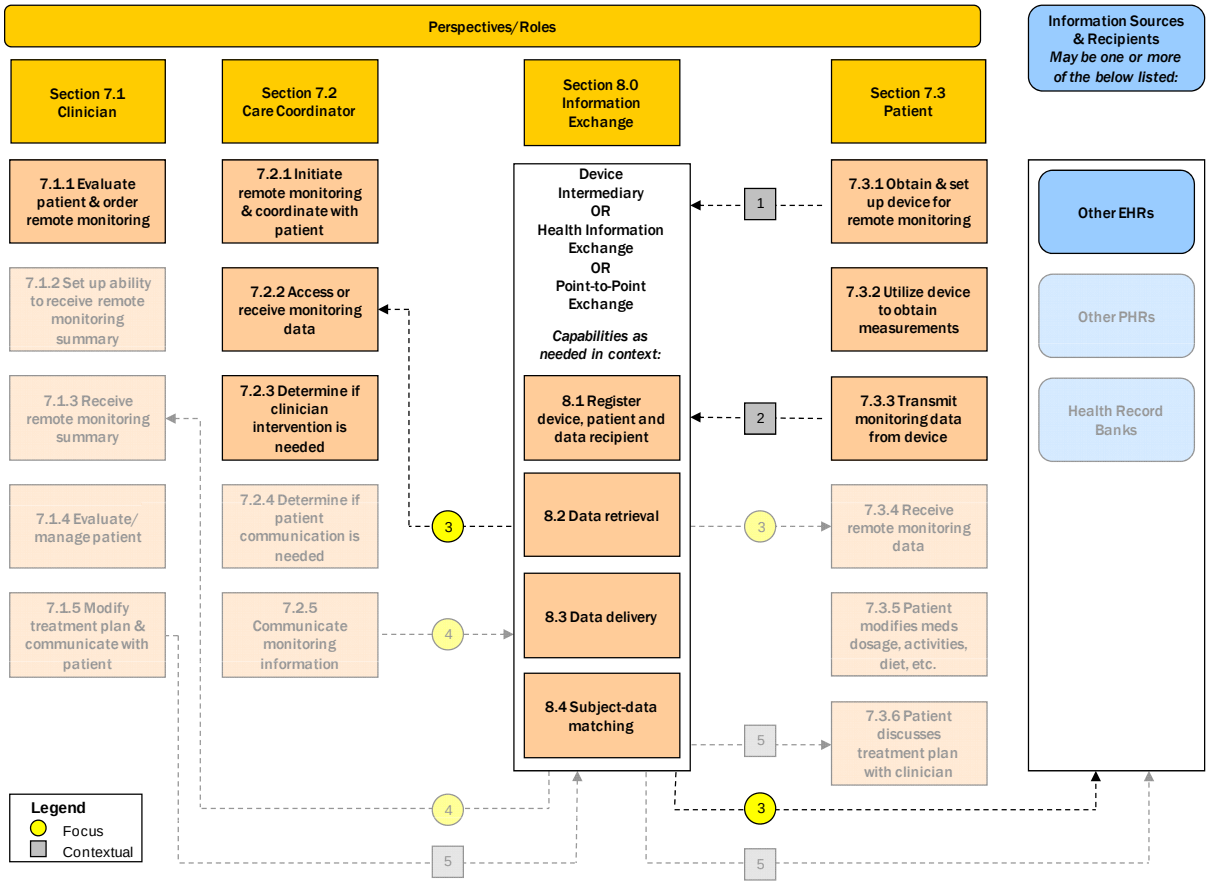
The Common Device Connectivity Extension/Gap Document focuses on the communication of device information to EHRs. Specific events and information exchanges have been selected from previous use cases for contextual purposes.

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 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.

As expressed in Events 7.3.3 and 7.2.2, the device information is transmitted and communicated from the patient device to the care coordinator and incorporated into an EHR. Therefore, information flows 2 and 3 should be referenced and 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; and
- The ability to set and communicate limits and safeguards for device settings from the EHR to a device.

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 by a variety of organizations including: free-standing or geographic health information exchanges (e.g., Regional Health Information 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, 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 of elements 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, and device setting information.

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.

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.

Device Types and Modules – Information that assists in the identification of clinical devices and associated device modules. 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, infusion devices, ventilators, and vital signs monitors.

Measurement/Monitoring Data Types – 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 data types include blood glucose, blood pressure, heart rate, and temperature.

Measurement Metadata – 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.

Alarm and Alert Types – Parameters for 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 a 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.

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

Device Module: A device that may be associated and used in conjunction with another device to enable operation. An example 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.

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. This example and analysis is included for discussion purposes and may or may not be included in the final document.

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 Use Case 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), 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)
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 and associated device modules. 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 Data Types – 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

	o Central Venous o Left Atrial o Pulmonary Arterial o Pulmonary Capillary Systemic o Right Atrial o Umbilical Venous o Pulse Oximetry Peripheral Heart Rate o Respiratory Rate o Temperature (Temp) o Airway Temp o Arterial Temp o Core (Body) Temp o Esophageal Temp o Injectate Temp o Nasopharyngial Temp o Rectal Temp o Skin Temp o Unspecified Temp o Venous Temp
D.2.	Pulmonary Artery (PA) Catheter o Cardiac Output o Pulmonary Artery Systolic Pressure o 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 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 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 Metadata – 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 – Parameters for 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 a 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 Sample Alarm Types:

	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