Integrating the Healthcare Enterprise

IHE Patient Care Device
Technical Framework Supplement

Pulse Oximetry Integration
(POI)

Trial Implementation

Date: August 16, 2012
Authors: IHE PCD Technical Committee
Email: pcd@ihe.net

Foreword

This is a supplement to the IHE Patient Care Device Technical Framework V2.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of August 16, 2012 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Patient Care Device Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/pcd/pcdcomments.cfm.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

General information about IHE can be found at: www.ihe.net

Information about the IHE Patient Care Device domain can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

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Introduction to this Supplement

This supplement specifies how implementers could use the existing DEC and PCD-01 transaction to exchange pulse oximetry observation sets with clinical information systems. It constrains the existing transaction to better accommodate the content of pulse oximetry measurement observations.

Pulse oximetry is sometimes referred to as the "fifth vital sign," along with blood pressure, heart rate, temperature and respiration rate. Pulse oximetry is a widely used procedure in many health care settings today. Currently pulse oximeter devices are not capable of sending result measurements using standard-based messaging and terminology. As a consequence, these devices cannot exchange data with clinical information systems, often forcing clinicians to enter pulse oximetry observation sets manually into their clinical information system. This can cause patient safety events due to the lack of timely data and/or transcription errors that could generate incorrect information in the patient chart.

When medical devices and information systems are able to communicate, the devices require adapters and software solutions to enable proprietary device observation sets to be communicated to the enterprise information system used to compile the patient's EHR.

The use of standards and native terminologies would help medical device manufacturers to accelerate the integration of pulse oximetry devices with enterprise systems and would lead to improvements in workflow documentation, and would provide considerable value to clinicians and patients.

This specification is derived from a detailed analysis of the interoperability capabilities that are deemed important to clinicians in order to integrate pulse oximetry observation sets into clinical information systems and is intended to inform device manufacturers. This analysis can also be used by Device Manager systems that are used to augment the interoperability capabilities of today's devices. For example, Device Managers can be used to associate patient identity with device reporting results, convert units of measurement and other coded variables to standard terminologies, and transform proprietary protocols to a standard-based interchange recognized by certified EHR systems.

This document focuses strictly on devices intended to exchange observation sets and alert information with clinical information systems and medical record systems designed to maintain a longitudinal view of patient electronic records.

Out of scope for this specification: pulse oximeter devices that are not capable of information exchange (do not have the ability to export data in a digital form).

Open Issues and Questions

- As soon as they become available from LOINC, the codes corresponding to "Respiration Rate" and "Perfusion Index" will be added to this supplement.
- As soon as it becomes available, implementers could include observations (i.e., OBX segments) corresponding to other types of relevant information about the pulse oximetry

observation set. These may include an identifier for the type of probe used by the operator at the point of care.

- The pilot projects are expected to develop a comprehensive containment tree to be used in OBX-4. For now, this supplements refers implementers to default guidance provide in the IHE PCD Technical Framework.

Closed Issues

This supplement specifies how standard-based terminology can bridge the differences and enable the exchange of medical device data with clinical information systems. The totality of issues resolved and identified during this project is documented in the Pulse Oximetry Integration Requirements Analysis document.

This supplement specifies the use of the PCD-01 transaction to support the needs of pulse oximetry clients as follows:

- In order to specify the clinician at the point of care, field OBR-10 will be populated by a sending system.
- To specify both the local and standard/universal device identifier, field OBX-18 will be populated by a sending system.
- To specify the procedure and mode of operation for the pulse oxmimeter, fields OBR-44 and OBR-45 are available to implementer along with recommended SNOMED-CT codes that are typically recognized by receiving information systems conformant with Meaningful Use criteria for EHR systems as specified in the US.
- In order to specify the signal strength, this supplement recommends the use OBX-9 – Probability as a means of conveying the precision associated with the observation.
- In order to specify whether the observations were validated by the clinician/operator at the point of care, implementers are advised to use OBX-11 field – Observation result status.
- This specification reuses the abnormal flag field (OBX-8) exactly as specified in the IHE PCD Technical Framework in order to convey that measurements could not be acquired from a device. Along with OBX-11it may be used to specify the fact that information is not available.
- The project team confirmed that this specification may be used in a diverse set of situations when continuous or intermittent pulse oximetry measurements are required (e.g., neonatal assessment, critical care assessment, physical examinations).
- The Messaging Workbench profile for this implementation guide is available for unit testing:

http://mdip.wikispaces.com/file/detail/Pulse+Oximetry+Integration+using+PCD-01-ORU_R01.mwb.zip

Volume 3 – Content Modules

This supplement builds on existing integration profiles (i.e., PCD, DEC) and transactions (i.e., PCD-01) and specifies content constrained for exchanging pulse oximetry data in order to best meet the expectations of clinicians.

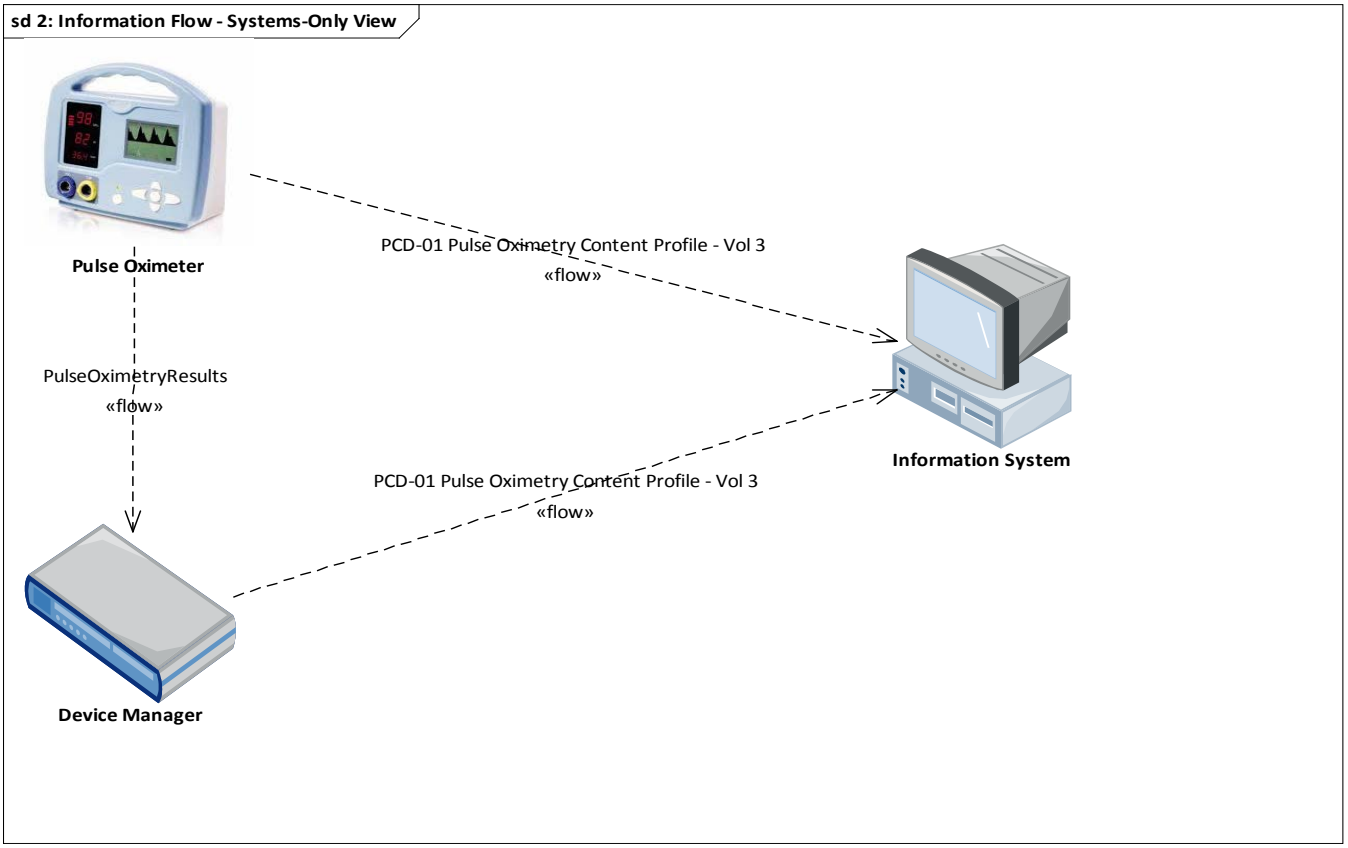

Figure 1: PCD-01 transactions are reused with constraints specific to the pulse oximetry observation sets

1 Pulse Oximetry Integration

The following message specification was auto-generated using the Messaging Workbench tool from a message profile that contains all the data elements intended to be sent by a medical device or a device manager to a clinical information system. It specifies which information is mandatory/required or information that should be part of the transaction if the device or its device manager capture it.

This specification was auto-generated from a standard-based message profile. The comments and annotations included in this specification are those provided by the message profile authors as implementation notes and notes included in the associated Messaging Workbench file.

The following is a sample PCD-01 message exchanging pulse oximetry results with a clinical information system:

```
MSH|^~\&|Pulse_Oximeter_Vendor_X^0123456789ABCDEF^EUI-
64||||20120530112345||ORU^R01^ORU_R01|9879790003|P|2.6|||NE|AL|USA|ASCII|EN^E
nglish ^ISO659||IHE PCD ORU-R01 2006^HL7^2.16.840.1.113883.9.n.m^HL7

PID|1||980980||EVERYPERSON^EVE

PV1|1|I|ICU^2^23

OBR|1|||44616-1^Pulse oximetry panel ^LN|||20120512031234-
05||||||||||||||||F|||||||||||||||||252465000^Pulse
oximetry^SCT|7087005^Intermittent^SCT

NTE|1||This comment refers to all the results in the battery


OBX|1|NM|59408-5^Oxygen saturation in Arterial blood by Pulse
oximetry^LN^150456^MDC_PULS_OXIM_SAT_O2^MDC|1.11.2.1||%^Percent^UCUM|97-
99|NAV|10||X|||20120530112340|||AMEAS^auto-
measurement^MDC|0123456789ABCDEF^Pulse_Oximeter_Vendor_X^0123456789ABCDEF^EUI
-64||49521004^left external ear structure^SCT

NTE|1||Missing results - see abnormal flag for reason


OBX|2|NM|59408-5^Oxygen saturation in Arterial blood by Pulse
oximetry^LN^150456^MDC_PULS_OXIM_SAT_O2^MDC|1.11.2.2|96|%^Percent^UCUM|97-
99|L|99||R|||||AMEAS^auto-
measurement^MDC|20120530112340|0123456789ABCDEF^Pulse_Oximeter_Vendor_X^01234
56789ABCDEF^EUI-64||49521004^left external ear structure^SCT

NTE|1||This is a comment about the oxygen saturation reading


OBX|3|NM|8889-8^Heart Rate by Oximetry^LN^149530^
MDC_PULS_OXIM_PULS_RATE^MDC|1.11.2.3|55|{beats}/min^beats per minute^UCUM|35-
125||99||R|||20120530112340|||AMEAS^auto-
measurement^MDC|0123456789ABCDEF^Pulse_Oximeter_Vendor_X^0123456789ABCDEF^EUI
-64||49521004^left external ear structure^SCT

NTE|1||This is a comment about pulse measurement
```


1.1 Content Profile Overview

Specification Name	*Pulse Oximetry Integration using PCD-01*
Organization	*IHE PCD*
HL7 Version	*2.6*
Application Role	*Sender*
Conformance Type	*Implementable*
Encodings	*ASCII Encoding Rules*
Event Description	*ORU/ACK - Unsolicited transmission of an observation message*
Message Type	*ORU*
Event Type	*R01*
HL7 Message Structure Id	*ORU_R01*
Accept Acknowledgement	*NE – for validated results, ER – for unvalidated results*
Application Acknowledgement	*AL – for validated results, NE – for unvalidated results*

Note: The use of enhanced acknowledgement mode to indicate error (code "ER") has the effect of accelerating the information exchange between the device or its manager and the destination information system.

1.2 Message Syntax

This supplement constrains the PCD-01 transaction profile. The following expressions represent a simplification of the PCD-01 message syntax that focuses on the information elements required for interoperability with a clinical information system.

HL7 syntax expression specifies mandatory, repeated, and optional:

```
MSH,PID,[PV1],OBR,{[NTE]},{[(RESULTS_NOTES)OBX,[NTE]]}
```

The following table is an explicit representation of the message syntax that identifies the subset of segments used in the exchange of pulse oximetry results:

Segment	Description	Usage	Min	Max
MSH	Message Header	R	1	1
PID	Patient Identification	R	1	1
PV1	Patient Visit	RE	0	1
OBR	Observation Request	R	1	1

NTE	Notes and Comments	RE	0	*
RESULTS NOTES Group		*RE*	*1*	*
OBX	Observation/Result	R	1	1
NTE	Notes and Comments	RE	0	1

The RESULTS_NOTES group contains the observation and associated notes that may be sent with pulse oximetry observations.

This document illustrates how the Observation/Result (OBX) segment is used to convey null observations, oxygen saturation observations, and pulse/heart rate observations reported by pulse oximeters.

1.3 Segment Profiles

1.3.1 Observation Request (OBR) for Pulse Oximetry Panels

The Observation Request characterizes the entire panel of measurements. Along with specifying the procedure that produced the measurements, this segment allows for sets of observations that correspond to a specific time period to be exchanged in one transaction.

Table 1-1 illustrates how a device may send a single set of observations for a spot-check (intermittent) procedure at a point of time in a single message.

Table 1-1: OBR used to send a single spot-check/intermittent observation

```
OBR|1|||44616-1^Pulse oximetry panel ^LN|||20120512031234-
05||||||||||||||||||F|||||||||||||||||||252465000^Pulse
oximetry^SCT|7087005^Intermittent^SCT
```

Table 1-2 illustrates how a device may send one hour worth of data at one time using a single message. It may also send result s for each timed observation using the pre-defined measurement frequency configured in the device.

Table 1-2: OBR used to send one-hour worth of observations

```
OBR|1|||44616-1^Pulse oximetry panel ^LN|||
20120512031200-05|20120512041200-05
||||||||||||||||F|||||||||||||||||||252465000^Pulse
oximetry^SCT|255238004^Continuous^SCT
```

1.3.1.1 Observation Request Detail

	Element	*Notes*	*Data Type*	*Max Length*	*Use*	*Min/Max Repetitions*	*Table*	*Sample Value*

OBR.1	**Set ID - OBR**		SI	4	RE	0	1		1
OBR.2	**Placer Order Number**		EI	427	RE	0	1		
OBR.2.1	**Entity Identifier**		ST	199	RE	0	1		
OBR.3	**Filler Order Number**		EI	427	RE	0	1	0360	
This field identifies the "session" from the time the patient and device are associated with each other to the end of that transaction.									
OBR.3.1	**Entity Identifier**		ST	199	RE	0	1		
OBR.4	**Universal Service Identifier**		CWE	705	R	1	1		
This field is used to specify and characterize the pulse oximetry results. It may specify a pulse oximetry or other battery identifier. This field is coded using LOINC or SNOMED- CT..									
OBR.4.1	Identifier		ST	20	R	1	1		44616-1
This field is used to encode the pulse oximetry battery for spot-check or continuous measurements as specified in OBR.45. This field contains 252465000 representing a Pulse oximetry procedure. Pulse oximetry results may also be transmitted as a part of a larger panel of results, like Vital Signs, in which case, OBR.4.1 would contain the identifier for the Vital Signs panel. LOINC specifies code '44616-1' for a Pulse oximetry panel									
OBR.4.2	Text	*This field holds the display label associated with the identifier code (OBR.4.1).*	ST	199	RE	0	1		Pulse oximetry panel
OBR.4.3	Name of Coding System	*The code system used to specify the observation is SNOMED-CT (SCT) or LOINC (LN).*	ID	20	RE	0	1	0396	LN
OBR.7	**Observation Date/Time #**		DTM	24	Conditional	0	1		20120512031234-05
This field specifies the start of the time interval corresponding to the first measurement in the battery. It is used to specify a one-time/spot-check or a continuous monitoring interval.					**Predicate:** Continuous monitoring of pulse oximetry: OBR.45.code = '255238004'				

OBR.8	**Observation End Date/Time #**	*This field is used to specify the ending date/time of continuous monitoring interval.*	DTM	24	Conditional	0	1		
This field specifies the end of the time interval corresponding to the first measurement in the battery. It is used to specify a one-time/spot-check or a continuous monitoring interval.					**Predicate**: Continuous monitoring of pulse oximetry: OBR.45.code = '255238004'				
OBR.10	**Collector Identifier *+**	*This field is used to specify the operator at the point-of-care.*	NDL	1634	RE	0	1		
OBR.10.1	**Name**		CNN	409	RE	0	1		
OBR.10.1.1	***ID Number***	*This field holds the value of the user identifier of the operator responsible for acquiring the results at the point of care.*	*ST*	*15*	*R*	*1*	*1*		
OBR.10.1.2	***Family Name***	*Family (last) name of operator*	*ST*	*50*	*RE*	*0*	*1*		
OBR.10.1.3	***Given Name***	*First name of operator*	*ST*	*30*	*RE*	*0*	*1*		
OBR.25	**Result Status +**	.	ID	1	RE	0	1	0123	F
This flag is used to specify whether the results are stored as final/verified or slated for storage as unverified results. "F" means the results were verified or selected at the point of care. "R" means that the results are intended to be stored but they have not yet been verified. If the field is not valued, the default is "R"..									
OBR.44	**Procedure Code**		CNE	705	RE	0	1	0088	
This field specifies the type of procedure. In this case, Pulse oximetry: • 252465000 | Pulse oximetry | Procedure									
OBR.44.1	**Identifier**	*Coded value of the procedure used to obtain the measurements.*	ST	20	R	1	1		252465000

OBR.44.2	**Text**	*Display value describing the procedure.*	ST	199	RE	0	1		Pulse oximetry
OBR.44.3	**Name of Coding System**	*SNOMED-CT is the primary coding system specified for procedure.*	ID	20	RE	0	1	0396	SCT
OBR.45	**Procedure Code Modifier**		CNE	705	RE	0	1	0340	
The procedure modifier specifies if the pulse oximetry measurements were collected as intermittent/spot-check or continuous values. Example values: • 7087005 | Intermittent | Qualifier value • 255238004 | Continuous | Qualifier value									
OBR.45.1	**Identifier**	*Coded value of the modifier.*	ST	20	R	1	1		7087005
OBR.45.2	**Text**	*Display value of the modifier.*	ST	199	RE	0	1		Intermittent
OBR.45.3	**Name of Coding System**	*SNOMED-CT is the primary coding system specified for procedure modifier.*	ID	20	RE	0	1	0396	SCT

1.3.2 Missing results (OBX content profile for missing results)

The following section describes how the OBX segment may be used to convey that a device could not acquire a result. The signal strength or the attachment of the probe could be the reason for the error.

Table 1-3: Missing results example using the generic structure provided by this supplement

```
OBX|1|NM|59408-5^Oxygen saturation in Arterial blood by Pulse
oximetry^LN^150456^MDC_PULS_OXIM_SAT_O2^MDC|1.11.2.3||%^Percent^UCUM|97
-99|NAV|10||X|||20120530112340|||AMEAS^auto-
measurement^MDC|0123456789ABCDEF^Pulse_Oximeter_Vendor_X^
0123456789ABCDEF^EUI-64||49521004^left external ear structure^SCT

NTE|1||Missing results due to low signal detection
```

This segment represents the generic structure used to exchange pulse oximetry observation. It illustrates how we would convey an oxygen saturation measurement if it could not be acquired by the device (due to a low signal strength, for instance).

1.3.2.1 Observation/Result - null result sample Detail

Id	Element	Notes	Data Type	Max Length	Use	Min/Max Repetitions		Table	Sample Value
OBX.1	**Set ID - OBX**		SI	4	R	1	1		1
OBX.2	**Value Type**	*The value type for pulse, oxygen saturation, and, if available, respiratory rate are all numeric ("NM").*	ID	3	R	0	1	0125	NM
OBX.3	**Observation Identifier**		CWE	705	R	1	1		
This field identifies the type of measurement reported by the device. This field is encoded using LOINC as the principal encoding and IEEE 11073 as the alternate encoding systems.									
OBX.3.1	**Identifier**	*The first identifier is always a LOINC code*	ST	20	R	1	1		59408-5
OBX.3.2	**Text**	*Text label corresponding to the LOINC code.*	ST	199	RE	0	1		Oxygen saturation in Arterial blood by Pulse oximetry
OBX.3.3	**Name of Coding System**	*The code corresponding to the coding system (e.g., LOINC is encoded as LN).*	ID	20	R	1	1	0396	LN *Fixed*
OBX.3.4	**Alternate Identifier**	*The alternate identifier is an ISO/IEEE 11073 code.*	ST	30	RE	0	1		150456
OBX.3.5	**Alternate Text**	*The display name associated with the alternate code.*	ST	199	RE	0	1		MDC_PULS_OXIM_SAT_O2
OBX.3.6	**Name of Alternate Coding System**	*Specifies "MDC" for the IEEE 11073 nomenclature.*	ID	20	RE	0	1	0396	MDC
OBX.4	**Observation Sub-ID**	*Please refer to the IHE PCD TF for more*	ST	20	R	0	1		1.11.2.3

		information on the use of this id..							
OBX.5	**Observation Value**		NM	647	Conditional	0	1		
This field specifies the measured parameter as a numeric value. OBX.6 - units - specifies the units of measure for this observation/measurement. In this example the result could not be acquired.					Predicate: This field may be empty if the measurement could not be obtained (i.e., OBX.11 = X).				
OBX.6	**Units**	*This field is used to specify the units of measure as a coded element using standard nomenclature (UCUM) to specify the units using a code.*	CWE	705	R	1	1		
OBX.6.1	Identifier	*The units of measure code (e.g. %).*	ST	20	R	1	1		%
OBX.6.2	Text		ST	199	RE	0	1		Percent
OBX.6.3	Name of Coding System		ID	20	RE	0	1	0396	UCUM
OBX.6.7	Coding System Version ID		ST	10	Conditional *Predicate:*	0	1		
OBX.7	**References Range**		ST	60	RE	0	1		97-99
If the device supports it, the device reference range is specified here. This reference range is used to determine if a result is abnormal.									
OBX.8	**Abnormal Flags**		IS	4	RE	0	*	0078	NAV
If the device supports a reference range, it is useful to include a device- supplied abnormal flag. This abnormal flag along with the reference range will be available to the information systems to determine if a result or set of results requires additional action from the clinicians reviewing the results. This may also be used to specify that a value could not be acquired (OBX.11 = X). • No information – NI • Not applicable, no proper value – NA • Temporarily not available. Information is not available at this time but it is expected that it will be available later – NAV • Numeric measurement function is available but has been deactivated by user – OFF • Masked (as for security) – MSK									

- Value not in domain – OTH
- Not a number – NAN
- Positive infinity – PINF
- Negative infinity - NINF

OBX.9	**Probability**		NM	5	RE	0	1		10

This field is used to specify the signal strengths as a percentage of the full strength (e.g., 80 for 80% signal strength). This represents means of evaluating the precision a measurement and thus any possible uncertainty of the measurement.

This field is useful to determine how well the measurement could be evaluated by the sending system/device manager.

OBX.11	**Observation Result Status**		ID	1	RE	0	1	0085	X

This field is used to specify whether the results were verified by the operator of the device. Verification includes verifying that the referenced device is correlated to the correct patient.

F: final. Verified

R: entered, not yet verified

X: indicates that the measurement could not be acquired by the device

OBX.14	**Date/Time of the Observation**	This is the most accurate date/time of the measurement (Date/time may be specified by a device manager).	DTM	24	R	1	1		20120530112340
OBX.16	**Responsible Observer**		XCN	4766	RE	0	*		

This field may be used to specify the clinician who validated the results, if they are identified as "Final" in OBX.11 (i.e., OBX.11 = 'F').

OBX.16.1	**ID Number**		ST	15	RE	0	1		
OBX.17	**Observation Method**		CWE	705	RE	0	*		

Typically this field is used to specify whether a results was measured (automatically/manually), calculated, or it expresses a device setting (rather than an actual observation).

For pulse oximetry, these values are always an automatically measured value, if specified.

OBX.17.1	**Identifier**		ST	20	R	1	1		AMEAS
OBX.17.2	**Text**		ST	1	RE	0	1		auto-measurement
OBX.17.3	**Name of Coding System**		ID	1	RE	0	1	0396	MDC

OBX.17.7	**Coding System Version ID**		ST	10	Conditional Predicate:	0	1		
OBX.18	**Equipment Instance Identifier**	Device identifier	EI	2206	RE	0	*		This field may be used to specify a local or a standard/universal identifier (e.g. FDA unique device identifier),
OBX.18.1	**Entity Identifier**		ST	199	RE	0	1		0123456789ABCDEF
OBX.18.2	**Namespace ID**		IS	999	RE	0	1	0363	Pulse_Oximeter_Vendor_X
OBX.18.3	**Universal ID**		ST	999	RE	0	1		0123456789ABCDEF
OBX.18.4	**Universal ID Type**		ID	6	RE	0	1	0301	EUI-64
OBX.19	**Date/Time of the Analysis**		DTM	24	RE	0	1		
Date and time supplied by the device. This time stamp may not be as accurate as the OBX.14 date/time value.									
OBX.20	**Observation Site**		CWE	705	RE	0	*	0163	
This field is used to specify the body site including anatomical orientation (e.g., laterality). The body position may be an additional observation, if recorded, at the point-of-care. This value set may be extended with the other body site codes specified in SNOMED-CT									
OBX.20.1	**Identifier**	This component holds the coded descriptor.	ST	20	RE	0	1		49521004

1.3.3 Result for Oxygen Saturation (OBX Content Profile for Oxygen Saturation)

This segment definition was constrained for the exchange of oxygen saturation observation set acquired using a pulse oximeter.

315 **Table 1-4: Abnormal Oxygen Saturation Example**

```
OBX|2|NM|59408-5^Oxygen saturation in Arterial blood by Pulse
oximetry^LN^150456^MDC_PULS_OXIM_SAT_O2^MDC|1.11.2.3|96|%^Percent^UCUM
|97-99|L|99||R|||||AMEAS^auto-
measurement^MDC|20120530112340|0123456789ABCDEF^Pulse_Oximeter_Vendor_
X^0123456789ABCDEF^EUI-64||49521004^left external ear structure^SCT

NTE|1||This is a comment about the oxygen saturation reading
```

The following details how the generic structure of an observation is used to convey an oxygen saturation reading from a pulse oximeter:

1.3.3.1 Observation/Result for Oxygen Saturation Detail

Id	*Element*	*Notes*	*Data Type*	*Max Length*	*Use*	*Min/Max Repetitions*		*Table*	*Sample Value*
OBX.1	**Set ID - OBX**		SI	4	R	1	1		2
OBX.2	**Value Type**		ID	3	R	0	1	0125	NM
This field contains the value type for pulse, oxygen saturation, and, if available, respiratory rate measurements which are all numeric ("NM").									
OBX.3	**Observation Identifier**		CWE	705	R	1	1		
This field identifies the type of measurement reported by the device. This field is encoded using LOINC as the principal encoding and IEEE 11073 as the alternate encoding systems.									
OBX.3.1	**Identifier**		ST	20	R	1	1		59408-5
The first identifier is always a LOINC code for the oxygen saturation measurement. • 44612-0 Oxygen saturation in Episode maximum Capillary blood by Oximetry • 44613-8 Oxygen saturation in Episode minimum Capillary blood by Oximetry • 44614-6 Oxygen saturation in Episode mean Capillary blood by Oximetry • 59405-1 Oxygen saturation in 8 hour maximum Arterial blood by Pulse oximetry • 59406-9 Oxygen saturation in 8 hour minimum Arterial blood by Pulse oximetry • 59407-7 Oxygen saturation in Blood Preductal by Pulse oximetry • 59418-4 Oxygen saturation in Blood Postductal by Pulse oximetry • 59408-5 Oxygen saturation in Arterial blood by Pulse oximetry • 59409-3 Oxygen saturation in Arterial blood by Pulse oximetry --during treatment • 59410-1 Oxygen saturation in Arterial blood by Pulse oximetry --on room air • 59411-9 Oxygen saturation in Arterial blood by Pulse oximetry --post bronchodilation • 59412-7 Oxygen saturation in Arterial blood by Pulse oximetry --post exercise • 59413-5 Oxygen saturation in Arterial blood by Pulse oximetry --post treatment 5 • 9414-3 Oxygen saturation in Arterial blood by Pulse oximetry --pre bronchodilation • 59415-0 Oxygen saturation in Arterial blood by Pulse oximetry --pre physiotherapy • 59416-8 Oxygen saturation in Arterial blood by Pulse oximetry --pre treatment									
OBX.3.2	**Text**		ST	199	RE	0	1		Oxygen saturation in Arterial blood by Pulse oximetry
OBX.3.3	**Name of Coding System**	The code corresponding to the coding system (e.g., LOINC is encoded as LN).	ID	20	R	1	1	0396	LN *Fixed*
OBX.3.4	**Alternate Identifier**	The alternate identifier is an	ST	20	RE	0	1		150456

		ISO/IEEE 11073 code.							
OBX.3.5	**Alternate Text**	The display name associated with the alternate code.	ST	199	RE	0	1		MDC_PULS_OXIM_SAT_O2
OBX.3.6	**Name of Alternate Coding System**		ID	20	RE	0	1	0396	MDC
OBX.4	**Observation Sub-ID**	**Please refer to the IHE PCD TF for more information on the use of this id.**	ST	20	R	0	1		1.11.2.3
OBX.5	**Observation Value**		NM	647	Conditional	0	1		96
This field specifies the measured parameter as a numeric value. OBX.6 - units - specifies the units of measure for this observation/measurement.					Predicate: This field may be empty if the measurement could not be obtained (i.e., OBX.11 = X)				
OBX.6	**Units**	This field is used to specify the units of measure as coded element using standard nomenclature (UCUM) to specify the units using a code.	CWE	705	R	1	1		
OBX.6.1	**Identifier**	The units of measure code (e.g. %).	ST	20	R	1	1		%
OBX.6.2	**Text**		ST	199	RE	0	1		Percent
OBX.6.3	**Name of Coding System**		ID	20	RE	0	1	0396	UCUM
OBX.6.7	**Coding System Version ID**		ST	10	Conditional *Predicate:*	0	1		

OBX.7	**References Range**	ST	60	RE	0	1		97-99

If the device supports it, the device reference range is specified here. This reference range is used to determine if a result is abnormal.

OBX.8	**Abnormal Flags**	IS	1	RE	0	*	0078	L

If the device supports a reference range, it will be useful to include a device- supplied abnormal flag. This abnormal flag along with the reference range will be available to the information systems to determine if a result or set of observations requires additional action from the clinicians.

This may also be used to specify that a value could not be acquired (OBX.11 = X).

- NI –No information
- NA – Not applicable, no proper value
- NAV – Temporarily not available. Information is not available at this time but it is expected that it will be available later
- OFF –Numeric measurement function is available but has been deactivated by user
- MSK – Masked (as for security)
- OTH –Value not in domain
- NAN – Not a number
- PINF –Positive infinity
- NINF – Negative infinity

OBX.9	**Probability**	NM	5	RE	0	1		10

This field is used to specify the signal strengths as a percentage of the full strength (e.g., 10 for 10% signal strength). This represents means of evaluating the precision a measurement and thus any possible uncertainty of the measurement.

This field is useful to determine how well the measurement could be evaluated by the sending system/device.

OBX.11	**Observation Result Status**	ID	1	R	1	1	0085	R

This field is used to specify whether the results were verified by the operator of the device. Verification includes verifying that the referenced device is correlated to the correct patient.

F: final. Verified

R: entered, not yet verified

X: indicates that the measurement could not be acquired by the device

OBX.15	**Responsible Observer**	XCN	4766	RE	0	*		

This field may be used to specify the clinician who validated the observation set, if they are identified as "Final" in OBX.11 (i.e., OBX.11 = 'F'). This field may specify the device operator.

OBX.15.1	**ID Number**	ST	15	RE	0	1		
OBX.16	**Observation**	CWE	705	RE	0	*		

	Method								
This field may be used to specify the clinician who validated the observation set, if they are identified as "Final" in OBX.11 (i.e., OBX.11 = 'F').									
OBX.16.1	**Identifier**		ST	20	R	1	1		AMEAS
OBX.16.2	**Text**		ST	1	RE	0	1		auto-measurement
OBX.16.3	**Name of Coding System**		ID	1	RE	0	1	0396	MDC
OBX.17	**Date/Time of the Observation**	This is the most accurate date/time of the measurement	DTM	24	R	1	1		20120530112340
OBX.18	**Equipment Instance Identifier**	Device Identifier	EI	2206	RE	0	*		This field may be used to specify a local or a standard/universal identifier (e.g. FDA unique device identifier)
OBX.18.1	**Entity Identifier**		ST	199	RE	0	1		0123456789ABCDEF
OBX.18.2	**Namespace ID**		IS	999	RE	0	1	0363	Pulse_Oximeter_Vendor_X
OBX.18.3	**Universal ID**		ST	999	RE	0	1		0123456789ABCDEF
OBX.18.4	**Universal ID Type**		ID	6	RE	0	1	0301	EUI-64
OBX.19	**Date/Time of the Analysis**	Date and time supplied by the device. This time stamp may not be as accurate as the OBX.14 date/time value (it may be specified by a device manager).	DTM	24	RE	0	1		
OBX.20	**Observation Site**		CWE	705	RE	0	*	0163	
This field is used to specify the body site including anatomical orientation (e.g., laterality). The body position may be an additional observation, if recorded, at the point-of-care. *This value set may be extended with the other body site codes specified in SNOMED-CT*									
OBX.20.1	**Identifier**	This component holds the	ST	20	RE	0	1	0163	49521004

		coded descriptor from table 0163

1.3.4 Pulse Measurement (OBX content profile for Pulse)

320 This segment represents the specific structure used to exchange pulse measurements obtained during pulse oximetry.

Table 1-5: A normal pulse reading represented using OBX

```
OBX|3|NM|8889-8^Heart Rate by Oximetry^LN^149530^
MDC_PULS_OXIM_PULS_RATE^MDC|1.11.2.3|55|{beats}/min^beats per
minute^UCUM|35-125||99||R|||20120530112340|||AMEAS^auto-
measurement^MDC|0123456789ABCDEF^Pulse_Oximeter_Vendor_X^0123456789ABC
DEF^EUI-64||49521004^left external ear structure^SCT

NTE|1||This is a comment about pulse rate measurement
```

1.3.4.1 Observation/Result - Pulse example Detail

Id	*Element*	*Notes*	*Data Type*	*Max Length*	*Use*	*Min/Max Repetitions*		*Table*	*Sample Value*
OBX.1	**Set ID - OBX**		SI	4	R	1	1		3
OBX.2	**Value Type**		ID	3	R	0	1	0125	NM
The value type for pulse, oxygen saturation, and, if available, respiratory rate are all numeric ("NM").									
OBX.3	**Observation Identifier**		CWE	715	R	1	1		
This field identifies the type of measurement reported by the device. This field is encoded using LOINC as the principal encoding and IEEE 11073 as the alternate encoding systems.									
OBX.3.1	**Identifier**		ST	20	R	1	1		8889-8
The first identifier is always a LOINC code : • 8889-8 Heart rate by Oximetry • 44609-6 Heart rate Episode maximum by Oximetry • 44610-4 Heart rate Episode minimum by Oximetry • 44611-2 Heart rate Episode mean by Oximetry									
OBX.3.2	**Text**	**Display label**	ST	199	RE	0	1		Heart Rate by Oximetry
OBX.3.3	**Name of Coding System**	**The code corresponding to the coding system (e.g. LOINC is**	ID	20	R	1	1	0396	LN *Fixed*

		encoded as LN).							
OBX.3.4	Alternate Identifier	The alternate identifier is an ISO/IEEE 11073 code.	ST	30	RE	0	1		149530
OBX.3.5	Alternate Text	The display name associated with the alternate code.	ST	199	RE	0	1		MDC_PULS_OXIM_PULS_RATE
OBX.3.6	Name of Alternate Coding System		ID	20	RE	0	1	0396	MDC
OBX.4	Observation Sub-ID	Please refer to the IHE PCD TF for more information on the use of this id.	ST	20	R	0	1		1.11.2.3
OBX.5	Observation Value		NM	647	Conditional	0	1		55
This field specifies the measured parameter as a numeric value. OBX.6 - units - specifies the units of measure for this observation/measurement.					Predicate: This field may be empty if the measurement could not be obtained (i.e., OBX.11 = X)				
OBX.6	Units	This field is used to specify the units of measure as coded element using standard nomenclature (UCUM) to specify the units using a code.	CWE	705	R	1	1		
OBX.6.1	Identifier	The units of measure code (e.g., degF, %).	ST	20	R	1	1		{beats}/min
OBX.6.2	Text		ST	199	RE	0	1		beats per minute

OBX.6.3	**Name of Coding System**		ID	20	RE	0	1	0396	UCUM
OBX.6.7	**Coding System Version ID**		ST	10	Conditional Predicate:	0	1		
OBX.7	**References Range**	If the device supports it, the device reference range is specified here. This reference range is used to determine if a result is abnormal.	ST	60	RE	0	1		35-125
OBX.8	**Abnormal Flags**		IS	1	RE	0	*	0078	

If the device supports a reference range, it will be useful to include a device- supplied abnormal flag. This abnormal flag along with the reference range will be available to the information systems to determine if a result or set of results requires additional action from the clinicians.

This may also be used to specify that a value could not be acquired (OBX.11 = X).

- No information – NI
- Not applicable, no proper value – NA
- Temporarily not available. Information is not available at this time but it is expected that it will be available later – NAV
- Numeric measurement function is available but has been deactivated by user – OFF
- Masked (as for security) – MSK
- Value not in domain – OTH
- Not a number – NAN
- Positive infinity – PINF
- Negative infinity - NINF

OBX.9	**Probability**		NM	5	RE	0	1		99

This field is used to specify the signal strengths as a percentage of the full strength (e.g., 80 for 80% signal strength). This represents means of evaluating the precision a measurement and thus any possible uncertainty of the measurement.

This field is useful to determine how well the measurement could be evaluated by the sending system/device

OBX.11	**Observation Result Status**		ID	1	R	1	1	0085	R

This field is used to specify whether the results were verified by the operator of the device. Verification includes verifying that

the referenced device is correlated to the correct patient. F: final. Verified R: entered, not yet verified X: indicates that the measurement could not be acquired by the device									
OBX.14	**Date/Time of the Observation**	This is the most accurate date/time of the measurement. ***(It may be specified by a device manager).***	DTM	24	R	1	1		20120530112340
OBX.16	**Responsible Observer**		XCN	4766	RE	0	*		
This field may be used to specify the clinician who validated the observation set, if they are identified as "Final" in OBX.11 (i.e., OBX.11 = 'F').									
OBX.16.1	**ID Number**		ST	15	RE	0	1		5444233
OBX.17	**Observation Method**		CWE	705	RE	0	*		
Typically this field is used to specify whether an observation set was measured (automatically/manually), calculated, or it expresses a device setting (rather than an actual observation). For pulse oximetry, these values are always an automatically measured value, if specified.									
OBX.17.1	**Identifier**		ST	20	R	1	1		AMEAS
OBX.17.2	**Text**		ST	1	RE	0	1		auto-measurement
OBX.17.3	**Name of Coding System**		ID	1	RE	0	1	0396	MDC
OBX.18	**Equipment Instance Identifier**	Device identifier	EI	2206	RE	0	*		*This field may be used to specify a local or a standard/universal identifier (e.g. FDA unique device identifier)*
OBX.18.1	**Entity Identifier**		ST	199	RE	0	1		0123456789ABCDEF
OBX.18.2	**Namespace ID**		IS	999	RE	0	1	0363	Pulse_Oximeter_Vendor_X
OBX.18.3	**Universal ID**		ST	999	RE	0	1		0123456789ABCDEF

OBX.18.4	Universal ID Type	ID	6	RE	0	1	0301	EUI-64
OBX.19	**Date/Time of the Analysis**	**DTM**	**24**	**RE**	**0**	**1**		
Date and time supplied by the device. This time stamp may not be as accurate as the OBX.14 date/time value.								
OBX.20	**Observation Site**	**CWE**	**705**	**RE**	**0**	*	0163	
This field is used to specify the body site including anatomical orientation (e.g., laterality). The body position may be an additional observation, if recorded, at the point-of-care. This value set may be extended with the other body site codes specified in SNOMED-CT								
OBX.20.1	**Identifier**	This component holds the coded descriptor from table 0163.	ST	20	RE	0	1	0163	49521004

1.4 Table of values

1.4.1 ID: 0003 ID: 0004 Table Patient class

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	B	Obstetrics
2	C	Commercial Account
3	E	Emergency
4	I	Inpatient
5	N	Not Applicable
6	O	Outpatient
7	P	Preadmit
8	R	Recurring patient
9	U	Unknown

1.4.2 ID: 0078 Table Abnormal flags

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

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Order	Code	Description
1	<	Below absolute low-off instrument scale
2	>	Above absolute high-off instrument scale
3	A	Abnormal (applies to non-numeric results)
4	AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)
5	B	Better--use when direction not relevant
6	D	Significant change down
7	H	Above high normal
8	HH	Above upper panic limits
9	I	Intermediate*
10	L	Below low normal
11	LL	Below lower panic limits
12	MS	Moderately susceptible*
13	N	Normal (applies to non-numeric results)
14	null	No range defined, or normal ranges don't apply
15	R	Resistant*
16	S	Susceptible*
17	U	Significant change up
18	VS	Very susceptible*
19	W	Worse--use when direction not relevant

1.4.3 ID: 0085 Table Observation result status codes interpretation

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	C	Record coming over is a correction and thus replaces a final result
2	D	Deletes the OBX record

Order	Code	Description
3	F	Final results (verified); Can only be changed with a corrected result.
4	I	Specimen in lab; results pending
5	N	Not asked; used to affirmatively document that the observation identified in the OBX was not sought when the universal service ID in OBR-4 implies that it would be sought.
6	O	Order detail description only (no result)
7	P	Preliminary results
8	R	Results entered -- not verified
9	S	Partial results
10	U	Results status change to final without retransmitting results already sent as 'preliminary.' E.g., radiology changes status from preliminary to final
11	W	Post original as wrong, e.g., transmitted for wrong patient
12	X	Results cannot be obtained for this observation

1.4.4 ID: 0088 Table Procedure Code

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Sample listing of possible values.

Order	Code	Description
1	10141	INCISION AND DRAINAGE OF HEMATOMA; COMPLICATED

1.4.5 ID: 0103 Table Processing ID

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	D	Debugging
2	P	Production
3	T	Training

1.4.6 ID: 0104 Table Version ID

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	2.0	Release 2.0
2	2.0D	Demo 2.0
3	2.1	Release 2. 1
4	2.2	Release 2.2
5	2.3	Release 2.3
6	2.3.1	Release 2.3.1
7	2.4	Release 2.4
8	2.5	Release 2.5
9	2.5.1	Release 2.5.1
10	2.6	Release 2.6

1.4.7 ID: 0123 Table Result status

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

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Order	Code	Description
1	A	Some, but not all, results available
2	C	Correction to results
3	F	Final results; results stored and verified. Can only be changed with a corrected result.
4	I	No results available; specimen received, procedure incomplete
5	O	Order received; specimen not yet received
6	P	Preliminary: A verified early result is available, final results not yet obtained
7	R	Results stored; not yet verified
8	S	No results available; procedure scheduled, but not done
9	X	No results available; Order canceled.
10	Y	No order on record for this test. (Used only on queries)
11	Z	No record of this patient. (Used only on queries)

1.4.8 ID: 0125 Table Value type

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	AD	Address
2	CE	Coded Entry
3	CF	Coded Element With Formatted Values
4	CK	Composite ID With Check Digit
5	CN	Composite ID And Name
6	CP	Composite Price
7	CX	Extended Composite ID With Check Digit
8	DT	Date
9	ED	Encapsulated Data
10	FT	Formatted Text (Display)
11	MO	Money
12	NM	Numeric
13	PN	Person Name
14	RP	Reference Pointer
15	SN	Structured Numeric
16	ST	String Data.
17	TM	Time
18	TN	Telephone Number
19	TS	Time Stamp (Date & Time)
20	TX	Text Data (Display)
21	XAD	Extended Address
22	XCN	Extended Composite Name And Number For Persons
23	XON	Extended Composite Name And Number For Organizations
24	XPN	Extended Person Name
25	XTN	Extended Telecommunications Number

1.4.9 ID: 0155 Table Accept/application acknowledgment conditions

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	AL	Always
2	ER	Error/reject conditions only
3	NE	Never
4	SU	Successful completion only

1.4.10 ID: 0163 Table Body site

Concept ID	Body Site
SNOMED-CT Concept ID: 7569003 (finger structure) Body structure]	finger
SNOMED-CT Concept ID: 83738005 (index finger structure) [Body structure]	index finger (second finger)
SNOMED-CT Concept ID: 12406000 (little finger structure) [Body structure]	fifth finger (little finger)
SNOMED-CT Concept ID: 65531009 (middle finger structure) [Body structure]	third finger
SNOMED-CT Concept ID: 82002001 (ring finger structure) [Body structure]	fourth finger
SNOMED-CT Concept ID: 76505004 (thumb structure) [Body structure]	thumb
SNOMED-CT Concept ID: 78883009 (hallux structure) [Body structure]	big toe
SNOMED-CT Concept ID: 182308006 (lesser toe) [Body structure]	little toe (fifth toe)
SNOMED-CT Concept ID: 55078004 (second toe) [Body structure]	second toe
SNOMED-CT Concept ID: 78132007 (third toe) [Body structure]	third toe
SNOMED-CT Concept ID: 80349001 (fourth toe) [Body structure]	fourth toe
SNOMED-CT Concept ID: 302547009 (entire toe) [Body structure]	toe
SNOMED-CT Concept ID: 76578001 (nail of toe) [Body structure]	nail of toe
SNOMED-CT Concept ID: 48800003 (ear lobe structure) [Body structure]	ear lobe
SNOMED-CT Concept ID: 52795006 (forehead structure) [Body structure]	forehead (frontal region)
SNOMED-CT Concept ID: 314140006 (region of frontal cortex) [Body structure]	region of frontal cortex
SNOMED-CT Concept ID: 302553009 (entire abdomen) [Body structure]	abdomen
SNOMED-CT Concept ID: 279026008 (upper abdomen) [Body structure]	upper abdomen

Concept ID	Body Site
SNOMED-CT Concept ID: 279027004 (lower abdomen surface region) [Body structure]	lower abdomen
SNOMED-CT Concept ID: 58602004 (flank structure) [Body structure]	flank
SNOMED-CT Concept ID: 314870004 (tongue surface region) [Body structure]	tongue
SNOMED-CT Concept ID: 60819002 (cheek structure) [Body structure]	cheek
SNOMED-CT Concept ID: 362729008 (entire left upper extremity) [Body structure]	entire left upper extremity
SNOMED-CT Concept ID: 362728000 (entire right upper extremity) [Body structure]	entire right upper extremity
SNOMED-CT Concept ID: 72098002 (entire left upper arm) [Body structure]	left arm
SNOMED-CT Concept ID: 368236001 (entire left wrist) [Body structure]	left wrist
SNOMED-CT Concept ID: 368225008 (entire left forearm) [Body structure]	left forearm
SNOMED-CT Concept ID: 368456002 (entire left hand) [Body structure]	left hand
SNOMED-CT Concept ID: 368107006 (entire left shoulder region) [Body structure]	left shoulder
SNOMED-CT Concept ID: 1927002 (entire left elbow region) [Body structure]	left elbow
SNOMED-CT Concept ID: 302545001 (entire foot) [Body structure]	foot
SNOMED-CT Concept ID: 239919000 (entire left foot) [Body structure]	left foot
SNOMED-CT Concept ID: 239830003 (entire right foot) [Body structure]	right foot
SNOMED-CT Concept ID: 213384005 (entire left lower leg) [Body structure]	left leg
SNOMED-CT Concept ID: 51636004 (structure of left ankle) [Body structure]	left ankle
SNOMED-CT Concept ID: 209672000 (entire left thigh) [Body structure]	left thigh
SNOMED-CT Concept ID: 210659002 (entire left knee) [Body structure]	left knee
SNOMED-CT Concept ID: 368235002 [Body structure] entire right wrist [Body structure]	right wrist
SNOMED-CT Concept ID: 368224007 [Body structure] entire right forearm [Body structure]	right forearm
SNOMED-CT Concept ID: 368455003 [Body structure] entire right hand [Body structure]	right hand
SNOMED-CT Concept ID: 368106002 [Body structure] entire right shoulder region [Body structure]	right shoulder
SNOMED-CT Concept ID: 71889004 [Body structure]	right elbow

Concept ID	Body Site
entire right elbow region [Body structure]	
SNOMED-CT Concept ID: 18944008 [Body structure] right eye structure [Body structure]	right eye
SNOMED-CT Concept ID: 8966001 (left eye structure) [Body structure]	left eye
SNOMED-CT Concept ID: 49521004 (left external ear structure) [Body structure]	left external ear structure
SNOMED-CT Concept ID: 69838001 (right external ear structure) [Body structure]	right external ear structure
SNOMED-CT Concept ID: 424431000 (structure of right half of face) [Body structure]	right half of face
SNOMED-CT Concept ID: 423781004 (structure of left half of face)	left half of face
SNOMED-CT Concept ID: 59126009 (entire right upper arm) [Body structure]	right arm
SNOMED-CT Concept ID: 53840002 (structure of calf of leg) [Body structure]	calf
SNOMED-CT Concept ID: 244015008 (entire calf of leg) [Body structure]	calf
314870004 (tongue surface region) [Body structure]	tongue surface region
SNOMED-CT Concept ID: 68426009 (nasal septum) [Body structure]	nasal septum
SNOMED-CT Concept ID: 45206002 (nasal structure) [Body structure]	Nose

1.4.11 ID: 0200 Table Name type

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	A	Alias Name
2	B	Name at Birth
3	C	Adopted Name
4	D	Display Name
5	I	Licensing Name
6	L	Legal Name
7	M	Maiden Name
8	N	Nickname /"Call me" Name/Street Name

9	P	Name of Partner/Spouse (retained for backward compatibility only)
10	R	Registered Name (animals only)
11	S	Coded Pseudo-Name to ensure anonymity
12	T	Indigenous/Tribal/Community Name
13	U	Unspecified

1.4.12 ID: 0300 Table Namespace ID

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	No suggested values	No suggested values

1.4.13 ID: 0301 Table Universal ID type

Coding System: HL7 Defined Codes -

Table type: HL7 DEFINED

Order	Code	Description
1	DNS	An Internet dotted name. Either in ASCII or as integers
2	GUID	Same as UUID.
3	HCD	The CEN Healthcare Coding Scheme Designator. (Identifiers used in DICOM follow this assignment scheme.)
4	HL7	Reserved for future HL7 registration schemes
5	ISO	An International Standards Organization Object Identifier
6	L,M,N	These are reserved for locally defined coding schemes.
7	Random	Usually a base64 encoded string of random bits. The uniqueness depends on the length of the bits. Mail systems often generate ASCII string "unique names," from a combination of random bits and system names. Obviously, such identifiers will not be con
8	UUID	The DCE Universal Unique Identifier
9	x400	An X.400 MHS format identifier
10	x500	An X.500 directory name
11	EUI-64	

1.4.14 ID: 0302 Table Point of care

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	No suggested values	No suggested values

1.4.15 ID: 0303 Table Room

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	No suggested values	No suggested values

1.4.16 ID: 0304 Table Bed

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	No suggested values	No suggested values

1.4.17 ID: 0305 Table Person location type

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	C	Clinic
2	D	Department
3	H	Home
4	N	Nursing Unit

5	O	Provider's Office
6	P	Phone
7	S	SNF

1.4.18 ID: 0340 Table Procedure Code modifier

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Amb Care: Sample listing of possible values.

Order	Code	Description
1	57	DECISION FOR SURGERY

1.4.19 ID: ID: 0360 Table Degree

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

365

Order	Code	Description
1	AA	Associate of Arts
2	AAS	Associate of Applied Science
3	ABA	Associate of Business Administration
4	AE	Associate of Engineering
5	AS	Associate of Science
6	ASC	ASSOCIATE
7	BA	Bachelor of Arts
8	BAC	BACCALAUREATE
9	BBA	Bachelor of Business Administration
10	BE	Bachelor or Engineering
11	BFA	Bachelor of Fine Arts
12	BN	Bachelor of Nursing
13	BS	Bachelor of Science
14	BSL	Bachelor of Science - Law
15	BT	Bachelor of Theology
16	CDP	CERTIFICATE/DIPLOMA

Order	Code	Description
17	CER	Certificate
18	DBA	Doctor of Business Administration
19	DED	Doctor of Education
20	DIP	Diploma
21	DO	Doctor of Osteopathy
22	DOC	DOCTORAL
23	HS	High School Graduate
24	JD	Juris Doctor
25	MA	Master of Arts
26	MAS	MASTER'S
27	MBA	Master of Business Administration
28	MCE	Master of Civil Engineering
29	MD	Doctor of Medicine
30	MDI	Master of Divinity
31	ME	Master of Engineering
32	MED	Master of Education
33	MEE	Master of Electrical Engineering
34	MFA	Master of Fine Arts
35	MME	Master of Mechanical Engineering
36	MS	Master of Science
37	MSL	Master of Science - Law
38	MT	Master of Theology
39	NG	Non-Graduate
40	PDF	POST-DOCTORAL (OTHER THAN RESIDENTS)
41	PharmD	Doctor of Pharmacy
42	PHD	Doctor of Philosophy
43	PHE	Doctor of Engineering
44	PHS	Doctor of Science
45	PMF	POST-MASTER'S FELLOWSHIP
46	RES	RESIDENCY/FELLOWSHIP
47	SEC	Secretarial Certificate

Order	Code	Description
48	TS	Trade School Graduate

1.4.20 ID: 0361 Table Sending/receiving application

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1		No suggested values

1.4.21 ID: 0363 Table Assigning authority

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Enrollment Address Cleansing Project, prelim doc for RT1 segment

Order	Code	Description
1	AUSDVA	Australia - Dept. of Veterans Affairs
2	AUSHIC	Australia - Health Insurance Commission
3	CANAB	Canada - Alberta
4	CANBC	Canada - British Columbia
5	CANMB	Canada - Manitoba
6	CANNB	Canada - New Brunswick
7	CANNF	Canada - Newfoundland
8	CANNS	Canada - Nova Scotia
9	CANNT	Canada - Northwest Territories
10	CANNU	Canada - Nanavut
11	CANON	Canada - Ontario
12	CANPE	Canada - Prince Edward Island
13	CANQC	Canada - Quebec
14	CANSK	Canada - Saskatchewan
15	CANYT	Canada - Yukon Territories
16	LACS	Locatable Address Conversion System
17	NLVWS	NL - Ministerie van Volksgezondheid, Welzijn en Sport

Order	Code	Description
18	USCDC	US Center for Disease Control
19	USHCFA	US Healthcare Finance Authority
20	USNCOA	US National Change Of Address
21	USPS	US COA electronic file from the US Postal Service with forwarding address generated from enrollment letters
22	USSSA	US Social Security Administration
23	USVA	US Department of Veterans Affairs
24	USVABVA	US VA Board of Veteran's Appeals Application
25	USVAHBSC	US VA Health Benefits Service Center
26	USVAHEC	US VA Health Eligibility Center
27	USVAINS	US VA Philadelphia Insurance Center
28	USVAMC	US VA Medical Center
29	USVBA	US Veterans Benefits Administration
30	USVHA	US Veterans Health Administration

1.4.22 ID: 0396 Table Coding System

Coding System: HL7 Defined Codes -

Table type: USER DEFINED

Order	Code	Description
1	99zzz or L	Local general code (where z is an alphanumeric character)
2	ACR	American College of Radiology finding codes
3	ART	WHO Adverse Reaction Terms
4	AS4	ASTM E1238/ E1467 Universal
5	AS4E	AS4 Neurophysiology Codes
6	ATC	American Type Culture Collection
7	C4	CPT-4
8	C5	CPT-5
9	CAS	Chemical abstract codes
10	CD2	CDT-2 Codes
11	CDCA	CDC Analyte Codes
12	CDCM	CDC Methods/Instruments Codes

Order	Code	Description
13	CDS	CDC Surveillance
14	CE	CEN ECG diagnostic codes
15	CLP	CLIP
16	CPTM	CPT Modifier Code
17	CST	COSTART
18	CVX	CDC Vaccine Codes
19	DCL	DICOM Class Label
20	DCM	DICOM modality codes
21	DQL	DICOM Query Label
22	E	EUCLIDES
23	E5	Euclides quantity codes
24	E6	Euclides Lab method codes
25	E7	Euclides Lab equipment codes
26	ENZC	Enzyme Codes
27	FDDC	First DataBank Drug Codes
28	FDDX	First DataBank Diagnostic Codes
29	FDK	FDA K10
30	HB	HIBCC
31	HCPCS	HCFA Common Procedure Coding System
32	HHC	Home Health Care
33	HI	Health Outcomes
34	n	HL7 Defined Codes where nnnn is the HL7 table number
35	HPC	HCFA Procedure Codes (HCPCS)
36	I10	ICD-10
37	I10P	ICD-10 Procedure Codes
38	I9	ICD9
39	I9C	ICD-9CM
40	IBT	ISBT
41	IC2	ICHPPC-2
42	ICDO	International Classification of Diseases for Oncology
43	ICS	ICCS

Order	Code	Description
44	ICSD	International Classification of Sleep Disorders
45	ISOnnnn	ISO Defined Codes where nnnn is the ISO table number
46	IUPC	IUPAC/IFCC Component Codes
47	IUPP	IUPAC/IFCC Property Codes
48	JC8	Japanese Chemistry
49	LB	Local billing code
50	LN	Logical Observation Identifier Names and Codes (LOINC(r))
51	MCD	Medicaid
52	MCR	Medicare
53	MDDX	Medispan Diagnostic Codes
54	MEDC	Medical Economics Drug Codes
55	MEDR	Medical Dictionary for Drug Regulatory Affairs (MEDDRA)
56	MEDX	Medical Economics Diagnostic Codes
57	MGPI	Medispan GPI
58	MVX	CDC Vaccine Manufacturer Codes
59	NDA	NANDA
60	NDC	National drug codes
61	NIC	Nursing Interventions Classification
62	NPI	National Provider Identifier
63	OHA	Omaha System
64	POS	POS Codes
65	RC	Read Classification
66	SDM	SNOMED- DICOM Microglossary
67	SCT	Systemized Nomenclature of Medicine (SNOMED)
68	SNM3	SNOMED International
69	SNT	SNOMED topology codes (anatomic sites)
70	UC	UCDS
71	UCUM	Unified Code for Units of Measure
72	UMD	MDNS
73	UML	Unified Medical Language
74	UPC	Universal Product Code

Order	Code	Description
75	UPIN	UPIN
76	VADODFAC	DOD Facility (DMIS)
77	VAFACTYP	VA Facility Type
78	VASTANUM	VA Facility Station number
79	W1	WHO record # drug codes (6 digit)
80	W2	WHO record # drug codes (8 digit)
81	W4	WHO record # code with ASTM extension
82	WC	WHO ATC
83	MDC	IEEE 11073

2 Requirements Analysis

The following information is provided as background for the content profiles documented in this supplement.

2.1 Use Case Analysis

Requirements analysis begins with use case analysis. Use case analysis is intended to surface requirements by identifying the main systems, capabilities and human users that are involved in the activities at the center of a project. Therefore, requirements gleaned from a particular use case are specific to that use case.

Our team focused this analysis on the use case intended to support automated exchange of pulse oximeter observation set and alarm conditions with clinical information systems.

Note: This use case analysis does not cover the landscape of requirements for all medical device interoperability.

Figure 1: "Communicate Pulse Oximetry Results to Information Systems" depicts our main use case at a high-level and shows the actors and roles, along with the systems involved in sending pulse oximetry observation set to a patient's medical record managed in the information system (EHR).

The primary monitoring modes of pulse oximeter operation (continuous, spot-check/intermittent) are analyzed as sub-use cases and further described below in the Use Cases and Information Flows sections of this document.

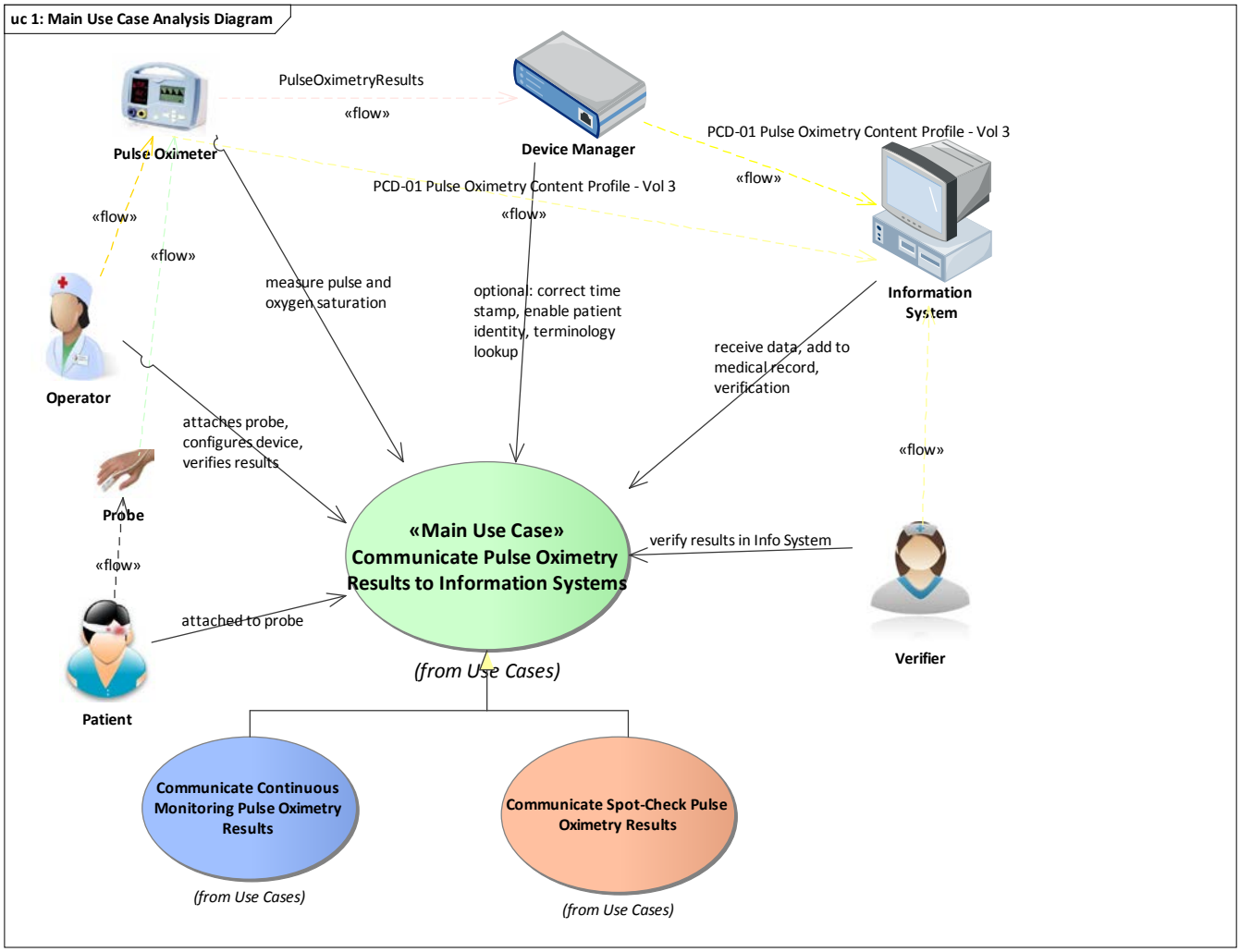

Figure 1: Main Use Case Analysis Diagram

Device Manager (Actor)

395 This actor is one of the most important actors in our use case if the pulse oximeter is not capable of sending standard-based transactions, and/or requires functionality to associate patient identity with the pulse oximeter device.

The device manager is the server and software used to transform proprietary transmission protocols to standards-based interchange used by clinical information systems (EHR-S).

400 This actor is also responsible for translating local (proprietary) codes used by pulse oximeter devices into standards-based terminologies recognized by information systems and optionally as necessary, may be used to associate patient identity with results if the pulse oximeter is not able to include patient identity.

Information System (Actor)

This actor represents the electronic health record system or any information system that is used by clinicians (verifier, operator) in caring for a patient, and is the system in which the record of care is documented.

Operator (Actor)

This actor represents the clinician who operates the pulse oximeter, connects the probe, and who can also act as a verifier for the observation set as required.

Patient (Actor)

The patient is connected to the probe by the pulse oximeter operator.

Pulse Oximeter (Actor)

The pulse oximeter is the computerized device connected to the probe which is connected to the patient, and is responsible for measuring the patient's physiological parameters.

Verifier (Actor)

This actor represents the clinician responsible for reviewing and validating the observation set to be added to the patient's medical record in the information system.

Note: Not all pulse oximeter observation set must be verified.

Probe (Actor)

This actor represents the component that acquires the signal that is processed by the pulse oximeter. The probe, also called probe, is attached to the patient, usually on the finger or ear lobe, and is used to measure the amount of saturated hemoglobin in tissue capillaries by transmitting a beam of light through the tissue to the pulse oximeter receiver.

Two modes of transmission by which probes communicate pulse oximetry measurement signals are reflection mode and transmission mode.

2.1.1 Use Cases

The following section describes the main use case and sub-use cases that are the focus of this requirements analysis.

2.1.1.1 Communicate Pulse Oximetry Results to Information Systems (Use Case)

This is the main use case depicted in Figure 1.

Pulse oximeter observation set is transmitted differently depending on the monitoring mode that is set on the device for the patient. Results may be reported to the information system in a number of ways:

- spot-check (intermittent),
- or continuously

The following scenario illustrates the main use case and the importance of automatically reporting pulse oximeter measurements in a timely manner to ensure that clinicians have the clinical information necessary to intervene appropriately and to ensure patient safety. Had the pulse oximeter been able to transmit clinical alerts to the information system based on a number of factors as described in this scenario, the patient's abnormal pulse oximetry values would have been recognized sooner and patient care would have been improved.

"Maria Registered Nurse (RN), is working the evening shift and is caring for John, a 60 year old male, postoperative day 1 open cholecystectomy. He is obese with a history of Chronic Obstructive Pulmonary Disease (COPD) and may have sleep apnea but is awaiting a sleep study. During her initial physical assessment she notes that he is afebrile, abdomen slightly tender, + bowel sounds, and without cyanosis. He is on 2L of oxygen. The pulse oximeter probe is connected to his right index finger with a good waveform reading 97%. The alarms are turned on. He is sleeping but easily aroused. He states his pain is still 5 on a 1-10 scale. Maria previously double-checked the Patient Controlled Analgesic (PCA) settings with another nurse and confirmed he is receiving Morphine at 1 mg/hr continuously with 2 mg q 10 min on demand (30 mg 4 hr lockout). Maria notices he is not using the demand often. She reviews proper PCA use with the patient and his wife who is at the bedside.

Two hours later, a Nursing Assistant (NA) was taking vital signs. She called Maria to the room to report that his respiratory rate is 8. Maria sees he is taking shallow breaths and is having apneic spells. He is aroused only with deep stimulation. She finds his pulse oximeter probe on the floor. She connects it to John and it displays 89% with a good waveform. Maria told the NA to call for a rapid response team. The patient is treated and recovers from this incident.

While speaking with his wife after the event she tells Maria that she kept hearing her husband moan in his sleep so she would push the PCA button for him. The alarm to the pulse oximeter had been turned off. The patient's wife said she saw how to silence and turn off the alarm and did not think it was a problem, since the alarm kept waking him up every time the probe fell off his finger. Maria took the opportunity to inform his wife about the safety concerns related to pushing the PCA button so frequently and to turning off the alarm on the pulse oximeter. His wife verbalized understanding."

2.1.1.2 Communicate Continuous Monitoring Pulse Oximetry Results (Use Case)

This sub-use case describes a situation where monitoring by pulse oximetry is intended to provide information that could alert clinicians at the earliest possible moment of critical conditions to avert adverse patient outcomes. (Alerts may be triggered by clinical conditions: e.g., patient becomes hypoxic), or technical conditions: e.g., transmission error conditions such as probe falling off, alarms disabled).

In continuous monitoring mode, physiological observation set are measured by the pulse oximeter through the probe on a frequent basis. The frequency of measurements may be configured based on patient physiological parameters and/or other patient context (e.g., OR/anesthesia, critical care or neonate unit, etc.).

Pulse oximetry results may be sent directly to the information system or through an intermediate device manager to the information system, depending on the interoperability capabilities of the pulse oximeter device.

Results may or may not require clinician verification prior to making results available in the information system. When results require a verifier, they can be verified individually, or as a selected group of results.

2.1.1.3 Communicate Spot-Check Pulse Oximetry Results (Use Case)

This sub-use case describes the situation where pulse oximeter measurements are taken on an intermittent basis (spot-check) rather than in continuous monitoring mode.

In this mode, pulse oximeter measurements may be verified by an operator (the clinician recording the measurement) before results are sent to the information system (or through a device manager).

In one example workflow, the operator may associate the patient identity with results information during the verification step, either in the pulse oximeter device, or in the device manager if the pulse oximeter doesn't have patient identity capabilities.

2.1.2 Information Flows

The following diagrams elaborate the information flows between the devices and the information system under conditions specific to continuous or spot-check result reporting.

At a high-level, information may flow from the pulse oximeter directly to the information system or through a device manager.

The device manager is required if the pulse oximeter cannot support standards-based interchange natively. It is also required if the pulse oximeter uses local proprietary codes in lieu of standards-based terminologies that must be transformed in order to be recognized by the information system.

Figure 2 depicts the high-level information flow between systems.

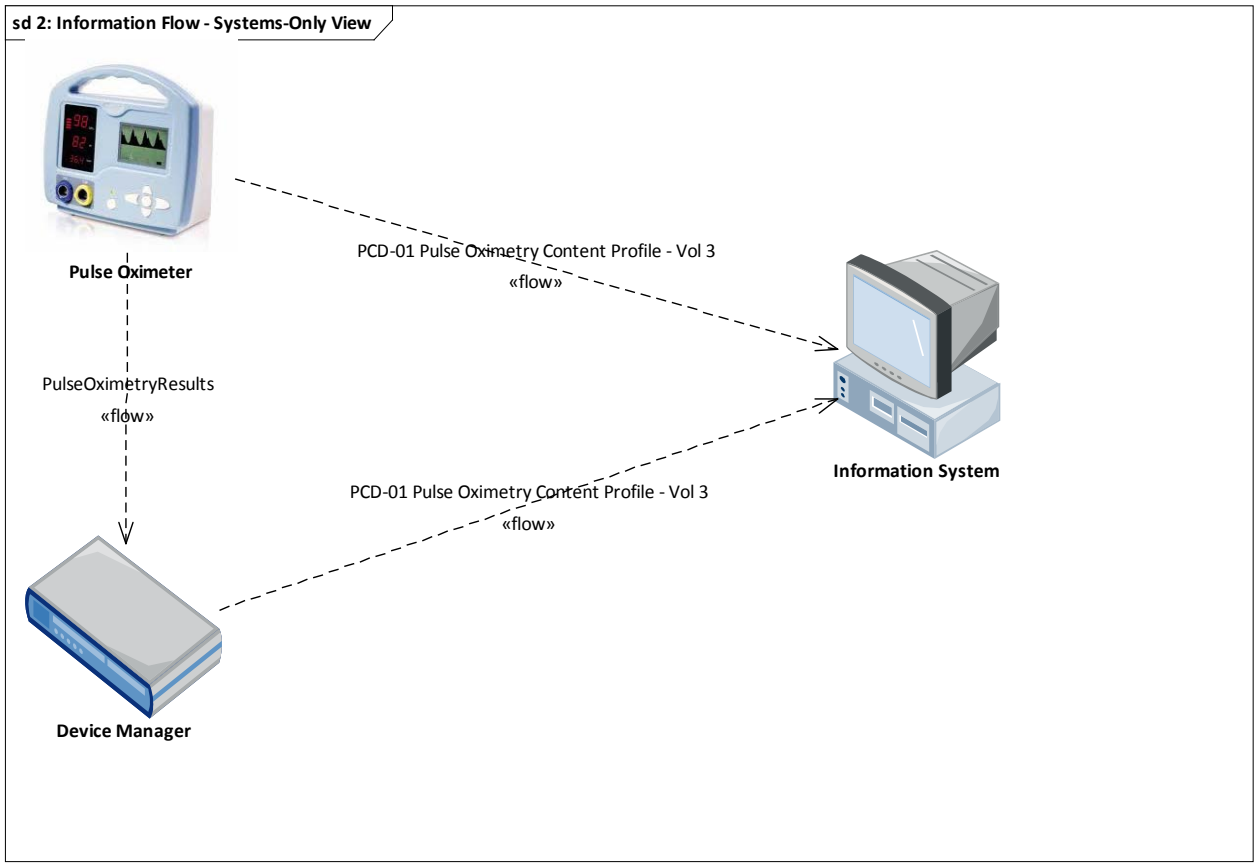

Figure 2: Information Flow - Systems-Only View

Figure 3 illustrates an alternative information flow, where results are validated at the point of care by the operator / verifier and flow directly from the pulse oximeter to the information system. This information flow assumes the pulse oximeter device is capable of sending a standards-based transaction that can be received by the information system (PCD-01 Pulse Oximetry Content Profile).

Optionally, pulse oximetry results could flow from the pulse oximeter through a device manager used to transform proprietary data protocols into a standards-based transaction (PCD-01).

The device manager can also be used to add patient context (including patient identity or other parameters) to the physiological measurements prior to transmitting results to the information system.

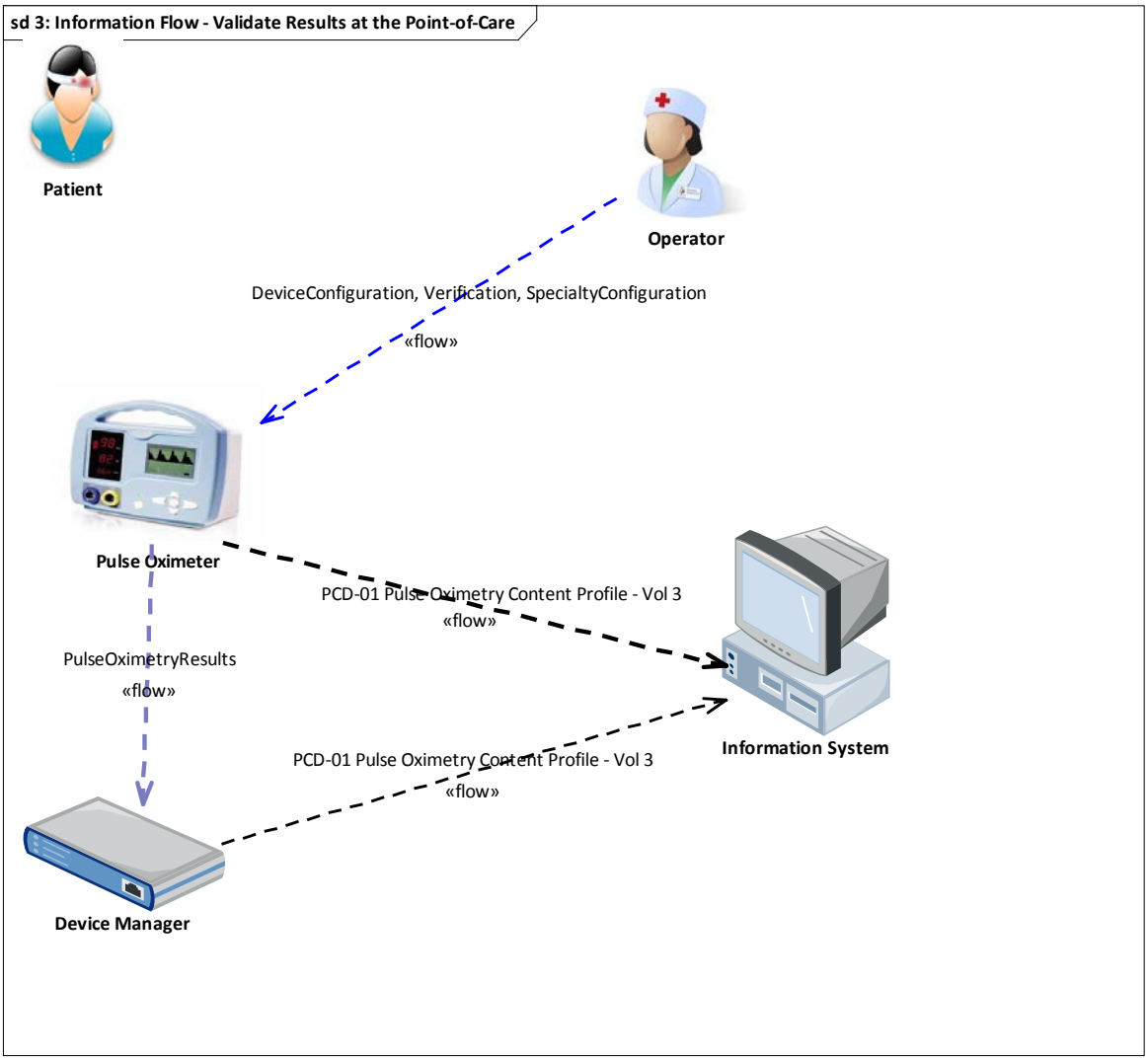

Figure 3: Information Flow - Validate Results at the Point-of-Care

Figure 4 illustrates an alternative information flow where results flow from the pulse oximeter to the information system and are then validated in the information system before being committed to the patient record in the information system.

Results verification can occur automatically or optionally, systems may be configured to require that results are verified manually in the information system.

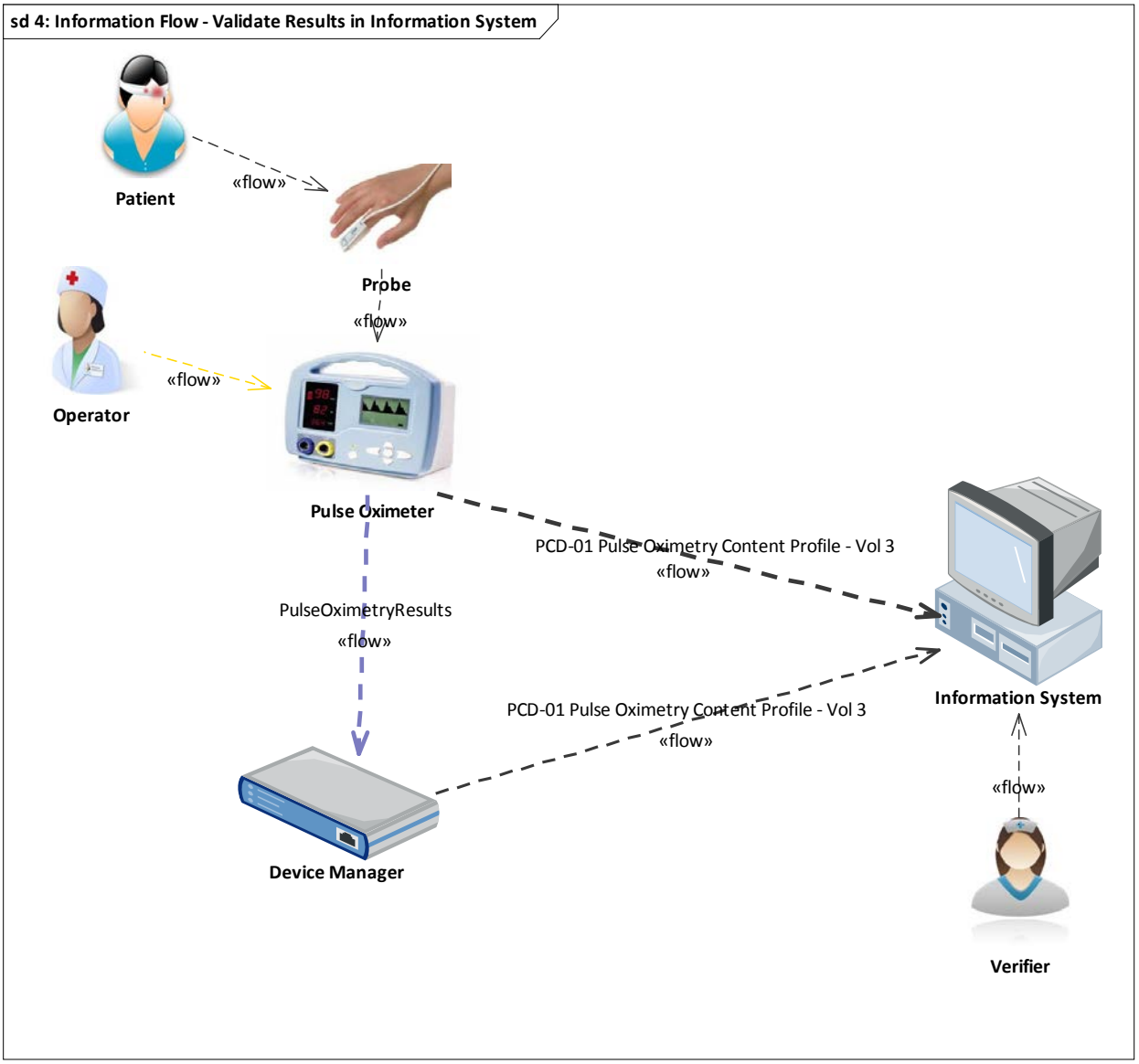

Figure 4: Information Flow - Validate Results in Information System

The information flow in Figure 5 specifies the systems required to support continuous pulse oximetry monitoring and the users required to validate the results, if validation is necessary. This information flow is consistent with the Operating Room or critical care environment where continuous monitoring results are reported, but it is mandatory that individual results be validated by clinicians prior to integrating those results into the patient's medical record.

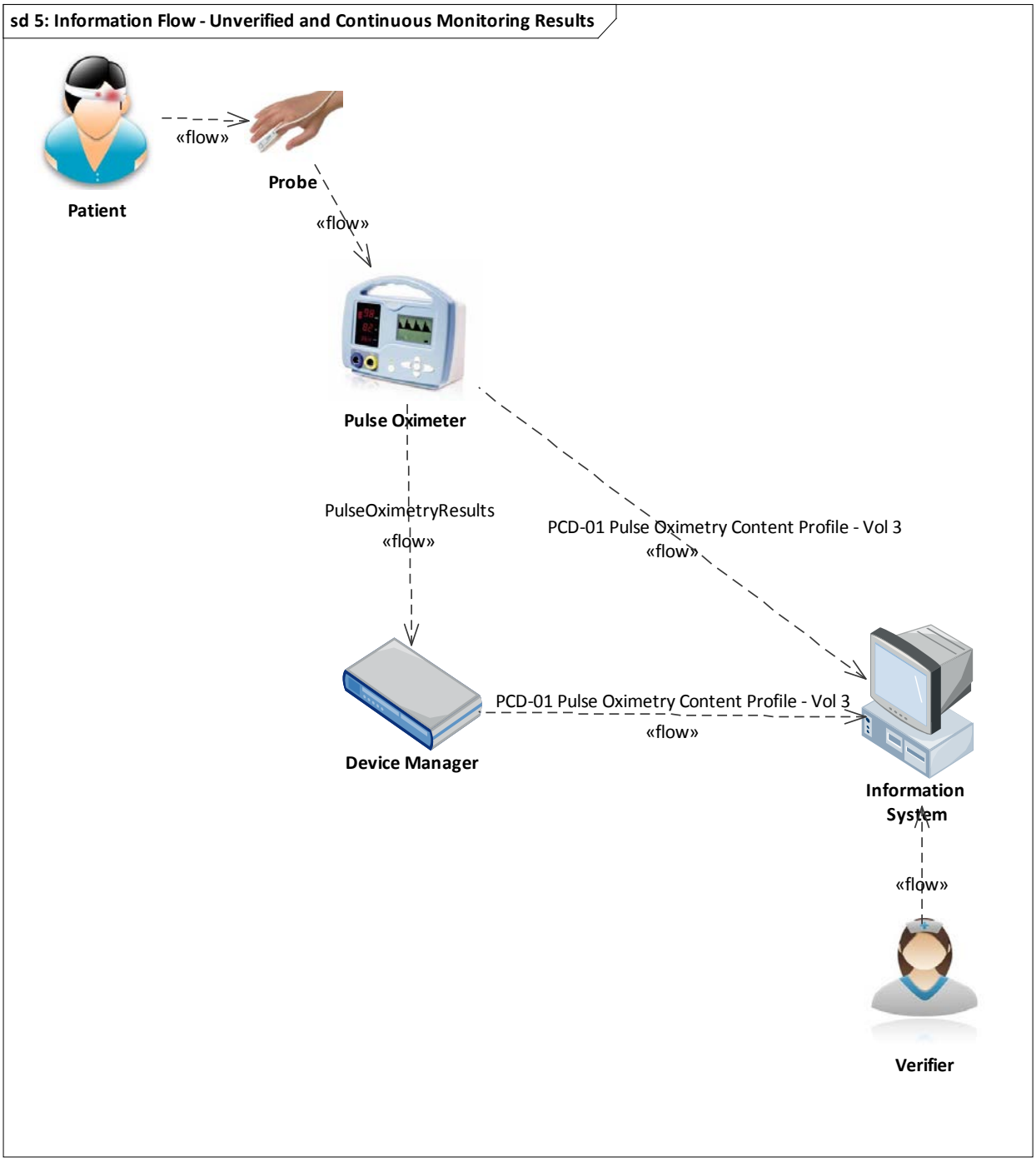

Figure 5: Information Flow - Unverified and Continuous Monitoring Results

2.2 Workflow Analysis

The use cases and information flows are further described in the detailed workflow diagram shown in Figure 6.

Workflow analysis enables us to identify not only major steps and decision points in the information flow, but also critical data elements that are the input or the result of the workflow activities.

Legend:

- The inputs and outputs to this workflow are depicted by a "Notes" icon (rectangle with upper right hand corner folded to "mark page"). These objects are described in the Data Objects section below. A white (open) arrow depicts an input data object; a black arrow depicts an output data object.
- Manual Processes are depicted by the 'Hand' icon.
- The 'Person' icon depicts a process that requires user intervention.
- The 'Gears' icon depicts an automated process.
- The 'Envelope' icons depict system transmit processes. A black envelope icon describes the system sending the data; a white (open) envelope icon depicts the system receiving the results data.
- Green circle represents start of the workflow (Initiate measurement).
- Black bulls-eye icon represent two terminate/end workflow events: Display and store results & Abort measurement.

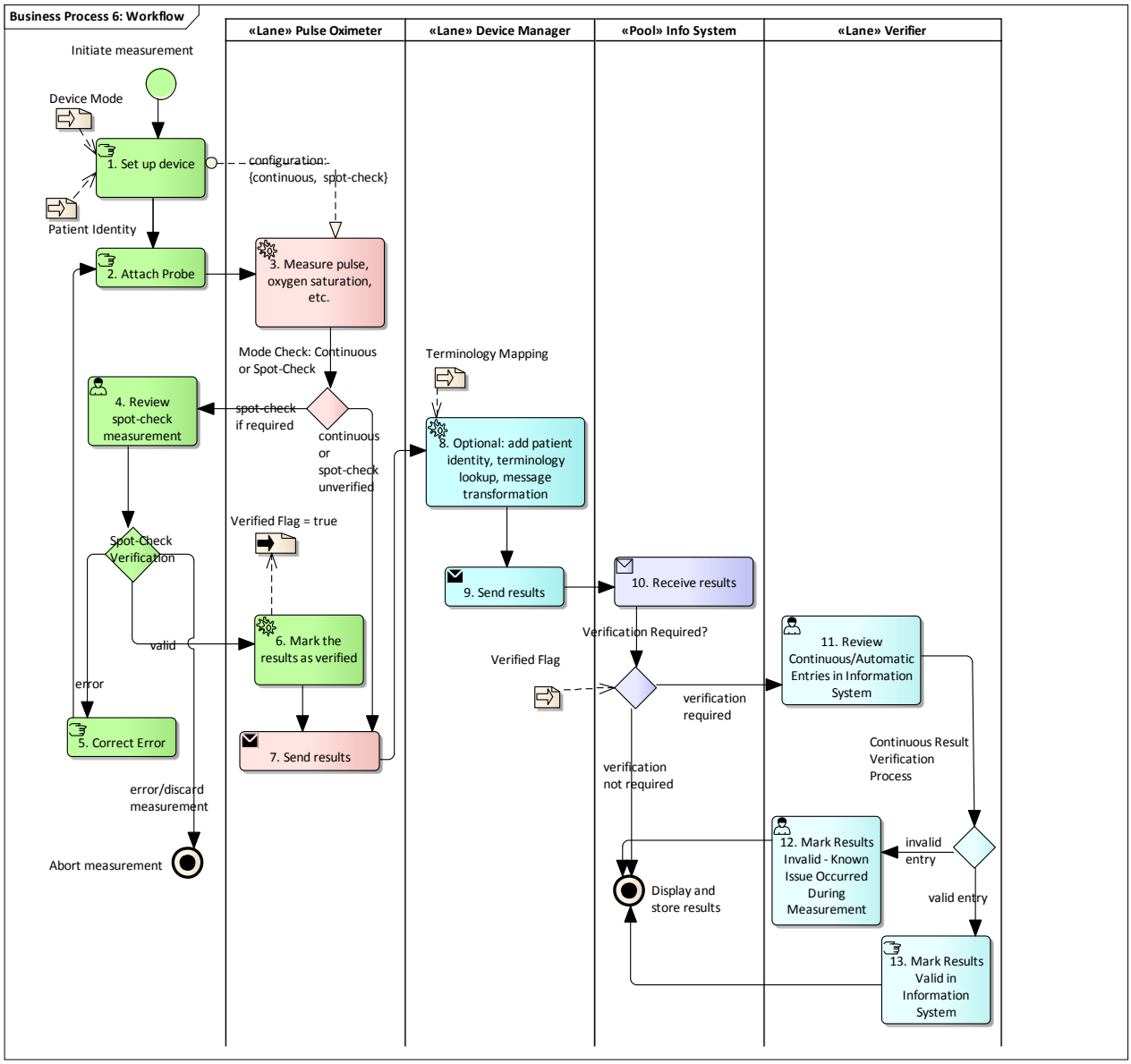

Figure 6: Workflow

1. Set up device (Activity)

The operator sets up the device configuration including device mode (e.g., continuous monitoring, spot-check) and establishes patient identity - assigning an individual patient to the results from the pulse oximeter device for the duration of time the patient's physiological condition will be monitored.

2. Attach Probe (Activity)

The operator attaches the probe to the patient. The probe may be attached to different body parts (body site) on a particular side (laterality) or region of the body (e.g., brain, lower extremity) to support Regional Oxygen Saturation.

3. Measure pulse, oxygen saturation, etc. (Activity)

The device will use the configuration and the mode to measure pulse, oxygen saturation, and in some cases, the respiratory rate of the patient. The device may also measure region-specific oxygen saturation (e.g., brain).

4. Review spot-check measurement (Activity)

When spot-check/intermittent results must be verified by a clinician operator, the results are reviewed, corrected if necessary, or discarded if the measurement is determined to be invalid or erroneous for this patient.

5. Correct Error (Activity)

If the measurement was taken in error, the operator corrects the problem (e.g., reattached probe) and retries the measurement.

6. Mark the results as verified (Activity)

Based on device and system configuration, some pulse oximetry results may have to be verified by an operator / verifier prior to being transmitted to the information system.

For pulse oximetry measurements that must be verified, this step marks results as valid prior to sending to the Information System. The diagram shows the Verified Flag set to true

7. Send results (Activity)

The pulse oximeter device sends the verified results to the information system or through a device manager.

8. Optional: add patient identity, terminology lookup, message transformation (Activity)

The Device Manager may be a very attractive solution for integrating legacy devices unable to support standard-based interoperability. The Device Manager may add information (e.g., patient identity, terminology mapping) and transform a proprietary protocol into a standard-based transaction consistent with IHE PCD-01.

9. Send results (Activity)

After performing whatever optional activities the device manager must perform to transform results data so they can be sent in standards-based transactions using standards-based terminologies that support interoperability, the Device Manager sends the pulse oximetry results to the receiving information system.

10. Receive results (Activity)

If the pulse oximetry results require clinician verification prior to making the results available in the information system, the verifier can use the information system to validate the results in Step 11. Once verified, results will be displayed for clinical use in the patient's medical record.

However, if the systems are configured to automatically incorporate results into the information system without clinician verification, the pulse oximetry results will be automatically stored in the information system and available for clinical use.

11. Review Continuous/Automatic Entries in Information System (Activity)

In this step, for those results that require verification, the clinician verifier uses the information system to review and approve pulse oximeter results prior to incorporating them into the information system.

Results can be verified as a selected group (i.e., clinicians are not required to verify each result individually. Instead, a group of results can be selected for review and verification in a single step).

12. Mark Results Invalid - Known Issue Occurred During Measurement (Activity)

This activity is intended to logically remove invalid results from the patient medical record, but it does not imply that information is physically deleted from the information system.

13. Mark Results Valid in Information System (Activity)

Assumption: more than one result can validated at a time - to avoid repetitive user actions.

Initiate measurement (StartEvent)

The process starts with a business need for pulse oximetry as identified in the clinical scenario.

Abort measurement (EndEvent)

Clinician determines that measurement is not correct, but decides not to correct error and instead, logically discards the results so they do not flow into the information system.

Display and store results (EndEvent)

Displaying and storing the results. This may include both verified and unverified data.

Mode Check: Continuous or Spot-Check

Based on the monitoring mode configured in the pulse oximeter device for the patient, the device may transmit results as either as a continuous stream (continuous monitoring) or as discrete measurements (spot-check/intermittent).

Spot-Check Verification

The operator determines whether the measurement was affected by a malfunction or probe placement issues.

Verification Required?

This check determines whether results must be verified by an operator / verifier prior to being stored in the patient record in the information system.

If verification is required, the operator is required to review (and correct if necessary) to mark the results as valid prior to storing them in the information system.

If the systems are configured such that results do not require verification, the results are automatically stored in the information system.

Continuous Result Verification Process

According to this analysis, clinicians need to be able to validate batches or groups of continuous results. Therefore, the information system must allow the verifier to select the results to be reviewed (e.g., by time range), as well as to allow selected results to be corrected or marked invalid prior to storing the results in the information system when necessary.

2.2.1 Data objects

The following is the list of data objects used as input or output in the workflow for pulse oximetry results communication.

Device Mode (DataObject)

The operator sets the pulse oximeter device to operate either as a continuously monitoring device or to measure one result at a time (spot-check or intermittent).

Patient Identity (DataObject)

An operator may set the patient identity, using a unique identifier in order to uniquely identify the patient with the pulse oximeter measurements to ensure results are associated with the correct patient. The Patient ID used to ensure patient identity may be the medical record identifier such as one retrieved from the enterprise Master Patient Index (MPI).

If the pulse oximeter does not support the device to patient association natively, the Device Manager can be used to associate patient identity with result(s).

Terminology Mapping (DataObject)

The Device Manager is responsible for translating Pulse Oximeter proprietary codes into standards-based terminologies that are used in the receiving Information System, if the Pulse Oximeter is not able to send standards-based codes natively.

Verified Flag (DataObject)

If Pulse Oximetry results must be validated by a verifier prior to committing the results to the information system, they will not flow into the information system until the Verified Flag is set to true.

The Verified Flag can be set by a verifier confirming the data, or it may be set automatically through device and system configuration.

Verified Flag = true (DataObject)

This verified flag is set to true when spot-check/intermittent results are marked as valid to be sent to the information system.

In general, it is assumed that an operator or verifier will perform this function, but spot-check results could be configured to be sent to the information system without requiring operator verification.

2.3 Data Analysis

The data analysis section identifies the information that will be sent by the pulse oximeter device and recorded in the information system.

The following tables contain a description of the information types and data elements.

Each table describes an information type (class) and its associated data elements (attributes) that have been identified during this analysis.

For each coded attribute, a representative value set (ENUMERATION) has been specified under the attribute name in the table.

An attribute is assumed to be REQUIRED (mandatory) unless it has been marked OPTIONAL in the table.

An attribute may only occur ONCE unless the attribute is specified as MAY REPEAT in the table.

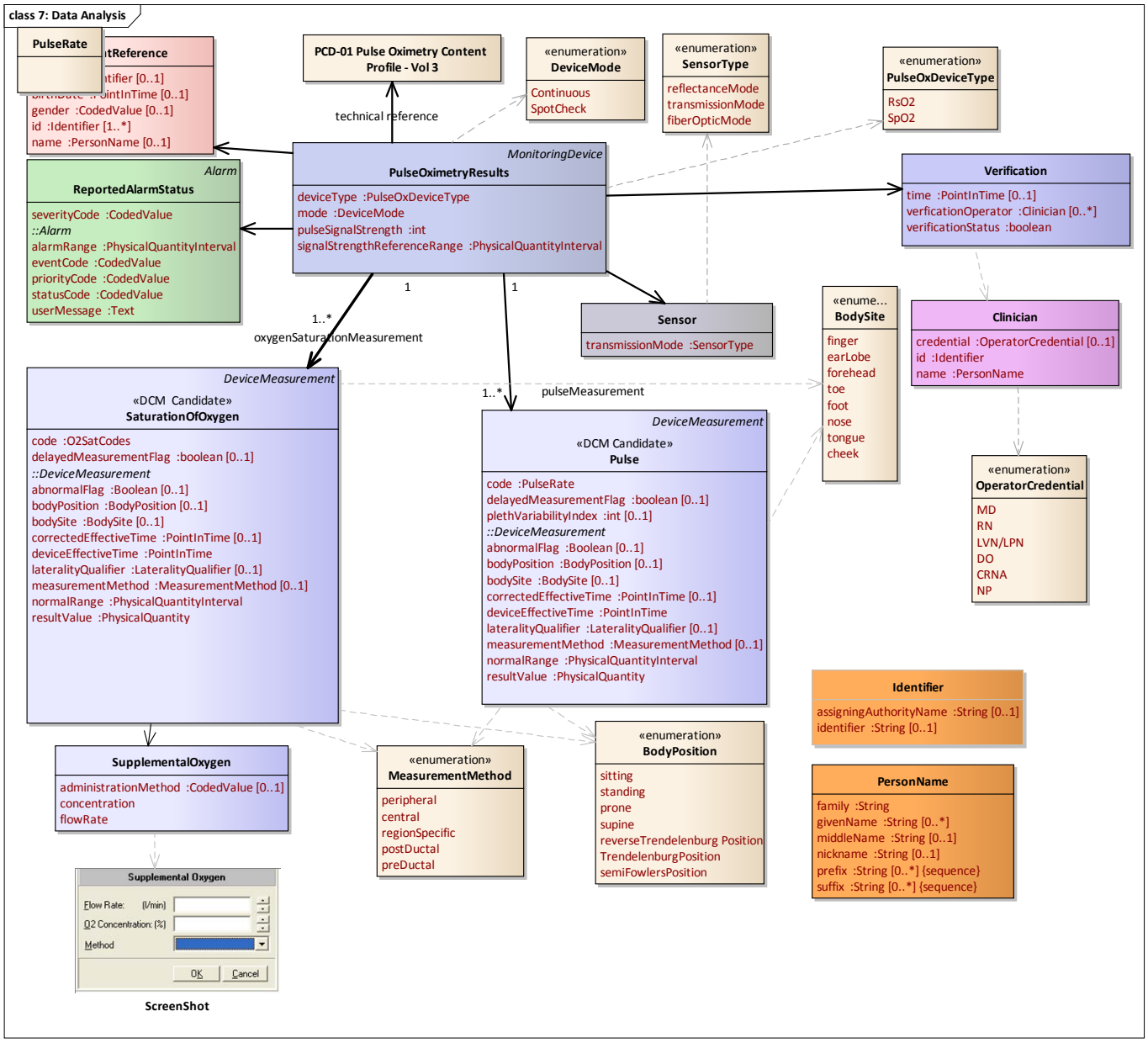

Figure 7: Data Analysis

PCD-01 Pulse Oximetry Content Profile - Vol 3 (Class)

690 The purpose of the project described in this document is to produce additional information related to the use of standard-based transactions to support pulse oximetry optimally. These types of use-case-specific profiles are organized into "Content Profiles" that are the subject of Volume 3 of an IHE Technical Specification.

Alarm (Class)

This is an abstract based class for both configured and reported alarm information.

Alerts can be physiological or technical. A disconnected probe will be a technical alarm. The disconnect events may be a normal part of clinical care and not necessarily required to be stored in the information system.

Within the context of this analysis, the Alarm class is not intended to be used to exchange alarms / alerts on a real-time basis to notify clinicians of urgent conditions. The standard PCD-01 transaction is not intended for this purpose.

This class instead, is used to transmit relevant alarm / alert data from the device to the information system for historical purposes only (e.g., event reporting, quality, etc.)

Attribute	Notes
alarmRange PhysicalQuantityInterval Public	This optional attribute specifies the minimum and maximum value for the parameter that causes the alarm. These ranges may be configured by clinicians.
eventCode CodedValue Public	Represents the reason that the alarm occurred (e.g., probe disconnected, battery low, result out of range).
priorityCode CodedValue Public	Communication priority (e.g., panic). This may be used to specify that the alarm requires a specific level of attention.
statusCode CodedValue Public	The alarm status (e.g., new, completed). This status is useful for alarm management - to indicate if an alarm was resolved.
userMessage Text Public	A user-friendly message indicating the reason that the alarm occurred. This is necessary since error codes (eventCode) are generally not human-readable and may be not be fully standardized across vendors.

ReportedAlarmStatus (Class)

Device alarm (i.e., a type of Alarm specific to device operation) and their configuration are very important to the clinicians using these medical devices. This class describes the information reported when an alarm condition occurs.

Attribute	Notes
severityCode CodedValue Public	The severity of the alarm event. This is dependent of the degree detected at the time the error occurs.

PulseOximetryResults (Class)

This class is intended to capture the properties specific to a Pulse Oximeter. It is a specialization of MonitoringDevice class and thus it inherits those attributes as well.

Attribute	Notes

Attribute	Notes
deviceType PulseOxDeviceType Public	This attribute is used to distinguish the type of pulse oximetry device that is used to generate the pulse oximeter results. Region specific monitoring (Rs02) is a specialized type of pulse oximeter device that is used to preserve major organ functions and provides real-time monitoring of changes in regional oxygen saturation (RsO2) of blood in the brain or other body tissues. SpO.
mode DeviceMode Public	This data element identifies whether the device is operating as continuous, or as a periodic/on-demand spot check pulse oximeter.
pulseSignalStrength int Public	The pulse signal strength indicates how well the probe is able to acquire a signal for processing. The signal strength is s numeric value.
signalStrengthReferenceRange PhysicalQuantityInterval Public	This is a range that represents the strength of the signal transmitted between the probe attached to the patient and the pulse oximeter device receiver interpreting the results measurement. This is an important indicator as the signal strength may impact the actual results measurement. The strength of the signal is generally a represented as a visual indicator on a device screen (e.g., a logarithmically scaled segmented bar graph between a range 0 - 9, or 1 - 5, indicating lowest to highest signal strength). This range is analogous to the bars on a mobile telephone, indicating the strength of the available cell phone service. While the signal strength reference range is not standardized, the signal strength should map to a standardized reference range value containing enumerations such as Strong, Moderate, Weak, Unobtainable.

DeviceMeasurement (Class)

715 This class is used to describe a generic device observation or parameter. This may be a vital sign measurement, a glucose value, a ventilator setting, etc.

This class describes the overall structure of a measurement and it may be constrained for use with pulse oximetry parameters.

Attribute	Notes
abnormalFlag Boolean Public [0..1]	The abnormal flag indicating that the observation value if out of normal range.
bodyPosition BodyPosition Public [0..1]	This optional and coded attribute refers to the position of the patient at the time the measurements are taken. Example body positions include sitting, standing, prone, supine, etc.
bodySite BodySite Public [0..1]	The coded attribute represents the site on the patient's body for the placement of the pulse oximetry probe.
correctedEffectiveTime PointInTime Public [0..1]	This optional attribute may be added by the Device Manager System if the legacy system is not networked and thus unable to keep its clock synchronized over time.
deviceEffectiveTime PointInTime Public	This attribute specifies the date/time when the physiological parameter was measured and is the time reported by the pulse oximeter device. The correctedEffectiveTime attribute is used to indicate the actual date/time of the

Attribute	Notes
	measurement within accuracy of "n" seconds - where "n" represents the number of seconds in delay that is clinically acceptable. Note: correctedEffectiveTime may not be available from all pulse oximeters. For those pulse oximeter devices, the device manager is required to provide a corrected time stamp.
lateralityQualifier LateralityQualifier Public [0..1]	This coded attribute qualifies the body site location by specifying the side of the body where the probe is positioned to acquire the measurements (e.g., left, right).
measurementMethod MeasurementMethod Public [0..1]	This attribute specifies the method that was used to obtain the measurement result that gets stored in the information system (e.g., measured or calculated). This attribute is optional when LOINC is used for the "code" data element, because LOINC specifies the measurement method as part of the code's definition/description.
normalRange PhysicalQuantityInterval Public	Typically this range is set to the normal, physiological range for the parameter measured. If this range is configurable on the device, it may also specify other limits imposed by the patient's condition (e.g., Chronic Obstructive Pulmonary Disease (COPD), asthma, bronchitis, or age – pediatric, geriatric).
resultValue PhysicalQuantity Public	This attribute is used to specify the value and including units of measure.

Verification (AssociationClass)

This association class is intended to capture the date/time when the observation is validated by a clinician and persisted in the EHR-System. Validated results are typically required for a complete medical record. The verification is completed by the Clinician (e.g., device operator).

Attribute	Notes
time PointInTime Public [0..1]	Date/time when a clinician verified the device observation entered in the information system.
verficationOperator Clinician Public [0..*]	The clinician who verified the results to be stored in the information system.
verificationStatus boolean Public	This attribute holds the status of the result with respect to whether it has been verified by a clinician and is marked to be posted to the patient's electronic health record and made available in the information system. Note: Not all results must be verified by clinicians to be incorporated into the information system.

Clinician (Class)

This class identifies the clinician who operates/configures the devices or validates (verifies) the pulse oximetry measurements to be recorded in the information system (e.g., as seen in the nursing flowsheet, EHR-S).

Attribute	Notes
credential OperatorCredential Public [0..1]	This coded attribute represents the operator / verifier's credential during the workflow as reflected by the user log in that is associated with the patient result measurements (e.g., RN, LVN/LPN, MD, DO, CAN).
id Identifier Public	Pulse Oximeter device operator's unique identifier assigned by an organization.
name PersonName Public	Pulse Oximeter device operator's name.

730 PatientReference (Class)

This class contains the attributes used typically to associate a patient with a device. Note that this list of patient identifying traits is not comprehensive and, depending on the accuracy of the identifiers, some demographic traits are redundant.

Attribute	Notes
account Identifier Public [0..1]	The patient account number is sometimes used in addition to the medical record number.
birthDate PointInTime Public [0..1]	Patient's date of birth.
gender CodedValue Public [0..1]	This attribute reflects the gender of a person used for administrative purposes (as opposed to clinical gender).
id Identifier Public [1..*]	Patient Identifier (e.g., Medical Record Number identifier in the enterprise Master Patient Index). Note that the identifier is always fully qualified by an assigning authority (to ensure uniqueness across entities).
name PersonName Public [0..1]	Patient name

735 Identifier (Class)

This data type is a constraint of the HL7 Version 3 II data type.

Attribute	Notes
assigningAuthorityName String Public [0..1]	A human readable name or mnemonic for the assigning authority. The Assigning Authority Name has no computational value. The purpose of an Assigning Authority Name is to assist an unaided human interpreter of an II value to interpret the authority. Note: no automated processing must depend on the assigning authority name to be present in any form.

Attribute	Notes
identifier String Public [0..1]	A character string as a unique identifier within the scope of the identifier root.

PersonName (Class)

The name of a person participating in this use case. The person can be the patient or a clinician (verifier, operator). Uses a constrained version Person Name data type used in HL7 Version 2 and Version 3.

Attribute	Notes
family String Public	"Family name, this is the name that links to the genealogy" (HL7)
givenName String Public [0..*]	"Given name (don't call it "first name" since given names do not always come first)" (HL7)
middleName String Public [0..1]	This is an optional name that may fall between givenName and family name.
nickname String Public [0..1]	"A call me name is (usually a given name) that is preferred when a person is directly addressed." (HL7)
prefix String Public [0..*]	"A prefix has a strong association to the immediately following name part. A prefix has no implicit trailing white space (it has implicit leading white space though). Note that prefixes can be inverted" (HL7) A Person Name Prefix is usually an academic or nobility title. An Academic title includes a prefix like "Dr." There are still people with nobility titles (aristocrats). German "von" is generally a nobility title, not a mere voorvoegsel. Others are "Earl of" or "His Majesty King of..." etc. Rarely used nowadays, but some systems do keep track of this.
suffix String Public [0..*]	"A suffix has a strong association to the immediately preceding name part. A prefix has no implicit leading white space (it has implicit trailing white space though). Suffices cannot be inverted" (HL7).

SaturationOfOxygen (Class)

This is a candidate Detailed Clinical Model (DCM) for conveying the details of saturation of oxygen (SPO2) result as measured by a pulse oximeter device.

This class inherits all the attributes and associations of a DeviceMeasurement class.

If the probe is disconnected from the patient, the device may produce an alarm condition rather than a result.

Attribute	Notes
code O2SatCodes Public	This attribute specifies the code of the observation using a standard code system (e.g., LOINC, 11073, SNOMED-CT).
delayedMeasurementFlag boolean Private [0..1]	This optional data element identifies that the result was previously acquired, and is an extrapolated value, not a current measurement. The deviceEffectiveTime or correctedEffectiveTime will indicate the actual date/time within an accuracy of "n" seconds - where "n" represents the number of seconds in delay that is clinically acceptable for measurement accuracy.

Pulse (Class)

This is a candidate Detailed Clinical Model (DCM) for conveying the details of a pulse result as measured by a pulse oximeter device.

This class inherits all the attributes and associations of DeviceMeasurement.

Attribute	Notes
code PulseRate Public	This attribute specifies the code of the observation using a standard code system (e.g., LOINC, 11073, SNOMED-CT).
delayedMeasurementFlag boolean Private [0..1]	This optional data element identifies that the result was previously acquired, and is an extrapolated value, not a current measurement. The deviceEffectiveTime or correctedEffectiveTime will indicate the actual date/time within an accuracy of "n" seconds - where "n" represents the number of seconds in delay that is clinically acceptable for measurement accuracy.
plethVariabilityIndex int Public [0..1]	The pleth variability index is a qualifier specific to pulse measurements. Pleth Variability Index (PVI) is a new algorithm that allows continuous and automatic estimation of respiratory variations in the pulse oximeter waveform amplitude. Pleth wave form shows a user the strength of the pulse by displaying the peaks and valleys of the blood pulsing in the form of a wave displayed on the oximeters screen. The stronger the pulse detected, the higher the difference is between the peaks and valleys of the wave. Since an oximeter must read arterial pulsing blood to obtain oxygen saturation levels, it can also additionally be used to read pulse rates. Some people often confuse the pulse rate with the heart rate. Although both rates usually correspond, they can differ. Heart rate indicates the actual heart beating. Pulse rate indicates the number of times a pulse is felt. Poor electrical conductivity of the heart or poor circulation can cause a variation in both rates.

RespiratoryRate (Class)

This is a candidate Detailed Clinical Model (DCM) for conveying the details of a respiratory rate as measured by a pulse oximeter device.

This class inherits all the attributes and associations of DeviceMeasurement.

Note: This type measurement is not commonly implemented by most devices at this time.

Attribute	Notes
delayedMeasurementFlag boolean Private [0..1]	This optional data element identifies that the result was previously acquired, and is an extrapolated value, not a current measurement. The deviceEffectiveTime or correctedEffectiveTime will indicate the actual date/time within an accuracy of "n" seconds - where "n" represents the number of seconds in delay that is clinically acceptable for measurement accuracy.

Probe (Class)

The probe is the component of the pulse oximeter that attaches to the body site of the patient, and used to transmit measurements to the pulse oximeter receiver where they are processed and analyzed.

A basic optical probe of a noninvasive pulse oximeter consists of a red and infrared light emitting diode (LED) and a silicon photodiode (PD).

Attribute	Notes
transmissionMode ProbeType Public	The coded attribute is used to identify the type of probe used to acquire the physiological measurements from the patient.

SupplementalOxygen (Class)

This class represents optional information that may be captured related to supplemental oxygen the patient may be on at the time the pulse oximetry measurement is taken, and can be used for interpreting the results.

Note: This type of information is not commonly captured in most pulse oximeters at this time.

Attribute	Notes
administrationMethod CodedValue Public [0..1]	This coded attribute represents the method by which supplemental oxygen is being administered to the patient while being monitored by a pulse oximetry device (e.g., mask, nasal cannula, re-breathing mask, respirator, etc.)
concentration Public	This attribute specifies the concentration of oxygen being delivered to the patient during the administration of supplemental oxygen while being monitored by pulse oximetry.
flowRate Public	This attribute specifies the oxygen flow rate that was prescribed for the patient when supplemental oxygen is administered (e.g., liters per minute).

ScreenShot (Class)

The screen shot in the lower left hand corner Figure 6 illustrates how supplemental oxygen information is captured at the VA. Supplemental oxygen data may be manually added to the pulse oximetry results information once the pulse oximetry results have been stored in the information system.

2.3.1 Terminology Analysis

The value set analysis describe here is intended to be implemented using standards-based terminologies. The following set of standards is intended to address the terminology needs of this specification:

- SNOMED-CT®
- LOINC

- Pulse Oximetry – ISO/IEEE 11073 -10404 Pulse Oximeter
- ISO/IEEE 11073- 20601 Personal Health Device Information Model
- IHE PCD Device Enterprise Communication (DEC) profile
- X 73 nomenclature

LateralityQualifier (Enumeration)

This attribute is used to express the side of the patient's body that was used to attach the probe.

Attribute	Notes
left Public	
right Public	

2.3.1.1 O2SatCodes (Class)

This value set contains the codes of observations related to Saturation of Oxygen in arterial blood by pulse oximeter measurement using codes from a standard code system.

2.3.1.2 OperatorCredential (Enumeration)

This is a representative value set of codes intended to reflect the credential of the operator who verified the pulse oximetry results in the system.

Attribute	Notes
MD Public	Doctor of Medicine
RN Public	Registered Nurse
LVN/LPN Public	Licensed Vocational / Practical Nurse
DO Public	Osteopath
CRNA Public	Certified Registered Nurse Anesthetist
NP Public	Nurse Practitioner

2.3.1.3 PulseOxDeviceType (Enumeration)

This enumeration is a representative list used to distinguish region specific pulse oximetry devices.

Attribute	Notes
RsO2 Public	Oxygen saturation (amount of oxygen bound to hemoglobin in arterial blood) (SaO2) as measured using a Region Specific Oxygen Saturation device (RsO2).
SpO2 Public	Oxygen saturation (amount of oxygen bound to hemoglobin in arterial blood) (SaO2) in the blood as measured by pulse oximetry (SpO2)

2.3.1.4 PulseRate (Class)

This value set contains the codes of observations related to pulse rate as measured by pulse oximeter using codes from a standard code system.

2.3.1.5 ProbeType (Enumeration)

This enumeration is a representative list of the types of probes used in pulse oximetry.

Attribute	Notes
reflectanceMode Public	In reflectance mode, the photodiode detects reflected or back scattered light which enables measurements from multiple locations on the body where transmission measurements are not feasible. Normally, the probe is applied to the forehead region, but is not restricted to this location. An alternative and more generic term is "surface probe." Reflectance pulse oximetry uses reflected rather than transmitted light on a single-sided monitor. It can therefore be used more proximally anatomically e.g., forehead, feet, chest, bowel, although it may be difficult to secure. Other than using specific reflection spectra, the principles are the same as for transmission oximetry. Reflectance pulse oximetry has recently become an important new clinical modality with potential benefits in fetal monitoring where the only accessible location is the fetal head.
transmissionMode Public	In transmission pulse oximetry, the probe is usually attached to a fingertip, foot, or earlobe, such that the light emitting diode and photodiode are placed on opposite sides of the peripheral pulsating vascular bed (e.g., finger, ear lobe, etc.). Transmission mode pulse oximetry is limited to areas of the body where transmitted light can be readily detected. Most accessible body sites are peripheral areas of the body such as fingertips, ear lobes and toes in adults, and the foot or palms in infants.
fiberOpticMode Public	Fiber optic photoplethysmographic (PPG) probes eliminate the risk of RF burns associated with the use of conductive cables and probes in MRI. The Fiber Optic Probes contain no magnetic or electrically conductive materials and eliminate the risk of RF burns caused by improper use of conventional pulse oximeter probes and cables in the MRI environment.

2.3.1.6 BodyPosition (Enumeration)

This enumeration lists the representative values of body position codes for a pulse oximetry result.

Attribute	Notes
sitting Public	Specifies the body position during the measurement.
standing Public	Specifies the body position during the measurement.
prone Public	Specifies the body position during the measurement.
supine Public	Specifies the body position during the measurement.
reverseTrendelenburg Position Public	The reverse Trendelenburg position is surgical position in which the lower extremities are leveled lower than the head and neck. It is the opposite of the Trendelenburg position, in which the head and the neck are below the lower extremities.
TrendelenburgPosition Public	In the Trendelenburg position the body is laid flat on the back (supine position) with the feet higher than the head by 15-30 degrees. This is a standard position used in abdominal and gynecological surgery. It allows better access to the pelvic organs as gravity pulls the intestines away from the pelvis. It was named after the German surgeon Friedrich Trendelenburg.
semiFowlersPosition Public	The Semi-Fowler's position is when a patient is lying in bed in a supine position with the head of the bed at approximately 30 degrees. Patients who are on tube feedings are typically placed in the Semi-Fowler's position. Were the patient to lay flat the tube feeding fluid can possibly run into the lungs. Elevating the head of the bed to 30 degrees decreases the risk of the patient aspirating the tube feeding fluid.

2.3.1.7 BodySite (Enumeration)

This enumeration lists the representative values of a body site code for a pulse oximetry result.

Attribute	Notes
finger	
earLobe	
forehead	
toe	
foot	
nose	
tongue	
cheek	

2.3.1.8 MeasurementMethod (Enumeration)

This enumeration lists the representative values of measurement method codes for a pulse oximetry result.

If the DeviceMeasurement.code is encoded using LOINC, this attribute is likely not to be necessary, since the measurement method is part of the code definition/description.

Attribute	Notes
peripheral Public	
central Public	
regionSpecific Public	This type of indirect measurement of oxygen saturation (amount of oxygen bound to hemoglobin in arterial blood) measures of tissue oxygen saturation and is intended to preserve major organ function often during surgery (e.g., brain, heart, lungs, etc.).
postDuctal Public	The measurement of oxygen saturation (amount of oxygen bound to hemoglobin in arterial blood) by pulse oximetry in a neonate patient where the probe is applied to one foot. Post-ductal saturations become lower than pre-ductal when there is mixing of pulmonary blood through the duct, i.e., in congenital heart defects that are duct dependent.
preDuctal Public	Indirect measurement of oxygen saturation (amount of oxygen bound to hemoglobin in arterial blood) using pulse oximetry where the probe is applied to the right hand of a neonate patient. Pre-ductal saturations in a newborn are measured in the right hand and is a measurement of the arterial blood oxygen saturation after the blood leaves the heart and before it reaches the ductus arteriosus in the aorta. This is the blood that is perfusing the brain.

2.3.1.9 DeviceMode (Enumeration)

This enumeration lists the representative values of device mode codes for a pulse oximetry result.

Attribute	Notes
Continuous Public	Continuous/automatic monitoring of pulse oximetry as conducted in the operating room, intensive, or critical care.
SpotCheck Public	Intermittent pulse oximetry measurement performed by a clinician for assessments, physical exams, etc.

Glossary

The following is a summary of terms used in this document:

Term	Type	Description
Actor	Technical	An actor in the Unified Modeling Language (UML) "specifies a role played by a user or any other system that interacts with the subject." "An Actor models a type of role played by an entity that interacts with the subject (e.g., by exchanging signals and data), but which is external to the subject."
Association	Technical	A relationship between two or more entities. Implies a connection of some type - for example one entity uses the services of another or one entity is connected to another over a network link.
Candidate Standard validation	Business	Executing the Candidate Standard validation approach. HL7 will have a modified open approach to candidate standard validation. All those participants that made a non-binding commitment in step (5) will be included if they choose to honor the commitment. Others may be added to achieve a balance or for other necessities for validation. The previous notwithstanding, HL7 will limit the number of participants to ensure a manageable process and reasonable time frame.
Class	Technical	A logical entity encapsulating data and behavior. A class is a template for an object - the class is the design, the object the runtime instance.
Conformance Statement	Technical	A conformance statement is a claim that the behavior of an application or application module agrees with the constraints stated in one or more profiles. A Conformance Statement is documentation of the degree to which a particular application conforms to the specification. Part of that document will be a profile expressing the requirements relevant to a particular standard. Standard Profiling is based upon the consistent application of constraints to a set of base specifications. This document outlines the processes that govern the definition of profiles and conformance statements.
DAM	Technical	See Domain Analysis Model.
DCM	Technical	See "Detailed Clinical Model".
Detailed Clinical Model (DCM)	Technical	A Detailed Clinical Model (DCM) is an information model of a discrete set of precise clinical knowledge which can be used in a variety of contexts. Detailed Clinical Models (DCM) are descriptions of items of clinical information that include the clinical knowledge on the concept, the data specification, a model and where possible, technical implementation specifications. A DCM is a conceptual specification of the semantics of discrete structured clinical information. It provides the data elements and attributes, including the possible values and types of the attributes, needed to convey the clinical reality in a fashion that is understandable to both clinical domain experts and modelers. This includes the potential for use in health care information and communication technology, for example in EHR, Telehealth applications, messages, medical devices, computer algorithms, and deductive reasoning, decision support, among others. It provides unambiguous detail which is intended to be cross domain and cross discipline and standardized and reusable over domains, purposes, standards and implementations. DCM work currently includes clinical content analysis, quality assurance, information modeling, and repositories. DCM includes the structural model. Dynamic models are handled elsewhere, but some aspects of dynamics might be in the DCM.

Term	Type	Description
		"**Detailed Clinical Models** are small items of clinical, preventive and care information that are well defined and for which knowledge, data definition, vocabulary binding, and information model for use in information and communication technology are standardized and reusable over domains, purposes, standards and implementations." [ISO 13972 draft]
Domain Analysis Model	Technical	A Domain Analysis Model (DAM) is an abstract representation of a subject area of interest designed to provide a generic representation of a class of system or capability and to suggest a set of approaches to implementation. In HL7 a DAM is complete enough to enable the development of downstream platform-independent models: HL7 RIM-based information and service models. A DAM may also be used to constrain other standards for use in healthcare (e.g., to constrain access control markup standards). The process used to create a DAM is documented in the HL7 Development Framework (HDF). Framework (HDF).
Extends Relationship	Technical	A relationship between two use cases in which one use case 'extends' the behavior of another. Typically this represents optional behavior in a use case scenario - for example a user may optionally request a list or report at some point in a performing a business use case.
Extubation	Business	This term is used to describe the removal of a device from a hollow organ.
FiO2	Business	Fraction of inspired oxygen, a percentage of inhaled gas
HL7 Profile	Technical	An HL7 profile is an unambiguous specification of one or more HL7 standards that have been analyzed for a particular use case. It prescribes a set of precise constraints upon one or more standard HL7 artifacts. An HL7 profile is conformant, in all aspects, with the HL7 defined specification used in the profile according to the constraints or extension rules. It may specify constraints on the standard HL7 definition. An implementation profile fully describes an interoperability interaction between two or more systems through the combination of the following: a) one use case analysis, b) one or more dynamic definitions, and c) one or more static definitions.
Includes Relationship	Technical	A relationship between two use cases in which one use case 'includes' the behavior. This is indicated where there a specific business use cases which are used from many other places - for example updating a train record may be part of many larger business processes.
Industry outreach	Business	Depending on the goals of the project this may be as little as a set of announcements of work going on in HL7 targeted at the impacted stakeholder communities. For some projects it may involve scheduling out-of-cycle meetings, scheduling meetings jointly with other stakeholder organizations or some kind of "Town Hall" meetings similar to those used for the EHR Functional Requirements DSTU.
ISO/IEEE 11073-10101 Nomenclature	Technical	Within this standard nomenclature codes are defined, these give the possibility to clearly identify objects and attributes in relation to the so-called OID-Code). The nomenclature is divided in partitions, to demarcate codes with regards to content and functional.
LOINC	Technical	Logical Observation Identifiers Names and Codes (LOINC®) LOINC: A data set of universal identifiers for laboratory and other clinical observations to facilitate exchange and storage of clinical results or vital signs for healthcare. The purpose of LOINC® is to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set

Term	Type	Description
		of universal codes and names to identify laboratory and other clinical observations. The Regenstrief Institute, Inc., an internationally renowned healthcare and informatics research organization, maintains the LOINC database and supporting documentation, and the RELMA mapping program. loinc.org
Medical Device	Business	Any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article: 1) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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, disinfections of medical devices, providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and 2) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means." Reference: GHTF/SG1/N29R16:2005 published by the Global Harmonization Task Force, (2005):
Message Profile	Technical	Definition: An HL7 message profile is an unambiguous specification of one or more standard HL7 messages that have been analyzed for a particular use case. Each message profile may have a unique identifier as well as publish/subscribe topics.
NIF	Business	Negative inspiratory force, a measure of pulmonary mechanics used to assess readiness to wean
Non-volunteer resources	Business	Beyond the routine support, HL7 headquarters provides for balloting, etc., additional support may be required to assess potential funding requirements. Hosted projects will be expected to provide associated funding.
NTP	Technical	(Simple) Network Time Protocol - See SNTP.
PaCO2	Business	Partial pressure of carbon dioxide in the blood. Critical in regulating breathing levels and maintaining body pH.
PACU	Business	Post Anesthesia Care Unit
PaO2	Business	Partial pressure of oxygen in the blood.
Protocol Specifications	Technical	Protocol specifications encompass the following work products developed and supported by HL7: all Versions of the HL7 messaging standard; the Clinical Document Architecture (CDA); Arden Syntax; CCOW specifications; Service Oriented Architecture (SOA) standards; any other normative standards subsequently released by HL7; various functional models, implementation guides, and Implementation Technology Specifications (ITS); the Reference Information Model (RIM); and those informative documents initiated and balloted by the various Work Groups.

Term	Type	Description
Quality Criteria	Business	A project commitment to a measure of the quality for each step of the project cycle. It is expected that most projects will use or possibly adapt boiler-plate quality criteria developed as part of HL7's methodology.
Quality Review	Business	An evaluation of whether the work products of a step meet the pre-established quality criteria. At most steps the project team will self-assess against these criteria and take a vote (not a ballot) to move ahead to the next step.
Rosetta Terminology Mapping	Technical	The Rosetta Terminology Mapping (RTM)) IHE PCD Profile is focused on identifying a core set of semantics that are shared between multiple devices within the same modality (e.g., physiological monitors, ventilators, infusion pumps, etc.) and then mapping them to a standard terminology. The RTM mapping effort will initially include numeric parameters and their associated units of measurement and enumerated values. http://wiki.ihe.net/index.php?title=PCD_Profile_Rosetta_Terminology_Mapping References: ISO/IEEE 11073-10101 Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature, First edition, 2004-12-15. ISO and IEEE, 2004. The 'Unified Code for Units of Measure' (UCUM).
RR	Business	Respiration rate, in breaths per minute
RTM	Technical	See "Rosetta Terminology Mapping".
SaO2	Business	The saturation level of oxygen in hemoglobin, as measured by samples obtained from arterial puncture.
Sequence Diagram	Technical	UML Sequence diagrams are a dynamic modeling technique, as are collaboration diagrams and activity diagrams. UML sequence diagrams are typically used to: 1. Validate and flesh out the logic of a usage scenario. A usage scenario is exactly what its name indicates – the description of a potential way that your system is used. The logic of a usage scenario may be part of a use case, perhaps an alternate course; one entire pass through a use case, such as the logic described by the basic course of action or a portion of the basic course of action plus one or more alternate scenarios; or a pass through the logic contained in several use cases, for example a student enrolls in the university then immediately enrolls in three seminars. 2. Explore your design because they provide a way for you to visually step through invocation of the operations defined by your classes. 3. To detect bottlenecks within an object-oriented design. By looking at what messages are being sent to an object, and by looking at roughly how long it takes to run the invoked method, you quickly get an understanding of where you need to change your design to distribute the load within your system. In fact some CASE tools even enable you to simulate this aspect of your software. 4. Give you a feel for which classes in your application are going to be complex, which in turn is an indication that you may need to draw state chart diagrams for those classes
Service Interface	Technical	System interfaces are also known as "application roles" or "service interfaces".
SME	Business	Subject Matter Expert or Domain Expert: a person with domain knowledge that represent the users of IT systems and their business needs.
SpO2	Business	The saturation level of oxygen in hemoglobin; can be determined by noninvasive

Term	Type	Description
		method of pulse oximetry.
Stakeholder	Business	A person or a company that requests a new standard, a technical correction to an existing standard, or an enhancement.
UCUM	Technical	The Unified Code for Units of Measure is a code system intended to include all units of measures being contemporarily used in international science. www.unitsofmeasure.org/
UML	Business	Unified Modeling Language (UML) is a standardized general-purpose modeling language in the field of software engineering. The standard is managed, and was created by, the Object Management Group. UML includes a set of graphic notation techniques to create visual models of software-intensive systems.
Use Case	Technical	A Use Case represents a discrete unit of interaction between a user (human or machine) and the system. A Use Case is a single unit of meaningful work; for example creating a train, modifying a train and creating orders are all Use Cases. Each Use Case has a description which describes the functionality that will be built in the proposed system. A Use Case may 'include' another Use Case's functionality or 'extend' another Use Case with its own behavior. Use Cases are typically related to 'actors'. An actor is a human or machine entity that interacts with the system to perform meaningful work.
Unverified	Business	Results that are flagged to be reviewed by a user prior to being incorporated into the information system.
Verified	Business	Results that are stored in the information system because they were marked as Verified (by device configuration) and did not require user review, or because they were selected at the point of care and reviewed by a user prior to being incorporated into the information system.
WNL	Business	Within normal limits

