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Comments by:

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Comments on:

**IHE Patient Care Device Technical Framework Supplement – Pulse Oximetry Integration (POI), Rev. 1.0 – 2012-06-14**

**General comment on scope and goals:**

The Use Case 2.1.1. page 46 describes a clinical scenario in which the respiratory depression of an over-narcotized patient on a PCA system is not detected by a hospital clinician (typically RN at nursing central station) because the pulse oximetry probe had slipped off the finger and a probe-off alarm was not communicated to the staff.

The section below states that the goal of this project was to address this use case by communicating pulse oximeter data and alarm conditions:

2.1 line 339-340

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

However, “clinical information systems” are not used to provide real-time alarms (clinical or technical) and therefore would not be able to notify clinical staff to the imminent threat to the patient described in the Use Case. The apparent de-scoping of this profile to CIS-only communication appears to be confirmed by the following section:

Line 146-9

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

and by

Line 656-660

“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-01transaction 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.)”

In summary: While there is clearly value in achieving standards-based transmission of pulse oximetry data to clinical information systems, it is not clear to me that this document provides a solution to the unsafe condition described in the Use Case.

**Specific Comments**

**Page 15: OBX.9: Signal Strength**

“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.”

It is rare for signal strength (pulse amplitude) to exceed 20%.

It is not used to evaluate the precision of the SpO2 measurement. It is used as a proxy for blood flow or perfusion. Perhaps the Signal Strength referred to in this section refers to something other than pulse amplitude? \*See below

**OBX.14 Date/Time**

Should be in UTC, and contain information to permit local offset.

**LOINC terminology referencing oxygen saturation in “Arterial” blood by Pulse Oximetry.**

The use of “arterial” in this context is incorrect. It cannot be determined at which specific vascular level the pulse oximetry measurement is performed, and it almost certainly includes components of arterial, capillary, mixed tissue, and venous blood.

See this definition of pulse oximetry from IEC 80601-2-61

“non-invasive estimation of FUNCTIONAL OXYGEN SATURATION of arterial haemoglobin (SpO2) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow”.

That is why the term “SpO2” was developed to mean “oxygen saturation as measured by pulse oximetry”. Note that SpO2 does not include an “a” for arterial in contrast to terms such as PaO2 (arterial) or PAO2 (alveolar). \*See Note below

**OBX.20**

The term “subcutaneous tissue structure” is used repeatedly. But the pulse oximeter probe is normally applied to intact skin, not subcutaneous tissue. Whether the light traverses subcutaneous tissue or other tissue is not relevant and cannot be determined in use. Therefore the body site should only state, for example, “finger tip”, and not state “subcutaneous tissue structure of finger”. There are research techniques that measure tissue oxygenation – and measurements from those techniques may be confused with pulse oximetry data in an electronic data repository if these terms are sued. It appears that codes that better represent the actual pulse oximetry probe application sites are needed.

**OBX.3**

The correct term for SpO2-derived rate is “Pulse Rate”, not Heart Rate. (Table at Line 710 states Pulse Rate and is correct). \*See Note below.

**OBX.14 “Most accurate time”**

This term is unclear to this reader.

**OBX.18**

Is “Universal ID” intended to be the same as the FDA UDI – which stands for Unique Device ID? If not, where will UDI value be held?

**Line 718**

“Sensor” should be replaced with “Probe” – the current standardized term in ISO and IEC \*See Note below

**Table at line 765**

Remove this clause: “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.” The statement is factually incorrect and not useful for this document.

**Table at line 780**

Explanation of “central” vs “peripheral” SpO2 measurement being based on the size (“larger”) is not correct. \*See Note below

**Page 73**

“PaO2 - Partial pressure of oxygen in the blood.”

Correct to: “PaO2 - Partial pressure of oxygen in arterial blood.”

\*See Note below

**Other Comments:**

1. Include Probe type (if known by device) (not the same as OBX.20 body site)

2. Include signal averaging setting

3. Include sensitivity or gain setting

4. Include device serial number

**\*NOTE:**

There are a number of statements in this document which are technically incorrect. (I did not have time to identify and comment on all of them.) Some of these errors could lead to inappropriate use of the data, thereby undermining the intent of this document to enable improvements in clinical care.

I recommend that the authors collaborate with technical experts from standards committee IEC 62D / ISO TC 121 SC3, JWG5 Pulse Oximeters, via the conveners David Osborn (d.g.osborn@ieee.org) and Sandy Weininger, PhD (sandy.weininger@fda.hhs.gov)