

## Monitoring Medical Device Data Quality for Safe Smart and Autonomous Medical Systems (SaAMS) – A Closed Loop Infusion System Study

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**Introduction:** Recent advances in medical device interoperability have shown that coordinating medical devices into Smart and Autonomous Medical Systems (SaAMS) – such as physiologic closed loop control (PCLC) TIVA systems - may improve efficiency, safety, and patient outcomes. SaAMS leverage interoperable sensors, actuators, and apps (Software as a Medical Device, or SaMD), on open health platforms such as OpenICE ([www.openice.info](http://www.openice.info)). The quality of data produced by medical devices may vary due to sensor auto-calibration or drifting, device failure, and conditions like communication delays. Variation and degradation of data quality can cause data consumers, such as other devices and algorithms, to make unsafe clinical decisions if no mechanism is provided to proactively detect and address it. The lack of a consensus definition of medical device data quality, together with the limitations of existing devices to emit data-quality metadata, make it challenging for SaAMS to capture comprehensive system context that is critical for safe interoperability [1].

**Method:** We investigated the definition of medical device data quality and requirements for interoperable platforms to monitor and safeguard data quality degradation. In accord with ISO 25012 standard [2], we defined a preliminary data quality model to capture accuracy, completeness, consistency, credibility, and currentness quality attributes of medical device data. Based on this model, we extended medical device interfaces to augment each output data sample with Data Quality Index (DQI) metadata, which adds data quality attributes to that sample. Using our OpenICE research interoperability platform we established a mechanism to continuously monitor medical device data degradation by comparing DQIs from connected devices with predefined quality thresholds. The mechanism informs relevant data consumers of data quality degradation as it is detected in individual devices and permits the system to enter a safety fallback mode (if present) should system-wide data quality degradation be detected.

**Result:** We developed a prototype PCLC fluid resuscitation system on top of OpenICE to demonstrate and evaluate the proposed medical device data quality model and monitoring mechanism. The prototype system consists of AthenaGTX and Philips MX800 patient monitors, a Q Core Sapphire IV infusion pump, and a control algorithm that adjusts the fluid delivery rate based on BP measures from one of the two patient monitors, to maintain the target BP levels. Two additional apps were developed in OpenICE – one implementing the data quality monitoring (DQM) mechanism and the other implementing an example cardiac arrest monitoring (CAM) algorithm. The CAM app reports a cardiac arrest condition when vital signs meet pre-defined rules and no data quality degradation is reported. The control algorithm uses invasive BP data from the MX800 monitor, and switches to NIBP data from AthenaGTX should data quality degradation occur to the IBP signal, triggering BP cuff inflations at AthenaGTX when NIBP data is needed. This switch however is prohibited when the CAM app reports a cardiac arrest condition, as NIBP measurements in this situation are no longer trustworthy.

Our experiments confirmed that the DQM app could monitor and report synthetic data quality degradation conditions introduced to MX800 and AthenaGTX data or when network QoS was degrading across the system. The control algorithm could switch between different BP sources as expected upon notifications from the DQM and CAM apps.

**Conclusion:** The proposed concept of monitoring medical data quality for safer interoperability has been included in the JHU/APL medical device interoperability reference architecture [3]. We believe our data quality model suggests a possible direction for medical device manufacturers to enrich the metadata output from their products, e.g., in the form of Medical Device Interface Data Sheets (MDIDS) [4], to advance interoperability in a safer manner.

### References:

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