Hardware-in-the-Loop Testbed and Program to Support Verification of Interoperable Medical Devices for Closed-Loop Control of Anesthesia

Presenting Author: Julian M Goldman, M.D.
Co-authors: Yi Zhang, Ph.D., David Arney, Ph.D.

Closed-loop control (CLC) of anesthesia [1] has been a long-time goal of the anesthesia research and innovation community. CLC systems have been demonstrated to reduce or eliminate manual drug titration and have the potential to improve the quality, efficiency, and safety of anesthesia and intensive care [2].

We have established a hardware-in-the-loop (HIL) testbed to promote prototyping, simulation, and verification of CLC anesthesia techniques. Based on the OpenICE interoperability platform [3], the testbed follows the FDA-recognized Integrated Clinical Environment (ICE) standards-based reference architecture [4] to coordinate CLC algorithms with devices such as anesthesia machines, ventilators, and infusion pumps. Open-source ICE interfaces have been developed for a range of monitoring, IV infusion, and anesthesia delivery devices, enabling communication with the testbed and control algorithms. Studies demonstrate that our HIL testbed offers flexibility and transparency for design, deployment, and evaluation of real-time clinical decision support and CLC algorithms in a clinical context [5].

The HIL testbed provides a platform for characterizing the technical and interoperability capabilities of interoperable medical devices regarding their suitability for use in different CLC medical systems. We are currently working on extending two FDA-approved standalone infusion pumps through external control capabilities, and using the testbed to assess how quickly they achieve a stable infusion rate upon executing commands from an external CLC algorithm. Preliminary results show that these two pumps demonstrate significantly different responsiveness when the new infusion rate is low, which can affect their suitability for certain clinical applications.

A key regulatory consideration for interoperable medical devices to be successfully used as components of interoperable systems, especially CLC systems, is the establishment of suitable safety assurance cases to provide compelling evidence that the CLC application will be safe [6]. This can be challenging since the devices may be used as components of (a new) CLC systems in a manner that may not have been anticipated by the component manufacturers. Characterizing the interoperability capabilities of medical devices, with the support of HIL testbeds like ours, could allow manufacturers to establish safety assurance evidence acceptable to regulators to enable adoption. We believe that realizing this vision requires all stakeholders (including regulators, device manufacturers, clinicians, and standards organizations) to collaborate to establish consensus regulatory requirements that can be used as a baseline to characterize the interoperability capabilities of medical devices.

We have been continuously engaging with the US FDA, standards organizations like AAMI and UL, and device manufacturers to establish the consensus technical, interoperability, safety and security requirements for interoperable medical devices. This engagement has produced standards (e.g. AAMI 2700-1 [4] and AAMI/UL 2800-1[7]) and techniques (e.g., Medical Device Interface Data Sheet [8]) as the foundation towards such consensus requirements. We are currently establishing a forum, called Smart & Autonomous Medical Devices (SAMD) program, as a mechanism to further facilitate and improve the communication and engagement among stakeholders. We welcome participation in the SAMD program from all interested parties.

References:

[1] Dumont GA and Ansermino JM, Closed-loop control of anesthesia: a primer for anesthesiologists, Anesth. Analg. 2013 Nov; 117(5):1130-8.

[2] Biblan S, Dumont GA and Black I, Closed-loop target-controlled infusion systems: stability and performance aspects, Mil. Med., 2015 Mar; 180(3 Suppl): 96-103.

[3] OpenICE, http://www.openice.info.

[4] ANSI/AAMI 2700-1: 2019 Medical devices and medical systems – Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model

[5] Arney D, Zhang Y, Goldman JM, and Dumas B, Implementing Real-Time Clinical Decision Support Applications on OpenICE: A Case Study Using the National Early Warning System Algorithm, Medical Cyber Physical Systems Workshop 2019, Washington, DC, Sept 2019.

[6] Introduction of Assurance Case Method and its Application in Regulatory Science. https://www.fda.gov/media/125182/download

[7] ANSI/AAMI/UL 2800-1: 2019, Standard for safety for medical device interoperability

[8] Weininger S, Jaffe MB, Rausch T, and Goldman JM, Capturing essential information to achieve safe interoperability, Anesth Analg, 2017 Jan; 124(1): 83-94.