Abstract Title: **Porting a Vertically Integrated Closed-Loop Control TIVA System to an Interoperable Platform**

Presenting Author: Yi Zhang PhD
Co-Authors: David Arney PhD, MPH; Simon Kelly; Braga Aroulmozhi MS, Mosa Al Zowelei MS, Michael Jaffe PhD; Julian M. Goldman MD
Affiliation: Medical Device Plug-and-Play Interoperability & Cybersecurity Program, Massachusetts General Hospital, Boston, MA

Problem and Motivation. Recent advancements in automation and computational intelligence have enabled increasing development of physiological closed-control control (PCLC) anesthesia systems [1]. Typically, these are vertically integrated systems of sensors, actuators, and processing platforms. Evaluating alternative control algorithms, sensors, and actuators is challenging due to this vertical integration.

Porting integrated PCLC systems onto interoperable platforms can enable rapid development of hardware-in-the-loop (HIL) testbeds. Simulation capabilities can be introduced and alternate actuators/sensors can be easily replaced to facilitate system modification and testing. PCLC anesthesia systems can also benefit from the services offered by interoperability platforms, such as safety fallbacks, security, and data logging, to alleviate R&D and risk management burdens.

Method. We chose the EasyTIVA PCLC anesthesia system from MedSteer [2] as the subject system and ported it onto our OpenICE interoperability research platform [3]. The EasyTIVA system uses two Alaris GH infusion pumps to administer propofol and remifentanil to the patient for anesthesia during surgical procedures, where its control algorithm automatically titrates the infusion rates of both pumps based on the patient's depth of anesthesia measured by a VISTA BIS monitor.

OpenICE follows the standard Integrated Clinical Environment (ICE) architecture [4] to safely coordinate medical devices and software applications ('apps'). We developed two communication apps in OpenICE, one for the Alaris GH pumps and the other for the BIS monitor, to intercept and forward the communication between these devices and the EasyTIVA control algorithm (installed and running on a separate computer). In this ported configuration, the control algorithm and medical devices are 'talking' to the communication apps rather than directly to each other. These apps also broadcast the communicated data and commands to the rest of OpenICE to support testing and future clinical investigation.

Implementing the communication apps only requires the knowledge of the control algorithm's communication protocols with medical devices, including the handshaking procedure, timeout periods of waiting for responses from the devices, and contingency actions upon connection failures. No modification to the EasyTIVA control algorithm is needed.

Result. Preliminary testing of the OpenICE-based EasyTIVA variant using synthesized BIS data confirmed that it performed equivalently to the vertically integrated system under the test protocols we executed. The control algorithm correctly received BIS scores and other data from the BIS monitor and titrated the propofol and remifentanil infusion rates; and the Alaris pumps correctly received and executed control commands from the control algorithm.

We also implemented a simulated BIS monitor app that feeds the EasyTIVA control algorithm with pre-defined BIS trend at the expected frequency. This app allowed us to test EasyTIVA without a physical BIS monitor, which demonstrates the feasibility of leveraging the OpenICE-based variant into a HIL testbed for assessing EasyTIVA.

Conclusion. Our method of porting EasyTIVA onto OpenICE can potentially be generalized to other PCLC systems. Generalization may be limited by the lack of commercial medical devices that support external control or the publicly accessible documentation of their communication protocols. One way to tackle these limitations is to standardize the data interfaces of medical devices, such as in form of Medical Device Interface Data Sheet [5], that include adequate device information to enable safe external control.

Acknowledgement: this research, including the loan of the Medsteer EasyTIVA system and MedSteer technical assistance, was supported under the Medical Technology Enterprise Consortium (MTEC) Research Project Number W81XWH-22-9-0004. The views, opinions and/or findings contained in this paper are those of the authors and should not be construed as an official Department of Defense position, policy or decision unless so designated by other documentation.

Reference:

1. Jin X, Kim CS, Dumont GA, Anesrmino JM, Hahn JO. A semi-adaptive control approach to close-loop medication infusion. Int J Adapt Contr Signal Process. 2017;31(2):240-54.
2. Liu N, Bourgeois E, Chazot T, Murat I, Fischler M. Closed-loop administration of propofol and remifentanil guided by the bispectral index in patient requiring an emergency lung volume reduction. Paediatr Anes, 2007 Sep; 17(9):909-10.
3. Arney D, Plourde J, Goldman JM. OpenICE medical device interoperability platform overview and requirement analysis. Biomedical Engineering/Biomedizinische Technik. 2018 Feb;63(1):39-47.
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. Goldman JM, Weininger S, Jaffe MB. Applying medical device informatics to enable safe and secure interoperable systems: medical device interface data sheets. Anes Analg 2020 Sep; 131(3):969-976.