Development of a Prototype Generic Communication Protocol (GCP) for Infusion Pump Control for Automated Closed-Loop IV Anesthesia (ACLIVA) Systems

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Problem and Motivation: Recent advances in automation and computational intelligence have led to increased interest in adoption of Automated Closed Loop IV Anesthesia (ACLIVA) and TCI (Target Controlled Infusion) systems. ACLIVA Physiologic Closed-Loop Control Systems (PCLCS) use brain state monitoring to provide feedback to a control algorithm which adjusts the infusion of anesthetic agents to achieve a target level of anesthesia. Systems rely on control of the pump through an External Digital Interface (EDI) to adjust medication delivery. The absence of a common – or generic – pump communication protocol drives vertical integration in product development, reduces the ability to freely choose pumps to meet clinical needs and regional regulatory requirements, while complicating system safety and performance testing. Many of these challenges could be addressed through the adoption of a Generic Communication Protocol (GCP).

Methods: The authors collaborated to develop a GCP that was integrated into a Hardware-in-the-Loop research platform hosting the EasyTIVA (Medsteer, France) ACLIVA system. The GCP was developed with insights from clinicians, engineers and other stakeholders to ensure that it enables pump data transmission and control commands to meet all identified use cases. The original EasyTIVA system connects to two Alaris GH infusion pumps to administer propofol and remifentanil, where both infusion rates are continuously controlled by the EasyTIVA expert system which uses the patient's depth of anesthesia as measured by a Medtronic BIS monitor. The GCP modified platform hosting the EasyTIVA algorithm maintains the same hardware and control algorithm but uses the GCP for all pump-related communications. To translate the GCP commands to the Alaris GH pump commands, we developed a "Translator App" on OpenICE that interfaces with the EasyTIVA modified platform and the infusion pump(s). The Translator app sits in the middle of all EasyTIVA-pump communications and translates the GCP commands to the specific commands used by the infusion pump.

OpenICE is a reference implementation of ANSI/AAMI standard 2700-1 for the Integrated Clinical Environment (https://mdpnp.mgh.harvard.edu/astra-portfolio/openice/). Implementing the GCP within the EasyTIVA platform with OpenICE as a translator for the pumps only requires knowledge of the structure of the GCP and the specific communication protocol for the infusion pump - the EasyTIVA control algorithm does not require modification. Based on initial success of the OpenICE Translator app to communicate with the Alaris GH pumps, the capability to communicate with a research version of the NeuroWave AccuPump (externally-controllable multi-channel infusion pump) was added to the OpenICE Translator app.

Result: Bench testing of the GCP modified EasyTIVA platform connected to OpenICE using synthesized BIS data or a Medsteer BIS digital twin, confirmed that it performed equivalently to the vertically integrated system under the test protocols we executed. The control algorithm correctly received BIS index and other data from the BIS monitor and adjusted the target propofol and remifentanil infusion rates, while both the Alaris GH pumps and the NeuroWave AccuPump correctly received and executed control commands from the OpenICE Translator App.

Conclusion: The successful development and testing of a prototype Generic Communication Protocol lays the foundation for interoperability in applications such as Automated Closed Loop IV Anesthesia Systems that require control of infusion pumps via electronic data interfaces. This configuration allows for hardware-in-the-loop testing of system components and informs the transition of ACLIVA PCLCS control systems to use GCPs and pumps to adopt GCP in the future. This research is serving as a foundation to build a Medical Device Development Tool (MDDT) for controllable infusion pumps suitable for ACLIVA. (https://www.fda.gov/medical-devices/medical-device-development-tools-mddt) Collaboration to ensure diverse expert participation in the development of the MDDT will be pursued through the SaAMS Collaborative Community. (https://mdpnp.mgh.harvard.edu/saams-cc/)

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