Assessing a Foreign Closed-Loop Control Anesthesia System for US Military Care Using a Novel Interoperability Platform-Based Testing Methodology

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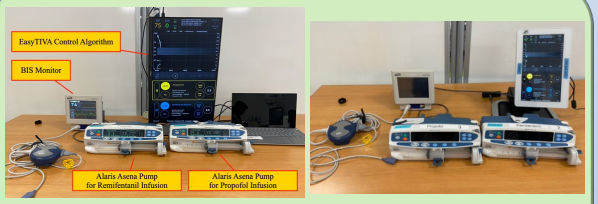
Background and Objectives

Physiological closed-loop control (PCLC) systems, such as autonomous total intravenous anesthesia (TIVA) systems, can decrease caregiver cognitive and task workload while improving patient care [1]. Therefore, PCLCs are promising as force-multipliers for expanding the capabilities of frontline caregivers, optimizing combat casualty care, and maximizing combat power of US and Joint forces.

Adoption of PCLC technologies in military and civilian healthcare has not met clinical demand, in part because of historically complex regulatory and safety requirements. Therefore, it is important for stakeholders – government, industry, academia, and healthcare organizations – to develop consensus requirements and test methods for assuring safety, security, interoperability, and performance (SSIP) of PCLC systems to expedite their market availability and adoption.



a) Research Prototype Version b) Clinically deployed Version (in demo mode)

Fig 1. The MedSteer EasyTIVA SYSTEM

Objectives & Methods

Subject PCLC System: The EasyTIVA autonomous anesthesia system from MedSteer (France) [2] was chosen as the study subject due to its maturity and extensive clinical trials in Europe. EasyTIVA uses an expert system to automatically adjust the infusion rates of Propofol and Remifentanil to achieve a target processed EEG (BIS) value.

Objectives: This research assessed EasyTIVA for potential application to military casualty care and established extensible testing methodology to 1) assess the SSIP properties of EasyTIVA in a hardware-in-the-loop (HIL) manner; and 2) enable rapid evaluation and testing of different implementation options of EasyTIVA, such as using mission-specific IV pumps or and other hardware , to improve deployment flexibility and availability.

Methods:

1. Defined 10 categories of 47 SSIP requirements as test objectives for EasyTIVA, based on an analysis of the IEC 60601-1-10 PCLC standard [3], the FDA draft PCLC guidance [4], and relevant US military clinical practices guidelines (CPGs) such as JST CPG-40.
2. Leverage the MGH-developed OpenICE open-source interoperability platform [5] into a HIL testbed to enable and facilitate the testing.

Porting EasyTIVA to the OpenICE Platform

The EasyTIVA System: as shown in Fig 1, the expert system control algorithm is running on a PC, and a Medtronic BIS depth of anesthesia monitor and two Alaris Asena IV pumps are connected via serial connections. Based on the BIS processed EEG score, the control algorithm automatically titrates the infusion of Propofol and Remifentanil to maintain the user-specified target BIS (typically 40~60) during surgical procedures.

Porting EasyTIVA to OpenICE: two device interfaces were developed in the OpenICE platform for the BIS monitor and the Alaris pump respectively, to communicate with these devices via serial communication. A translation application (app) was also developed to intercept and forward the communication (data and control) between the control algorithm and the Alaris pumps. As shown in Fig. 2, OpenICE is running on a separate computer from the control algorithm, and the EasyTIVA control algorithm and all the devices are now 'talking' to OpenICE instead of to each other.

Additionally, simulated BIS monitor and Alaris pump apps were developed on OpenICE to allow testing without physical devices.

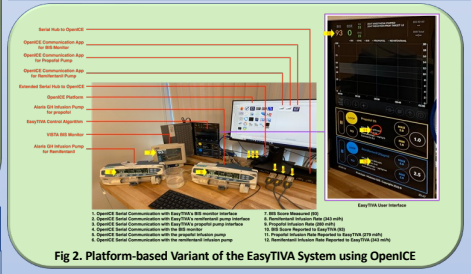


Fig 2. Platform-based Variant of the EasyTIVA System using OpenICE

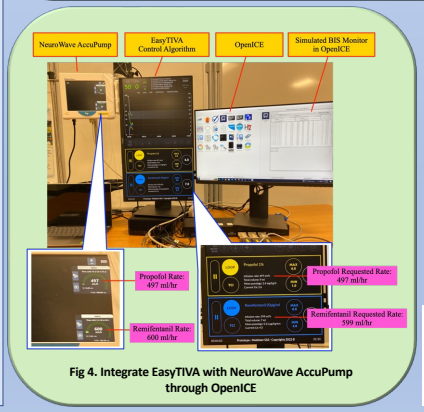


Fig 4. Integrate EasyTIVA with NeuroWave AccuPump through OpenICE

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Testing EasyTIVA using the OpenICE Testbed

Test Cases: Six (6) test cases were developed, based on a literature survey, with BIS values under normal conditions and during known sources of measurement interference. These test cases were fed to EasyTIVA by the simulated BIS monitor app for testing.

- **System performance testing:** The actual volumes of Propofol and Remifentanil infused were consistent with what were commanded by the control algorithm for all BIS test cases (e.g., see Fig. 3)
- **System reliability and safety testing**: Alaris pump interface and the simulated BIS monitor app were modified to feed the EasyTIVA control algorithm with simulated pump alarms and comprised BIS data. Testing results confirmed that: 1) EasyTIVA incorporated appropriate risk controls for all Alaris pump alarms; and 2) its fallback mechanism functioned as specified when the BIS signal quality degraded for 120 seconds.
- **Assessing the impact of porting to OpenICE**: EasyTIVA demonstrated consistent system behavior, in terms of drug infused over time, in its original setting and OpenICE-based variant under all test cases. Minor differences were observed, possibly due to slightly different communication patterns in these settings (e.g., more inquires were sent to Alaris pumps in one setting, causing them more time/effort to respond).

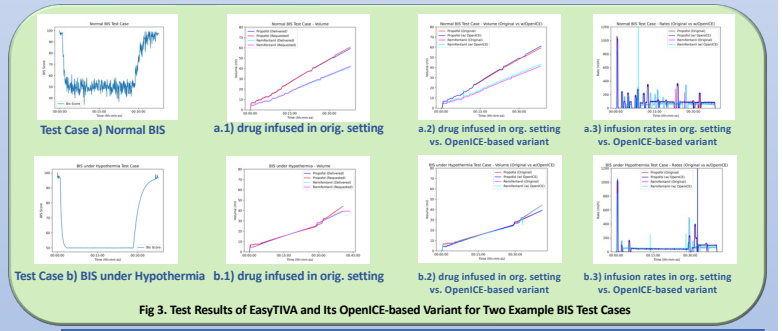

Fig 3. Test Results of EasyTIVA and Its OpenICE-based Variant for Two Example BIS Test Cases

Integrating EasyTIVA w/ Different IV Pump via OpenICE

Porting EasyTIVA to the OpenICE platform makes it possible to connect the EasyTIVA control algorithm to new IV pumps to evaluate the safety and performance of alternative implementations. We experimented integrating EasyTIVA with the NeuroWave AccuPump externally controllable 2-channel IV pump. The integration was enabled by a device interface that translates AccuPump communication of infusion data and control commands to the Alaris pump protocol which is used by EasyTIVA.

Results:

By executing the same 6 BIS test cases, it was confirmed that the NeuroWave AccuPump can correctly report infusion status to the expert system control algorithm and execute corresponding titration commands, as shown in Fig. 4.

Reference

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Conclusion

The presented methodology leveraged the OpenICE interoperability platform into a HIL testbed for autonomous TIVA systems. Services provided by the OpenICE platform, such as device simulation, swappable components, and data logging, can improve the efficiency of RDT&E of these systems. This methodology can be generalized and extended to support the assessment of other foreign PCLC technologies for US adoption and the advance of regulatory science on such technologies.