A Proof-of-Concept Framework for Testing and Validating Networked Medical Device Applications and Closed-Loop Physiology Management Systems for Critical and Perioperative Care

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Managing physiology in critical and perioperative settings could benefit from closed-loop control of interventional systems driven by data from patient monitors. While in the United States clinicians manually operate medical devices, augmented clinician performance though TCI (Target Controlled Infusion) and closed-loop control are widely adopted in other countries[1]. While the FDA has interest in potential benefits, difficulties and expenses likely will continue encumber approvals in the US[1,2]. We are addressing acquisition of data and costs hoping to facilitate system approvals.

Thorough verification and validation of closed-loop control systems are critical to improving and ensuring safe, robust operation before and during clinical testing. During early control system development, being able to test ideas reproducibly with realistic simulation over wide ranges of individual parameters and multivariate combinations is desirable. In later development, unplanned combinations of control systems could be tested for maladaptive behavior and graceful moderation in potentially dangerous situations.

Extensive, repeatable evaluation of many variations in biological animal or human physiology experiments is not achievable at any price. However, the use of *in silico* patients (computer models of patient physiology) is gaining credibility[3,4]. We have developed and validated an open-source proof-of-concept system that leverages the open-source Pulse Physiology Engine[5], developing a hardware-software system that allows *in silico* patients to interact with automatic closed-loop control systems (which includes standard, non-modified patient monitor and infusion pump) in real-time.

Our current physiology models are limited in their ability to produce simulation over a wide and realistic range of observed physiological variation. Passive recording of physiological parameters from clinical situations can augment simulator model development, producing higher fidelity and more sophisticated simulations for testing. In addition, during testing, robust logging of digital activity at every control and response node would provide the necessary data for debugging undesirable behavior. The same devices used to implement recording for enhancement of simulation could provide these testing functions. Our system includes components useful for both recording to augment high fidelity physiological simulation, and data logging for robust understanding of control system behavior.

We hope to engage others in expanding the range of these open source tools.

References

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