Towards Safe Medical Device Remote Control in Tele-Critical Care Applications

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Introduction: The COVID-19 pandemic has advanced market awareness of the benefits of remote-controlled ventilators to reduce the exposure of healthcare workers to patients with COVID-19, enable more rapid and frequent ventilator setting adjustment, and preserve limited personal protective equipment. The US FDA permitted manufacturers to add remote monitoring and control capabilities to ventilators and infusion pumps through immediate in effect guidance [1,2]. When integrated with tele-critical care systems, remote control of medical devices allows distant clinical experts to collaborate with local clinicians to "virtually" manage the therapy of patients at hotspots. Core remote control capabilities can also be used by software applications to implement medical device control algorithms for Software as a Medical Device (SaMD).

The US Army /TATRC launched the National Tele-Critical Care Network (NETCCN) to rapidly develop and deploy a platform to support COVID-19 disaster response [3]. We are investigating technical solutions, communication protocols, and safety assurance measures for integrating remote control of medical devices to the NETCCN systems.

Methods: We developed an architecture and a prototype system (Figure 1) to investigate safety, security, and interoperability requirements for integration of remote control of medical devices with tele-critical care systems. The prototype system is based on OpenICE [4], an open-source interoperability platform developed by our program to transmit data and control medical devices at the patient's bedside. Customized interfaces (hardware and software) translate device proprietary protocols to ISO/IEEE 11073-10101 terminology over DDS middleware.

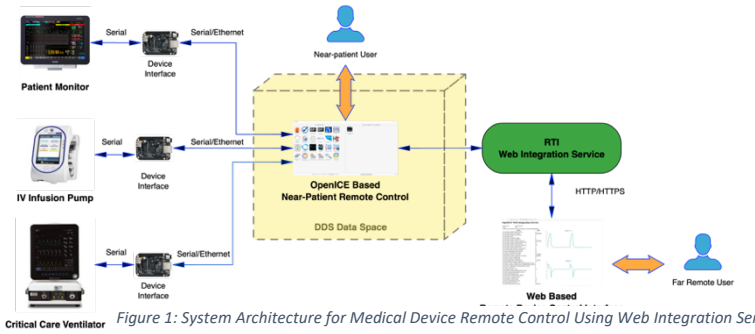

Figure 1: System Architecture for Medical Device Remote Control Using Web Integration Service

Remote control applications of devices connected to OpenICE are implemented as either stand-alone OpenICE apps, which can be deployed inside or immediately outside the patient's room, or as web-based apps, which can be launched from any location to communicate with the OpenICE system. We refer to the former as "near-patient remote control", which may be at the bedside or co-located outside the room, and the latter as "far remote" control where the operator does not have physical access to the patient or medical equipment. Our prototype system uses the RTI Web Integration Service [5] to enable web-based control applications to communicate with the connected devices.

Results: The generic architecture in Figure 1 is device agnostic: it can be used with critical care ventilators, IV infusion pumps, and other devices, provided that the device interfaces support remote control. As a proof of concept, we applied this architecture to a Q Core Sapphire IV infusion pump using a non-clinical control interface, and confirmed that the infusion rate could be adjusted by both near-patient and far remote (web) control applications with generally acceptable delays (3~8 seconds from remote control action until the pump executes the change). This prototype system allows the exploration and validation of risks associated with medical device remote control in the tele-critical care context. An example of a risk identified in our study relates contention between near and far "loci of control". Unexpected device behavior can occur if there is no mechanism to 1) explicitly prioritize loci of control that may occur simultaneously (e.g., always prioritize local control over far control to enable the local provider to regain control or prevent remote control); and 2) clearly indicate where the locus of control resides.

Other risks may arise due to issues related to cybersecurity, network QoS, permission for remote control, and usability (e.g., use errors associated with far remote control due to the lack of a real-time view of the patient). We are collaborating with the AAMI InterOperability Working Group (IOWG) to share the experience and lessons learned in this effort to develop a safety standard for medical device remote control, and with other performers in the NETCCN portfolio.

References:

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