Title: Demonstration of Remote Control of Critical Care Ventilators and the Integrated Clinical Environment

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Introduction: The COVID-19 pandemic posed numerous challenges to patient care, including extensive PPE use, patient care in isolation rooms, inadequate numbers of intensivists particularly in rural communities, use of unfamiliar ventilators that would be partially remedied by the ability to remotely control lung ventilation. The goals of the project were to study the intended use, risk management, usability, cybersecurity for remote control of ventilators and demonstrate the use of a single interface for several different ventilators.

Methods: Clinical scenarios were developed including remote control of the ventilator from an antechamber of an isolation room, nursing station within the same ICU, and remote control from across the country. A risk analysis and was performed and a risk management plan established using the AAMI Consensus Report--Emergency Use Guidance for Remote Control of Medical Devices. A cybersecurity plan is in progress. Testing was done at the MDPNP laboratory.

We worked with Nihon Kohden OrangeMed NKV-550, Santa Ana, CA, and Thornhill Medical MOVES SLC, Toronto, Canada. Both companies modified their devices to allow remote control by and application operating on DocBox's Apiary platform. Apiary is a commercially available ICE solution, DocBox Inc, Waltham, MA. An expert panel was created to provide guidance on the design of a single common, simple to use graphical user interface (GUI) for both ventilators. Manufacturers' ventilation modes were mapped to ISO 19223 vocabulary, data was logged using ISO/IEEE 11073-10101 terminology using AAMI 2700-2-1, Medical Devices and Medical Systems — Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Requirements for forensic data logging.

Results: We demonstrated that both ventilators can be controlled and monitored using common user interface within an institution and across the country. Pressure and flow waveforms were available for the NKV-550 ventilator, and usual ventilator measurements were displayed in near-real time. The interface allowed changing FiO2, ventilation mode, respiratory rate, tidal volume, inspiratory pressure, and alarm settings. At times, increased network latency negatively affected the transmission of waveforms.

Conclusions: We were able to demonstrate remote control of 2 ventilators with a common user interface. Further work needs to be done on cybersecurity, effects of network perturbations, safety of ventilator remote control, usability implications of having a common UI for different devices needs to be investigated.

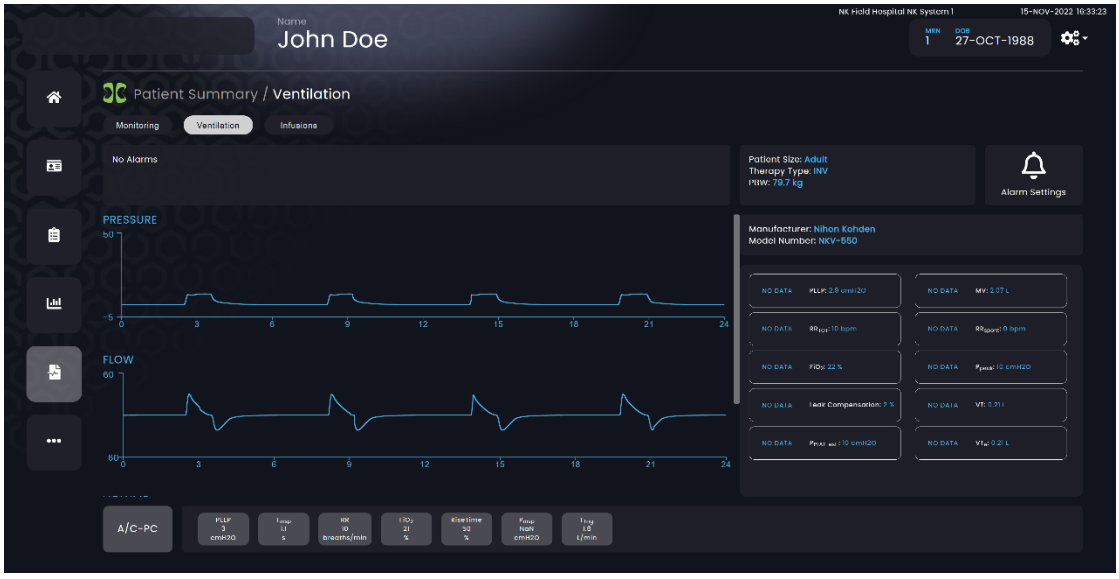

Figure: Browser based remote view for both the NKV-550 Ventilator and the MOVES SLC life support system.

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