Systematic Testing of a Ventilator Remote Control System Towards Safe Use in Tele-Critical Care and Prolonged Care

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Background & Objectives

During the COVID-19 Public Health Emergency, the US Food and Drug Administration issued a regulatory enforcement policy that provided a streamlined pathway for vendors to add remote control to marketed ventilators and other devices (Fig. 1a and 1b) to more efficiently provide care to COVID-19 patients, protect frontline providers, and conserve PPE [1,2]. The U.S. Army Telemedicine & Advanced Research Center (TATRC) Technology in Disaster Environments (TiDE) initiative leveraged the FDA policy to support manufacturers and other stakeholders to advance remote control technologies to facilitate Tele Critical Care (TCC). Remote-control capabilities are broadly applicable to enhance care in many healthcare delivery settings, including Prolonged Casualty Care (PCC).

Under the TiDE initiative, Nihon Kohden OrangeMed (NK) and DocBox, supported by the MD PnP program at MGH, developed a prototype system for network-based far remote-control of the NKV-550 ventilator, a critical care ventilator (Fig. 1c), with the goals of identifying and implementing foundational remote-control capabilities, and exploring essential performance, interoperability, and cybersecurity requirements, needed by TCC systems in public health emergencies, disasters, and for PCC.

The safe and effective use of ventilator remote control in TCC systems can be affected by factors unique to the TCC context, such as unstable network performance. Consequently, systematic testing is needed to evaluate the function, usability, and system safety and resilience of any ventilator remote control system before its deployment.

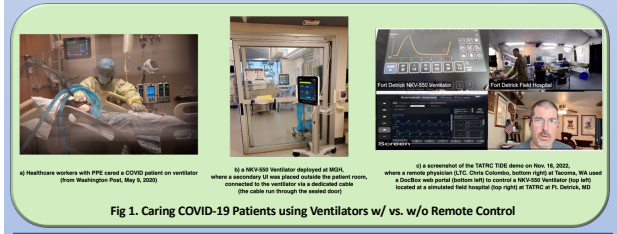

Fig 1. Caring COVID-19 Patients using Ventilators w/ vs. w/o Remote Control

NK-DocBox Ventilator Remote Control System

The NK-DocBox ventilator remote control system (Fig. 2) includes:

- The commercially available NKV-550 ventilator enhanced with a network communication protocol, as well as necessary software and hardware updates, to enable remote control.
- The DocBox app, a remote-control application on the DocBox Apiary interoperability platform – a bedside interoperability platform conforming to the AAMI 2700-1 Integrated Clinical Environment (ICE) standard [2] – to control the NKV-550 from a location close to the patient and ventilator ("**NEAR-PATIENT REMOTE CONTROL**").
- The DocBox web portal, a web-based application that communicates with the Apiary platform at the patient's bedside and in turn control the NKV-550 ventilator connected to it from anywhere across the Internet ("**FAR REMOTE CONTROL**").

These components follow the ISO/IEEE 11073-10101 [3] and ISO 19223 [4] standard terminologies to interoperate. A system demo video is available at https://vimeo.com/784432343 .

Testing Strategy

The MD PnP team established a simulated clinical use environment in the MD PnP lab to verify the overall NK-DocBox system at the component, integration, and system levels. Testing included:

1. **Communication protocol testing**: evaluate functionality and robustness of the network protocol in NKV-550 to enable safe remote control.
2. **System integration testing**: assess correctness & resilience of the NK-DocBox system in normal and simulated austere use environments; quantify minimal network requirements for the system to function.
3. **Usability testing**: evaluate the human factors design of the DocBox app and web portal with the targeted user population – Registered Respiratory Therapists (RRTs).

In addition, the MD PnP and DocBox teams collaborated with MITRE and identified the essential set of cybersecurity threats associated with the NK-DocBox remote control system and possible security enhancements.

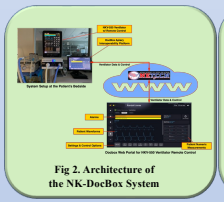

Fig 2. Architecture of the NK-DocBox System

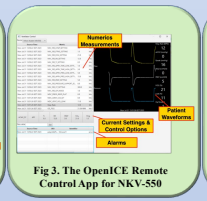

Fig 3. The OpenICE Remote Control App for NKV-550

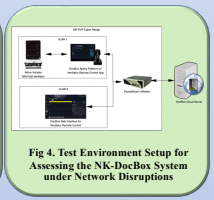

Fig 4. Test Environment Setup for Assessing the NK-DocBox System under Network Disruptions

Communication Protocol Testing

Method: A remote control app was developed on the OpenICE interoperability platform [5] (Fig. 3) to verify the communication procedure, data terminology/adequacy/frequency, and control functions of the NKV-550 network protocol. The remote-control app was also modified to transmit to the NKV-550 ventilator normal and ill-formed control commands at varied frequencies to assess remote-control robustness against possible transmission errors.

Results: Our testing confirmed that:

- The NKV-550 network protocol transmits sufficient device, patient, and alarm data and reliable remote-control capability to enable a remote caregiver to safely provide virtual TCC.
- The ventilator can work as expected when remote controls are received as frequently as once per second; and can ignore remote controls that attempt to set invalid ventilation modes or out-of-range ventilation parameters.

System Integration / Resilience Testing

Method: As shown in Fig. 4, two separate LANs were set up in the MD PnP cyber range to deploy the NKV-550 ventilator + DocBox Apiary ICE platform and the DocBox web portal, respectively. A high-precision PacketStorm 8XG WAN emulator was placed in the data pathway of both LANs to pre-process network traffic and inject various network disruptions (e.g., bandwidth throttling, delay, and jitter).

Results: By executing test cases using the DocBox Apiary app and web portal to change in NKV-550 ventilator modes, parameters, and alarm settings (i.e., both near-patient and far remote control), we confirmed that:

- The minimum network Quality of Service (QoS) required for the NK-DocBox system is ≥12Mb/s bandwidth, ≤ 500ms delay, ≤ 100ms jitter, ≤ 1% data drop rate, and ≤ $1e^{-6}$ bit error rate.
- When the minimum QoS was met, both the DocBox app and web portal correctly controlled NKV-550 with minimal appreciable delay.
- When the minimum QoS was not met, transmission of controls to the ventilator was delayed, and visualization of ventilator data was noticably degraded (e.g., waveforms were skewed, frozen, and/or out of sync with the ventilator), or the connection with the ventilator failed. This performance degradation could affect the remote user's ability to perform TCC, including remote control (but would be evident to the remote user).

Usability Testing

Method: The NK and MD PnP teams conducted simulated use testing with 15 respiratory therapists, who used the DocBox web portal from their office in Boston, MA to control an NKV-550 ventilator located in Irvine, CA, or vice versa. All participants watched a 3-minute training video before testing; during the testing, they were asked by a trained facilitator to perform a set of 19 tasks, such as view/interpret ventilator data, adjust ventilator settings, and respond to alarms, critical to safe use of the remote-control system.

Results:

- The participants successfully completed all 285 tasks (100%) without any use error observed that might lead to a hazardous situation, and without assistance from the facilitator.
- All participants confirmed the ease-of-use of the DocBox web portal, with only two difficulties observed re. locating the ventilator remote control tab and ventilator numeric measurement sections of the UI.

Conclusion

Medical device remote control technologies are emerging to address modern healthcare needs, such as telemedicine, TCC, and autonomous medical systems. The testing presented in this poster effectively verified critical system properties that developers, system integrators, and end users need to consider to ensure the safety of these technologies. Manufacturers can use these novel test methods, which the MD PnP program continues to improve and provides as a service, to assess the safety and security of their novel remote-control technologies towards real-world adoption.

Stakeholders across the healthcare ecosystem need to collaborate to develop standard terminologies, and consensus safety requirements and test methods to promote the innovation and adoption of safe, secure, and effective medical device remote control technologies. We believe this project constitutes a solid step towards this vision.

Acknowledgement

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SCAN ME

Reference

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