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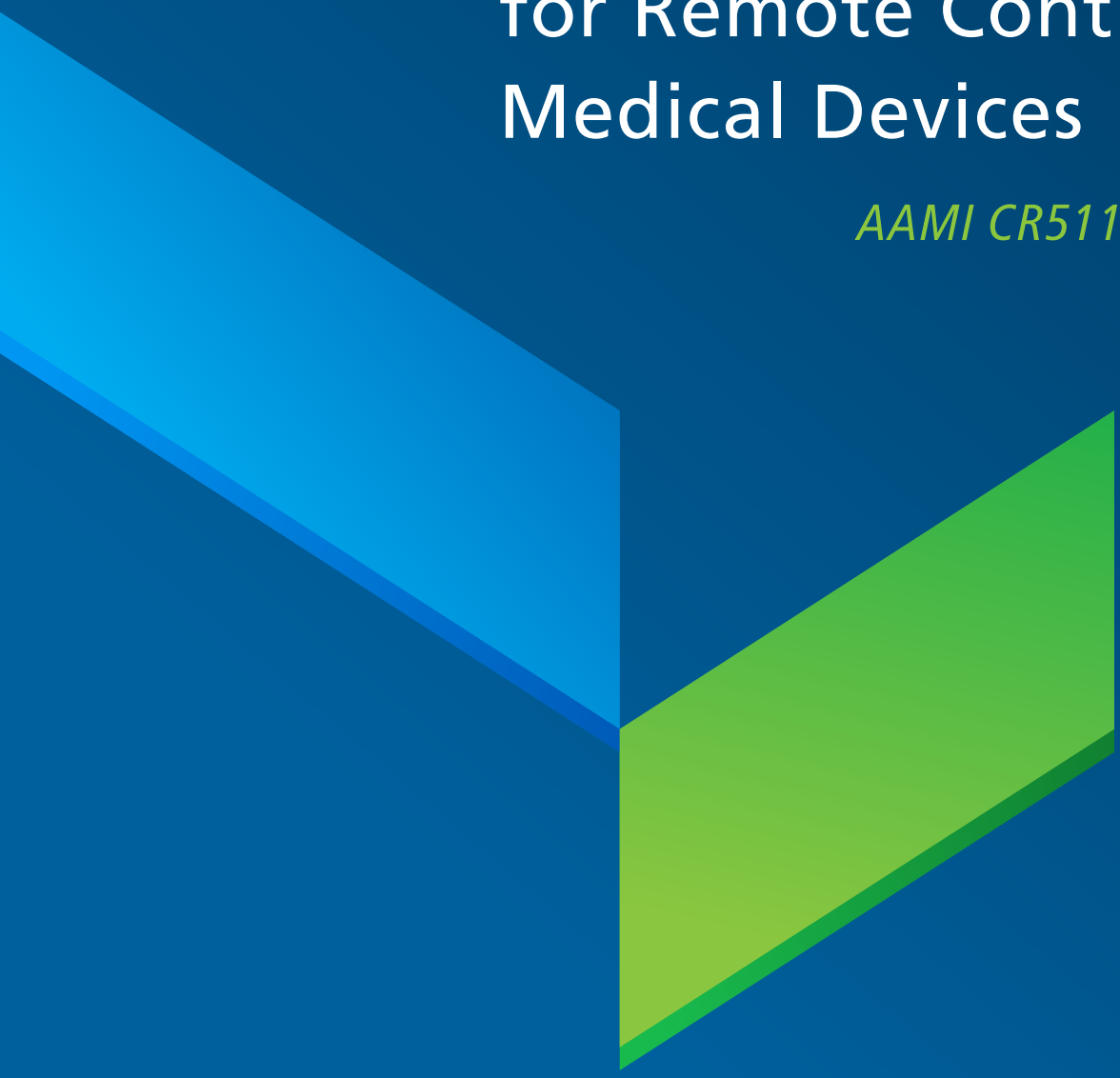
Advancing Safety in Health Technology

AAMI Consensus Report

Emergency Use Guidance for Remote Control of Medical Devices

AAMI CR511:2020/(R)2022



Emergency use guidance for remote control of medical devices

Revisions are expected to be made to this document as the COVID-19 situation evolves. Please go to https://www.aami.org/covid_cr to find the most current version as well as past versions. This document is freely available and may be shared with all interested stakeholders. Contact celliott@aami.org with any comments or questions.

Approved 16 December 2020 and reaffirmed 6 October 2022 by
AAMI

Abstract: The purpose of this document is to provide a general overview of key safety issues to be considered when developing medical equipment under the scope of an FDA emergency use authorization (EUA) such as the FDA Emergency Use Authorization (EUA) on Ventilators, issued March 24, 2020.

Keywords: COVID-19

AAMI Consensus Report

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Published by

AAMI
901 N. Glebe Rd., Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-780-8

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Association for the Advancement of Medical Instrumentation

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NOTE Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Acknowledgements

This draft AAMI CR is based on research performed by the Massachusetts General Hospital MD PnP program (and collaborators), which is intended for publication in a scientific journal. The research is being shared as the foundation for this AAMI CR. The research has been funded in part by US gov research contracts (PI - Julian Goldman).

Emergency use guidance for remote control of medical devices

1 Purpose

This document provides design guidance to enable rapid development of remote-control capabilities using an auxiliary Human Machine Interface (HMI) to a medical device for treating patients with COVID-19. This document is intended to guide the regulatory review of these devices.

1.1 Scope

This document provides targeted design guidance to enable rapid development of remote-control capabilities using an auxiliary HMI with a medical device to treat patients with COVID-19. Such devices may include ventilators, infusion pumps, and vital signs monitors.

With respect to this guidance, “remote control” refers to the operation of a medical device from a location not co-located with the patient, device, or its primary HMI. The auxiliary HMI functions as the remote-control and typically includes components inside and outside the patient care environment to allow viewing of data typically displayed on the medical device as well as manipulating device setting. The auxiliary HMI may be connected via wired or wireless communication.

This guidance assumes that remote control and monitoring using an auxiliary HMI will be an additional capability of legally marketed devices that conform to existing safety and performance standards. As such, this document provides guidance only for risks related to implementation of remote control through an auxiliary HMI. It is assumed that the remote control system, whether it is a general-purpose computer or other technology, meets its applicable electrical safety requirements.

This consensus report (CR) includes requirements relevant to the remote control system’s architecture, components, security, usability, and related issues. This CR considers known and foreseeable hazardous situations that could potentially arise from device-control along with appropriate risk control methods.

The requirements outlined in this document presume usage in traditional healthcare facilities (e.g., hospitals, assisted living facilities, nursing homes) as well as spaces converted for the care of COVID-19 patients (e.g., convention centers, university dormitories, motels). This CR presumes that the operators of these devices are trained professional health care workers (HCWs) and not lay persons.

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3 Terms and definitions

3.1
human machine interface
HMI
an interface for HCW to interact with a medical device

3.2
auxiliary human machine interface
an interface for HCW to interact with a medical device that is additional to the primary HMI of the medical device

3.3
primary device (primary medical device)
primary device, or primary medical device, is the device that is located with the patient; primary device includes a primary HMI

3.4
primary human machine interface
an interface for HCW to interact with a medical device that is co-located with the medical device and the patient

3.5
remote control
the action to control a medical device by the operators from a location not co-located with the patient, medical device, or its primary HMI

3.6
remote control system
remote control system typically consists of the auxiliary HMI, the communication link, the receiving unit, the associated software and any accessories required to configure the remote control system such as mounting hardware

4 Introduction

The care of COVID-19 patients requires the use of infection control measures to reduce the transmission of the virus to healthcare workers (HCW) and other patients. These measures include specialized patient isolation rooms and the donning of personal protective equipment (PPE) by a HCW prior to entering the patient's room. The ability to remotely control therapeutic and monitoring devices from outside of the isolation room can:

a) Reduce the need for entering the patient's room to adjust device settings;

b) Allow for a response to clinical changes more rapidly;

c) Enable a more comprehensive real-time patient assessment and management; and

d) Reduce the donning and doffing frequency of PPE.

The benefits of reducing the need for room entries to deliver care include:

a) Reducing HCW exposure to infectious material;

b) Improving the quality of patient care;

c) Reducing consumption of PPE; and

d) Improving HCW patient-care workflow efficiency thereby increasing HCW availability to provide care for other patients.

5 Background

5.1 Case for remote control

During pandemics of highly contagious diseases such as COVID-19, the HCW is at a greater risk of infection than the overall population due to their frequency and duration of contact with infected patients. The HCW will enter the patient room to administer care and manage therapeutic equipment. This management may require frequent device adjustments, which may be delayed due to the need for the HCW to protect themselves by donning PPE prior to entering the patient room. PPE may include the use of gowns, gloves, face shields, and boots. PPE is doffed upon leaving the patient room. A recent study (Suen, 2018) reported times of 7 minutes for donning and 10 minutes for doffing, although donning and doffing processes can exceed 15 minutes depending on PPE used.

Infectious diseases confer a synergistic burden on and risk to the patient due to the requirements for isolating the patient (Abad et al., 2010), including poorer care and impaired coordination of care (Mehrotra et al., 2013), significantly fewer HCW and family visits (including patients not on precautions) (Morgan et al., 2013), increased rate of adverse events (Stelfox et al., 2003), and increased patient depression (compared to other inpatients, Day et al., 2011). The use of remote control and monitoring can eliminate treatment delays, reduce infection risk to the HCW, help preserve limited supplies of PPE, and improve patient care. In recognition of improved patient care as the result of remote control, the FDA issued an Immediate in Effect Guidance for Ventilators, which notes:

"Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters (i.e., adjustment of parameters by trained health care providers from outside an isolation unit to avoid unnecessary exposures)" are *"examples of circumstances where FDA currently believes a modification would not create such undue risk."* (Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. Guidance for Industry and Food and Drug Administration Staff, March 2020; IV.B.6.) https://www.fda.gov/media/136318/download

Other applicable FDA Immediate in Effect Guidance and Emergency Use Authorization documents include:

EUA Letter of Authorization - Ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories (March 24, 2020) https://www.fda.gov/media/136423/download

Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories. Pre-Emergency Use Authorization (EUA)/EUA Interactive Review Template (updated April 21, 2020) https://www.fda.gov/media/137172/download

Facts Sheets for Healthcare Providers, Emergency Use of Ventilators During the COVID-19 Pandemic (March 24, 2020) https://www.fda.gov/media/136424/download

Appendix A: Criteria for Safety, Performance and Labeling https://www.fda.gov/media/136437/download

Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, April 2020 https://www.fda.gov/media/136701/download

Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (revised June 2020) https://www.fda.gov/media/136290/download

5.2 Current practice

Critically ill patients with an infectious disease will often require monitoring and therapeutic support with ventilators and infusion pumps. Although the remote management and the limited control of smart infusion pump settings (with manual confirmation) is available, the remote control capabilities of most commercially available medical devices are quite limited.

Examples of remotely controlled ventilator implementations used during the COVID-19 pandemic:

a) permitted the primary display to be detached and positioned a distance away from the ventilation component using a cable (e.g., Hamilton G5). Off-label modifications to other ventilators have been published, including anesthesia workstations (e.g., GE Aisys and Aisys CS2), which enable the display to be detached for remote control and monitoring (Connor, 2020).

b) provided a ventilator-specific auxiliary graphic user interface (GUI) via direct cable connection (e.g., Nihon Kohden NKV550 with Protective Control®, 510(k) cleared by FDA, permits full ventilator operation except silencing the power-off alarm).

c) provided a custom control software application (e.g., Medtronic Omnitool software for control of compatible PB 980 ventilators) that permits complete remote control over a directly connected or networked Windows OS computer.

6 System elements

6.1 Construction

The remote control system transmits signals to actuate all needed operating functions for control of the medical device. The remote control unit may display applicable data. Typical components of a remote control system consist of the auxiliary HMI, the communication link, the receiving unit, the associated software and any accessories required to configure the remote control system such as mounting hardware. There can be different interface types for communicating between components and externally to the auxiliary HMI as shown in Figure 1. The controlled device and auxiliary HMI may be directly connected via cables or wirelessly to transmit data, video or control signals.

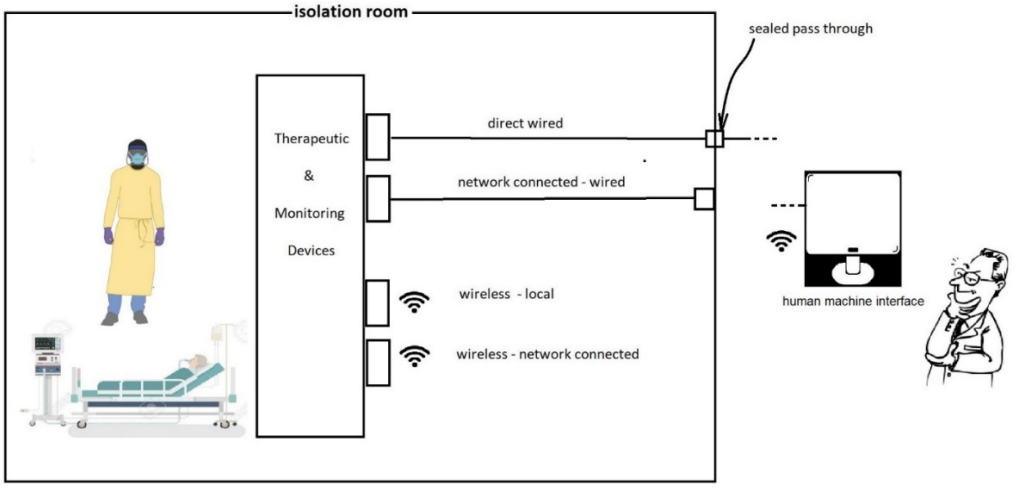

Figure 1—Different interface types are depicted with a clinician in PPE inside the patient room and another clinician without PPE outside the patient room

NOTE Clipart from: https://www.123rf.com/clipart-vector/medical_ventilator.html?sti=lvridru068vdkxy2t2|

7 Safety requirements and risk control measures

Risk management shall be performed to ensure that risk has been reduced to an acceptable level, or failing that, determining that the benefits of using the remote control system outweigh the risk that remains after reducing the risk as low as reasonably practicable.

7.1 Disclosure of communication architecture

The architecture of communication shall be disclosed with sufficient detail in the Instructions for Use to allow the healthcare delivery organization to verify implementation and acceptably manage risk.

Disclosed information shall include whether the remote control system annunciates audible alarm signals.

Note 1 Implementation details may be dependent on both the device manufacturer and the health delivery organization's infrastructure. Sufficient detail in this context includes the aspects of the safety requirements in this section.

Note 2 Remote control systems may be constructed from constituents from different manufacturers – those manufacturers may address use hazards somewhat differently, e.g., they may provide (1) different ways of informing the operator about the current state and (2) different controls for operating their respective devices.

Note 3 The signal pathways in the remote-control system that are relevant to this guidance document are the four paths listed below. The details of the IT network other than those relating to cybersecurity will not be addressed.

a) Direct Wire (point to point) — A direct wired connection is a point to point connection with a single cable or multiple cables that transmits bi-directionally the signals required for monitoring and control of the equipment. This type of connection may use pass-through connectors inside and outside the patient room to maintain a negative room pressure.

b) Network Connected-Private/Isolated — A network connected (Private/Wired) connection is a connection where the medical electrical equipment inside the room and/or the auxiliary HMI is connected with a cable to a local area network.

c) Wireless-Private/Isolated — A wireless local connection is a wireless connection of the equipment inside the room and/or the auxiliary HMI to each other through a network that is isolated from other networks. This connection is typically a Wi-Fi (See IEEE 802.11x) connection.

d) Wireless/Wired-Shared network connection

Note 4 Example of factors affecting risks for different signal pathways listed above include: EMC, QoS, Cybersecurity, Co-existence, Connector and cabling reliability, Primary/Auxiliary identification.

Note 5 Protocols that allow components to transmit information between them can be used to support levels of interoperability (e.g., syntactic, semantic, conceptual). (See ISO/IEEE 11703-10201)

7.1.1 Degradation or loss of information

Means shall be provided to prevent unacceptable risk arising from degraded or loss of information that is exchanged between the remote control system and the primary medical device.

Connection/disconnection of the remote control system shall not interfere with the intended use of the primary medical device.

Note 1 Causes of degradation can include physical interference with the signal (e.g., electromagnetic in origin (EMC), physical integrity (cable issues)

Note 2 Causes of QoS degradation can include bandwidth, latency, jitter, packet drop.

Note 3 The loss of function of the remote control system whether through loss of mains power or failure of the power supply, or other cause, will disable the auxiliary HMI and potentially lose the display of information, device control, and alarm display and annunciation. Similarly, loss of auditory or visual alarms may reduce the ability of the clinicians to respond in a timely manner.

7.1.2 Conflicting commands

There shall be a means for ME EQUIPMENT to prevent or resolve conflicting control arising from user action on the remote control system.

7.1.3 Authorization of the remote control system communications

When the remote control system communicates with the primary medical device for the first time, there shall be a means to confirm that the auxiliary HMI has the authority to remotely control the primary medical device.

7.2 Component issues and physical hazards

7.2.1 Basic safety

Means shall be provided to assure basic safety of the remote control system.

Medical Electrical (ME) Equipment shall comply with relevant standards.

NOTE Remote control system is considered part of the ME system. The basic safety and essential performance aspects of 60601-1 apply. The protection against direct physical hazards under normal and single fault conditions is implied and includes tripping on the components of the system such as the cables and a cart if used.

Manufacturer shall disclose the residual risk.

7.2.2 Power

Disclosed information shall include whether the remote control system will operate while the medical device is not connected to mains power.

Means may be provided for backup power to the auxiliary HMI.

In the event of loss of mains power, the behavior of the auxiliary HMI shall be disclosed. However, loss of power to the remote control system shall not inadvertently affect the operation of the medical device with its primary HMI.

NOTE Without backup power, a loss of power will shut down the remote control system and may create a hazardous situation.

7.2.3 EMC

IEC 60601-1-2 is recommended but not required.

Rationale: The tests of IEC 60601-1-2 are time consuming and expensive and need very specialized equipment. Requiring these tests would delay availability such that new designs might not be available when needed. Disclosure that these tests have not been performed and that other equipment must be kept at a distance should be considered sufficient.

Note 1 The hardware used for the remote control system may be vulnerable to radio frequency and electro-magnetic pulses, static discharge, brownouts and voltage spikes. The impact can range from temporary disruption of command and control to permanent damage to circuit boards. Proper shielding, grounding, power conditioning, and/or surge suppression is recommended.

7.3 Locus of control, information focus

7.3.1 Locus of control

Means shall be provided to manage contention for control from multiple sources.

Note 1 Functions which require the direct observation of the patient or physical proximity may not be suitable for control from the auxiliary HMI.

Note 2 ME Equipment that was previously designed with one input pathway for data/control (e.g., a medical device front panel by the patient's bedside) will now have at least two input pathways (e.g., the bedside and remote front panel). (adapted from UL-2800-1 Annex L)

Note 3 ME Equipment that were previously designed with one output pathway for data/control (e.g., a medical device front panel by the patient's bedside) will now likely have at least two pathways (e.g., the bedside and remote device front panel). (adapted from UL-2800-1 Annex L)

To allow authorized operators to take over control when necessary, the ability to control critical device settings and modes of operation should be available on both of the operator interfaces of the ME equipment and operator interfaces of the remote control system.

The conditions under which locus of control transfer occurs shall be addressed by the risk management process and disclosed.

Note 4 Such transfers may be necessary to allow an operator to easily stop, modify, and restart the automated processes controlled by system application logic in case of problems or abnormal situations. disclosure may occur in instructions for use, on operator interface of the ME equipment or on the operator interface of the relevant remote control system as justified by risk management.

Note 5 In the event of a remote control system display malfunction, the operator needs to transfer control of the ME Equipment to the bedside.

Note 6 The auxiliary HMI may display to an operator who is external to the patient room, all or some of the setting and physiologic information that is available inside the room. Considerations include:

a) Do changes to the local control unit (bedside) have priority over the auxiliary HMI or vice versa? Under what conditions should alternate control at the auxiliary HMI be "locked" out?

b) Are there any functions that can be performed at the bedside using the local control unit that should be disabled remotely?

c) Can all of the controls on the primary control unit be mirrored on the auxiliary HMI? Are there any mechanical settings on one control that are electronic on the other?

d) Are there current/active controls that must be easily perceivable to avoid treatment delays and minimize errors?

Means shall be provided to indicate that an auxiliary HMI is operational.

7.3.2 Correlation of the remote control system with the primary device

Manufacturers shall take necessary measures to mitigate the risks relating to mistakenly using a remote control system to control a wrong target primary device.

Note 1 The risk may be mitigated through a direct cable connection where 1:1 relationship between the remote control system and the target primary device is clear.

Note 2 If the remote control is achieved through a wireless connection or network connection, means shall be provided by the manufacturer to allow HCW to clearly identify which primary device is controlled by the remote control system.

7.4 Cybersecurity, access, and privacy

7.4.1 Cybersecurity risk management

Manufacturer shall perform cybersecurity risk management. Specific cybersecurity risks in relation to the network connection (wired or wireless) between the remote control system and the primary device shall be carefully mitigated.

NOTE 1 See for example AAMI TIR57 Principles for medical device security - Risk management. Manufacturer should address confidentiality, integrity, availability, and authentication and consider a defense-in-depth strategy where appropriate.

NOTE 2 TCP/IP connections over a general network are not secure. The use of SSL/TLS/HTTPS protocols and SSL certificates should be considered.

NOTE 3 TCP ports, not required for the operation of the remote control system, should be locked down. This may include common ports including TCP ports associated with HTTP, POP3, FTP, SMTP and other protocols.

NOTE 4 The use of unsecured communication ports on the HMI could allow the connection of malicious devices.

NOTE 5 With transmission of patient data to and from an HMI over a network, there is risk for a breech in confidentially, integrity and availability of the information if the information is not properly secured, the connection not properly authenticated and sufficiently reliable.

NOTE 6 The Health Insurance Portability and Accountability Act (HIPAA) requires that all Protected Health Information (PHI) be encrypted when transmitted, and covered entities who fail to properly safeguard PHI can face significant penalties.

7.4.2 User access control

Means shall be provided to control access to the remote control system when it is located in an unsecure location.

Note 1 Access and use of the auxiliary HMI remote control system can be limited via physical area control or electronic control mechanisms.

Note 2 Remote access risk can also be mitigated with cabling from the therapeutic device directly to an auxiliary HMI outside the room, not connected to any network.

Note 3 Unauthorized access to the auxiliary HMI may provide the opportunity to make changes to the patient's therapy leading to serious consequences. Improper access to the auxiliary HMI can lead to any of the following:

- Physical theft of data and hardware;
- Physical damage or destruction of data and hardware;
- Unauthorized changes to the functional environment (e.g., data connections, unauthorized use of removable media, adding/removing resources);
- Disconnection of physical data connections;
- Undetectable interception or changes of data (command spoofing, keystroke and other input logging, rephrased-from National Institute of Standards and Technology (NIST);
- Accidental change (e.g., bumped or tipped).

7.4.3 Patient Visualization

If indicated by risk management, the manufacturer shall provide a means to observe the patient or shall disclose that when the auxiliary HMI is used, the operator must have a means to observe the patient in order to confirm the status of patient and equipment.

NOTE Observation may be accomplished by a line-of-sight view of the patient or a video connection, as determined by clinical needs and risk management. In case of a video monitor, HIPAA compliance shall be considered.

7.5 Privacy

Manufacturer shall determine if the auxiliary HMI user access controls have safety requirements, clinical access requirements, and a remotely-controllable feature set.

NOTE 1 Patient identifying and care information (such as PHI) may be visible on the HMI display.

NOTE 2 For example, the possibility of viewing of PHI on HMI displays by those not associated with the care of the patient.

7.6 Use-related

Foreseeable use errors within the remote control system should be mitigated to reduce the risks as far as possible to an acceptable level. Changes to clinical workflow that result from the use of remote control and data access shall be considered in risk management.

7.6.1 Usability design principles

Operator interfaces provided by the remote control system should be assessed for usability risks and controls provided consistent with recommended or best clinical practices.

NOTE Application of IEC 62366-1 and applicable FDA human factors guidance is recommended but not required due to time and resource constraints inherent in delivering EUA products for COVID-19 pandemic patient care.

7.6.2 User interface and controls

An indication of the locus of control should be displayed on the local operator interfaces of both the (local) ME equipment and the remote control system.

NOTE Modification of the primary HMI to indicate locus of control may require more time or resources than is feasible during the Pandemic.

Information critical to safe remote operation of ME equipment, as determined by a risk management process, shall be accessible through the auxiliary HMI.

Data timeliness and consistency shall be considered in risk management.

A means shall be provided for the user to determine whether the displayed data on the auxiliary HMI is real-time relative to the primary HMI.

A common clock reference shall be used and displayed on all HMIs.

Information critical to safe remote operation shall include operational modes and settings of the ME equipment, and system response to remote user actions, shall be disclosed in the Instructions for Use.

NOTE 1 Information critical to safe remote operation includes user instructions for remote operation and variability in network latency.

The same operator actions on operator interface controls with similar purposes should produce equivalent effects in conceptually similar situations on both constituent components and ME equipment operator interfaces.

The manner in which the following risks are addressed shall be described in the Instructions for Use:

a) risks associated with potential confusion from competing loci of control and information, including alarm signals, introduced by the use of the remote control system.

NOTE 2 For example, risks should be considered when an alarm signal at the bedside is audio paused when a remote alarm signal is available.

NOTE 3 Physical access to the auxiliary HMI may need to be restricted to approved personnel, e.g., through location of physical deployment or through software access controls, considering safety and clinical access requirements.

7.7 Data logging

Realizations of remote control should provide a mechanism to log operator actions and other events with sufficient details as to enable post-hoc reconstruction of user actions in forensic analysis of incidents or system failures. There should be means to log whether commands are local or remote.

7.8 Informational resources

Informational resources necessary to understand feedback or to operate ME equipment when the ME equipment is under remote control should be readily available to the operator.

NOTE Informational resources may be provided through labeling, operator manuals, or within the operator interface.