

AAMI Consensus Report

**Emergency Use Guidance
for Remote Control of
Medical Devices**

AAMI/CR511:2020

Emergency use guidance for remote control of medical devices

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Approved 16 December 2020 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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Task Group representation

Association for the Advancement of Medical Instrumentation

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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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62 **3 Terms and definitions**

63 **3.1**

64 **human machine interface**

65 **HMI**

66 an interface for HCW to interact with a medical device

67 **3.2**

68 **auxiliary human machine interface**

69 an interface for HCW to interact with a medical device that is additional to the primary HMI of the medical
 70 device

71 **3.3**
72 **primary device (primary medical device)**
73 primary device, or primary medical device, is the device that is located with the patient; primary device
74 includes a primary HMI

75 **3.4**
76 **primary human machine interface**
77 an interface for HCW to interact with a medical device that is co-located with the medical device and the
78 patient

79 **3.5**
80 **remote control**
81 the action to control a medical device by the operators from a location not co-located with the patient,
82 medical device, or its primary HMI

83 **3.6**
84 **remote control system**
85 remote control system typically consists of the auxiliary HMI, the communication link, the receiving unit, the
86 associated software and any accessories required to configure the remote control system such as mounting
87 hardware

88 **4 Introduction**

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

- 94 a) Reduce the need for entering the patient's room to adjust device settings;
- 95 b) Allow for a response to clinical changes more rapidly;
- 96 c) Enable a more comprehensive real-time patient assessment and management; and
- 97 d) Reduce the donning and doffing frequency of PPE.

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

- 99 a) Reducing HCW exposure to infectious material;
- 100 b) Improving the quality of patient care;
- 101 c) Reducing consumption of PPE; and
- 102 d) Improving HCW patient-care workflow efficiency thereby increasing HCW availability to provide
103 care for other patients.

104 **5 Background**

105 **5.1 Case for remote control**

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

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

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

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

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

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

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

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

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

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

145 **5.2 Current practice**

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

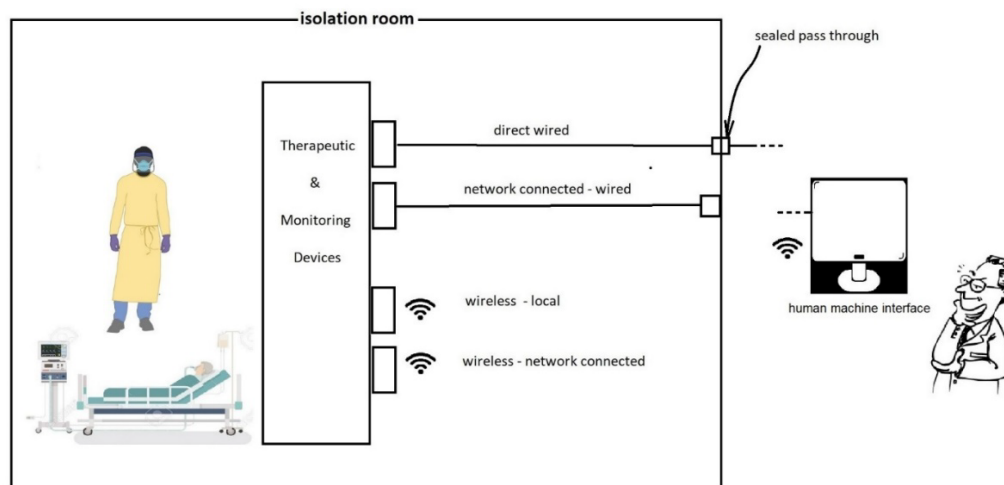
150 Examples of remotely controlled ventilator implementations used during the COVID-19 pandemic:

- 151 a) permitted the primary display to be detached and positioned a distance away from the ventilation
152 component using a cable (e.g., Hamilton G5). Off-label modifications to other ventilators have been
153 published, including anesthesia workstations (e.g., GE Aisys and Aisys CS2), which enable the
154 display to be detached for remote control and monitoring (Connor, 2020).
- 155 b) provided a ventilator-specific auxiliary graphic user interface (GUI) via direct cable connection (e.g.,
156 Nihon Kohden NKV550 with Protective Control®, 510(k) cleared by FDA, permits full ventilator
157 operation except silencing the power-off alarm).
- 158 c) provided a custom control software application (e.g., Medtronic Omnitool software for control of
159 compatible PB 980 ventilators) that permits complete remote control over a directly connected or
160 networked Windows OS computer.

161 **6 System elements**

162 **6.1 Construction**

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



170 **Figure 1—Different interface types are depicted with a clinician in PPE inside the patient room and**
171 **another clinician without PPE outside the patient room**
172

173 NOTE Clipart from: https://www.123rf.com/clipart-vector/medical_ventilator.html?sti=lvridru068vdkxy2t2j

174 **7 Safety requirements and risk control measures**

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

178 **7.1 Disclosure of communication architecture**

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

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

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

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

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

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

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

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

197 d) Wireless/Wired-Shared network connection

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

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

202 **7.1.1 Degradation or loss of information**

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

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

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

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

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

213 **7.1.2 Conflicting commands**

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

216 **7.1.3 Authorization of the remote control system communications**

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

220 **7.2 Component issues and physical hazards**

221 **7.2.1 Basic safety**

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

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

224 NOTE Remote control system is considered part of the ME system. The basic safety and essential performance aspects of 60601-
225 1 apply. The protection against direct physical hazards under normal and single fault conditions is implied and includes tripping on the
226 components of the system such as the cables and a cart if used.

227 Manufacturer shall disclose the residual risk.

228 **7.2.2 Power**

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

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

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

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

236 **7.2.3 EMC**

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

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

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

245 **7.3 Locus of control, information focus**

246 **7.3.1 Locus of control**

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

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

250 Note 2 ME Equipment that was previously designed with one input pathway for data/control (e.g., a medical device front panel by
251 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
252 Annex L)

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

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

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

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

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

265 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
266 information that is available inside the room. Considerations include:

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

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

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

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

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

274 **7.3.2 Correlation of the remote control system with the primary device**

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

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

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

281 **7.4 Cybersecurity, access, and privacy**

282 **7.4.1 Cybersecurity risk management**

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

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

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

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

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

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

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

298 **7.4.2 User access control**

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

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

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

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

307 — Physical theft of data and hardware;

308 — Physical damage or destruction of data and hardware;

309 — Unauthorized changes to the functional environment (e.g., data connections, unauthorized use of removable media,
310 adding/removing resources);

311 — Disconnection of physical data connections;

312 — Undetectable interception or changes of data (command spoofing, keystroke and other input logging, rephrased-from
313 National Institute of Standards and Technology (NIST));

314 — Accidental change (e.g., bumped or tipped).

315 **7.4.3 Patient Visualization**

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

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

321 **7.5 Privacy**

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

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

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

326 **7.6 Use-related**

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

330 **7.6.1 Usability design principles**

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

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

335 **7.6.2 User interface and controls**

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

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

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

342 Data timeliness and consistency shall be considered in risk management.

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

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

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

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

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

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

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

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

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

359 **7.7 Data logging**

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

363 **7.8 Informational resources**

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

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