Massachusetts General Hospital
Founding Member, Mass General Brigham

Remote Control of Medical Devices

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What is remote control?

- "Remote Control" is enabled by devices that permit control of the device via an external data interface – it could be called "External Control"
- If a device has enabled external control, a human or an algorithm could use that capability
- The control can be performed by a person in the same room – like a TV remote control, or by someone in nearby location ("Alexa, turn on the downstairs light"), or by someone far away ("set the vacation home thermostat to 68 degrees"). Each of these control scenarios has different clinical implications that may depend on the clinical context, device, and distance.

Clinical Benefits and Applications of Remote Control

Potential applications and benefits of remote control for care in the Operating Room, ICU, interventional radiology, procedural suite, and remote settings:

- Activate ventilatory pause for neuro, cardiac, and vascular imaging
- Enable more rapid response for urgent patient care needs from outside the patient room/OR (for example, increase FiO2, adjust vasopressor infusion rate, pause oxytocin)
- Reverse isolation - Reduce room entries to decrease risk of infection.
- Reduce PPE consumption
- Long-distance remote control can permit remote experts to support on-site staff in under-resourced and austere environments

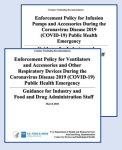
Integrated Clinical Environment (ICE)

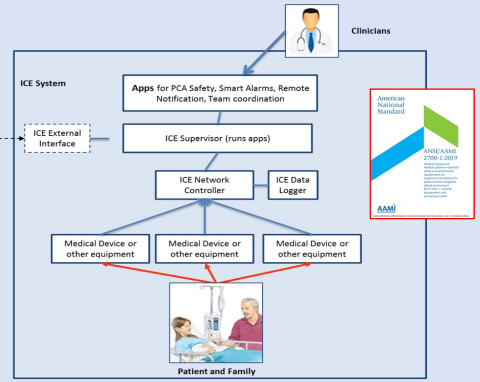
AAMI Standard 2700-1

The ICE standard provides an architecture and requirements to provide:

- App platform for smart and autonomous apps to connect to medical devices for secure data access and control
- Plug-and-play connectivity
- Data logging (black box recorder)
- Patient ID-data binding
- Correct time stamping of all data
- Security

A medical device remote control standard is under development in the AAMI Interoperability Working Group





Standard recognized by FDA in August 2013

"Levels of Automation" for Autonomous Medical Systems

"Autonomous" is often imprecisely used interchangeably with "automation".
Automation exists along a continuum, from simple to complex.

There have been extensive efforts to classify Levels of Automation to gain a better understanding of the physical and cognitive complexity and associated risks related to these systems.
Frameworks for Levels of Automation, especially in the fields of manufacturing, automobile transportation, and robotics, have been under development for decades. In 1996 Draper identified 6 levels of automation ranging from no automation to fully automated operation.*

Level of Automation	Society of Automotive Engineers (SAE)	Autonomous Medical Systems-proposed	Autonomous Medical Systems - Example
0	human driver does everything	human provider does everything	Manually setting device alarm limits
1	system on the vehicle can sometimes assist the human driver conduct some parts of the driving task	can sometimes assist the caregiver conduct some tasks	Use data from multiple sensors to detect arrythmia, clinical impact, and present contextual treatment guidance. Suppress non-actionable alarms during the event to reduce cognitive overload.
2	**system on the vehicle can actually conduct some parts of the driving task, while the human continues to monitor the driving environment and performs the rest of the driving task**	**can actually conduct some parts of patient management**	**Control an infusion pump to titrate a sedative-hypnotic to maintain a target depth-of-anesthesia (or sedation) score. The provider continues to monitor the clinical environment and performs the remaining associated patient care tasks** **As above – automatically adjust anesthetic agent vaporizer to maintain a target end-tidal anesthetic agent level**
3	system can both actually conduct some parts of the driving task and monitor the driving environment in some instances, but the human driver must be ready to take back control when the automated system requests	can both actually conduct some parts of the clinical management tasks and monitor the clinical environment in some instances, but the provider must be ready to take back control when the automated system requests	Anesthesia machine with closed-loop end-tidal agent control that is capable of automatically transitioning the depth of anesthesia from induction, to maintenance, to emergence. An artificial pancreas that uses continuous glucose monitoring and a dedicated algorithm linked to a controllable insulin pump
4	system can conduct the driving task and monitor the driving environment, and the human need not take back control, but the automated system can operate only in certain environments and under certain conditions	can conduct the clinical tasks and monitor the patient environment, and the provider need not take back control, but the AMS system can operate only in certain environments and under certain conditions. The AMS would be initiated by providers after ensuring that the medical treatment requirements are within the capabilities of the AMS	Automatically treat an acute burn patient by adjusting IV fluids and analgesics based on urine output. Automatic adjustment of FiO_2 to achieve a target SpO_2. In both examples, if the AMS determines that the controlled variable (urine output or SpO_2) cannot be achieved, or if the delivered IV fluid or FiO_2 exceed pre-set limits, caregiver is notified and control may revert to the caregiver.
5	system can perform all driving tasks, under all conditions that a human driver could perform them	can perform all medical tasks, under all conditions that a human caregiver could perform them	Autonomous Medical System is activated to treat a burn injury. The system determines that IV fluids are needed, and administers the correct amount of fluids to provide burn-related fluid resuscitation.

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