A Medical Device Information Data Sheet (MDIDS) to Support the Interoperability of Externally Controllable Infusion Pumps for Tele-Critical Care

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Problem & Motivation

Medical device remote control technologies can enable remote experts to contribute to patient-care during tele-critical care during public health emergencies like COVID-19. Clinical care may be further enhanced if one remote-control application can operate multiple interoperable medical devices (e.g. multiple types of ventilators or IV pumps) to support the typical diversity of deployed medical devices. However, due to the variation in capabilities of different makes/models of the same device type, unified remote-control capability requires the standardization of the data interfaces of similar devices to present to the user sufficient information about the devices' capabilities and state of operation to enable safe remote control.

Method

Medical Device Interface Data Sheets (MDIDS) [1] provides a useful tool for documenting current and future device interface requirements and capabilities. We examined several clinical use scenarios where externally controllable infusion pumps are used to support tele-critical care, based on which we generalized an MDIDS for remotely controllable infusion pumps.

We validated this generalized MDIDS by cross-checking it with the capabilities of several externally controllable infusion pumps: the NeuroWave Accupump, Eitan Medical Sapphire, and the BD Alaris GH.

We also built software on the open-source OpenICE platform to implement the interfaces of these pumps and support remote monitoring and control in a benchtop testbed. This enabled us an assessment of the differences in capabilities among these pumps.

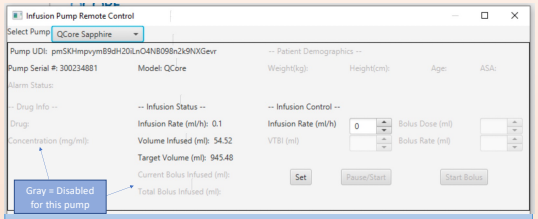

Figure 1. OpenICE Infusion Pump Remote Control panel for the Eitan Medical Sapphire Pump (labelled as "Qcore Sapphire")

Parameter	Definition	Units of Measure
Fluid delivery rate	Volume rate delivered by pump	volume/time (ml/s, ml/min, L/s, L/min)
Drug delivery rate	Drug delivery rate to patient	mass/time (mg/s, mg/min)
Bolus Delivery Duration	Time interval of high flow for bolus delivery	s, min, h, d
Lock out interval	Time interval for prevention of bolus delivery	s, min, h, d
Infusion Volume	Total fluid volume delivered since start of infusion	mm^3, cm^3, ml, L
Fluid delivery time	Time elapsed since start of this step of flow rate; may be used as a setting together with delivery rate to deliver a certain volume	s, min, h, d
Infusion time remaining	The time calculated by the pump until time for this step of flow elapses	s, min, h, d
Drug concentration	Concentration of drug in fluid delivered to patient	mass/volume (mg/ml)

Table 1. Exemplar of selected MDIDS elements related to infusion pump external control

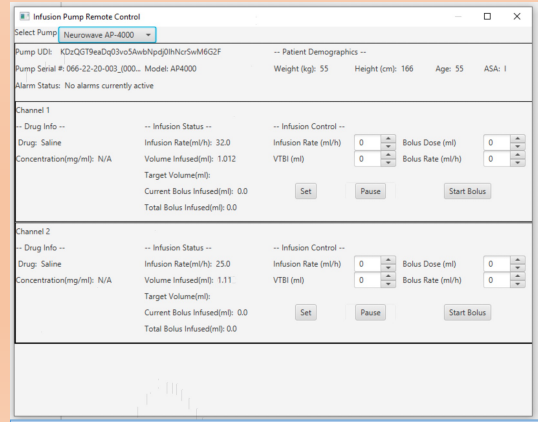

Figure 2. OpenICE Infusion Pump Remote Control panel for the Neurowave Accupump AP-4000

Results

During the development of the generic remotely controllable infusion pump MDIDS, we identified the common and specific data elements that different infusion pumps need to provide at their data interfaces, considering the great diversity in these devices related to infusion mechanism, infusion programming methods, device alarms and alerts, and system settings.

The resulting MDIDS includes over 100 data elements, many of which are essential for safety, including those common across different pump types (e.g., maximum settable infusion rate, occlusion alarm) and those specific to certain pump types (e.g., syringe size for syringe pumps).

Figures 1 and 2 respectively show the remote-control apps we developed for the Eitan Medical Sapphire pump and the Neurowave Accupump based on the generalized MDIDS. Data not supplied by the pump or control not supported by the pump are disabled in these apps. The difference between Figures 1 and 2 reflects the differences in electronic interfaces and capabilities of these two pumps.

Conclusions

MDIDS for externally controllable medical devices can provide a solid basis for manufacturers and 3rd party developers to improve the safety and interoperability of medical devices and remote and closed-loop control applications.

We applied the MDIDS methodology to infusion pumps and ventilators to support the integration of these devices to the U.S. Army Telemedicine & Advanced Technology Research Center (TATRC) National Emergency Tele-Critical Care Network (NETCC) initiative Technology in Disaster Environments (TiDE).

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References

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