

OpenICE Prototype:

A New, Open Interoperable Medical Device Clinical Research Platform

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The MD PnP Program (<http://mdpnp.org>) has developed an open source implementation of the Integrated Clinical Environment (ICE) standard as described in ASTM 2761-09(2013) and made it freely available on SourceForge. The platform consists of software device adapters for medical devices (including anesthesia machines, ventilators, and patient monitors), OMG DDS standard middleware, and demonstration applications. Applications can be built on this platform to implement smart alarms, physiologic closed-loop control algorithms, data visualization, and clinical research data collection.

The ICE standard defines an architecture for building a safe patient-centric Integrated Clinical Environment. It defines roles for device adapters, a network controller that mediates traffic, a supervisor capable of hosting applications, a data logger for forensic analysis, and external interfaces to hospital resources such as an EHR, ADT, or pharmacy system.

Safe interoperability requires that participants on the network all play by the same rules. DDS was chosen as the middleware for this prototype because it supports the expression of a wide range of quality of service parameters, allowing us to experiment with a variety of clinical scenarios on the way to achieving widespread adoption.

Applications (“apps”) in this implementation announce that they are interested in receiving particular pieces of data. Other network participants publish updates to data as it becomes available, and the middleware matches publishers to subscribers. Apps can publish data, so an application could, for example, receive a variety of heart rate signals from a number of medical devices and then publish a “canonical heart rate” topic. In this way, data from apps can be indistinguishable from physical medical devices, for example, enabling the development and sharing of sophisticated data processing apps that may generate data for use by other system components

Matching publishers to subscribers requires that all of the participants use a common set of terms. For this work, a subset of the ISO/IEEE 11073-10101 nomenclature was used. This allows for components (applications or devices) to be interoperable. Using this approach, it is our intent that a device manufacturer will be able to produce a device with an electronic interface that will work with any ICE application, and any ICE application will work with any device that provides the necessary data elements.

We are presenting an initial implementation here with the expectation that it will be useful to clinical researchers in its current state. We look forward to feedback, suggestions, and bug reports from the clinical research community to help with the development of future versions that will be suitable for mainstream clinical use. Updates will be available to the community via our SourceForge site (<http://sourceforge.net/projects/mdpnp>), and we are working on an ICE Application exchange (ICE AX) site where researchers and developers can post and download ICE applications.

We are very interested in forming a broad user/developer community by collaborating with diverse clinical research groups to inform the direction of development (http://www.mdpnp.org/Get_Engaged.html). We believe that our OpenICE implementation will reduce the time and cost of performing clinical studies, and lead to the development of an ecosystem of commercial and research interoperable apps and devices.