Demonstration Paper : Connecting Medical Devices Through ASTM-2761-09 - Schedule Conflict Detection Prototype

Vince Stanford
NIST
100 Bureau Dr.
Gaithersburg, Md 20899
+1-301-975-5399
vincent.stanford@nist.gov

Lukas Diduch
NIST
100 Bureau Dr.
Gaithersburg, Md 20899
+1-301-975-6399
lukas.diduch@nist.gov

Antoine Fillinger
NIST
100 Bureau Dr.
Gaithersburg, Md 20899
+1-301-975-4265
antoine.fillinger@nist.gov

Kamran Sayrafian
NIST
100 Bureau Dr.
Gaithersburg, Md 20899
+1-301-975-5479
kamran.sayrafian@nist.gov

ABSTRACT

The Integrated Clinical Environment (ICE) ASTM-2761 Standard specifies an architecture for real-time medical device interoperability, and a set of Clinical Concepts of Operations (CConOps). Based on an analysis of the CConOps, all showing improved patient safety, we developed an ICE prototype reflecting the ICE Synchronization with Safety Interlock Scenario, but with no risk to human participants, using wireless Medical Devices of different vendors.

Categories and Subject Descriptors

C.2.4 Distributed Systems, Client/server, Distributed applications. C.3 Special-Purpose And Application-Based Systems, Microprocessor/microcomputer applications, Process control systems, Signal processing systems

General Terms

Algorithms, Measurement, Performance, Design, Reliability, Experimentation, Security, Standardization, Verification.

Keywords

Interoperability, Standardization, Plug-and-Play System

1. INTRODUCTION

The ASTM-2761 ICE Standard [1] is intended to improve patient safety by providing development of an interoperable environment for medical device integration. The application domain ranges from independent medical monitoring of an individual at home to application in acute care such as operating rooms and intensive care units. To improve patient safety and provide interoperability an ICE includes some of the following capabilities: Medical Device Plug-and-Play Interoperability (MDPnP), Synchronization with Safety Interlock, Physiological Closed Loop Control (PCLC), Smart Alarm, Decision Support and Forensic Data Logging. Most relevant to this paper are the first two:

Medical Device Plug-and-Play in this context refers to the capability of interconnecting ICE compatible medical devices of different type from different vendors before or while the system is in operational state. While several solutions implementing a modular or pair-wise approach of combining devices or sensors into one system exist (e.g. a Patient Monitor), products of this type are usually tied to a specific vendor or product line. This not only reduces the pool of devices to chose from in terms of quality and cost but also removes the possibility to replace a device for another due to vendor incompatibility in case of a fault or emergency. **Synchronization with Safety Interlock** refers to the capability of acquiring the devices schedules and using it to orchestrate the operation of a group of devices to ensure safe operation which would be potentially hazardous in case the devices operate independently.

Due to the length of this paper readers not familiar with the ICE conceptual architecture as well as the philosophy and functional aspects of ICE are referred to the standard document [1].

Numerous technological challenges must be addressed before implementations of this standard become possible. The specific challenges with such interoperable medical device architectures or Medical Application Platforms (MAPs) are addressed in more detail in [4]. Specific challenges for this demonstration are real-time data collection from unreliable sources, real-time visualization as well as time-synchronization of the data streams. In this demo paper we will describe an ICE instance based on NIST Data Flow System II which implements acquisition and processing of data from wireless sensors in a distributed system, addressing the use case of device schedule conflict detection, which is one of the many capabilities of ICE.

2. PROTOTYPE IMPLEMENTATION

For this demo, we have simulated a scenario as close as possible to the original use case B2.2 from the ASTM 2761-09 standard ('*Synchronization with safety interlock*') but without involvement of a closed loop or an adverse event. Implementing a realistic closed loop system requires an accurate physiological patient model which is not available at this time. Scenario B2.2 addresses taking an x-ray image of a patient connected to an ventilator. In order to take a usable x-ray the artificial ventilation of the patient has to be temporarily interrupted, which can potentially lead to multiple problems in case of human or equipment error (e.g. ventilation is not being restarted on schedule after performing the x-ray). A system aware of the schedule of both devices, can automatically detect a schedule conflict, and in a closed loop scenario, can orchestrate the proper schedule between the devices in order to either insure re-starting of the ventilation or throw smart alarms. Our prototype implements an open loop scenario addressing scheduling conflict between two devices but with the difference of a missing actuator device like the ventilator. The demo has been presented successfully at multiple occasions in front of an audience with either technical or medical background.

The demonstration platform involves networked computers and two Personal Health Devices (PHDs) connected via IEEE 802.15.1 (Bluetooth). It focuses solely on demonstrating the schedule conflict between the two devices: 1) Nonin Onyx II Pulse-Oximeter and 2) A&D Blood-Pressure Monitor. Both devices are attached to the *same limb* of a patient. While the sphygmomanometer cuff is inflating it can potentially interfere

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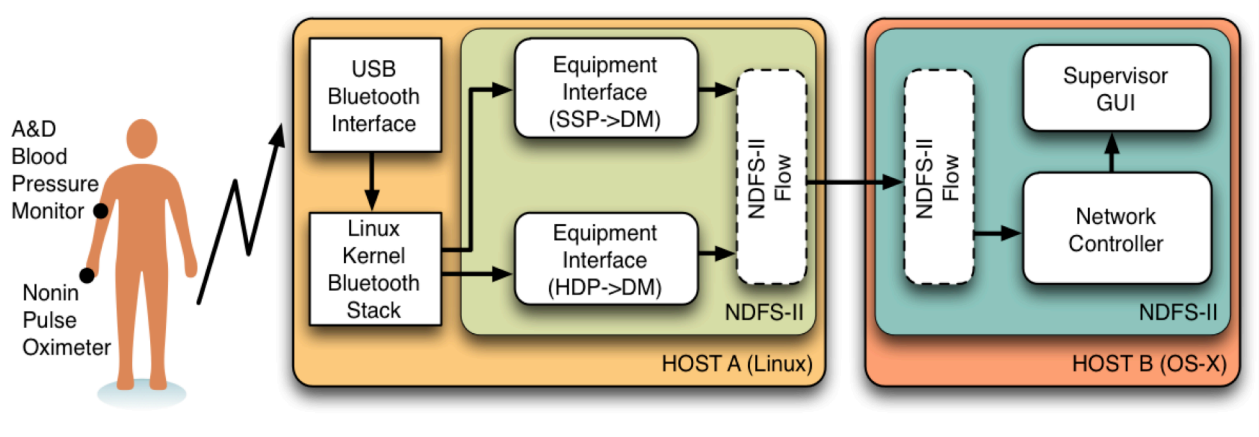

Figure 1: Diagram of the Prototype Application Setup

with the pulse-oximeter reading. In case the pulse-oximeter cannot measure the Blood-Oxygen (SP02) level or heart-rate it throws a Technical Alarm by requirement, which in this specific case is a **false-positive or nuisance-alarm**. An algorithm module loaded at runtime into the system for **Scheduling Conflict Detection** is used to detect and present the conflict to the operator looking at the Supervisor GUI.

The system is being run on multiple computers, using the NIST Data-flow System II (NDFS-II) distributed middleware with the Multimodal Data Fusion extensions for synchronization implemented in C++ and Java. The NDFS-II follows a data-flow publish and subscribe paradigm using processes interacting with each other in a networked environment [2]. Furthermore wireless communication to the PHDs is using two distinct Bluetooth profiles. Device 1 is interfaced via the SPP (serial port profile) and provides a raw byte-stream, which has to be decoded and interpreted into a suitable format for further processing. Device 2 is using the HDP (health device profile) in combination with the Antidote Software library [3] implementing IEEE 11073-PHD agent/manager paradigm and exporting data from the devices in a XML format. The prototype diagram as seen in Fig. 1 follows the ASTM-2761-09 conceptual architecture of medical devices connected to the network controller via an ICE Interface. The scheduling conflict detection and final signal processing is being performed in the Supervisor Module and visualized by the GUI. Time-synchronization of the data streams in being performed in the network controller module.

The Demonstration consists of three stages:

1) Ensuring wireless connections to the capture PC are established: this involves pairing of the wireless devices with the PC platform and starting an agent/manager system via a script run by the operator.

2) Starting the NDFS-II application map, which instantiates all components and spawns the Supervisor GUI. The GUI prompts for user information e.g. procedure, patient, devices to monitor, and creates an application specific user interface of the system. Additionally the user needs to load the runtime-modules, in this case the schedule conflict detector.

3) Monitoring Phase: continuous gathering of data from devices and detection as well as indication of a scheduling conflict. A scheduling conflict detector is run under the ICE Supervisor.

3. CONCLUSION AND FUTURE WORK

MAPs in a wireless sensor context will remain a highly challenging task for academia and industry for many years to come, as this and other prototypes already demonstrate major obstacles in reliability and safe operation in a medical context. ASTM-2761 is a first step towards achieving operational safety and interoperability among the medical device domain.

In future efforts we are extending our prototype to explore clinical data logging methods compliant with the ASTM 2761 standard. This involves dealing with security issues like: detection of log tampering, data integrity and replay of medical data, logging of device events like clinical- or technical-alarms, application messages like the demonstrated schedule conflicts as well as system component interaction data.

4. ACKNOWLEDGEMENT

The Authors would like to express their thanks and appreciation to Renaud Mathieu, Luc Lenotte and Xavier Schmitt for their contributions in implementing the prototype system, as well as Dave Arney and Julian Goldman, MD from CIMIT for dedicating their time for discussions about the application issues related to real-world medical scenarios. We would also like to thank the reviewers for their useful and constructive comments.

5. REFERENCES

[1] ASTM 2761-09 Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model, ASTM International, West Conshohocken, PA, USA

[2] Middleware and Metrology for the Pervasive Future. Fillinger, A. et al. Pervasive Computing, IEEE Volume: 8 , Issue: 3_ p. 74-83., http://www.nist.gov/smartspace/talksAndPubs.html

[3] Signove, Antidote, IEEE 11073-20601 stack, http://oss.signove.com/index.php/Main_Page

[4] Rationale and Architecture Principles for Medical Application Platforms; J. Hatcliff, A. King, I. Lee, A. WacDonald, A. Fernando, M. Robkin, E. Wasserman, S. Weininger; J. Goldman

NOTE

Reviever 1:

Other than demonstrating the implementation of well-known previously articulated concepts, the paper does not contribute novel ideas to the state of the art. As such it is suitable for a demo, not a full-length paper.

- Reviewer recommends paper for demo paper, which has been addressed.

Reviewer 2:

- fixed mentioned typos

This paper is very difficult to follow. The introduction, which should demonstrate the need for this type of technology, did not make a clear, strong case for why this is important. Page 1: You need to define "plug and play" and why it's important.

What is an SP02 device? Why was it blocking getting a proper measurement?

- defined pnp schedule conflict detection and clarified the need for this technology

- cut addressed parts, due to 2 page format

- defined acronyms

- clarified why blocking occurs

It's not clear what challenges this prototype is addressing

- challenges addressed in introduction

A stronger case for why BP and PulseOx were chose as the health assessment methods tested needs to be made

- clarified the relationship between the original scenaro and the prototype scenario.

- Scenario B2.2 clarified

Reviewer 3:

- fixed typos

Weakness: no real data or results from the system.

- 2 page format too short now to discuss results and findings, but demo presentation/poster will be demonstrating/addressing the particular challenges experienced: signal strength, degenerated communication channel, synchronization of data streams, real-time signal processing

Reviewer 4:

The prototype involves 2 computers which does not constitute a good demonstration of network controlling. It would seem more reasonable to have each sensor device connected to its own ICE interface on a separate computer, then have 3 networked machines.

- Networking in this demo is being used to distribute the computational load allowing the sensors to capture data uninterrupted. The proposed setup by the reviewer has been implemented in our lab on desktop computers for the stated reason but will not be possible to demonstrate due to missing resources.

Interoperability

- mentioned that different devices from different vendors are being used

Overall this paper is hard to read, and the wording is awkward in places, eg "utmost gravity to patient safety" -> "utmost importance".

All acronyms should be defined, eg NTP, SPO2.

- Acronyms have been defined, the mentioned awkward wording has been removed.