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Ensuring Patient Safety by using Colored Petri Net Simulation in the Design of Heterogeneous, Multi-Vendor, Integrated, Life-Critical Wireless (802.x) Patient Care Device Networks

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Abstract— **Hospitals and manufacturers are designing and deploying the IEEE 802.x wireless technologies in medical devices to promote patient mobility and flexible facility use. There is little information, however, on the reliability or ultimate safety of connecting multiple wireless life-critical medical devices from multiple vendors using commercial 802.11a, 802.11b, 802.11g or pre-802.11n devices. It is believed that 802.11-type devices can introduce unintended life-threatening risks unless delivery of critical patient alarms to central monitoring systems and/or clinical personnel is assured by proper use of 802.11e Quality of Service (QoS) methods. Petri net tools can be used to simulate all possible states and transitions between devices and/or systems in a wireless device network, and can identify failure modes in advance. Colored Petri Net (CPN) tools are ideal, in fact, as they allow tracking and controlling each message in a network based on pre-selected criteria. This paper describes a research project using CPN to simulate and validate alarm integrity in a small multi-modality wireless patient monitoring system. A 20-monitor wireless patient monitoring network is created in two versions: one with non-prioritized 802.x CSM protocols and the second with simulated Quality of Service (QoS) capabilities similar to 802.11e (i.e., the second network allows message priority management.) In the standard 802.x network, dangerous heart arrhythmia and pulse oximetry alarms could not be reliably and rapidly communicated, but the second network's QoS priority management reduced that risk significantly.**

I. INTRODUCTION

WIRELESS patient monitoring networks using industry-standard IEEE 802.x technologies that can facilitate patient mobility and clinical flexibly are part of the focus of IEEE Standards Association's X.73 RF Medical Device Working Group . In addition to RF interference issues, there is a concern that using common Wi-Fi (or other) RF network systems to interconnect multiple life-critical medical devices vendors may be create unanticipated patient safety problems by preventing or delaying delivery of critical patient alarms to central monitoring systems. This current research demonstrates the use of Petri net tools to simulate the possible message states and transitions between devices and/or systems. It is hoped that such tools will allow detection of high-risk failure modes in advance of medical network selection, purchase, and installation. In this research, a Colored Petri Net (CPN) simulation tool was used to tracking - and control – several basic medical device alarms according to selected criteria. This paper also shows how the CPN model can verify and validate wireless-networked medical device alarms that would be generated in wireless patient monitoring systems.

Medical device manufacturers and hospitals are leveraging the integration of medical device and information system technologies to provide wireless LAN-based medical device architectures (Briggs 2004, Cohen 2001, Health Consultants 2003, Sloane 2001, Sloane 2002). Implemented or proposed systems are often based on the cheap, widely available Wi-Fi (IEEE 802.11x) or Bluetooth (IEEE 802.15x) wireless network software and hardware.

Unfortunately, the most common 802.11a, 802.11b, 802.11g, and the emerging 802.11n systems all use Internet Protocol (IP) network designs that are based on random collision detection (CD) algorithms, which cannot guarantee that any specific message, such as a life-critical alarm, can or will be delivered in a timely manner. The alarms and clinical data streams are broken into small packets and sent through the device's antenna to a shared wireless network access point (typically on or in the ceiling), which is the source of the potential problem. Heart monitors may be constantly sending a stream of clinical waveforms in digital packets that must be assembled in correct sequence at a central station or computer system before display or analysis. When more than one packet of data arrives at an antenna at the same time from different devices, the CD protocol senses the collision and each device is instructed to wait a random delay period before resending their packet. When multiple devices work in the same vicinity, they will likely share the access point(s), creating the possibility of many CD delays.

Some situations require a means to assure that certain signals receive priority on a wireless network, which may be referred to as Quality of Service (QoS). The use of QoS is widely being discussed by vendors such as Cisco Systems in the Voice over Internet Protocol (VoIP) because is helps avoid unacceptable gaps and wavering in telephone-type discussions when using 802.x networks. QoS is covered in a supplemental IEEE standard known as 802.11e which must be applied in addition to the other basic 802.11x protocols. Unfortunately, 802.11e has not yet emerged in

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the form of industry-wide standard off-the-shelf compatible network components.

Absent the 802.11e QoS features, in a standard wireless network, all data packets are treated as if they are alike. Fortunately, most physiological waveforms have relatively low data rates and are not life-critical, so random delays may not be important. Life-critical alarms, however, such as ventricular fibrillation that accompanies a heart attack should not be delayed, which is the motivation for this present study. The risks of system failures or defects can be very serious; government reports have documented that as many as 90,000 American patients may be injured or killed by medical errors each year, and complex systems with defects could make these problem worse (Institute of Medicine). Although medical device manufacturers must validate their software-based products to FDA standards, no such requirements exist for hospitals.

There are several formal modeling and validation, and verification techniques from different industrial contexts that can be applied to such problems (Gehlot 1988, Reisig 1985). This current research is part of an ongoing effort to apply such techniques in health-care settings and to show that there are benefits to be drawn from such an approach. In particular, we have tried to show by means of a simple example how Petri Nets (Reisig 1985) may be used to model wireless medical device network scenarios in hospitals.

As stated in prior research (Sloane and Gehlot, 2004) Petri nets are a good tool for modeling systems with interacting concurrent components. Because there are over 50 automated Petri net tools available, flexible, adaptable, and visual capabilities and strong analytic options can be found.

In the next sections, we give a formal definition of a Petri net, we show we can use a Petri net to represent simple wireless medical device network with such the tool, and then we show how we can validate and verify the system.

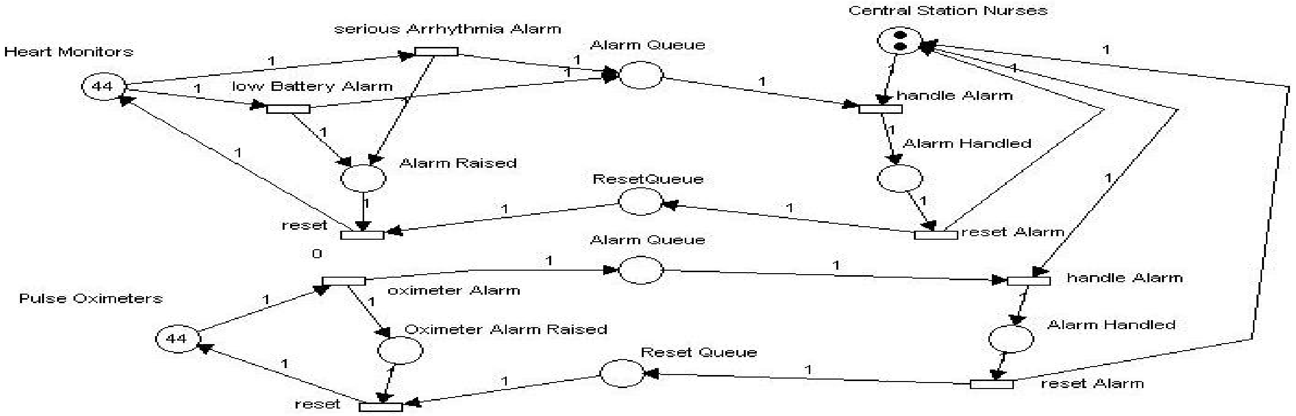

Figure 1 Simple medical device Petri net without individual message identity or prioritization capability.

II. PETRI NET AND COLOR PETRI NET SIMULATION

Petri nets are described in prior articles (Gehlot and Sloane, 2004). In brief, the abstraction of a Petri net includes ``state-like" objects (*S*) and ``event-like" objects (*T*) and dependencies between these objects (*F*). The basic idea being that ``any" phenomena or system can be described in terms of ``cause and effect". The state-like objects become the cause for the event-like objects to ``occur" and the effect of which is ``another" state-like object. Thus, A Petri net consists of the following:

- A finite set of *states* or *places* (denoted *S*)
- A finite set (disjoint from *S*) of *transitions* or *events* (denoted *T*)
- A finite subset of $(S \times T) \cup (T \times S)$ called the *flow relation* or the *dependency relation* (denoted *F*)
- A mapping from *S* to natural numbers (including infinity) called marking (denoted *M*), i.e., $M{:}S \rightarrow N$

Figure 1, below, shows the basic Petri net model that was used initially (Sloane and Gehlot, 2004). This simple model was able to demonstrate alarm delays, but it could not track individual alarms to determine how any single patient might be endangered. Also, since individual alarm types or severity are not tracked in the model, there is no way to simulate QoS-like improvements for high-severity messages.

The Colored Petri Nets (CPNs) used in this present research are an enhancement of general Petri Nets in that the tokens have "colors" or types [Jensen]. This allows one to distinguish various types of tokens. This enhancement is attractive in our situation, where we would like to analyze behaviors of different kinds of alarms. Furthermore, the CPN Tool, which is a computer tool for editing, modeling, simulating, and analyzing CPNs employs a powerful programming language called CPN ML for declarations and net inscriptions [CPNTool]. This language is an extension of a well-known functional programming language called ML. This linguistic support within the tool allows one to model varieties of behaviors which are otherwise impossible to model in a Petri Net. In our case, we define several functions using CPN ML to impose some quality of service requirements. The CPN Tool also includes the timed extension of CPNs which is useful in capturing and simulating temporal behavior of a system. The time concept is based on the notion of a global clock which represents model time (not actual physical time). A token may optionally be declared as a timed token. Such tokens carry a time stamp through simulation. The time stamp governs the availability of such tokens. W e use timed tokens to govern the generation and handling of various alarms.

We extended our basic model of a patient monitoring system presented in [Sloane and Gehlot, 2004] created a model using Colored Petri nets that incorporated Quality of Service capabilities. Figure 2 depicts this model. In creating this model, we separated three categories (colors) of alarms: Red, Orange, and Yellow. The Red alarms are generated by heart monitors (transition labeled **HMAlarm**). The Orange alarms are pulse oximetry alarms (transition labeled **POAlarm**) and the Yellow alarms indicate low heart monitor battery situations that could signal the impending complete failure of a heart alarm monitor (transition labeled **LoBatAlarm**).

The CPN modeling tools handle time-dependent events quite differently than simple stochastic Petri net tools. Because of this, specific software was written to simulate realistic alarm events. The Red heart alarms fired infrequently, as one would expect for recovering patients. The Yellow battery alarms occurred least frequently because good hospital maintenance practices should ensure stable battery performance. The Orange pulse oximetry alarms occurred quite frequently, as they are prone to many false-positives due to patient movement sensitivity. The timings were programmed to occur at intervals closely similar to the prior published values [Gehlot and Sloane, 2004], and they are described with each simulation below.

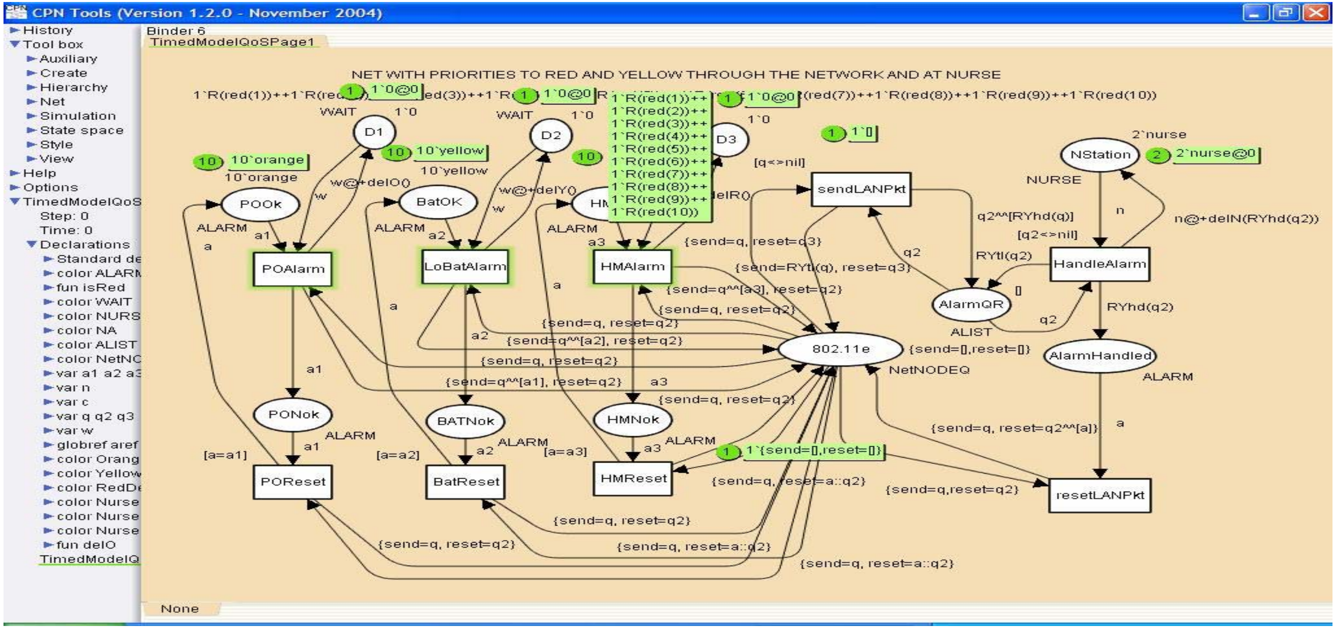

Figure 2 Colored Petri net (CPN) model of wireless medical device network with Quality of Service capability.

In Figure 2, the oval shaped place labeled **802.11** represents a wireless LAN network access point. All alarms and reset requests go through this network fabric. The packet queues are modeled using CPN ML's list data structure. The central station is modeled as two nurses managing the monitors and alarms (transition labeled **HandleAlarm**).

We used the CPN Tool to run several simulations of the model described above. The parameters of simulations were set as follows:

- color OrangeDelay = int with 1..2;
- color YellowDelay = int with 100..500;
- color RedDelay = int with 2..50;
- color NurseDelayY= int with 1..5;

These represent random values uniformly distributed over the specified range. We were able to include or exclude QoS prioritization and examined the differences. Without QoS, we found situations in our simulation runs where a Red alarm may be significantly delayed substantially. For example, the heart monitor alarm from one patient may not get handled until many less critical pulse oximetry alarms get cleared.

QoS version is shown in Figure 2, which has priority-based queuing policy implemented as CPN ML program functions below. In essence, these programs are designed to prioritize the passage of Red tokens ahead of Yellow ones, and Yellow ones ahead of Orange ones to ensure that critical heart alarms or heart monitor battery failure alarms propagate ahead of the less critical pulse oximetry alarms. The code for Red tokens look like this:

```
fun isRed(R(red(_)))= true
|    isRed(_) = false;
fun hasRed(l) = List.exists isRed l;
fun remR (l) =
if l=[] then []
else if isRed(hd(l)) then tl(l)
else hd(l) :: remR(tl(l));
fun getFstR(x::y) = if isRed(x) then x
else getFstR(y);
```

The main functions in these simple ML programs are **RYhd** and **RYtl.** These give priority to Red and Yellow alarm over Orange alarm. Furthermore, a Red alarm has priority over Yellow alarm. With these modifications incorporated, we ran several simulation runs and found no Red alarms getting delayed.

Discrete Red tokens (red(1) through red(10)) can be seen in Figure 2, which allows timing each of each of ten potential heart monitor alarms through the entire network. In larger, more complex networks, more colors and priority schemes may be needed to handle all of the clinical risks properly.

III. RESULTS

In the basic simulation shown in Figure 1 we found that many heart alarms were delayed for several minutes, representing a potentially life-threatening delay. In the QoS simulation shown in Figure 2, though, the minimum delay was 0, the maximum (rare) was 4, and the average delay was about 1.5.

It is important to realize that these problems are not due to the total bandwidth of the system but the random nature of the collision detection mechanism in standard 802.x systems. In our QoS simulation of the supplemental 802.11e protocol, however, although more frequent alarms from the pulse oximeters monitors caused more collisions, they cannot delay the life-critical alarms. This is an important capability, as more severe bandwidth demands and collision management needs are likely to emerge in the years ahead, especially as these wireless networks begin to be shared with other, non-clinical uses like mobile phones, and/or doctors and nurses with laptops and PDA's. Such uses could inadvertently tie the access points up with lengthy email, patient chart data (including images or multimedia content), or even entertainment data streams, causing ever-greater patient safety risks.

Although Figure 2's simulation was very much improved, it was not perfect. Any 4-minute heart alarm delay is unacceptable, so careful network design will be necessary in order to ensure that no heart alarm will be delayed more than about 10-15 seconds.

These CPN simulations suggest several practical conclusions:

1. Design and deployment of a wireless patient monitoring network may not be a simple process
2. Use of common, industry standard 802.11x (Wi-Fi) network components may create an artificial sense of security, as their successful use for less risky network applications is not at all like life-critical medical signals;
3. QoS-compliant (i.e., 802.11e) network equipment may be necessary for life-critical applications;
4. CPN tools can be programmed to simulate wireless medical device networks with, and without, QoS; and
5. Simulation of network performance with a tool such as CPNtool may become an invaluable way to predict and avoid life-threatening data delays, and can also be a powerful product selection, design, and negotiation tool for clinical engineers.

Many more devices will likely communicate with each other and with central information systems in the decade ahead. Similar risks can exist in wired networks, too, and CPN tools should prove useful for them as well. Ad hoc implementation of heterogeneous medical device networks without appropriate design and testing can jeopardize patient lives unnecessarily and inappropriately, can cause erratic and unreliable system performance, and can waste precious hospital human and fiscal capital. Other researchers should be encouraged to begin using CPN and/or other formal methods to simulate, verify, and validate wireless medical device networks., and clinical engineers should explore adoption of these tools for problem avoidance or detection.

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