Distributed Real-Time Emulation of Formally-Defined Patterns for Safe Medical Device Control

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Safety of medical devices and of their interoperation is an unresolved issue causing severe and sometimes deadly accidents for patients with shocking frequency. Formal methods, particularly in support of highly reusable and provably safe patterns which can be instantiated to many device instances can help in this regard. However, this still leaves open the issue of how to pass from their formal specifications in logical time to executable emulations that can interoperate in physical time with other devices and with simulations of patient and/or doctor behaviors. This work presents a specification-based methodology in which virtual emulation environments can be easily developed from formal specifications in Real-Time Maude, and can support interactions with other real devices and with simulation models. This general methodology is explained in detail and is illustrated with two concrete scenarios which are both instances of a common safe formal pattern: one scenario involves the interaction of a provably safe pacemaker with a simulated heart; the other involves the interaction of a safe controller for patient-induced analgesia with a real syringe pump.

1 Introduction

Each year, just in the US hospitals, a shocking and almost unacceptable number of medical accidents occur. In a 2009 study, reports estimate 40,000 instances of medical harm occur daily, and from the 2005 through 2007 period, at least 92,882 deaths were potentially preventable [4]. Many of these accidents happen due to mistakes and failures in the interoperation of medical devices. A modern hospital’s operating room is in fact a quite complex distributed embedded system (DES) with many devices involved in either passively monitoring the patient state or actively performing different parts of a procedure. Both the safety of the individual devices and the safety of interoperation between devices (and between the patients and doctors) are of paramount importance. Presently, this safety is not adequately guaranteed.

When the reported accidents are analyzed, it becomes clear that many of them could and should have been avoided if the DES formed by the devices, the patient, and the doctors had been properly designed and analyzed, so that many unsafe interactions become impossible by design. The use of formal methods can clearly help in this respect, and promising research advances have already been made in this direction (see, e.g., [1][2][8][3]).

In our recent work [9][10], we have developed a scalable and highly reusable approach to the safety of medical devices by means of formally verified patterns that: (i) are formally specified as real-time rewrite theories in Real-Time Maude; (ii) are generic, so that they apply not to a single device but to a wide range of devices, and are therefore specified as parameterized modules; (iii) come with explicit formal requirements (specified in their parameter theories) that must be met by any pattern instantiation to be correct; and (iv) come with formal safety guarantees that will be satisfied by any correct instantiation of the pattern. For example, in [9] we present one such pattern and show how it can be instantiated to
obtain safe controllers for quite different devices, such as a pacemaker, an infusion pump for analgesia, and the interoperation of a ventilator with an X-ray machine.

However, there is still a substantial gap between the verified safety of designs in formal specifications and the actual safety of real medical devices, patients and doctors in an operating room for at least two reasons. First, the formal specifications are somewhat idealized abstractions in which, for example, time is not the actual physical time that devices need to operate in, but logical time, and the code of the actual devices and controllers is not used but instead some formal specifications are used. Second, it is important to consider not just the safety of a single device or small collection of devices, but also that of their interoperation with other devices and with the patient and the doctors. This work takes some first steps towards the goal of bridging the gap between formal specifications and actual devices in a hospital to help ensure that safety properties are preserved in the passage from specification to actual code and physical devices. To achieve this goal we propose the use of virtual emulation environments in which:

1. formally verified patterns \cite{10} can be instantiated to obtain various concrete specifications of desired devices and controllers;

2. the so-obtained formal executable specifications of devices and controllers are used directly to generate emulators that perform the same specified behavior in physical time;

3. actual devices, as well as actual executable models of patient and doctor behavior, can be seamlessly integrated with specification-based emulators to validate the safety not just of individual devices but also of various DESs that are needed in practice in actual operating room conditions and scenarios.

The advantage of point (1) is a great degree of reusability, and amortizing the formal verification effort across potentially many devices. The advantage of (2) is that, since each specification-based emulator executes the exact same formal specification that has been proved safe for the given device, the safety of such an emulator is automatically guaranteed, and a path remains open to correctly generate actual code for it preserving such safety in an actual implementation. The advantage of point (3) is that system experimentation with physical time and actual devices becomes available from very early in the design process and are available afterwards along the entire development process: initially, only specifications may be emulated; at intermediate stages, both specifications and actual devices form the virtual emulation environment; and in the end the emulating environment seamlessly becomes an actual implementation.

Technically, the way such virtual emulation environments are obtained from formal specifications is by using a key idea first demonstrated by Musab Al-Turki to semi-automatically pass from a Real-Time Maude formal executable specification operating in logical time to a corresponding physical emulation of the same specification operating in physical time and possibly interacting with other devices in a distributed way. The key observations are: (i) in Real-Time Maude rewrite rules are either 0-time rules requiring no time, or time-advancing rules moving the entire system forward in logical time; (ii) time advancing rules (typically a single such rule) can be physically implemented by an external object that sends time ticks according to physical time; (iii) although so-called 0-time rules do take some physical time to be executed, if this time is small enough in comparison with the time granularity of the physical time period chosen, for all practical purposes they can be considered to take 0 time units to execute; and (iv) the Maude infrastructure for Maude computations to interact with external objects via sockets can be used to interface the Maude objects in the formal specification with the external ticker object and also to other external devices.
1.1 Our Contribution.

This is the first work we are aware of in which formal specifications of real-time components are directly used in the area of distributed embedded systems for medical applications to obtain a virtual emulation environment in which specifications, patients, doctors, and actual devices can be emulated in physical time, and such that the correctness of verified specifications is preserved, provided adequate timing constraints are obeyed (see Section 7). This work is a first step towards a seamless integration of formal specification, verification, and system development and testing for safe medical systems. The associated notion of a virtual emulation environment plays a crucial role in passing from specifications to code and devices, and from logical time to physical time. We have demonstrated both the feasibility and the usefulness of these methods in two concrete scenarios: one in which a pacemaker interacts adaptively in physical time with a simulated model of a patient heart and keeps heart rates within a safe envelope; and another in which a safety controller for patient-controlled analgesia interacts in physical time with an actual drug infusion device and with a simulation of patient behavior.

In the passage from formal real-time specifications to their corresponding emulators there are additional novel contributions that were required for this work, including: (i) advancing time by the maximum time elapsable as opposed to by a fixed ticking period; (ii) handling asynchronous interrupts in addition to synchronous communication; (iii) emulating the interaction of real medical devices, patient models, and formal specifications; and (iv) generating a timed wrapper for each component specification almost for free with deterministic Real-Time Maude specifications using both a time ticker and the computation of the maximum time elapsable for each time advance.

The paper is organized as follows: Section 2 provides the high level ideas of the framework from formal patterns to real-time execution. Section 3 covers the basics of Real-Time Maude and Maude’s support for socket programming. Section 4 and 5 describes the core of the execution framework which allows seamless passage from Real-Time Maude specifications to execution with physical time and physical devices. Section 6 covers case studies for a pacemaker and a syringe pump to evaluate the feasibility of using formal models to execute medical devices. Finally, we describe some fundamental assumptions required for formal model execution to work for medical devices in Section 7 and we conclude in Section 8.

2 Overview of the Model Execution Framework

An envisioned design framework from generic design patterns to executable specifications is shown in Figure 1. We start with a safety pattern, which is a parameteric module with well-defined parameters with formal requirements provided by an input theory. The next stage is to instantiate the pattern to a concrete instance, which will of course still satisfy all the safety properties ensured by the pattern. Finally, in the last stage (the focus of this paper), the entire executable specification of a system can really be executed in the real world by encapsulating the specification in an external wrapper for model execution. Figure 1 illustrates these various stages for the design of a cardiac pacemaker system.

The first step formally defines a safety pattern as a parameterized module. In our pacemaker example, the pattern is a generic safety wrapper for medical devices. We briefly describe the pattern in this paper, summarizing the details presented in [9][10]. The safety wrapper filters the input commands, so that state changes in a medical device fall within safe physiological ranges and constraints. The white boxes in the diagram denote pattern parameters that must be instantiated. For the device safety wrapper these parameters include the type of device that is being considered, the period for updating device states, states of the device considered stressful for the patient, etc. Aside from the parameters, there are also formal
Figure 1: From Formal Patterns to Real-Time Execution
constraints that these parameters must conform to in order for a parameter instance to be acceptable. For example, stress states and relaxed states must be disjoint for a device.

The next stage is to instantiate the parameters of the pattern. In our example, the medical device safety wrapper is instantiated to filter the input commands to a pacemaker. The state of the pacemaker is assumed to be its pacing rate. The necessary parameters are then filled in. The period for updating the pacing rate is every 10 ms; pacing rates between 90 bpm to 120 bpm are considered stressful for the patient; etc. This instantiated model will satisfy the safety properties guaranteed by the safety pattern, provided all the parameters satisfy the necessary constraints and formal parameter requirements. Furthermore, once instantiated, the wrapped pacemaker is just another executable Real-Time Maude model. Thus, we can use this model for simulation and model checking purposes in Real-Time Maude.

In the final stage, which is the main focus of this paper, we transform the model to execute in real world time with physical devices in a medical device emulation environment. For this purpose, we take the model of the wrapped pacemaker and wrap it again in an external execution wrapper (Figure 2). The execution wrapper is responsible for conveying to the model the notion of real world time as well as providing a communication interface to the external world. A dedicated timer thread is responsible for “ticking” the model by sending a minimal number of messages to advance the model’s logical time. The timer thread also intercepts all asynchronous (interrupt) messages and relays them to the model. Another aspect of the execution wrapper is the ability to map external I/O messages to communicate with the external devices. For example, in the pacemaker specification, an internal message called paceVentricle may be mapped into an entire client configuration to send a message for setting the final voltage on a pacing lead.

For the design of a medical device or, more generally, of any safety-critical system, all the stages can work together to achieve a modular component design, and to support experimentation and testing in the context of other real devices that the safe component being designed has to interact with. In the first stages of safety pattern specification, we create a parameteric formal specification that essentially isolates important safety properties of a device from the rest of the system. We then can use theorem proving techniques to provide provable properties of the safety pattern. Although theorem proving may be time-consuming, as we show with our case studies one safety pattern can be applied to many different applications, so the time spent proving properties of the pattern is well worth the effort. The second stage with pattern instantiation is necessary to obtain a fully specified and executable model. The last
stage of course takes the existing models, with minimal auxiliary information for external interfaces, and provides an executable prototype essentially for free. In this way, it becomes possible to emulate the behavior of safe medical components in an experimental environment involving interactions with real medical devices.

3 Real-Time Maude and Sockets

In this section we briefly cover the important constructs we used from Real-Time Maude and Maude Sockets. We assume the reader is familiar with basic Maude constructs including modules (mod), sorts (sort), operators (op), unconditional and conditional equations (eq and ceq) and unconditional and conditional rules (rl and crl).

3.1 Full Maude and Real-Time Maude

Full Maude [3] is a Maude interpreter written in Maude, which in addition to the Core Maude constructs provides syntactic constructs such as object oriented modules. Object oriented (OO) modules implicitly add sorts Object and Msg. Furthermore, OO-modules add a sort called Configuration which consists of a multiset of terms of sort Object or Msg.

Objects are represented as records:

< objectID : classID | AttributeName : Attribute, ... >

Rewrite rules are then used to describe state transitions of objects based on consumption of messages. For example, the following rule expresses the fact that a pacemaker object consumes a message to set the pacing period to T:

rl setPeriod(pm, T)
< pm : Pacing-Module | pacing-period : PERIOD >
=> < pm : Pacing-Module | pacing-period : T > .

Real-Time Maude [6] is a real-time extension of Maude in Full Maude. It adds syntactic constructs for defining timed modules. Timed modules automatically import the TIME module, which defines the sort Time (which can be chosen to be discrete or continuous) along with various arithmetic and comparison operations on Time. Timed modules also provide a sort System which encapsulates a Configuration and implicitly associates with it a time stamp of sort Time. After defining a time-advancing strategy, Real-Time Maude provides timed execution (trew), timed search (tsearch), which performs search on a term of sort System based on the time advancement strategy, and timed and untimed LTL model checking commands.

3.2 Deterministic Timed Rewriting in Real-Time Maude

We are interested in emulations of real-time systems specified in Real-Time Maude. For useful real execution, a self-evident condition is that the time-advancing rewrite rules in the specification should be deterministic. This can be achieved by defining only one time-advancing rewrite rule on the system with two auxiliary operators tick and mte [7]. In our specification this is captured in TIME-ADV-SEMANTICS, which is included by all other timed modules:
The rewrite rule at the end is assumed to be the only timed rewrite rule (a rewrite rule that advances the time stamp of the system) in the system specification. The \textit{mte} operator defines the maximum time elapse before any 0-time rewrite rule can be applied. The \textit{tick} operator defines how the system state changes due to time advancement between applications of 0-time rewrite rules. We also define a default time elapse, \textit{def-te}, and maximum time elapse, \textit{max-te}, inside the module to be used as parameters during real execution.

\subsection*{3.3 Socket Programming in Maude}

Maude supports the Berkley sockets API for TCP communication. This is done by having a special gateway object, denoted $<$>, to consume all the messages responsible for setting up sockets and communicating to an external environment (e.g. \texttt{createClientTcpSocket}, \texttt{send}, \texttt{receive}). The gateway object will also generate messages upon status updates from the socket (e.g. \texttt{sent}, \texttt{received}, \texttt{closedSocket}). Consuming and generating messages from the gateway object is captured by external rewrite rules which can be executed using the \texttt{erew} command in Core Maude. An important thing worth pointing out about external rewrite rules is that \textit{external rewrite rules are only applied when no internal rewrite rules can be applied}. Also, using external rewrite rules with Real-Time Maude specifications (built on top of Full Maude) requires reflecting the specification down to a Core Maude module before executing.

\section*{4 Mapping Internal Messages to External I/O}

Validating the design of a device in an execution environment requires handling its outputs. After all, the end validation of a system’s behavior is based on its outputs. Thus, it seems reasonable to talk about how internal messages in the model can be converted into messages for communicating with the external world. This section also serves as an explanation for unfamiliar readers of how Maude sockets are used.

In order to talk about external communication, we must first define in the model what is external. The model will have an internal distributed actor configuration with internal messages as well as messages to be output to the external world. Thus, the first definition is \texttt{EXTERNAL-CONFIGURATION} which defines external messages \texttt{ExtMsg} as subsort of \texttt{Msg}. Furthermore, external messages are classified in terms of incoming external messages \texttt{InExtMsg} and outgoing external messages \texttt{OutExtMsg}. A configuration is called \textit{open} if there are external messages present in the configuration: either an incoming external message has not been delivered, or an outgoing external message has not been sent. The predicate \textit{open?} is defined accordingly.

\begin{verbatim}
subsorts InExtMsg OutExtMsg < ExtMsg < Msg .

op open? : Configuration -> Bool .
\end{verbatim}
eq open?(C C') = open?(C) or open?(C') .
eq open?(O) = false .
eq open?(M) = M :: ExtMsg .

Actually sending an external message may be more complex than just forwarding the message through the gateway object. External messages may not be the same in the internal configuration and in the external configuration. For example, a simple output message in the internal configuration may need to be mapped to a client object that initiates the communication to deliver the message. Operators in-adapter and out-adapter are defined to perform these mappings from external message client configurations to internal messages.

An example of an output adapter for a pacemaker message to beat the heart may be:

eq out-adapter(shock)
    = createSendReceiveClient(pacer-client, "localhost", 4451, "SetLeadVoltage 5V")

In this example, the message shock is transformed into a client object which sends a message on port 4451 with the string "SetLeadVoltage 5V" indicating that the proxy server will then proceed to set a 5V voltage on the pacemaker lead.

4.1 One-Round Communication Clients

Once the external message is mapped into a client configuration, we must define the rewrite rules to specify how the communication protocol works with the external device. Here we describe a simple SEND-RECEIVE-CLIENT which is responsible for establishing communication, sending a message, receiving a reply, and then closing the communication. Although simple, this type of protocol is sufficient for most of the communication for medical devices we have used in our case studies.

(mod SEND-RECEIVE-CLIENT is ...
    op createSendReceiveClient : Oid String Nat String -> Configuration .
    eq createSendReceiveClient(CLIENT, ADDRESS, PORT, SEND-CONTENTS)
        = < CLIENT : SendReceiveClient | ... >
        createClientTcpSocket(socketManager, CLIENT, ADDRESS, PORT) .
    op msg-received : Oid String -> InExtMsg .
...endm)

After creating the client and establishing communication, the client goes into one round of send and receive before the socket is closed. Once the socket is closed, the entire client object is converted into one reply message to be delivered to the internal configuration using the operator msg-received.

--- send contents
rl createdSocket(CLIENT, socketManager, SOCKET-DST)
    < CLIENT : SendReceiveClient | ... send-contents : SEND-CONTENTS >
    => < CLIENT : SendReceiveClient | ... > send(SOCKET-DST, CLIENT, SEND-CONTENTS) .
--- receive contents
rl sent(CLIENT, SOCKET-DST) < CLIENT : SendReceiveClient | ... >
    => < CLIENT : SendReceiveClient | ... > receive(SOCKET-DST, CLIENT) .
--- close socket
rl received(CLIENT, SOCKET-DST, RECEIVE-CONTENTS) < CLIENT : SendReceiveClient | ... >
    => < CLIENT : SendReceiveClient | ... recv-contents : RECEIVE-CONTENTS >
    closeSocket(SOCKET-DST, CLIENT) .
--- done
rl closedSocket(CLIENT, SOCKET-DST, "")
    < CLIENT : SendReceiveClient | ... recv-contents : RECEIVE-CONTENTS >
    => msg-received(CLIENT, RECEIVE-CONTENTS) .
5 Distributed Emulation of Safe Medical Devices

The external execution wrapper is an object that encapsulates the original formal model. It is primarily responsible for interfacing constructs between the physical world (the real interfaces to devices) and the logical world (the world as seen by the formal model). In particular, the execution wrapper is responsible for conveying the measurement of real time elapsed to the model and also for mapping logical communication messages to communication configurations that can deliver the message to real devices. The most important feature of the external execution wrapper is its modularity. Aside from adding the minimal information about how to map external I/O to messages in the model, no further specifications are required to execute the logical model within an external environment.

5.1 Mapping Logical Time to Physical Time

As mentioned earlier, time advancement of the system is achieved by defining the tick and mte operators. Ideally the system continuously evolves over time (possibly nondeterministically). Of course, we cannot capture the notion of continuous time without abstractions in the model, so to advance time discretely, an mte (maximum time elapsable) operator is introduced. A correctly defined mte operator ensures that if a system is in state $S$, then for any time $T < mte(S)$, no 0-time rewrite rules (state transitions) can apply to $\text{tick}(S, T)$. That is, if a system is in state $S$, and $T \leq mte(S)$, then $\text{tick}(S, T)$ will be equivalent to the state $S$ advancing in continuous time for $T$ time units. This ideal semantics of time is shown on the left side of Figure 3. The figure shows that 0-time rewrite rules are assumed to take zero time, and ideally, the system continuously evolves over time between the 0-time rewrite rules.

Of course, in a real execution of the model, the ideal notion of time with 0-time rewrite rules and time-advancing rules is only an idealized abstraction. Performing rewrites cannot take zero time, and we cannot continuously rewrite states of the system over time. We could of course create a model in discrete time with very fine time granularity and drive it by a high frequency clock like in hardware. However, this would introduce a lot of unnecessary overhead in terms of communication of timing messages and performing rewrite rules to change the model for every clock tick. We resolve this problem by observing that the actual internal state of the model is not important at most instants in time unless it is communicating with the external world. The model states only generate output messages with 0-time rewrite rules,
so we can essentially let the model in state $S$ remain unaffected by the passage of time until the next time instant in which a 0-time rewrite rule can be applied; this is exactly $\text{mte}(S)$ time units later. This method of driving execution is shown in the right part of Figure 3. We have created a dedicated timer server thread (in Java) that has access to the system time. When the execution of the wrapped model starts, it will send a start request which includes the time units of the model or the minimum granularity of time for model execution in milliseconds. Once the timer thread processes all the initial information, it will send a Go! message to signal the model to start executing. The model then calculates the maximum time elapsable (which is 10 seconds in the example) and sends this information to the timer thread. The model then proceeds to sleep until the timer thread wakes it in time for the next 0-time rewrite rule. The process then continues. There are two key points to notice about this example. The input and output messages from the model may be delayed by an amount of time equal to the communication jitter plus the time to complete rewriting. Normally this delay is on the order of 10 ms, but this is still suitable for medical devices which normally receive commands on the order of seconds or more. Also, the timer thread sets the timeout from the last time it sent a time advancement message to the model and not from the time it receives the $\text{mte}$ message from the model. This ensures that clock skew and jitter are bounded over time.

5.2 Synchronous Timed Execution

The communication wrapper ($\text{commwrap}$) is represented as an object with the attributes for the communication state, the socket information for communication, and the internal wrapped (Real-Time Maude) system model being executed. The top level system is of sort $\text{CommWrapConfiguration}$ for any communicating model.

```plaintext
op commwrap : Configuration -> CommWrapConfiguration .
op wrap-client : Configuration -> Configuration .
eq wrap-client(C) = { client : TickClient |
  state : start, internal : [ {C} in time 0 ], socket-name : no-oid } .
op init-client : -> CommWrapConfiguration .
eq init-client = commwrap( <> wrap-client(internal)
  createClientTcpSocket(socketManager, client, addr, port) ) .
```

The communication wrapper initializes a wrapped communication client that receives messages from the tick server (a Java thread executing in real-time that sends it messages for time advancement). After creating the TCP socket, the first message sent from the client to the tick server is the time-granularity ($\text{time-grain}$), which is a rational number specifying the number of milliseconds in one time unit. Then, the actual execution starts when the communication wrapper receives a Go message from the tick server. The time when the tick server sends the Go message is the starting point from which time elapses are being measured. Upon receiving the Go message, the formal model will immediately start to execute (state : run).

```plaintext
rl [send-init] :
  commwrap( <> createdSocket(...) < client : TickClient | ... > )
  => commwrap( <> < client : TickClient | ... > send(..., string(time-grain)) ) .
rl [wait-for-go] :
  commwrap( <> sent(...) < client : TickClient | ... > )
  => commwrap( <> < client : TickClient | ... > receive(...) ) .
rl [start-running] :
  commwrap( <> received(..., "GO\r\n") < client : TickClient | ... > )
  => commwrap( <> < client : TickClient | state : run, ... > ) .
```

The formal model executes until $\text{mte}$ becomes non-zero (no other 0-time rewrite rules can be applied), and the model sends a message to request the next time advancement message after the maximum
time elapse and blocks. After sending this waiting duration, the tick server will sleep for this time duration and then send a time advancement message when the time has expired. The model will then advance time (tick) the model for the time duration expired and perform 0-time rewrite rules. The model now blocks again for the next \( mte \), and the cycle repeats.

\[
crl \text{[request-wait-timer]} : \\
\text{commwrap(} \text{<>} \\
\text{< client : TickClient |} \\
\text{state : run,} \\
\text{internal : [ \{C\} in time T ]}, \ldots \text{) } \\
\text{=> commwrap(} \text{<>} \\
\text{< client : TickClient |} \\
\text{state : request, \ldots >} \\
\text{send(..., string(mte(C, T))) }) \\
\text{if mte(C,T) \::\: TimeInf} /\ mte(C,T) > 0 /\ \text{not open?(C)} \ldots \\
\]

\[
rl \text{[block]} : \\
\text{commwrap(} \text{<>} \text{sent(...)} \\
\text{< client : TickClient |} \\
\text{state : request, \ldots >} \\
\text{=> commwrap(} \text{<>} \\
\text{< client : TickClient |} \\
\text{state : wait, \ldots >} \\
\text{receive(SOCKET-NAME, client) ) .} \\
\]

\[
rl \text{[wake-up]} : \\
\text{commwrap(} \text{<>} \text{received(..., ADV-STR)} \\
\text{< client : TickClient |} \\
\text{state : wait, \ldots >} \\
\text{=> commwrap(} \text{<>} \\
\text{< client : TickClient |} \\
\text{state : run,} \\
\text{internal : [ \{tick(C, rat(ADV-STR))\} in time rat(ADV-STR) in time T ]}, \ldots \text{) .} \\
\]

5.3 Handling Asynchronous External Events

So far, the model can only handle synchronous events (polling and blocking communication). However, in general a useful design must be able to react to external events from the environment. For example, an EKG sensor detects a QRS waveform, and sends this information to the pacemaker. This points to the fact that our model needs to be able to handle external events asynchronously.

An external message would trigger a 0-time rewrite rule to receive the message by some object and process it. More precisely, if we have \( C_M \) and \( C_{Ext} \) as the model configuration and the external (environment) configuration respectively, the maximal time elapse for the system \( C_MC_{Ext} \) should be \( \min(mte(C_M), mte(C_{Ext})) \), where \( mte(C_{Ext}) \) denotes time duration before the next interrupt message. This semantics is captured by having interrupt messages forwarded by the timer thread, as shown in Figure [4]. The timer thread will only check for interrupts when it is waiting for the next timeout, so when the interrupt message arrives, it will wake up and immediately forward the interrupt message to the model with the amount of time that has elapsed. Any future timeouts are canceled. Introducing the notion of interrupts requires us to modify the wake-up rule for the model to not only advance time, but also check for potential interrupt messages as well.

\[
rl \text{[wake-up]} : \\
\text{commwrap(} \text{<>} \text{received(client, SOCKET-NAME, INTR-STR)} \\
\]

Figure 4: Handling Interrupts and Asynchronous Communication Semantics

6 Case Studies

6.1 A Pattern for Medical Device Execution

We briefly described in the introduction at a high level that the model execution framework is to support rapid prototyping of instantiated medical device safety patterns. In [10] and [9], we have described in detail the command shaper pattern for medical device safety. In essence, the command shaper pattern can modify commands to an existing medical device to guarantee specific safety properties in terms of limiting durations of stressful states and limiting the rate of change (Figure 5).

6.2 Pacemaker Simulation Case Study

One of the applications for the command shaper pattern is a pacemaker system [10]. At a high level the safety properties guaranteed by the command shaper pattern is that the pacemaker will not pace at fast heart rates too frequently or for too long, and the pacing rate will change gradually. We omit the details of instantiating the medical device pattern, but the final wrapper object provided by the pattern is:

\[
\text{<pacing-module : EPR-Wrapper\{Safe-Pacer\} | }\]

\[
\text{eq wrapper-init =}
\text{< pacing-module : EPR-Wrapper\{Safe-Pacer\} |}
\]

\[
\text{< tick(\{C \} in time T },
\text{recv->rat(INTR-STR)) recv->conf(INTR-STR)}
\text{in time recv->rat(INTR-STR) in time T}
\text{>,}
\text{socket-name : SOCKET-NAME }) .
\]
inside:
< pacing-module : Pacing-Module |
   nextPace : t(0),
   period : safe-dur >,
val : safe-dur,
next-val : safe-dur,
disp : t(period),
stress-intervals : (nil).Event-Log{Stress-Relax} > .
... endtm)

This says that a wrapper is placed around a pacing module, and the initial pacing rate is set as the default safe-duration (safe-dur is 750 ms or 80 heart beats per minute). Verifying this instantiation (with a simple pacemaker lead model [9]) indicates that the safety properties are met by the pattern. However, with the power of the model emulation framework, we can immediately use this specification to run with an actual pacemaker. In this paper we demonstrate this emulation capability not on an actual pacemaker but on a pacemaker simulator (a Java widget that receives messages about when to pace and draws a simple line graph resembling an ECG trace). Before the system can be emulated with the pacemaker simulator, some interface information must be provided. The entire module providing all the necessary interface information is shown below:

(mod CREATE-TICKER is
  inc PARAM-PACEMAKER .
  inc TIME-CLIENT .
  inc SEND-RECEIVE-CLIENT .

  eq addr = "localhost" .
  eq port = 4444 .

  eq def-te = 1 .
  eq max-te = INF .
  eq time-grain = 10 . --- milliseconds

  op pacer-client : -> Oid .
  eq internal = wrapper-init .

  eq out-adapter(shock)
      = createSendReceiveClient(pacer-client, "localhost", 4451, "shock") .
  eq in-adapter(msg-received(pacer-client, "shocked\n"))
      = set-period(pacing-module, 50) .
endm)
The module first indicates that the TCP socket interface to the pacemaker simulator is *localhost* on *port* 4444. The default time elapse for one tick is 1 time unit. The maximum time elapse for one tick step is infinity (i.e. there is no maximum). The duration of one time unit is 10 milliseconds. The time units are in terms of milliseconds since the minimum time granularity provided by the Java time interfaces is 1 millisecond.

The equation for *internal* specifies that the internal configuration to be executed is the configuration defined by *wrapper-init* (as defined in *PARAM-PACEMAKER*). Also, the last two equations specify that the output message shock should be mapped to a string “shock” sent over the socket, and upon receiving the acknowledgment message “shocked” set the pacing period to 500 ms (120 bpm - a really fast heart rate). The last equation creates the scenario where a stressful heart rate is always being sent to the pacing module. Since the command shaper pattern should prevent this unsafe behavior, we should see the pacing automatically slow down from 120 bpm after some time interval.

The module is executed by first reflecting the CREATE-TICKER module down to Core-Maude (with the command **show all CREATE-TICKER**), and executing with the **erew** command. A snapshot of the “ECG” trace of the pacemaker simulator is show in Figure 6. For validation, we measured the jitter for executing such a system – the physical time required to completely execute 0-time rules and finish communication (Figure 7). The results were obtained from a 1.67 GHz Dual-Core Intel Centrino with Maude running in Windows through Cygwin (tracing was turned off). The main thing to notice is that the jitter is mostly below 0.1 seconds and almost never exceeds 0.2 seconds. This amount of jitter is tolerable since most medical devices need to respond in the order of seconds. The pacemaker is a bit more strict in terms of its timing requirements. To evaluate suitability for the pacemaker, we plotted the recorded the physical time duration between pacing events (Figure 8). Notice in this example the heart rate increases (duration decreases) up to a limit and then the heart rate starts to decrease (duration increases) and the cycle repeats. It is clear that the jitter in control seems tolerable since there are no sharp spikes in the graph of the pacing durations.

### 6.3 Syringe Pump Case Study

The pacemaker emulation example was demonstrated through a simulated pacemaker mostly because current pacemakers do not have external interfaces for setting when to pace (and rightly so). However, for devices such as electronic syringe pumps these interfaces are available. Syringe pumps and infusion pumps in general deliver intravenous injections into a patient. For this scenario, we assume that the syringe pump is delivering an analgesic (e.g. morphine) to the patient, and we would like to prevent overdose. We assume that for a normal patient overdoses do not occur at the base rate of infusion and
Figure 7: Model Execution Jitter Distribution

Figure 8: Pacing periods recorded by the pacemaker simulator (jitter effects are reflected by noise on the curve)
can only result if a bolus dose is administered too often for the patient. We again use the command shaper pattern to limit the frequency and duration of bolus doses. The instantiated pump is as follows:

\[
\text{(tomod PARAM-PUMP is }
\begin{array}{l}
\text{pr EPR-WRAPPER-EXEC\{Safe-Pump\} .}
\text{pr DELAY-MSG .}
\end{array}
\]

\[
\text{... eq msgs-init =}
\begin{array}{l}
\text{delay(set-mode(pump-module, bolus), t(9))}
\text{delay(set-mode(pump-module, bolus), t(11))}
\text{delay(set-mode(pump-module, bolus), t(12))} ...
\end{array}
\]

\[
\text{eq wrapper-init =}
\begin{array}{l}
\text{< pump-module : EPR-Wrapper\{Safe-Pump\} |}
\text{inside :}
\text{< pump-module : Pump-Module |}
\text{mode : base}
\text{> base,}
\text{val : base,}
\text{next-val : base,}
\text{disp : t(period),}
\text{stress-intervals : (nil).Stress-Relax-Log > .}
\end{array}
\]

\[
\text{... endtom)}
\]

This module shows the initialized wrapper object for the pump, with the initial state being the base rate of infusion. Furthermore, there is also a set of delayed messages that will be sent to the pump. In the term \text{msgs-init}, the model will send bolus requests at 9 time units, 11 time units, 12 time units, ... after the start of execution for the system. Again, creating a simulated patient model, we can verify the safety of the instantiated pattern [9]. Instantiating the pump is similar to instantiating the pacemaker, except that there are a few more types of output messages.

\[
\text{(mod CREATE-TICKER is }
\begin{array}{l}
\text{inc PARAM-PUMP .}
\text{inc TIME-CLIENT .}
\text{inc SEND-RECEIVE-CLIENT .}
\end{array}
\]

\[
\text{eq addr = "localhost" .}
\text{eq port = 4444 .}
\]

\[
\text{eq def-te = 1 .}
\text{eq max-te = INF .}
\text{eq time-grain = 1000 . --- milliseconds}
\]

\[
\text{ops pump-client pump-client' : -> Oid .}
\text{eq internal = wrapper-init msgs-init .}
\]

\[
\text{eq out-adapter(stop)}
\text{ = createSendReceiveClient(pump-client, "localhost", 1234, "STP") .}
\text{eq out-adapter(base)}
\text{ = createSendReceiveClient(pump-client, "localhost", 1234, "RAT1")
createSendReceiveClient(pump-client', "localhost", 1234, "RUN") .}
\text{eq out-adapter(bolus)}
\text{ = createSendReceiveClient(pump-client, "localhost", 1234, "RAT2")
createSendReceiveClient(pump-client', "localhost", 1234, "RUN") .}
\text{var S : String .}
\text{eq in-adapter(msg-received(pump-client, S))}
\text{ = none .}
\]
Distributed Real-Time Emulation of Formally-Defined Patterns for Medical Device Control

The model is communicating with localhost on port 4444. The time granularity is 1 second. The internal configuration being executed is the wrapped pump as well as the set of messages that will deliver bolus requests. The output requests are handled by a Java thread listening on port 1234 and forwarding the request string to the actual Multi-Phaser NE-500 Syringe Pump (Figure 9). A few important requests to the pump are: STP stop the pump, RAT <n> set infusion rate to n ml/hr, RUN start the infusion. Reflecting down the CREATE-TICKER module and executing with erew will now control the physical pump motor!

As a validation for correct pump control, we used a Salter Brecknell 7010SB scale to weigh the amount of liquid infused from the syringe pump over time (Figure 10). The data granularity is a bit rough since the scale can only measure within a precision of 0.1 oz. For this example, to clearly distinguish between two pump states, we let the base rate of infusion be zero (horizontal parts of the graph) and the bolus rate be the maximum infusion rate provided by the pump (positive sloped parts of the graph). Bolus requests are continuously sent to the pump. The safety properties require that bolus doses last no longer than 30 seconds, and there must be 10 seconds between bolus doses, and at most 3 bolus doses for a window size of 3 minutes. The graph validates that these properties are indeed satisfied for this particular execution of the pump.

7 Assumptions and Issues

In this section we discuss the timing assumptions that need to be taken into account to ensure that the emulation of a Real-Time Maude specification correctly implements the logical time behavior.

Figure 11 shows one round of communication between the time server and the formal model. \( t_{\text{comm},i} \) denotes the delays due to each stage of communication. \( t_{\text{rew},i} \) denotes the delays incurred by each stage of rewriting. \( t_{\text{proc}} \) denotes the time needed at the physical device interface to process the commands. Thus, the entire time to finish a round is \( t_{\text{round}} = t_{\text{comm}1} + t_{\text{rew}1} + t_{\text{comm}2} + t_{\text{proc}} + t_{\text{comm}3} + t_{\text{rew}2} + t_{\text{comm}4} \).

In logical time, no time advancement should actually take place in a communication round. All
Figure 10: Infusion Volume over Time

Figure 11: Timing Considerations
computation and message communication is assumed to take zero time. Of course, for proper timed operation we can relax these constraints to first allow the model to have a non-zero (but bounded) delay for these computations and communications. The maximum bound on these communications is $t_{round} \leq mte(C_{next})$. Otherwise, by the time the round has completed, the execution is already delayed past the time for the maximum time elapse for the next 0-timed rewrite rule; i.e., the maximum speed of execution of the formal model and communication is slower than the real-time requirements. Now, assuming that the constraint $t_{round} \leq mte(C_{next})$ is satisfied, there is still another problem we must deal with. The actual commands sent to the device are not received until $t_{jitter} = t_{comm1} + t_{rew1} + t_{comm2}$ time after they are actually supposed to be executed. This could be very problematic. Even if the model can keep up with real-time, the time in which it issues commands will be delayed. For example, the shocks from a pacemaker may be issued at the correct time by the model, but the real shock is not delivered until 0.1 seconds later. To meet this requirement, we need to look at the finer requirements of medical devices and patient parameters. How much jitter in control can a patient tolerate? As we have seen in the Section 6, the jitter seems to be tolerable for the applications we considered, and furthermore, the end-to-end round communication timing constraints are also satisfied by our case studies.

8 Conclusion

Safety of medical devices and of their interoperation is an unresolved issue causing severe and sometimes deadly accidents for patients. Formal methods, particularly in support of highly generic and reusable formal patterns whose safety properties have been verified can help in ensuring the safety of specific components, but this still leaves several open problems including: (i) how to pass from specifications to code and from logical time to physical time in a correctness-preserving ways; and (ii) how to experimentally validate medical safety architectures in realistic scenarios in which actual devices and models of patients and doctors can interact with formally specified and provably safe designs of device components.

By developing virtual emulation environments in which highly generic and reusable formally verified patterns in Real-Time Maude can be easily transformed into emulations in physical time which can interact with other real devices and with simulations of patient and/or doctor behaviors, we have taken some first steps towards a seamless integration of formal specification and verification with emulation and testing, and ultimately with deployment of medical DES systems that offer much stronger safety guarantees than what is currently available. Much work remains ahead. As we explain in [10], the provably safe formal pattern used in the experiments of this paper is just one such pattern: it covers a useful class, but does not cover other kinds of safety needed in other medical devices. Also, other safety concerns, such as so-called open-loop safety, ensuring that medical devices will always be in states safe for the patient even under key infrastructure failures, such as network disconnection, have not been addressed in this work. However, we believe that the general methodology presented here to pass from formal specifications to virtual emulation environments and eventually to deployed systems should also be applicable to those new formally verified patterns that have yet to be developed.

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