Position Paper for HCMDSS

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1. Introduction

I have chosen 3 topics (from the list of 8) as ones to focus on in this paper. I will present them in section 3. In this section, I give a bit of background on my research. I have been working in the area of assistive devices for the cognitively impaired population. Perhaps most related to this workshop, I have been attempting to both build and certify *adaptable* devices. I have found that if an assistive device cannot change its behavior to match changes in the user's physical, mental and environmental states, then it will be abandoned. There are several challenges in this work:

1. How can one construct assistive/medical devices that can change in real-time to meet the changing needs of a user?
2. How can one *certify* that a particular configuration of such a device meets certain safety properties?
3. How can one monitor data (from user and his or her environment) to support runtime adaptation?

I decided that I needed to define a new software engineering methodology that might answer these questions. The methodology I developed is one I call clinical software engineering, and in particular, clinical requirements engineering. An overview paper can be found off my website: see invited ICSE paper on http://www.cs.uoregon.edu/~fickas. In summary, my first interest is in building software-based devices that can adapt so they continue to assist a user over time. I am interested in both the methodology of building such devices and the infrastructure needed to make them work in the field.

My second interest is in formal modeling as a tool to support certification. The particular problem is that once one has an adaptable/configurable device, it is difficult to know whether any one configuration (out of potentially thousands) meets safety properties that have been established. This is made more complex in that the properties can (1) be specific to an individual user, and (2) change over time, themselves. My group has been attempting to grapple with this problem by setting up a device framework (in a formal modeling language) and also a means to extend (AKA adapt) the framework to specific configurations. We have chosen to work with a process-algebra language given its ability to construct and test different components separately, and then compose them into a system. The specific language we use is FSP, part of the LTSA toolkit (http://www.doc.ic.ac.uk/~jnm/book/ltsa/LTSA.html).

2. Current Work

My group is working on a UBICOMP system that combines some tasks from ADLs (Activities of Daily Living) with traveling within the community. We are just beginning to wire an assisted-living center in Eugene that supports the brain-injury population. Eventually we plan to have a resident's apartment include a desktop machine and a means of tracking certain items, e.g., meds. The resident will also be given a travel bag

that includes onboard computing to track location and to talk wirelessly with sensors in the environment. The figure below shows some of the components of the system. On the left is the breadboard for the bag. It includes an RFID reader, three Mica2 motes and an iPaq cradle. The picture on the right is a blow-up of the RFID reader and a tag that can be placed on everyday travel items, e.g., wallet, bus pass, pill bottle.

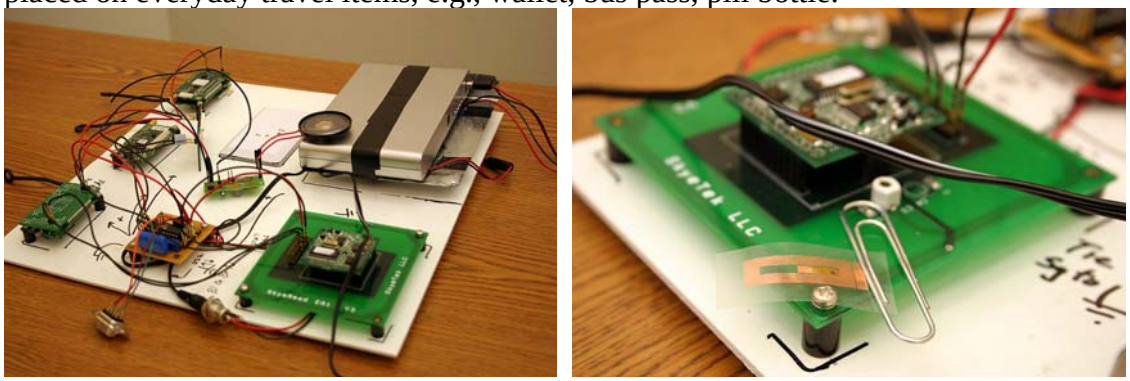

Figure 1: the guts of a travel bag for assisting a brain-injured traveler

We are now in the process of building a "bag framework" in FSP that will allow us to instantiate the framework for specific configurations we wish to study. At the same time, we are defining a set of properties that we might want to hold when the bag is in use. The goal of this work is to be able to certify various bag configurations related to both general and idiosyncratic properties of individual users. My ideal would be to do this on the fly: you detect the need for a change, you choose a configuration you believe will be most helpful, I tell you whether it meets certain properties before you actually put the configuration in place. Of course, I would like to automate all of this.

3. Answers to CFP questions

I will list three items from the list given in the CFP. Taken together, I will attempt to answer the 3 questions posted.

Item 2. *Foundations for Integration of Medical Device Systems/Models*

- Component-based foundations for accelerated design and verifiable system integration
- System of systems (including models, medical devices, care-givers, patients)

Item 6. *High-Confidence Medical Device Software Development & Assurance*

- Care-giver requirements solicitation and capture, design and implementation V&V (Verification and Validation)
- Heterogeneity in environment, architecture, platform in medical devices

Item 8. *Certification of MDSS*

- Quantifiable incremental certification of MDSS, role of design tools
- COTS, non-determinisitic and self-adaptive medical device systems

Answers:

a. There is a rich and extensive history of building component-based systems in software engineering. However, work on verifiable versions of such systems is

much smaller. I believe we need to look seriously at the tools available to do formal verification. And then consider how they can be made more effective in a component-based environment. My particular bias is in the area of composable models and formal frameworks. My group is also looking at means of connecting formal (and certified) models to actual implementations.

b. The issue of adaptable systems brings new challenges to certification. When tied to a clinical process, where each individual might have his or her own set of properties to maintain, we need to think about means of certifying specific configurations of a system. Whether this means attempting to do a pre-deployment, mass certification (unlikely to be feasible) or just-in-time certification is an interesting question.
c. Software engineering does not have a great track-record in the area of reasoning about what I call composite systems, ones that are composed of (medical) devices, software, and humans (care-givers, patients). My group has just started to build up models of brain-injured users as they interact daily with an assistive device. We are now attempting to use these models as testing components for future versions of a system. In general, we lack good models of both humans in the loop, and the environment the patient resides in.
d. *Roadmap*: (1) tools to support the verification of properties at the component level, and then to scale up to the (composed) system level, (2) tools to support verification of adaptive devices, (3) accurate models of not only a device itself, but also of users of assistive devices, careproviders, and the environment in which they live, (4) new software engineering methodologies that are more aligned with existing medical practice, and in particular, existing clinical practice in terms of assistive technology.

4. Short Bio

I am a Full Professor in the Computer Science Department at the University of Oregon. My general areas of interest are in requirements engineering and wearable computing. I have been involved with clinical rehabilitation research for the last 4 years. Supported by grants from NIDRR and NSF, my colleagues and I have done rigorous, longitudinal studies of the effects of adaptive, assistive devices within the brain-injury population. In a related effort supported by NASA and NSF, I have begun to look at means of reasoning formally about adaptive systems. I have established a field-lab at a local assisted-living center that will work with several brain-injured residents in terms of assisting them to regain access to their community. This lab includes both adaptive desktop applications and adaptive wearable applications (see figure 1). In a co-design effort, we are trying to build the models that will allow us to reason about the lab.

Through our focus groups we learned that to build a device to do “travel rehabilitation”, one must pay attention to more than simply whether a user is on a route. Other issues that come in to play include (1) meds – which is the user taking, has the user taken them, (2) physical well-being and stamina, and (3) emotional state. One thing I hope to gain from the workshop is some insight into integrating different models into a larger, coherent whole.