Safety Enhancements of Home Lift, Position and Rehabilitation (HLPR) Chair

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ABSTRACT
According to recent studies published in AI Magazine (2005), in 2000, "people aged 65 and older made up 12.3 percent of the U.S. population, while by 2030, they will constitute 19.2 percent, after which growth is projected to level off so that this cohort represents 20 percent of the population in 2050." In response to respective needs, the National Institute of Science and Technology (NIST), Intelligent Systems Division, began the Healthcare Mobility Project to address this healthcare issue of patient lift and mobility, and began developing the Home Lift, Position, & Rehabilitation (HLPR) chair to investigate specific areas of mobility and rehabilitation. The HLPR chair has been built as a prototype but a significant number of unresolved issues exist and are being researched. The objective of this particular project is to investigate the computer and software safety issues in the design, implementation and use of the HLPR chair.

Categories and Subject Descriptors
J.2 [**Computer Applications: Physical Sciences and Engineering**]: Engineering – *medical devices.*

General Terms
Design, Experimentation, Measurement

Keywords
Software Safety, Medical Devices, Testing, RFID

1. INTRODUCTION
Recent studies show [1] that "In 2000, people aged 65 and older made up 12.3 percent of the U.S. population, while by 2030, they will constitute 19.2 percent, after which growth is projected to level off so that this cohort represents 20.0 percent of the population in 2050. The most rapid growth will occur within a subgroup of this cohort—the so-called 'oldest old,' or people over the age of 80. Today this group makes up 3.2 percent of the U.S. population, while by 2030 that number will increase to 5.0 percent, and by 2050, to 7.2 percent". This group is subject to both physical and cognitive impairments. Such situation will have a profound impact on maintaining the elderly independent from caregivers.

As stated in [2], mobility is fundamental to health and social integration of human beings, and therefore is viewed as being essential to the outcome of the rehabilitation process of wheelchair dependent persons. It is estimated that some 2.5 million people in Europe and 1.25 million in the US depend upon a wheelchair for their mobility. Equally important as wheelchairs are the lift devices. As far as assistive technology for the mobility impaired including the wheelchairs, lift aids and other devices, is well established, the patient typically requires assistance to use the device. With more and more elderly, there is a need for improving these devices to make them more intelligent to ensure them independent assistance. The need for patient lift devices will also increase as generations get older.

In response to these needs, the National Institute of Science and Technology (NIST), Intelligent Systems Division, began the Healthcare Mobility Project to address this healthcare issue of patient lift and mobility, and began developing the Home Lift, Position, & Rehabilitation (HLPR) chair to investigate these specific areas of mobility, lift and rehabilitation [3]. The prototype of the HLPR chair, shown in Figure 1, is based on a manual, off-the-shelf forklift. The forklift includes a U-frame base with casters and a vertical frame. The patient seat mechanism is a double, nested and inverted L-shape where the outer L is a seat base frame that provides a lift and rotation point for the inner L seat frame. The outer L is bolted to the lift device while the inner L rotates with respect to the seat base frame at the end of the L. Drive and steering motors, batteries and control electronics along with their aluminum support frame provide counterweight for the patient to rotate beyond the wheelbase. When not rotated, the center of gravity remains near the middle of the HLPR Chair. When rotated to π rad (180 deg.) with a 136 kg (300 Lb) patient on board, the center of gravity remains within the wheelbase for safe seat access.

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The HLPR chair exists as a prototype and is being used for research purposes at the Florida Gulf Coast University (FGCU). A significant number of unresolved issues are being researched. The objective of this particular project is to investigate the computer and software safety issues in the design, implementation and use of the HLPR chair.

Figure 1. HLPR Chair [3].

2. SPECIFIC GOALS OF THE PROJECT

One particular problem is that currently there are no standards, or even adequate research, to guide developers and manufacturers regarding intelligent rehabilitation chairs and forklift technologies that use advanced sensors, computers and actuation systems. There is a strong sense that before intelligent chairs are commercialized and sold to the general public, a research based target safety practice should be in place. Our study is meant to address this gap.

The issue of primary importance is the patient safety. The chair is designed toward enabling safe mobility to all users, including all sorts of impairments that may include blindness, paralysis, Alzheimer's, obesity, etc. Because the HLPR Chair's ultimate purpose is to help disabled persons, it is important to remember the human impact during all of these projects. For safety purposes, humans should be assumed unreliable and unpredictable, thus safety studies must expect the extraordinary in regards to the functions to which the user will subjugate the chair.

As an example, in current design, when the patient is using joysticks to control the move and turn the chair, steering wheel design allows stopping the chair at just beyond 180 degrees for safety of the steering system. Steering is reverse Ackerman controlled as joystick left rotates the drive wheel counterclockwise and joystick right rotates the drive wheel clockwise [4]. The steering rotation amount can be limited by the amount of drive speed so as not to roll the frame during excessive speed with large steering rotation. This raises several important questions, however, regarding the implementation of safety functions in software. Some of the most critical issues include: chair stability (is there sufficient safety margin for abrupt rotations and tilt adjustment?), chair mobility (is the chair traceable, so it could be remotely controlled in case of a hazard?), software itself (is there enough protection embedded in software to keep the patient safe in case of equipment failures?). Some of these issues are discussed in the next section.

3. SELECTED ISSUES RELATED TO HLPR CHAIR SAFETY

3.1 Tilt Awareness and Stability

Some safety standards for the wheelchairs and forklifts already exist [5], and are implemented in current design. However, incorporating simple safety measures, such as electronic level detection and sensors to determine the chair lift's current height into the HLPR software, not allowing the user to take the chair past a predetermined angle, are necessary but not sufficient for full patient protection. This project is taking it a step further.

Under existing collaboration with NIST, testing for the HLPR chair's stability in load carrying situations has been conducted [6]. The research was aimed at looking for discrete angle of tip in the most and least stable configuration (Fig. 2). Several factors were included in the analysis, such as: load/lift height, load orientation, HLPR orientation on platform.

Several areas for stability testing were identified, including those listed below, and will be addressed in this research by developing respective stability algorithms and implementing them in software: forward and rearward dynamic stability on ramp, lateral dynamic stability on ramp, lateral dynamic stability while turning in circles, lateral dynamic stability while turning suddenly, dynamic stability while traversing a step.

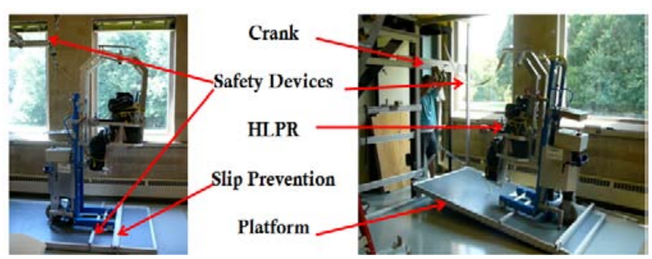

Figure 2. Illustration of Basic Chair Safety Issues [6].

3.2 Autonomous Motion

By incorporating a new controller feature of near real-time validation and execution, the HLPR chair could be made autonomous. In particular, previous studies have determined that the incorporation of RFID tags on the HLPR chair along with RFID readers in a building, would allow tracking of any HLPR chair and its user within a designated area. This implementation could also serve as a safety measure for prohibiting entrance to certain areas and automatically unlocking certain doors. However, full safety analysis regarding potential hazards and failure modes requires more significant attention, with specific requirements coming from the nursing objectives and is the subject of this study.

At this point, we developed a preliminary RFID tracking system that allows: (1) collecting the RFID tag data with search abilities, and (2) making the data available via the Internet (Fig. 3). The software allows a remote access to a server and pulling from it logs of what tags have passed through and when [7]. It has a user-friendly interface and socket-protocol accessibility, and will be used as a basis for the HLPR safety analysis with RFID.

Figure 3a. RFID Device Employed in the Project.

Figure 3b. Sample User Interface for RFID Control.

3.3 Software Safety

Software safety analysis is typically done by identifying potential hazards that may be caused by software failures. Analyzing software architecture is very helpful, in this respect, because it identifies the major components that may be potential sources of such hazards. The architecture of current HLPR chair controller is based on the RCS concepts outlined in [8] and illustrated in Figure 4. It does not, however, include any safety features.

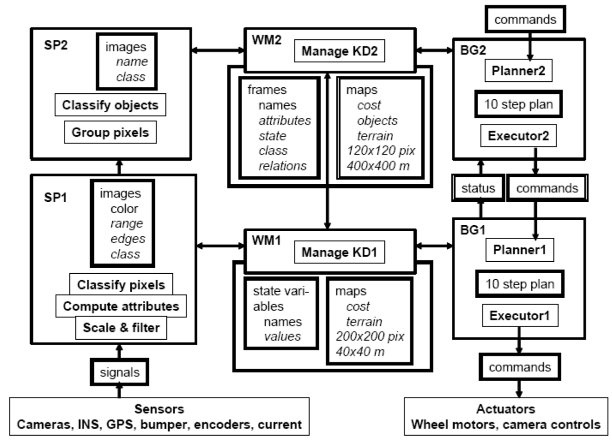

Figure 4. RCS Architecture Used in HLPR Controller Design [8].

To address the software safety issues we employ the concept of safety shell (Fig. 5), developed in collaboration with NASA [9], which relies on an architectural concept similar to that of RCS architecture [10] and fits well into the RCS scheme, enabling design of control systems [11]. Its essential element is the implementation of a "Test First" design element to prevent dangerous situations from occurring. In case of the HLPR chair, this design element is initiated with every change in input from the user and encoder. It is meant to catch any hazardous situation at its beginning; by "testing first" the processor will either validate or invalidate the current motion and/or the desired motion.

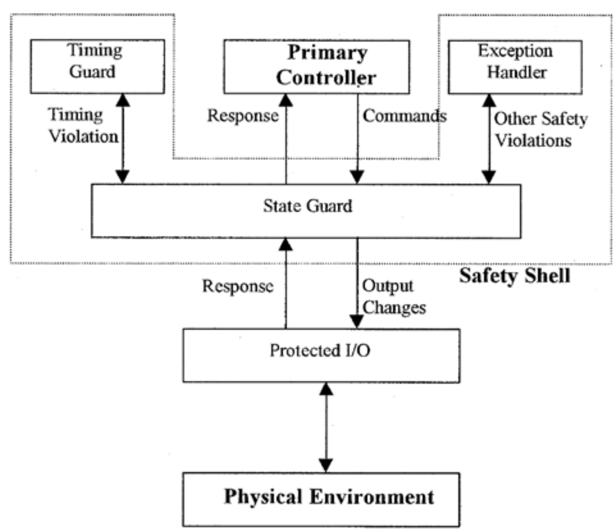

Figure 5. Safety Shell Architecture [9].

The safety shell for the HLPR chair is being implemented in the MOAST/UsarSims environment [12], which allows for virtual simulation, thereby simplifying safety testing for mapping and planning operations. Software safety requirements have been developed for this project, including requirements for external interfaces, input requirements, output requirements, processing requirements, and performance requirements, for all system modes and user classes. A sample of input requirements is given below:

- Software shall accept input from the designated sensor/user input device.
- Software shall validate or invalidate an input according to the environment.
- Software shall accept changing inputs from sensors/user input device.
- Software in the failsafe mode shall be able to override sensor/user input device.

4. CONCLUSION

The HLPR chair was designed at NIST to be a revolutionary patient lift and mobility system for wheelchair dependents, the elderly, stroke patients, and others requiring personal mobility and lift access. The system shows promise for moving these groups of patients into the work force and removing the burden placed on the healthcare industry. It has been prototyped to show the basic concept of such a patient lift and mobility system. However, the complete development of the HLPR chair from its current state all the way to its realization as an assistive technology in the hospital setting requires a significant additional work in several areas, including computer and software safety.

The current proposal addresses the safety issues in a comprehensive, interdisciplinary way, and aims at developing a safety model and its verification, to enable subsequent steps towards chair certification by the U.S. Food and Drug Administration (FDA).

The multidisciplinary approach is intended to cover all aspects of the complex problem of ensuring chair safety, both at the product level (to reconcile discrete safety assurance algorithms and continuous algorithms to ensure stability) and at the process level (to address domain requirements originating from computing, bioengineering and nursing).

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