

ADMINISTRATIVE INFORMATION:

- Proposal Number: N/A
- Project Name: Warfarin Automatic Home Medication Dispenser
- Project Number: P07009
- Track: Assistive Devices
- Start Term: Winter 20062
- End Term: Spring 20063
- Faculty Mentor: D. Phillips
- Faculty Coordinator: D. Phillips
- Customer organization and primary contact (name, phone, e-mail): Dr. Michel Berg, michel_berg@urmc.rochester.edu

PROJECT OVERVIEW:

Four million people in the US are taking warfarin (Coumadin) anticoagulation medication for a variety of medical conditions that place them at risk for intravascular blood clot formation including hypercoagulable states, deep venous thrombosis, and atrial fibrillation. Frequent adjustments of warfarin dosing are required in patients starting and often throughout the course of the anticoagulation. Such adjustments are based on the INR measured by a blood test that is usually performed weekly or biweekly for the first several months after anticoagulation is started. In most cases, on the day after the blood test, the physician or the physician's nurse contacts the patient by phone to make dosing adjustments. If a new pill size is required, then the physician (or physician surrogate) must also contact the pharmacy with a new prescription.

Warfarin is available in 9 different milligram sizes: 1, 2, 2.5, 3, 4, 5, 6, 7.5, and 10. The warfarin automatic home medication dispenser will provide a one month supply of medication of any unitary dose in the usual range (1 to 15mg dosed once per day.) It will also provide for 0.5 mg increments above 2.5 mg in the same range.

The objective of this project is to create a prototype home medication dispensing device that will supply a one month course of warfarin administration. The prototype will have 4 medication compartments designed to contain the following dose/number of pills combinations (1 mg/31 pills, 2 mg/62 pills, 2.5 mg/32 pills, 5 mg/62 pills) which can be combined to provide unitary doses from 1 to 15 mg per day.

STAFFING REQUIREMENTS:

Discipline (<i>number</i>)	Skills required (<i>concise</i>)
EE 1	Electromechanical and user interface electronics
ME 4	Mechanism and enclosure design
CE 1	Embedded, application and network software and hardware
ISE N/A	
Other N/A	

CONTINUATION, PLATFORM, OR BUILDING BLOCK PROJECT INFORMATION:

- Scaled down version of a multi-medication automated home medication dispenser – contact D. Phillips regarding prior work.

PRINCIPLE SPONSOR OR SPONSORING ORGANIZATION:

- Dr. Michel Berg, NSF

DETAILED PROJECT DESCRIPTION:

- Customer needs: The customer requires a prototype system that can flawlessly demonstrate the principles of operation and utilization scenarios for a portable medication system that can be accessed locally and programmed remotely. The demonstration system will comprise the medication dispenser device, connection via a common telephone connection to an internet based server that may be accessed via a common web-based application on a care-giver's computer system.
- Requirements:
 - Size: 6 by 6 by 6 inches or smaller, easily transportable.
 - Enclosed and locked with tamper evident indicator
 - User tracking system
 - Refurbishable for different users
 - One month supply of warfarin:
 - 4 compartment model - 4 bulk compartments: 1mg (31 tablets), 2mg (62), 2.5 (31), 5mg (62)
 - Loading of device done at pharmacy or factory
 - Either bulk loaded or loaded with cartridges filled at pharmacy or prefilled by company and refurbished at company.
 - Device returned each month to pharmacy for loading
 - Guarantee that correct pill size is in correct bin (no errors). (Lock and key or other mechanism.) - no loading errors!
 - Spill proof - transportable
 - Wireless connection to phone (telecommunications). Can have separate module to plug into phone.
 - Remote dose programming through web interface
 - Automatically generated messages from programmer to dispenser
 - Screen for messages
 - Single button for dose retrieval - or equivalent simple system.
 - Single button for message reading and acknowledgement - or equivalent simple system.
 - Rapid delivery of dose after dose button push
 - Dose based on remote programming by physician.
 - Update dosing information (physician programmed) prior to dose time (1 hour or so; usually dosed at bedtime)
 - Deliver correct dose without error
 - Enable one pill to be moved from bulk compartment to delivery compartment at a time.

Project Readiness Package - Coumadin Automatic Home Medication Dispenser Demonstration System

- Alert for service when pill supply low (may not be necessary if dates known)
 - Check that correct pill put into delivery cup or that cup has correct pills
 - Check system must be low cost
 - Warfarin tablets of known shape and size
 - Delivery system can be customized for each pill size*
 - Complete, up-to-date pill inventory
 - Delivery compartment with removable dose cup that needs to be in place prior to dispensing.
 - Need to check that delivery cup is empty prior to internal cup filling
 - Alarm to alert patient that it is time to take medication
 - System (such as prerecorded automatic phone message) to alert designated care-provider if medication dose not taken
 - Track dose, with data available to physician on web.
 - Small and light enough to be transported.
 - Powered by internal battery with low battery indicator.
 - Reasonably quiet.
 - Reasonably low cost
 - The unused portion could be reused, potentially by a different patient, and thus the box must be sealed and tamper evident
 - Expiration of the medications needs to be tracked as well as previous users to prevent (dissuade) intentional contamination.
 - should have alert if service needed
- Notes:
 - A months supply of brand Coumadin for 4 compartment model retails at \$173
 - the generic version of Coumadin, warfarin, is approximately 66% of the cost
 - a standard months supply of Coumadin of one pill size ranges from ~\$25-\$35

CUSTOMER DELIVERABLES:

- Stand-alone medication dispenser with
 - the capability to dispense dosages ranging from 1 mg to 15 mg based on a combination of 4 different pill sizes
 - a integral multi-line device display for user indication of operation and caregiver messages
 - a prototype communication system based on common telephone networking, internet service that a common laptop can be used to communicate with
 - software application that can be run on a common laptop via an internet connection

CUSTOMER AND SPONSOR INVOLVEMENT:

- The customer is extremely interested in interacting with participants and providing guidance as regards target audience interaction and will be available for regular meetings and interaction via email.

REGULATORY REQUIREMENTS:

- Unit will ultimately be constrained by appropriate UL and FDA regulations. Prototype design must keep these requirements in mind but not necessarily meet them. The prototype must be safe for any individuals or equipment involved in demonstrating its operations.

PROJECT BUDGET AND SPECIAL PROCUREMENT PROCESSES:

- Sponsor will provide funding for project.

INTELLECTUAL PROPERTY (IP) CONSIDERATIONS:

- While the idea regarding this concept has been made public, it is expected that innovative design concepts may be suitable candidates for IP protection.

OTHER:

- An important aspect of this design is that it could be reasonably scaled up to provide a nine (9) compartment device to provide the same overall capabilities with smaller numbers of individual pill dosages (1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, 10 mg).

DETAILED COURSE DELIVERABLES:

- The course deliverables include an operational demonstration system that includes
 - the dispenser mechanism
 - a functioning telephone to internet type communication network that includes a server mechanism that is accessible via a web-based application software program running on a common laptop computer.
 - The software application should allow the programming of the dispenser device in terms of a daily dosage schedule.
 - The dispenser system should provide
 - the daily dispensing of a specified dosage that can be comprised of multiple pills over a weekly schedule
 - sending and receiving text information via a phone line connection to the internet.
 - The device will be configurable to
 - alert the user of the daily administration of the specified dosage
 - be able to provide additional dosages if doses are not taken for either one or two days based on the programmed weekly medication regimen.
 - The device will have the capability of sending messages regarding patient compliance as far as retrieving the prescribing doses on a daily basis.
 - Complete documentation on design, implementation, testing, operation and maintenance of system

A crucial aspect of this project is the development of a fool-proof, fail-safe dispensing mechanism that retrieves and makes available for dispensing a warfarin dosage that may be comprised of multiple pill dosages.

PRELIMINARY WORK BREAKDOWN:

Mechanical Engineering:

- Development of a mechanism for retrieving controlled medication dosages based on the availability of four pill dosage sizes.
- Development of a controlled mechanism for dispensing warfarin dosages.
- Development of an enclosure system that
 - is secure in terms of access to medication
 - is portable

Project Readiness Package - Coumadin Automatic Home Medication Dispenser Demonstration System

- contains the retrieval mechanism and dispensing mechanism
- allows for expedient and accurate reloading of pills by a trained pharmacy professional
- provides a user interface that is
 - easily utilized with minimal
 - dexterity
 - strength
 - training
 - robust/durable

Electrical Engineering/Computer Engineering:

- Electronics necessary to control retrieving, dispensing, loading and access mechanisms
- User interface electronics
- Network interface
- Web-based caregiver application
- Simulated network environment demonstration system

GRADING AND ASSESSMENT SCHEME:

All acceptable achievement levels require full documentation regarding system design, operation and repair.

Minimal acceptable level (D) – Research and evaluation of potential dose retrieval and dispensing mechanisms comprised of a well-documented report and minimal software simulation of methods discussed

C – level achievement – D level plus prototype system that demonstrates successful operation of a recommended method to provide required retrieval and dispensing mechanism(s).

B – level achievement – C level prototype mechanism packaged in a finished, stand-alone device that provides required functionality via direct control by a custom application running on a laptop computer connected over a modem-based interface.

A – level achievement – B level system that demonstrates stand-alone operation of all customer functional requirements and can be accessed, controlled and queried over a simulated telephone accessible internet server – client system.

THREE WEEK SDI SCHEDULE:

Week 1 – Meet with sponsor/customer and ascertain requirements, objectives and necessary background sources.

Week 2 – Research regarding comparable or similar devices, systems and potential benchmark devices. Refine customer requirements and objectives with goal of initiating development of system functional specifications.

Week 3 – Development and evaluation of potential design concepts/solutions and presentation to customer/sponsor.

REQUIRED FACULTY / ENVIRONMENT / EQUIPMENT:

Category	Source	Description	Resource Available (mark with X)
Faculty	ME	Mechanism design including building material expertise	X
	ME/EE	Electromechanical actuator utilization/design	X
	EE/CE	Digital communication systems/network access/application S/W	X
	EE/CE	Embedded S/W, H/W development	X
Environment	ME	Machining, rapid-prototyping	X
	EE/CE	Development hardware/software/platforms (EE senior design lab)	X
Equipment	ME	Machining equipment, fabrication	X
	EE/CE	Development instrumentation/fabrication	X
Materials	ME	Mechanism and enclosure, actuators	X
	EE/CE	Electronic components	X
Other	TBD	Placebo medication pill models	X