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Re: ENSC 370 Functional Specification, NoverDose Automated  
Medication Dispenser

Dr. Rawicz,

The enclosed document describes the functional specification for Prescriptek's NoverDose Automated Medication Dispenser. Prescriptek is designing an automated delivery system that will ensure medications are taken at the proper times and in the correct amounts.

The functional specification will provide the framework on which we will base our design. It describes in detail the desired behaviour of the medication dispenser and its subsystems.

Feel free to contact any member of Prescriptek at the phone number indicated above if you wish to discuss our functional specification in further detail.

Sincerely yours,

**The Prescriptek Team:**

Bryce Pasechnik  
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Derek Young  
Rob Boyes  
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**ENSC 370**



**NoverDose®  
Automated Medication Dispenser  
Functional Specification**

**Team Members:**

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February 16<sup>th</sup>, 1999

## **Executive Summary**

The improper use of medication is a common occurrence for elderly and confused people, especially when multiple doses are taken at different times of the day. Of all people over the age of 65 that are hospitalized, 30% of these cases are due to over or under doses of medication. Large amounts of health care funding are required when nurses work door to door delivering the proper medication. Many elderly people are placed in old age homes when they are unable to take their medication. Prescriptek proposes an automated delivery system that will ensure medications are taken at the proper times and in the correct amounts. This device will allow for persons to remain independent in their homes, as well as save wasted taxpayer money. Proposed interfaces will ensure security for the user, as well as a means for the pharmacy to monitor the actual medication intake. A user-friendly interface, as well as an easy load system will reduce maintenance time and boost the safety features of the device. This medication delivery system gives peace of mind to the user.

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# 1. Introduction

## 1.1. Purpose

This document details the requirements for developing and using an automated medication dispensing system for usage by elderly persons. The details herein will give the client a clear idea of what Prescriptek Health Systems has developed as the best answer to problem of medication over-dosage and under-dosage by the elderly and the confused. Recommendations are based upon communications with professional pharmacists, health care workers and elderly persons. The design of the system will follow directly from the requirements specified in this document. This document will clarify the requirements of the system and enable us to easily discover any needed revisions, thereby reducing the cost of development in the long run.

## 1.2. Scope

The NoverDose medication dispenser provides a much easier, safer way for patients to take their pills. Currently, the bubble paper schedule sheets are used to assist the elderly with taking their medication. However, schedule sheets present a problem because the bubble sheets tend to be poorly organized and require too much input from the subject, resulting in medication non-compliance. The NoverDose will automatically dispense the correct number of each pill type at the correct time, providing a much safer and convenient means for the elderly to take their medicine. It will also eliminate the need for health care workers to make daily trips to patients' homes to ensure the patient doesn't miss their scheduled dosage. Nurse visits can be limited to a weekly or bi-weekly basis in order to refill the machine's pill supply. Using the NoverDose system would greatly decrease the cost to the health care industry and give patients an empowered feeling that they can take care of themselves.

## 1.3. Overview

This document is composed of four sections.

- **Section one:** Introduction - describes in short our objectives in undertaking this project, as well as a brief insight as to the functionality of our product. Also included are the purpose, scope and overview.
- **Section two:** General Description - gives the reader an overall picture of the system and major design considerations. It begins by introducing the environment the system will be operated in, as well as other

components/resources of the system. The introduction is followed by a general description of the functions the system will provide. The design considerations include user characteristics and external constraints that influence the requirements of the system. Assumptions and dependencies of the system are also covered in this section.

- **Section three:** Specific Requirements - provides more detailed accounts of the system and its requirements as described in section two. The functional requirements of the automated medication dispenser, which form the basis of the subsequent design phase of this project, are presented first. They are complemented by external interface requirements, which include user, hardware, software and communication interfaces. A description of the performance requirements in quantified terms follows, whereby the system performance can be evaluated objectively. This section also lays out the design constraints that limit the capabilities of the system, and attributes that will be used to measure system's qualitative merits. The section ends with a retained data model in a diagram that illustrates the data flow and relationships among various components of the system.
- **Section four:** System Evolution - considers features not needed in a prototype system, but might be useful and/or essential for a greater user base (e.g. more comprehensive audio cues for the blind).



## **2. General Description**

### **2.1. Product Perspective**

A pharmacist will upload medication data and scheduling information into the device via a serial port computer connection. The upload will require the device be brought to the pharmacy. Updating medication and scheduling information will only be necessary when medicine types are changed, or dosing methods are altered – both of which require intervention of a pharmacist. Once the data has been entered into the NoverDose, a health care worker will be required to refill the dispenser every two weeks. The system will dispense medication at the scheduled times and give reminders to the patient via audio and visual cues. This system will also detect if the pills are being taken and will dial out to an emergency contact with a warning message if the medication hasn't been taken after a certain length of time. This time can be set by the pharmacist to be customized to the patient's particular medication priority level (i.e. it may not be important if the patient misses his/her vitamin C, but non-compliance to taking heart medication may require immediate attention!). The unit can also alert patients to take other forms of medications – inhalants, hypodermic – by way of a visual reminder, rather than a dispensing method.

### **2.2. Product Functions**

The system will have the following types of functions:

- Software-based functions which allow pharmacists to access/update their client's information.
- Firmware-based functions which control the mechanical portions of the device, and control the audio/visual, medication compliance detection, and emergency dial out circuitry.

### **2.3. User Characteristics**

The intended users of this product are the patient, pharmacists, health care workers, and emergency contacts.

#### **2.3.1. Patient**

The main user group is the patient. The design of the NoverDose is geared towards minimizing the amount of programming interaction between the elderly user and the device. The user will see only a "black box" that dispenses medication and reminds him or her at what times, and with what dosing method (e.g. take with food) the pills should be taken. Thus, the interface will be designed to minimize interactive feedback from the user and

will consist of a “receive pills” button and a lighted display. In addition, the user will only have access to the medication during the scheduled times, thereby minimizing the risk of over-dosage.

### **2.3.2. Pharmacist**

The pharmacist group consists of professional pharmacists at drug stores. It can be assumed that they would be competent enough in computer usage to operate the GUI- based software used to program medication, scheduling, and patient information into the NoverDose. The pharmacist will enter the information into the program where it will be saved as a patient record file. When the dispenser is brought in for reprogramming, the pharmacist will connect the NoverDose to his computer via a serial cable and upload the information. Our software will handle the actual data transfer.

### **2.3.3. Health Care Worker**

The health care worker consists of people who regularly visit the patient’s home. The primary role of these people will be to refill the NoverDose unit with the patient’s medication. These workers will not have the ability to reprogram the machine. The NoverDose unit will allow these people to open the unit remove any unused medication, clean the machine, refill the medication and possibly reset the clock on the machine.

### **2.3.4. Emergency Contact**

The final user group is the Emergency contact person. This is the person that the NoverDose unit will in contact in case of patient non-compliance. This person will be contacted via phone and will be informed of the reason for the emergency. This person will then have some limited control of the unit over the phone, and will be expected to take whatever action is necessary to rectify the situation.

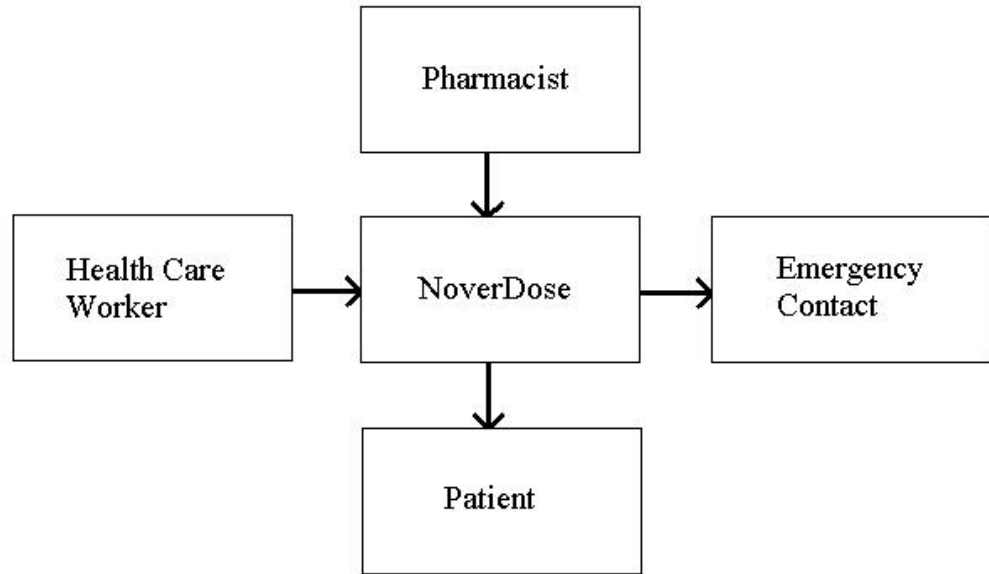


Figure 1. Relationships Between System and Users

## 2.4. General Constraints

This device will have certain physical constraints. The entire system should not be too large or heavy that it cannot be easily carried to the pharmacy for programming. It should also take up as little space as possible in the patient's home. The unit should however be able to hold enough medication to last the patient at least two weeks. This storage requirement will require the space for at most 400 pills at one time. The prototype should have a similarly sized foot print to a VCR or a regular hi-fi stereo component.

## 2.5. Assumptions and Dependencies

When constructing this device certain assumptions must be made. The patient using the system must not be mentally beyond taking his or her own medication. Any patient using this system must be capable of reading and understanding dosing instructions. They also must not be suicidal or overly violent. The system is designed for patients who simply have problems remembering a complex set of medication dosing instructions.

## 3. Specific Requirements

### 3.1. Functional and Design Requirements

- The devices functional and design requirements can be broken down into specific categories.

#### 3.1.1. Exterior Physical Layout and Operation

The physical layout of the machine is an integral part to it succeeding in the patient's home. The most important concern is to keep the final product easy to use and understand and extremely reliable in day to day operation while not deviating from the machine's original purpose. With this in mind, these characteristics have been assigned as requirements:

- Machine keeps the medicine inaccessible to the patient, except when dispensing medicine, at which point only the intended medicine is available
- Easy to reload, using a simple lock and key mechanism for refilling and cleaning
- Sample pills in magnified cases
- Numerical LED for each case, displays number of pills to be taken (a double checking method)
- Spaces available for labeling, which will contain dosing instructions and medicine information
- LED clock and count down timer
- Inoffensive, pleasant and non-threatening exterior packaging
- Robust and durable construction
- Patient interfacing easy to use – accessible for arthritic patients

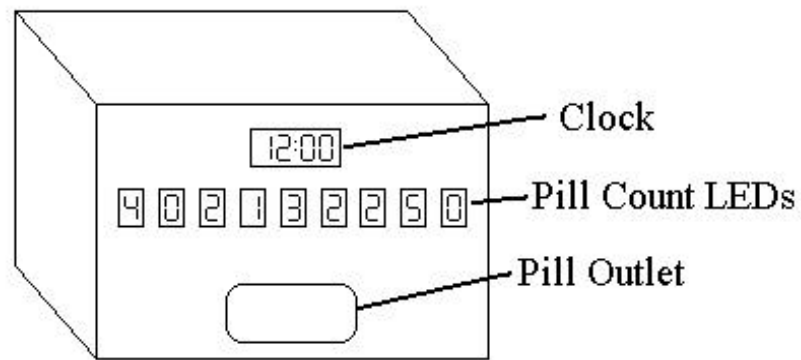


Figure 2. Exterior Physical Layout

### 3.1.2. Mechanical/Machine Requirements

The mechanical requirements are hidden from the end user, but are of utmost importance in the areas of reliability, safety and ease of use.

- Single pill holding/dispensing. Each pill is contained by itself to minimize the chance of over dispensing
- Storage capacity for up to 10 types of pills, approximately 40 spaces for each pill
- Pill holders easy to clean and load
- Holding stage where pills wait to be released by way of patient interaction
- Optical pill counter to ensure pill has been delivered to the holding stage
- Override if too many pills dispensed, pills are not released and are put into an a holding bin for disposal or re-loading
- Sensor to detect release from holding area
- Low noise during operation
- Low power consumption during operation
- Battery back up for clock and microprocessor
- Minimal moving components for increase reliability

### 3.1.3. Operational Characteristics

These define the actual operation of the machine and its specific functions

- Distributes medicine at preprogrammed times determined by the schedule
- Alerts user medicine is ready via audio and visual indicators
- Displays the number of pills received by the patient
- Emergency/Telephone mechanism
  - ⇒ Makes phone call if medicine is not taken from holding area in a specified window of time

- ⇒ Calls number until a tone signal from the emergency contact is received
- ⇒ Can contact a pager and leave an alpha-numeric message
- ⇒ Once signal is received from emergency contact the machine waits another window of time for medicine to be taken before calling back
- Sleep function set by health care worker or emergency contact allows machine to be “turned off” if patient is away for any length of time
- Clock adjustable by health care worker or emergency contact. Controls hidden underneath locking cover
- Errors – dose misses, pill delivery errors – are logged by the internal processor

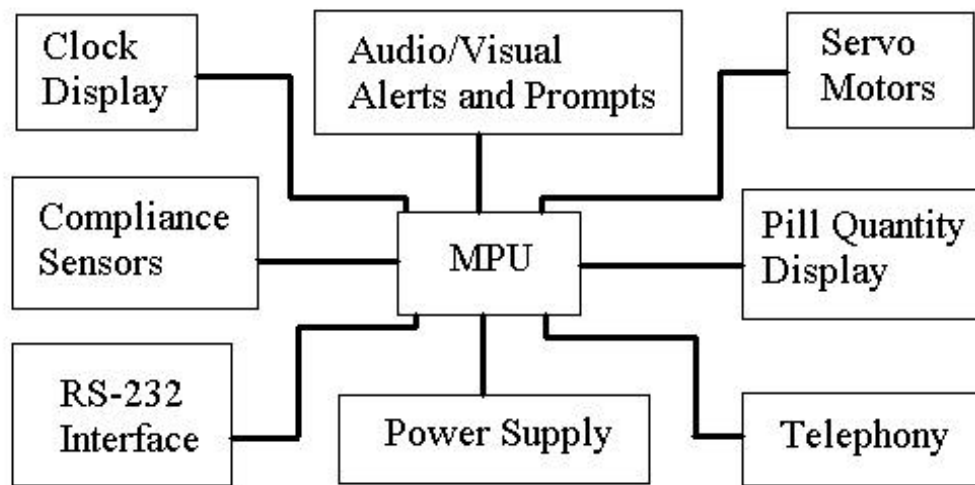


Figure 3. Device Subsections

### 3.1.4. Front End Characteristics

The internal processor controls all the external function based on the schedule and programmed parameters. The front end programs the schedule and the parameters via a Windows 95 GUI program used by the pharmacist.

- Easy to use point and click, drag and drop scheduling
- Downloads current schedule from machine to ease in reprogramming
- User friendly spread sheet type layout of programmed schedule
- Parameters that can be defined
  - ⇒ Multiple emergency numbers
  - ⇒ General wait times for emergency functions
- Scheduling Parameters
  - ⇒ Medicine type: Pill or External (inhalant, hypodermic)
  - ⇒ Times for dosing
  - ⇒ Dosing amounts

⇒ Relative importance of medicine, determines emergency waiting times

## 3.2. External Interface Requirements

### 3.2.1. User Interfaces

The NoverDose system will have numerous user interfaces for the various people that interact with the system.

#### 3.2.1.1. Patient

The patient will have a very limited interface with the machine. The unit will pre-load the patient's medication some time before the scheduled time. The patient will then be able to press a button to release the medication when they are ready to take it (within a specified time window). The pushing of the button will be the only input from the patient to the machine.

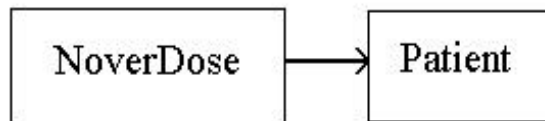


Figure 4. NoverDose-Patient I/O Path

#### 3.2.1.2. Pharmacist

The pharmacist's interface will consist of a Windows® based scheduling system. The pharmacist will be able to enter scheduling information for each pill type. They will also be able to put a sample pill in a display area as well as instructions on how to take that particular medication.

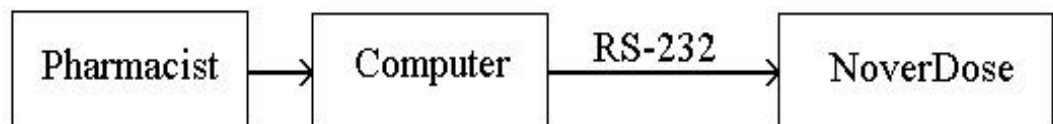


Figure 5. NoverDose-Pharmacist I/O Path

#### 3.2.1.3 Health Care Worker

The health care workers interface will be mainly mechanical. The nurse or care aid will be able to open a cover to allow refilling. It will also be possible for the health care worker to remove the mechanical portions of the pill dispenser system for cleaning. A small push button interface will be available for setting the machine's clock.

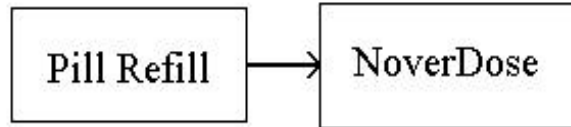


Figure 6. NoverDose-Health Care Worker I/O Path

#### 3.2.1.4. Emergency Contact

The emergency contacts interface will be entirely through the touch-tone phone system. They will receive voice prompts from the machine and will be able to give it simple commands through touch-tone codes.

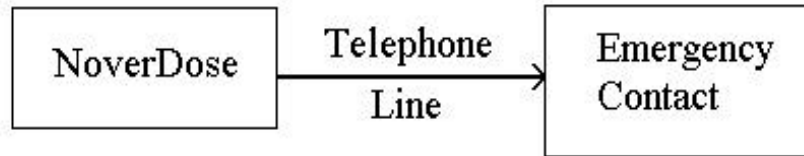


Figure 7. NoverDose-Emergency Contact I/O Path

#### 3.2.2. Hardware/Software Interface

The device will require an RS-232 serial port for programming at a pharmacy. It will also require a secured loading lid to allow a health care worker to reload the device and also to ensure that the stored medication is normally inaccessible to the patient to prevent overdoses. A touch-tone phone will be required by the emergency contact.

#### 3.2.3 Emergency Communication Interface

The emergency communication interface will use a regular telephone line to dial one or more stored emergency numbers and play a pre-recorded warning message. The device will be able to detect a confirmation response in the form of the contact person pressing a button on their touch-tone phone keypad. Failure of the contact to respond to the phone, or to confirm the call will result in a re-dial or of dialing an alternate contact, as circumstances dictate. The interface can also call an alphanumeric pager if wanted or necessary.

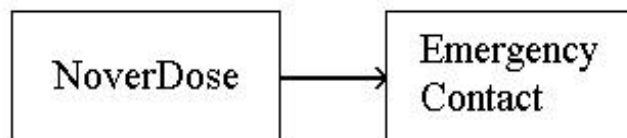


Figure 8. Emergency Communication



### **3.3. Performance Requirements**

The medication dispensing system will be required to dispense the correct number and type of pills to the patient. It will also be required to detect the number of pills dropped to ensure that an overdose or under-dose does not occur. The pill dispensing speed is not of high importance because the pills can be dispensed into a holding bay in advance and released to the user at the scheduled time.

### **3.4. Safety Requirements**

The device will be required to keep medication secured from the patient to prevent patient overdosing. The device must dispense the correct dosage of pills to the patient. The outer casing of the device will have no sharp or pointed edges which could cause harm to the patient. The device must also exhibit electrical isolation characteristics which prevent shock to any of the users of the device. In the event of a lack of medication to dispense, the device will call out to alert an emergency contact.

### **3.5 Reliability Requirements**

The NoverDose will be required to dispense the correct number of pills, 100% of the time. The device must be able to operate within a temperature range of –10 to +50 degrees Celsius. The device shall continue to operate during power outages and brown-outs, and shall be able to continue operating for up to two days with no external power at all. The working lifespan of the device will be ~20 years, after which no guarantees will be made as to the machine's performance.

### **3.6 Standards**

The NoverDose automated medication dispenser must be compliant with FCC electro-magnetic interference standards. It will also be compatible with EC regulations and contain electronic protection circuitry to protect the device in the event of brown-outs.

## **4. System Evolution**

This unit will be built in a modular fashion to allow addition of increased functionality.

#### **4.1. Increased User-Base Features**

The NoverDose system will have the ability to be expanded beyond its original design to allow usage by a broader range of patients. Some features that may be added to the NoverDose system are:

- Ability to have speech output of medication types and dosing instructions (for the vision-impaired)
- An emergency button that will automatically dial the emergency contact in case of error in the medication dispensing system.

## **5. Conclusion**

We have discussed in this document the functional considerations of building an automated medication dispenser system. The NoverDose system will be designed and built based on the functional specifications described above. By building a device based upon these requirements, we hope to provide a working prototype unit which can be used as a basis for an eventual production model. The NoverDose product has the potential to save millions of dollars in health care funding, save lives, and improve the quality of life for thousands of elderly individuals.