Using Technology to Measure Adherence of Complicated Medication Regimens

Product Design Specification

Team Members: Sujan Bhaheetharan, Cara Dunn, Farshad Fahimi, Nipun Yamdagni

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Function: This device should record a patient's adherence to their medicine regimen and alert them at the appropriate times to take their pills.

Client Requirements:

- Device must obtain data regarding patient's adherence of their medications.
- Device must be lightweight and durable.
- An alarm should alert patient to take medication.
- Total cost may not exceed $500.
- Normal use may not interfere with recording.
- Must consume low amounts of power to eliminate the need for frequent battery replacement.

Design Requirements

1. Physical and Operational Characteristics

a. *Performance Requirements*: The user may access the device at any time of the day and the prototype will record the exact time and date of operation. Everything will be logged so that the client may review the information when the device is returned to them. In addition, an alarm should be integrated into the final device in order to alert the user and remind them to take their medications. Alerting the user and recording the precise moment of operation are key performance requirements for this design.

b. *Safety*: All safety issues associated with the client's standard medication box will pertain to this device. Chemicals that are harmful to the device must be clearly stated for the user during the cleaning process. The audible/vibration level of the alarm must not be hazardous to the user's health.

c. *Accuracy and Reliability:* Accurate timing and logging is essential for this design. The final prototype must be able to record up-to-the-minute data on operation and stored correctly. Proper logging is necessary for the client's records. The alarm system should have a programmable alarm feature and should always have the correct time. The battery/power source for both the recording function and the alarm feature must be reliable in order to ensure accurate logging and to have on-time alerts.

d. *Life in Service*: The final device should be able to last as long as the power source and there should be no functional dilemmas due to normal wear and tear. The device may be idle for numerous hours while sitting in the client's residence, but could also be accessed at any given moment. The device, which may surround the medication box, must not be negatively affected by normal medication refills or being transferred between medication boxes or between patients. Given a good environmental setting, there should be no problem with the device traveling back and forth between the pharmacy and the patient every few weeks.

e. *Shelf Life*: The device should last for several years prior to being used, and should be operable for several years after purchase. To achieve this, proper materials must be selected and appropriate mechanisms must be employed. Additionally, battery life should be extended by use of power saving algorithms.

f. *Operating Environment*: The device will be used indoors on a daily basis. Patients might like to store their medicine in a bathroom, thus it should not be damaged if exposed to high humidity. It should also not be damaged from any accidental water spills. If the device is left in a car accidentally, it should be able to accommodate temperatures as low as -20^{o} C and as high as 50^{o} C. Furthermore, it should not be considered an extremely fragile device, as that may deter patient usage.

g. *Ergonomics*: The typical user of this device will be elderly and or disabled, with reduced strength and motility. Thus the device should be easy to hold and should not be physically challenging to operate. Additionally, the device should be intuitive for every patient, thus requiring little or no instruction.

h. *Size*: Despite the fact that the device will predominantly remain indoors, it will still need to be moved from time to time. Thus it cannot be a very large and bulky. The target size is approximately that of current pill boxes.

i. *Weight*: The device should not weigh more than between 5 and 10 pounds. It is vital that the patients, typically older, more fragile patients, be able to carry the adherence device.

j. *Materials*: The materials for the device should be easily cleanable surfaces. Plastic would be optimal to prevent medicine contamination. Porous materials are not to be used to ensure a healthy storage situation.

k. *Aesthetics, Appearance, and Finish*: The adherence device should be aesthetically pleasing, but has no specific requirements. A neutral color would be best with perhaps some color for easy recognition of the device. The form of the device should be easy for an elderly patient to hold and carry while still holding the maximum number of medications necessary. Patients should have no trouble using the final device and not mind placing it in areas they would normally store their pill box.

2. Production Characteristics

a. Quantity: One prototype of the medicine adherence device is necessary, but after a satisfactory design is created, a total of between 5 and 10 may be necessary.

b. *Target Product Cost*: The Client would like the prototype (both the compliance device and the wristwatch) to cost no more than $500, but when the design is in production, each device and wristwatch should cost approximately $200.

3. Miscellaneous

a. *Standards and Specifications*: There are few ISO standards that must be given careful thought during construction and testing. Two specific standards were found under biological evaluation of medical devices. ISO/NP 10993-3 (Tests for genotoxicity, carcinogenicity and reproductive toxicity) and ISO/DIS 10993-9 (Framework for identification and quantification of potential degradation products) pertain to this project and must be satisfied. This data is valuable information for clinicians, and will help in determining if additional medication is necessary. Also, the data can be used for improvement upon the medical adherence.

b. *Customer*: Device must be able to attract customer's attention, reminding him/her to take their medications.

c. *Patient-related concerns*: The device does not have to be sterilized between uses. The data gathered from the instrument must be safeguarded for confidentiality purposes.

d. *Competition*: Currently there is an instrument which can monitor the date/time an individual medication pill bottle is opened; such instrument uses Micro-Electro-Mechanical Systems (MEMS.) as well as the e-pill MD.2. Both tools do not work well for this project and a suitable solution must be developed.