

Using Technology to Measure Adherence of Complicated Medication Regimens

Product Design Specifications

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Function: This device should record a patient's adherence to their medicine regimen and remind them with an alarm each time medications should be taken.

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 and be on standby for 2 weeks without power failure.

Design Requirements

1. Physical and Operational Characteristics

a. *Performance Requirements:* The user may access the device at any time 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. In addition, an alarm should be integrated into the final device in order to alert the user and remind them to take their medications; however, this feature may be done separately via a wristwatch. Alerting the user and recording the precise moment of operation are the 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. If a wristwatch is implemented, the audible/vibration level 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 store it 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 correct medication 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 by 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. The wristwatch system will last as long as the battery's life.

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.

f. Operating Environment: The device will be used mostly 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, such as that caused by a shower. 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 -20°C as high as 50°C . Furthermore, it should not be considered an extremely fragile device, which 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 and require 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. The alarm wristwatch should be of minimal weight to ensure no harm is done to the patient.

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. The preferred materials for the wristwatch would be plastic, but a fabric band would be possible. Any adherents used should be able to last in the normal operational atmosphere without failure or harm the user.

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. The wristwatch should be small and attractive. If the user does not find the wristwatch appealing, they will be less likely to wear it and, therefore, will not receive reminders to take their medications.

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. The client requests one wristwatch for every medicine adherence device created.

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 no national or international specifications for gathering information on when a patient takes their medication. 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 a patient's medication adherence. Our client also desired that we develop a device that would remind the patient to take their medication.

b. Customer: Device must be able to get 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.)