Ophthalmic Dose Compliance Monitor March 1, 2006

Team Members:

1. Ben Roedl: Co-Team Leader bdroedl@wisc.edu

2. Nina Lewis: Co-Team Leader

nllewis@wisc.edu

3. Ashley Phillips: BWIG

amphillips2@wisc.edu
4. Brett Mulawka: BSAC

bsmulawka@wisc.edu
5. Patrick Schenk: Communications

pjschenk@wisc.edu

Function: Our objective is to develop and miniaturize a dose compliance monitor that would record (unknown to the client) when (date and time) a topical ophthalmic medication was delivered. There are currently older designs of compliance monitors designed for ophthalmic medications, but our design should be a cost effective improved model. Ideally we would be able to manufacture approximately 10 of these devices for use in studies. It could be as simple as some of the older models that recorded when the top of the bottle was removed and the bottle inverted. Maintenance of sterility of the medication is imperative.

Client requirements: Our client's requirements are as follows -

- Minimize the size of the circuit in order to discretely place on eye dropper bottle
- Device must be placed on the outside of the bottle
- Device must record date and time of each application

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements*: The device will be used daily based on prescription. It must be able to store each application's information for up to six weeks.
- b. *Safety*: In order to prevent contamination of the medication, the device must be applied to the outside of the bottle without opening the cap.
- c. Accuracy and Reliability: The device must record information only when the medication is used and not when it is simply moved from one place to another.

- d. *Life in Service*: Our device should be sustainable with every day use for a duration of up to six weeks.
- e. *Ergonomics*: The device cannot interfere with the patient's application of eye drops. It must be small enough to fit on the side or bottom of a 2cm diameter bottle. The device must also be unbeknownst to the patient.
- f. *Size*: The device must be miniaturized in order to discretely fit on an eye drop bottles of 5-15 mL volumes.
- g. Weight: Weight will be restricted due to the size.
- h. *Materials*: We will be using a circuit or sensor and an insulating sleeve.

2. Production Characteristics

- a. Quantity: 10
- b. Target Product Cost: \$100/bottle

3. Miscellaneous

- a. *Customer*: Any parent or pet owner that will be applying ophthalmic doses to their child or pet.
- b. *Patient-related concerns*: There should be no concerns because the patient should not be aware of the device.