

Product Design Specifications

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Title: Valve for bodily fluid drainage for paralyzed individuals

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Function: This valve will be designed to drain the urine bags of individuals with catheters at the discretion of the individual. The valve should be able to drain a 1000 cc bag in less than 5 minutes without the incidence of failure due to blockage from urine sediment or wiring failure. The valve must be durable, affordable, and as discrete as possible

Client Requirements:

- Fast drainage time (as quickly as possible, from testing this was determined to be approximately 20 seconds)
- Less failure due to blockage from urine sediment
- Less failure due to wiring problems
- Valve should not be attached to the wheelchair
- Operation controlled by a switch that requires continuous pressure.
- Device control with a switch that electrically activates it
- Device able to be powered by wheelchair batteries (12 to 24 volt energy requirement)
- Accidental drainage should not be possible

Design Requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:*
 - Valve should be usable any time during the day
 - Only used on average once a day
 - Should drain as quickly as possible
- b. *Safety:*
 - Electrical safety concerns: avoid exposed wires
 - Waterproofing of all electrical components to avoid shocks
- c. *Accuracy and Reliability:*
 - Functions repeated daily without failure
 - No accidental drainage
- d. *Life in Service:*
 - Functions 24 hours a day, 7 days a week
 - Should perform for at least 2 years without failure
- e. *Operating Environment:*
 - Should not be damaged when exposed to extreme hot and cold
 - Waterproof: resistant to snow and rain
 - Resistant to changes in humidity
 - Could be exposed to any environment
- f. *Ergonomics:*

- Switch needs to be in reach, likely near one of the arms of the chair
- Device should not interfere with daily routine of the client
- g. *Size:*
 - Small enough so that it is not in the way
 - Approximately 8 cm x 8 cm x 8 cm or less
- h. *Weight:*
 - Cannot be so heavy such that it detaches from bag
 - Approximately 500 gm or less
- i. *Materials:*
 - Noncorrosive materials
 - Able to operate within pH range of 5.0-7.0 (average pH of urine)
 - Able to operate within extreme temperature conditions (-20°F - +100°F)
- j. *Aesthetics:*
 - Preferably small enough so that it cannot be easily seen
 - If visible, the device should be of a color and style such that it is inconspicuous

2. Production Characteristics

- a. *Quantity:*
 - Just a prototype for the time being
- b. *Target Product Cost:*
 - Less than \$200
 - Cost depends greatly on the estimated life span

3. Miscellaneous

- a. *Competition:*
 - The solenoid valve currently produced by Automatic Switch Company (this valve is not produced for biomedical purposes, it was adapted by Dan and his brother)
- b. *Standards:*
 - It will have to meet FDA requirements if multiple units are produced.
 - If clinical trials were begun, NIH human subjects approval would be required