Product Design Specification (PDS)

Engineering World Health Aspirator (February 22, 2008)

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Problem Statement

Most developing world hospitals do not possess operating suction machines. The main problems are the lack of available spare parts, the cost of a replacement unit, and dependence on consistent electricity. The objective of this project is to design and develop a medical grade aspirator that can be manufactured inexpensively from locally available materials. Along with the device, an instruction manual will be produced to allow for proper usage and care in the future.

Client Requirements:

• Device should run on 12 V batteries with manual back-up.
• Device should provide the broadest range of applications possible, with a high setting for adult applications and anesthesia and a low setting for neonatal applications and gastrointestinal work.
• Device must include autoclavable suction tips.
• Device must be completely manufactured from locally available materials for under $100.

Design Requirements

1. **Physical and Operational Characteristics**
   a. *Performance requirements:* 0-550 mmHg vacuum, 0-30 lpm flow rate

   b. *Safety:* Entire device must be easily disinfected for use in a surgical setting. Aspirator tips and preferably collection flask should be autoclavable. Usage should be possible for sustained duration, preferably over eight hour intervals. Power source and motorized elements should be enclosed to minimize patient/user risk.

   c. *Accuracy and Reliability:* Pressure and flow adjustment dials must be able to be calibrated prior to use. Device must be able to provide reliable suction throughout an entire surgery or operation (up to 8 hours). Minimal maintenance required. Manual backup should provide reliable service.

   d. *Life in Service:* 5 years

   e. *Shelf Life:* 5 years

   f. *Operating Environment:* Must be able to be stored and function under temperatures ranging from -10 to 40 degrees Celsius and variable humidity.

g. *Ergonomics:* Aspirator should have minimal steps to turn on and begin use. Device, including manual back-up power and suction attachments, should be self-contained to create more space in the operating room.

h. *Size:* Less than 0.15 m^3 (2/3 by 2/3 by 1/3 m) Preference is for a device that is taller than it is wide, but not taller than the operating table for sterile purposes. Collection flask should be approximately 1-3 L.

i. *Weight:* Less than 10 kg without battery.

j. *Materials:* Completely manufactured using locally available parts.

k. *Aesthetics, Appearance, and Finish*: Moving parts, sharp edges, etc. need to be shielded from clinical environment.

2. Production Characteristics

a. *Quantity:* Device should be able to be widely implemented in a third world community.

b. *Target Product Cost*: < $100 per device using locally available materials.

3. Miscellaneous

a. *Standards and Specifications:* Device should ideally abide by safety standards and regulations set by the Association for the Advancement of Medical Instrumentation (AAMI) and the FDA.

b. *Customer:* EWH-affiliated medical professionals and institutions in developing communities. Instruction manual should be sensitive to language barriers.

c. *Competition:* Discarded medical aspirators from developed nations. Say more?