Pelvic Floor Muscle Biofeedback System

Project Design Specifications

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Function:
Our Pelvic Floor Muscle Biofeedback Systems will analyze both the function and capability of muscles incorporated in the urinary process, including the lower abdomen and anal sphincter, by use of EMG sensors. This data will then be integrated with a software system that will allow feedback that is immediate and entertaining to the clients at hand.

Client Requirements:
Our Client is looking for a system that:

- Maintains high standard of success rate
- Is updated and modernized
- Will be able to withstand a heavy schedule of use
- Held to safety standards of hospital equipment

Design Requirements:
Our design has two main components: hardware and software. For the course of this semester, and due to client time demands, we will focus mainly on constructing operational hardware. Physically, the system will include an EMG device that will record and output data to a computer interface running Windows and Android devices. Computational software will then analyze the strength of muscle contraction and integrate the variation into an educational and entertaining video game being played by the patient.

Physical and Operational Characteristics:
a. *Performance requirements*: This system will be used multiple times daily for the foreseeable future (1-3 years) the expectation is the software will run stably and consistently over that time.

b. *Safety*: Human factors set safety demands on our product that will not induce harm via muscle-stimulation or electrical malfunction

c. *Accuracy and Reliability*: Our system must output a low voltage to the computer software system with a range of error on the order of 100 mV. Outputs can be ~ 0 - 5 Volts.

d. *Life In Service*: Currently patients appointments are scheduled for 5 meetings per day, 5 days a week, for approximately the next year.

e. *Shelf Life*: No demands for product shelf life are currently anticipated due to the frequent use

f. *Operating Environment*: Hospital room setting, with no potential for exposure to conditions outside of normal indoors fluctuations in temperature and humidity. Temperatures will be at approximately 20 °C with a humidity of 30% to 50%.

g. *Ergonomics*: Sensors must be comfortable to apply and durable, maintain good contact throughout the potentially moving patient's exam

h. *Size*: Entire system must fit on 1 meter by 1 meter desktop. Sensors must be able to handle patients as low as 10 kg or as high as 150 kg.

i. *Weight*: Maximum weight is important only for handling product, expectations is that the weight will be 5 lbs.

j. *Materials*: Materials should not be flammable under any hospital situation. Intuitively, we will search for the most cost/benefit effective products required to meet previously described demands.

k. *Aesthetics, Appearance, and Finish*: The software requires a modern feel and capability- an upgrade from 1990's DOS operating systems.

Production Characteristics:
a. *Quantity*: We anticipate building at least one fully operational device and one backup device.

b. *Target Product Cost*: No real product cost or project budget has been established yet

Miscellaneous:
a. *Standards and Specifications*: We will be looking at meeting human product testing requirements and hospital safety requirement

b. *Patient Requirements*: An exceptionally high (95%+) success rate will be demanded from our patients

c. *Patent-Related Concerns*: Business related potential for this project will continue to be research with a possibility for a project design patent and potential production

d. *Competition*: A variety of devices currently exist to output data in a numerical form, and are less accurate than the current generation of product. Our end product will be even more precise and integrate gaming software for play.