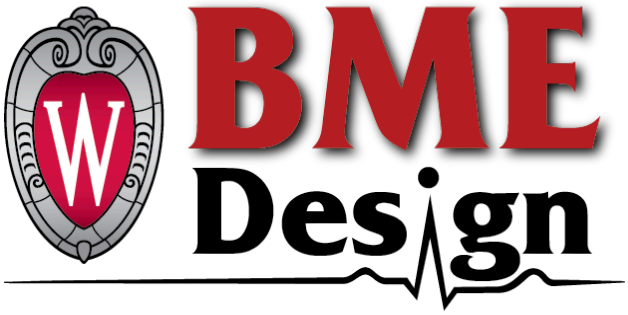

Adaptive Overhead Tether System for Freely Moving Swine

Preliminary Product Design Specifications

Fall 2026 BME 200/300 Lab 308

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P.I.G.

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Problem Statement:

The UW-Madison Department of Neurosurgery is developing a chronic large-animal neuromonitoring platform using multiple intracranial catheters for continuous or repeated brain interstitial fluid sampling to study the short-term effects of cardiac arrest on the brain. A cranial fixation device that organizes and protects these catheters has already been developed; however, the lab requires the development of a complementary overhead system that manages tubing and cables extending from the cranial device, while simultaneously allowing the animal to move naturally within a stationary enclosure. The developed system needs to be able to dynamically follow the animal, maintain appropriate tubing length, minimize tensile and rotational forces, prevent entanglement or kinking, and allow normal behaviors of the animal.

Client Requirements:

- The device moves to accommodate the animal rather than the animal moving to accommodate the device.
- Create a complementary device used on a pre-existing catheter device.
- The apparatus must allow the animal to participate in natural environmental behaviors.
- The device must prevent the entanglement of catheters and minimize tensile forces.
- The device must minimize the likelihood of agitation in the test animal.

Design Requirements:

1. **Physical and Operational Characteristics**
    - ***a. Performance Requirements***
        i. The apparatus must be able to accommodate the natural environmental behaviors of the animal subject, including movement within the environment, feeding, and resting.
        ii. The system should dynamically follow the animal, maintain appropriate tubing length under 1 meter that minimizes tensile and rotational forces, and prevent entanglement or kinking.
        iii. The tether management system must interface with the cranial catheter fixation device supplied by the client.
        iv. The system should withstand uninterrupted, constant daily use within the testing timeframe of approximately 2 weeks.
        v. The system must be reusable and adjustable to different catheter placements.
        vi. The apparatus must be able to incorporate all necessary monitoring equipment, including a Hemedex Bowman Perfusion Monitor [1].
    - ***b. Safety***
        i. The device must not harm the animal by tangling, strangling, or pulling out any of the catheters. It should not have any components that could pinch or cut the animal.

ii. The device should be designed with cleanliness in mind to prevent any infections and make any necessary cleaning of the device as easy as possible for caretaking staff.
iii. The device and restraint should cause the least amount of stress possible to the swine. Stress factors to be monitored include noise, visual motion, and physical disturbances.

c. Accuracy and Reliability

i. The animal-tracking device should be able to detect the cartesian coordinate position of the animal within a tolerance of ± 0.2 mm [2].
ii. The overhead tether system should be reliable enough to minimize tensile and rotational forces to protect the fiberoptic catheter and the wider plastic catheters from damage during a 2-week timespan.

d. Life in Service

i. The entire apparatus must maintain full operation for the entirety of each 2 week subject period with no maintenance required.
ii. With minimal maintenance, apparatus should be capable of full operation for the entirety of the studies length with minimal maintenance, approximately 3 years.
iii. Each subject period will last a maximum of 2 weeks, 336 hours.

e. Shelf Life

i. The entire system will be used on one test animal at a time for a period of up to 2 weeks.
ii. The entire apparatus must be able to be stored independently of the cranial fixation device until attachment takes place.

f. Operating Environment

i. The apparatus must be able to be utilized at room temperature temperature of approximately 20℃ - 22℃.
ii. The device will be stored in a WIMR - affiliated large-animal veterinary care facility. At this facility the device will be exposed to humidity, dirt or dust, animal bedding, animal waste and body fluids, and antibacterial chemical sanitizers.
iii. The apparatus will be used by both researchers and by veterinary care staff.

g. Ergonomics

i. The device must allow veterinary care staff access to clean the living area of the pig at least every three days to ensure dry resting and feeding areas [3].
ii. The device must allow veterinary staff frequent access to care for the pig eg. feeding, watering, vital measurements.

iii. The apparatus must allow staff to walk/guide the pig into the pen without requiring staff to lift them.
iv. The apparatus must allow staff to attach the cranial catheter fixation device and associated harness to the necessary medical equipment. Once attached, the pig should not need to be disconnected until the end of the 2 week study period. Due to the nature of the study, the disconnection method does not need to be "quick release", and should rather prioritize security over ease of use.

h. Size

i. The device must have a minimum floor space of 2.5 m^2 in order to adequately house the test animal in adherence with *Institutional Animal Care and Use Committee* guidelines. Furthermore, these guidelines suggest an optimal floor space within 2.5 – 3.7 m^2 for housing the test animal [4].
ii. The apparatus must fit within the designated laboratory space at the *UW-Madison Department of Neurological Surgery*, while also allowing for enough room for researchers to operate within the space as well.

i. Weight

i. For simple installation and transportation of the enclosure, the optimum weight of the apparatus is 20 – 30 kg [5].
ii. To ensure safety and structural integrity, the device must be able to withstand a minimum compression load of 6.0 kg to ensure that the Hemedex Bowman Perfusion Monitor and any other medical devices can rest on top of the enclosure [1].
iii. The flooring of the apparatus must also be able to support an additional 15 – 25 kg of the Wisconsin Miniature Swine test animal [6].
iv. The weight of the tethering strap used on the test animal must be no more than 2% of the animal's body weight [7].

j. Materials

i. The device must not use coarse fabric materials, materials with chemical treatment and dyes, or synthetic fibers like nylon and polyester to prevent irritation of the animal's skin [8].
ii. The apparatus should incorporate plexiglass or other visually transparent material that allows veterinary staff and researchers the ability to constantly monitor the swine subject [9].

k. Aesthetics, Appearance, and Finish

i. To prevent injury, the product should have a non-slip, non -porous and seamless finish that withstands chemical sanitization and animal rooting [10].

ii. The product must also have 0% optical opacity paneling allowing for visual transparency for observation [9].

2. **Production Characteristics**
    a. ***Quantity***
        i. The construction of one enclosure containing an adaptable tethering system for repeated use is required.
    b. ***Target Product Cost***
        i. A flexible budget has been administered based on design needs. The financial goal of the project is to develop a system that appropriately replaces long-term anesthetization of the animal subjects which costs the client up to $3,000 per day to maintain. Therefore, the target product cost should be reasonable and sufficiently low to provide a meaningful reduction in the client's overall operating expenses.
3. **Miscellaneous**
    a. ***Standards and Specifications***
        i. ISO 62366-1
            1. This standard outlines the usability engineering process for medical devices. It provides manufacturers with guidance on how to analyze, design, and test the user-friendliness of their medical devices, and how to identify and reduce risks that may arise during normal device use [11].
        ii. ASCE 7-22
            1. This standard provides a comprehensive guide on the minimum requirement caused by environmental loads for structural stability, adequate strength and structural integrity accounting for risk of human life, health, and welfare that can result from structural failure [12].
        iii. ISO 14971:2019
            1. This standard overviews Medical devices — Application of risk management to medical devices. Implementing these outlined practices enhances the swine subject's safety and the overall system's performance. These practices also encourage the early identification of potential hazards during design and development, when mitigation strategies are most cost-effective and impactful. [13]
        iv. ISO 9851:1990
            1. This standard provides the basic safety requirements for an overhead electrical rail, covering the materials handling, such as tracks, and load-supporting devices [14].
        v. Code of practice for the tethering of animals

1. This code of practice provides the guidelines of how animals must be safely tethered. The appropriate tether material that should be used, frequency of inspection, and duration of tethering [15].

b. Customer

i. The device is intended for housing 2-4 week old Wisconsin Miniature Swine [16]. In order to be suitable for this purpose, the device will need to adhere to the requirements of UW-Madison Institutional Animal Care and Use Committee for laboratory use of large-animals [17].

ii. The device is intended to assist laboratory researchers within the UW-Madison Department of Neurological Surgery, and therefore must be capable of aiding research by minimizing catheter lengths, reducing the likelihood of test animal agitation, and being detachable for use on multiple test animals.

c. Patient-related concerns

i. The apparatus must decrease the likelihood of causing excessive stress on the test animal. To promote animal well-being: operational noises must not exceed 85 dB, the test animal's movement should not be restricted by the tethering equipment, and devices implanted within the pig should be sterilized before use to avoid infection [18].

ii. In accordance with institutional policy UW-4091, medical records must be maintained for the test animals used in research [19]

d. Competition

i. *SAI Tethered Infusion System for Pigs* is a tether and jacket system that reduces the risk of pump damage by keeping the pump outside of the enclosure for easy accessibility and maintenance [20].

ii. *Ludomed Tether System for large animals* allows for uninterrupted delivery of test specimens while allowing the animal to comfortably move as a catheter integratable jacket minimizes stress on the animal [21].

iii. *LOMiR Medical Inc. Large Animal Tether* provides ease of movement, made up from an interlocking stainless steel, eliminating interference and damage to the catheter [22].

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