pH Probes to Diagnose Compartment Syndrome

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Team Members: Jonah Mudge, Lucas Ratajczyk, Hunter Huth, Nur Saidin
Advisor: Dr. Amit Nimunkar
Client: Dr. Christopher Doro

Function:

The pH probe interface must reliably display the pH level read by an ISFET sensor, and record it on a screen that is easily usable by a surgeon. It must be capable of recording pH data for a clinically relevant time period, while ensuring that no data or timestamps are lost. The device must also feature buttons (on a touch screen or otherwise) that are simple and reliable for a surgeon to interact with quickly, especially in high-stress situations in an OR. Along with probe interface is the ISFET probe casing, which must be able to fit into a 16 gauge needle while allowing accurate pH readings.

Problem Statement:

Compartment syndrome is a difficult-to-diagnose condition that occurs when tissue pressure in a muscle compartment rises enough to cause ischemia and possible muscle death. False-positive diagnosis of compartment syndrome can lead to expensive, invasive surgeries, and unnecessary surgeries. Our goal is to design and test a device for clinical use capable interfacing with an ISFET probe and measuring the pH within a muscle compartment, and using the pH as a reliable indicator of whether compartment syndrome is actually occurring.

Client requirements:

- Create a device capable of measuring intramuscular pH *in vivo*
- The device must be able to record at least 48 hours of pH measurements
- The device should be minimally invasive

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

- The probe should accurately measure the pH that relates to compartment syndrome that is within the range of 5 to 7.
- The probe must continuously record the pH inside the compartment up to 48 hours.

b. Safety:

- The electronics should not cause electrical shock to the user or patient.

- The device should not cause any infection to the muscle compartment.
- The device should not dissociate or fragment during compartmental insertion.
- The device must not release toxic materials into the patient.
- The device must be sanitizable to prevent transfer of infectious material.

c. Accuracy and Reliability:
- The device must be able to acquire the signal from the ISFET probe without noise
- pH read from the probe must be accurate within a range of 5 - 7
- Accuracy must be within 0.1 to ensure accurate readings and diagnosis

d. Life in Service:
- The probe must maintain its structure and function over many daily uses.
- The probe is disposable for a single use but the electronics of the pH sensor should last at least 5 years.
- The electronic systems must be resilient for repeated use without breakdown.

e. Operating Environment:
- The probe must survive insertion into a muscle compartment without shattering
- The probe casing must not degrade or otherwise allow any leakage into the muscle compartment during insertion and monitoring
- The main analyzer/probe interface must be able to survive falls in the case of an accidental drop
- The main analyzer/probe interface must be able to weather small spills of bodily fluids or chemicals that might occur during an OR situation

f. Ergonomics:
- The handheld probe interface should be shaped in a form that is easy to hold and does not pose any risks of injury from dropping

g. Size:
- The probe must fit through the hole of a 16 gauge needle
- The handheld portion of the device must not exceed a prism of the size 8”x8”x3”

h. Weight:
- The probe must not exceed 2 ounces in weight
- The handheld portion of the device must not weigh more than 16 ounces

i. Materials:
- Semiconductor for the probe
- Metal for the wiring to and within the handheld device
- Hard plastic for the housing of the handheld portion of the device

j. Aesthetics, Appearance, and Finish:

- Skin safe coating and material for use inside the body (muscle compartment)
- The device should be intuitive and simple to understand and operate
- The coating of the handheld portion of the device should have a rough texture to allow for better grip in time-sensitive situations

2. Production Characteristics

a. Quantity: 1 (prototype)

b. The budget is dependent upon grants received by the client with minimum immediately available funds exceeding $1,000

3. Miscellaneous

a. Standards and Specifications:

- The size of the needle is limited to a 16-Gauge needle to align with standards for use in trauma patients.

b. Customer:

- Customers (practicing trauma doctors) would desire a pH sensor that is placed inside a 16-gauge needle, which can read the real-time pH inside the muscle compartment of a patient who is at risk for compartment syndrome.

c. Patient-related concerns:

- The device must have a detachable and replaceable needle/sensor. The display and electronics casing should be sterilizable with an alcohol.
- Material of the device doesn't cause an inflammatory response, which could further increase pressure in the limb.

d. Competition:

- The Valkyrie by Odin Technologies uses Near-infrared spectroscopy to estimate the blood oxygenation. This device has a benefit of being completely non-invasive, but this technology has been around for decades without success in accurately diagnosing compartment syndrome.
- Patent (US7381186B2) by NASA is a system which uses the reflections of ultrasonic waves emitted into the compartment to estimate compartmental pressure.