Non-Invasive Hand-Held Brain Edema Monitoring System

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Patient Population and Clinical Need
- US: 1.7 million people incur traumatic brain injury (TBI) and 800,000 suffer a stroke
- Common effects of TBI and stroke:
  - brain edema
  - intracranial hematomas
- Raised intracranial pressure (ICP), main cause of death and disability
- Early detection and monitoring of brain edema may help in:
  - timely identification of patients in need of surgery
  - improve the outcomes of the surgery,
  - improve ability to monitor and care for patients
  - reduce cost of care

Envisioned Health Care Product
- A near infrared (NIR) based mobile imaging device to detect and continuously monitor brain edema at the site of injury and in the hospital
  - Light within the near infrared range can penetrate the tissue and water and blood content can be extracted
  - NIR can provide changes in water content earlier than ICP
  - Measure changes in water and blood content within the brain
    - Edema detection: an adjunct to CT scan
    - Edema monitoring: noninvasive, safe, reliable, portable, easy to use and affordable solution as compared to ICP monitoring

Current Methods
- Edema Detection: CT scan
  - Expensive, radiation exposure, availability
- Edema Monitoring: ICP Monitoring
  - Invasive

There is a need for a reliable, portable and affordable device for the early detection and continuous, follow-up monitoring of brain edema noninvasively

Objective and Milestones
To achieve a clinical proof of concept in humans of a NIR based mobile imaging device to detect and continuously monitor brain edema

<table>
<thead>
<tr>
<th>Milestone #</th>
<th>Description of milestone</th>
<th>Timeline in Quarters (Q)</th>
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<tr>
<td>1</td>
<td>ISS submission &amp; approval</td>
<td>Q1, Q2, Q3, Q4</td>
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<td>2</td>
<td>Develop and evaluate split probe brain edema monitor on laboratory phantoms</td>
<td>Q1, Q2, Q3, Q4</td>
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<td>3</td>
<td>Perform human testing with simultaneous recordings from other monitors, i.e., ICP, CPP, brain oxygen and GCS. Compare to CT assessment of edema</td>
<td>Q1, Q2, Q3, Q4</td>
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<td>4</td>
<td>Data analysis and performance evaluation of the proposed device through human tests</td>
<td>Q1, Q2, Q3, Q4</td>
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