

**Lead ChristianaCare Inventor**

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**The Invention**

The Risk Detection and Intervention Device to Prevent Sudden Death (SUDEP) and Sudden Unexplained Infant Death (SUID) uses software combined with a computing device capable of receiving or collecting accelerometer data and vitals.

The device is incorporated into a headgear and alerts a caregiver via mobile phone, or any appropriate network connected device, if the patient's head and body position puts them at risk for sudden death during sleep. It also is configured to provide a direct stimulus (electrical shock / alarm) to the patient that may help a patient to rouse himself.

Further, use of headgear allows for more than just detecting the face-down / prone position. For example, this device may include a smoke detector to alert of a fire condition.

**Unmet Need**

Sudden Unexpected Death in Epilepsy (SUDEP) and Sudden Unexplained Infant Death (SUID) are two causes of sudden death in large populations - and many cases are thought to be preventable with timely intervention by a caregiver.

SUDEP is the leading cause of mortality for people suffering from epilepsy. There are 3.5 million people living in the U.S. with epilepsy and an additional 6 million epileptic patients in Europe. Approximately 70% of victims of SUDEP are found lying in a prone position with a downward head position.

There are approximately 5 million infants born in the United States each year. While only a small number of infants are at risk for SIDS, the American Academy of Pediatrics and the CDC encourage all parents to use techniques to prevent SIDS. Currently the program is called "Safe Sleep Campaign".

There is a need for a device that can alert caregivers if a patient is sleeping in a position that puts them at risk for SUDEP or SUID, two conditions in which people can smother themselves and die if they are unconscious laying in a prone position with their head facing down.

**Opportunity**

There is a sizable market for SUDEP detection and intervention invention and it offers key advantages over its competitors. To date, the FDA has not cleared or approved a baby product to prevent or reduce the risk of SUID<sup>12</sup>.

Nonetheless there are several current consumer electronics devices for SUID / SUDEP prevention, some of which sell for ~ \$250-300 per unit.

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<sup>1</sup> JAMA. 2017 Jan 24;317(4):353-354. The Emerging Market of Smartphone-Integrated Infant Physiologic Monitors. Bonafide CP, Jamison DT, Foglia EE.

<sup>2</sup> FDA website, accessed 12/5/2019: <https://www.fda.gov/medical-devices/products-and-medical-procedures/baby-products-sids-prevention-claims>

People with epilepsy potentially needing this device provide a market potential exceeding \$3 Billion USD. Unlike infants, people with epilepsy have a need to use the device for many years or life and thus represent an opportunity for subscription-based pricing models to be effective. Some smart devices for SUDEP charge a single time purchase fee and also an annual subscription fee for the service.

Newborn infants at risk for SUID provide a projected commercial market size of approximately \$1.5 billion USD per year.

Regardless of the implementation, there appears to be a stable and sizeable market for the proposed invention.

#### Unique Attributes

The device is incorporated into a headgear and alerts a caregiver via mobile phone, or any appropriate network connected device, if the patient's head and body position put them at risk for sudden death during sleep. The device also could 1) be configured to give an audio warning signal in addition to the mobile alert to notify caregivers of a risky situation, and 2) monitor changes in heart rate and breathing with little modification, which would further improve its effectiveness at preemptively recognizing SUDEP or SUID.

Unlike other SUID or SUDEP smart detection devices the proposed invention monitors head position and smothering appears to be the proximate cause of death in most of these cases. Current technologies only monitor for a seizure which can precede SUDEP in many cases or for change in vital signs<sup>3</sup>

#### Clinical Applications

This device has numerous clinical applications and could be deployed in any environment that involved sleeping infants such as hospital, home, and day care settings, as well as home and hospital use for adult patients with epilepsy.

#### Stage of Development

Conceptual prototype.

#### Intellectual Property

Provisional patent application filed.

#### Collaboration Opportunity

Actively seeking licensee for commercial development.

#### Institutional Contact

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<sup>3</sup> Seizure. 2016 Oct;41:141-53. Non-EEG seizure detection systems and potential SUDEP prevention: State of the art: Review and update. Van de Vel A, Cuppens K, Bonroy B, Milosevic M, Jansen K, Van Huffel S, Vanrumste B, Cras P, Lagae L, Ceulemans B.