Improving Sleep & Sedation Safety for Patients in the ICU- Simple effective and low cost brainstem function monitor

BrainStemBiometrics
The Brain Eye Monitoring Company

UMASS M2D2 LOWELL • WORCESTER
Advancing Med Device & Biotech Innovations
CAPCaT
Center for Advancing Point of Care Technologies

MAJOR NEED TO IMPROVE SLEEP & SEDATION IN ICU

80% of critical care patients worldwide experience sedation and sleep deprivation. Sleep is less efficient, more fragmented, disrupted, less restorative and lighter than normal. Circadian rhythm is disrupted.

Unnecessarily deep and lengthy sedation has substantial medical and economic consequences such as;

- Increased 180-day mortality (3-5%)
- Costs of managing ICU (prolonged stays, 15% of hospital $)
- Greater long term reliance on healthcare (elderly, payors)

The NEW ENGLAND JOURNAL of MEDICINE

Grimm J. Sleep Deprivation in the Intensive Care Patient. Crit. Care Nurse. 2020 Apr 1;40(2):e16-e24
Shehabi, Yahya et al., Early Sedation with Dexmedetomidine in Critically Ill Patients, 2019/05/19, New England Journal of Medicine, P 2506-2517, 380, N 26, 10.1056/NEJMoa190471, 31112380, https://www.nejm.org/doi/full/10.1056/NEJMoa1904710

"It's a lot easier to manage what you can measure- 80% of the time we give sedatives and disrupt the sleep of our sickest patients in the Intensive Care Unit (ICU). We're looking for a way to measure sleep and sedation at the bedside."

--Dr. Yahya Shehabi MD PhD, MBBS, FANZCA, FJFICM, EMBA, GAICD critical care specialist and anesthetist

- Drug response varies in elderly co-morbid populations
- Combinatorial effect of polypharmacy on sleep and sedation is difficult to estimate (sedatives, analgesics, paralyzing agents, hypnotics and antipsychotic drugs, etc.)

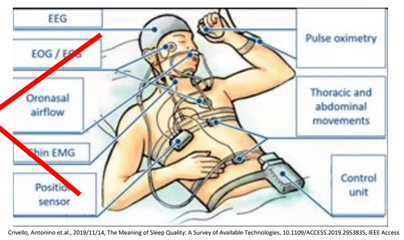
LABORATORY SLEEP TOOLS (PSG) NOT FOR ROUTINE ICU USE

Clinical standards of brain and sleep monitoring are expensive, cumbersome, require specialists to administer and perform post-hoc analysis, and are limited to specialty indications. ($500-$3,500 / test)

Electroencephalography (EEG)

https://consultqd.clevelandclinic.org/new-onset-seizures-during-hospitalization-making-the-case-for-a-follow-up-clinic/

Laboratory Polysomnography (PSG)



Crivello, Antonino et al., 2019/11/14, The Meaning of Sleep Quality: A Survey of Available Technologies, 10.1109/ACCESS.2019.2953835, IEEE Access

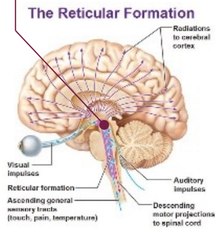
- Subjective physical exams are periodic, vary widely and wake patients and interrupt sleep
- Consumer trackers have not worked with ICU physiology

Chang VA, Owens RL, LaBuzetta JN. Impact of Sleep Deprivation in the Neurological Intensive Care Unit: A Narrative Review. Neurocrit Care. 2020 Apr;32(2):596-608. doi: 10.1007/s12028-019-00795-4. PMID: 31410770; PMCID: PMC7222162.
Beltrami FG, Nguyen XL, Pichereau C, Maury E, Fleury B, Fagondes S. Sleep in the intensive care unit. J Bras Pneumol. 2015 Nov-Dec;41(6):539-46. doi: 10.1590/S1806-37562015000000056. PMID: 26785964; PMCID: PMC4723006.

SOLUTION

Optimize sleep quality and titrate drug levels with a simple low cost and non-invasive brainstem function monitor

- Our technology: directly measure the brainstem, the neurological center for wakefulness, consciousness and circadian rhythm
- Continuous real-time sleep quality and sedation levels displayed on simple bedside monitor



Next generation technology:

Low cost disposable adhesive patch sensor (at left gold color)

Brainstem micro tremor signal (OMT)

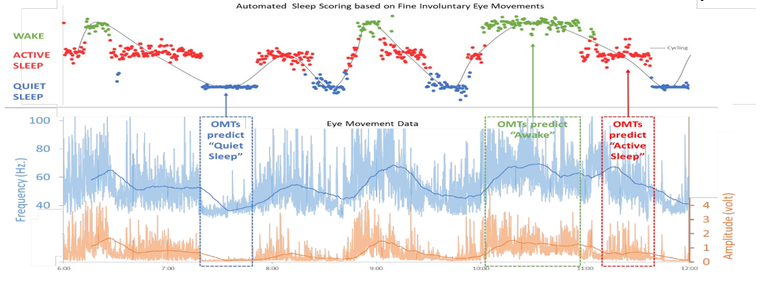
Actionable solution liked by nurses for easy rapid adoption

- Dosing sedatives to brainstem response goals
- Increasing REM ("dream") sleep
- Low cost $50/day, convenient, real-time display

INITIAL CLINICAL VALIDATION

Two clinical studies demonstrate correlation between brainstem signal and level of sedation

Point of care display of sleep level developed in a pilot sample



PROJECT TEAM AND COMPANY

Michael Baltay, MSEng., CEO

Tyler Hartman, MD Neonatal Sleep and Implementation Specialist

Julian Bunn, Ph.D., Principal Computational Scientist

- ☑ *Proven neuroscience*
- ☑ *7 patents, long life*
- ☑ *15 studies, validated*
- ☑ *FDA 510K predicate*
- ☑ *$2.4B ww market*
- ☑ *High margin recurring revenues (kits)*
- ☑ *OEM channel relationships*
- ☑ *NSF SBIR I&II*

NSF

www.brainstembiometrics.com

PROGRAM AND DELIVERABLES

Adaptation and advancement of signal processing and machine learning routines

- Collection of adult sleep records with simultaneous EEG/ PSG and OMT training data
- Adaptation of machine learning routines from neonatal work to adults

Clinical study: **Using Ocular Micro Tremor (OMT) as a Novel Means to Stage Sleep**

Dartmouth Health

- Dartmouth Hitchcock Clinics, Sleep Center
- 20 adult patients undergoing routine in-laboratory PSG
- Simultaneous recording of OMT signal
- 200 stage transitions scored and compared

Commercialization: program work will be used in two larger approved follow-on studies