Background
Newborns exposed to opioids in utero and infants born prematurely require lengthy hospitalization in the Neonatal Intensive Care Unit (NICU) where they are often exposed to loud noises that are potentially harmful to the developing infant:
- Disrupt sleep
- Impair autonomic function
- Prolong recovery
- Compromise outcomes

Purpose
Pilot study to evaluate “Neurosensorv, Environmental, Adaptive Technology” – NEATCAP Device.

Hypothesis: NEATCAP Device, a circumaural hearing protection device that dampens unsafe NICU noise, improves sleep and cardio-respiratory function in critically-ill infants treated in the NICU.

Primary Outcomes:
- Increase sleep duration
- Improve sleep quality
- Reduce cardio-respiratory events

Study Design
UMMS IRB Docket H00015487

Subjects
- 5 premature infants (<37 wks GA); studied at 32 and 36 wks PCA
- 5 opioid exposed full-term newborns

Methods
- Single-session bedside study UMMH NICU
- Within-subject design, convenience sample
- Full polysomnography recordings
- Compare physiology: NEATCAP Device ON vs OFF
- Wake vs Sleep States (Active, Quiet, Indeterminate)
- Cardio-respiratory (bradycardia, tachycardia; apnea, tachypnea)
- Thermoregulation
- Blood-oxygen saturation
- Movement –index of irritability
- Volume of feeds

NEATCAP Device – DREAMIES™ (NEATCap Medical, LLC)

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Intellectual Property
2 patents filed by NEATCap, LLC
- 2015 US Pat. Appl. 14/625, 325
- 2018 US Pat. Appl. 15/881, 111

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