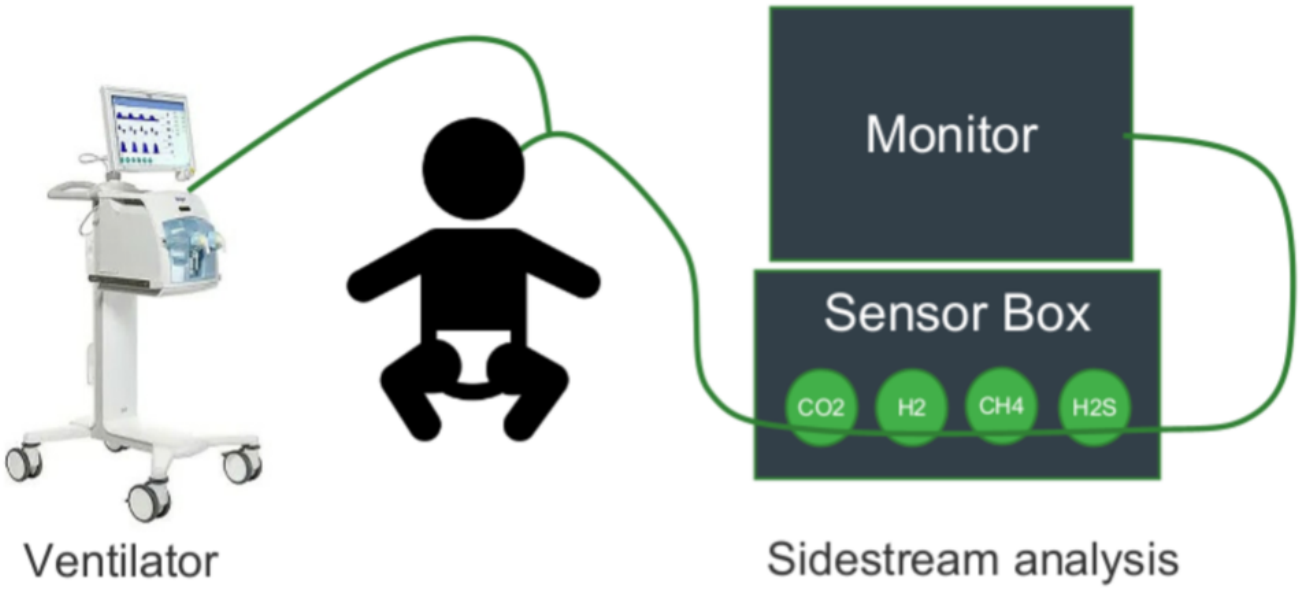
Docket #: S22-096

Disease Breathalyzer

Stanford BIODESIGN researchers have developed a disease breathalyzer for detecting necrotizing enterocolitis in newborns. Newborn babies face a high risk of blood infections (sepsis) and gastrointestinal inflammation and injury disease (necrotizing enterocolitis 'NEC'). NEC affects 1 of 1000 premature infants with mortality rates up to 50%. Currently there is no early detection method available. The BIODESGIN NEC breath analyzer will facilitate treatment and save up to ten thousand or more lives each year through early detection. The device may be adapted to detect sepsis, a deadly late-stage infection.

The device consists of four key components - breath collection, gas analysis , data processing algorithm, and a data readout. (See Schematic.) Breath is collected via main stream (sensor embedded in tubing) or side stream (breath carried to sensors in an external box). Electrochemical sensors, infrared spectroscopy, etc. analyzes exhaled CO2, H2, CH4, and H2S gases. The algorithm relates the gas measurements and in future iterations will integrate additional medical data such as gestational age. Bedside patient monitoring will be available on the data readout screen.



Schematic - Neonatal Breath Analyzer
Image courtesy of Stanford BIODESIGN

Stage of Development – Proof of Concept
A clinical study is underway using a decentralized analysis instrument (in lab gas chromatography). The next stage of development will be bedside analysis. BIODESGIN researchers are running a prospective clinical study to confirm the biomarkers, after which they will develop a continuous monitoring prototype. The fully functional prototype will be used for a follow-on study including feasibility for sepsis detection. If feasible, clinical study use will expand to monitoring of inpatient pediatric and adult patients.

Applications

- Bedside **neonatal ICU patient necrotizing enterocolitis disease detection and monitoring**.
- Potentially, inpatient pediatric and adult **sepsis detection**.

Advantages

- **Life-saving, first in class, early detection** of necrotizing enterocolitis - there are currently no detection methods or identified biomarkers for NEC.

Patents

- Published Application: WO2024192428
- Published Application: 20260007328

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