

Foot Pulse Oximeter for Screening Congenital Heart Disease in Newborns [LAB0031/LAB0038]

Background

- Congenital heart disease (CHD) affects **~40,000 newborns in the U.S. annually**, making it the most common and serious type of birth defect.
- Although it is possible to live a symptomless life with CHD, some cases can result in heart valve damage or heart failure if left untreated.
- Early diagnosis is critical for preventing life-threatening symptoms. CHD in newborns can be managed with palliation or surgical repair, which reduces CHD morbidity.
- As such, in 2011, the Department of Health and Human Services mandated the screening of all newborns for critical congenital heart disease (CCHD) using pulse oximetry.
- However, as 4.1 million babies born in the U.S. each year, **current pulse oximetry devices are not suitable for the large volume of newborn screenings** because they are slow, inaccurate due to artifact motion and ambient light, and costly (~\$18 per single-use sensor).
- There is an urgent need for a reliable, easy-to-use pulse oximeter designed specifically for newborns.

Innovation

- Dr. Ruey-Kang Chang has developed a **foot pulse oximeter specifically designed for screening CHD in newborns**.
- Conventional pulse oximeters employ single-use, clip-type sensors that are too big for newborns and require attachment with adhesives or Velcro, which adds to screening time and may result in inaccurate readings.
- Dr. Chang's pulse oximeter is designed with a small, hollow chamber that fits a newborn's entire foot.
- Use of a chamber in place of multiple wires and sensors that must be attached to a newborn's foot is ideal for quick testing of a large volume of infants.
- A disposable lining can be used with the device to reduce potential transmission of infection between uses.
- The front of the chamber has a screen that displays arterial oxygen saturation of hemoglobin (SpO₂), heart rate, and arterial waveforms.
- The device is user-friendly and is programmed to show a simple pass/fail indication for CHD based on SpO₂ levels.
- The chamber makes Dr. Chang's pulse oximeter highly cost effective by eliminating the need for disposable sensors.

Advantage

- Designed specifically for newborns
- Simple and reliable results
- Small and portable
- Cost-effective



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Applications

- Quickly and reliably screen for CHD in newborns
- Comply with the Department of Health and Human Services mandate for screening of CCHD in newborns

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IP Status

- U.S. Patent No. 9,763,606 issued September 19, 2017
- U.S. Patent No. 9,877,671 issued January 30, 2018
- U.S. Patent No. 10,653,348 issued May 19, 2020
- U.S. Patent No. 10,987,034 issued April 27, 2021