Eve™ Newborn Screening Application*

Combining Clinically Proven Masimo SET® Pulse Oximetry with Device-Guided Instruction to Help Clinicians More Effectively Screen for Critical Congenital Heart Disease (CCHD)

Clinically Proven Masimo SET® Pulse Oximetry

- In 2011, an expert workgroup recommended newborn screening with Measure-through Motion and Low Perfusion™ Pulse Oximetry to increase the detection of CCHD.[1]
- The CCHD workgroup cited the results of two large and independent prospective studies of 59,876 subjects that exclusively used Masimo SET® Measure-through Motion and Low Perfusion Pulse Oximetry[2,3] to increase the identification of CCHD with minimal false positives.
  - The Masimo YI infant sensor exclusively used in these two studies has an accuracy specification** of ±2% in infants and ±3% in neonates.
  - All Masimo SET® pulse oximeters and infant/neonatal sensors meet the CCHD workgroup criteria for newborn screening.
- In 2014, a third large study of 122, 738 newborns that also exclusively used Masimo SET® pulse oximetry showed similar, positive results as the first two large studies.[4]

Device-Guided Instruction to Help Clinicians More Effectively Screen for CCHD

- Newborn screening protocols may sometimes present challenges, among them; longer-than-necessary monitoring times, misapplication of sensors, calculation errors, and confusion interpreting results.
- The Eve Newborn Screening Software Application* in the Radical-7® Pulse CO-Oximeter automates each of the screening steps with animated instruction, including sensor application, measurement selection, and screening result determination.
- Institutions can also choose to add the Perfusion Index (PI) measurement available in all Masimo SET® pulse oximeters to the screening criteria, which has been shown to help identify CCHD or other illnesses not identified by physical exam or by SpO_2 measurements alone.[5]
- Use of the Eve Newborn Screening Software Application* is intended to:
  - Provide consistent application of the screening protocol to reduce method and operator-induced variability
  - Improve efficiency by automating the data capture and comparison between readings

Pre-ductal Application

Post-ductal Application

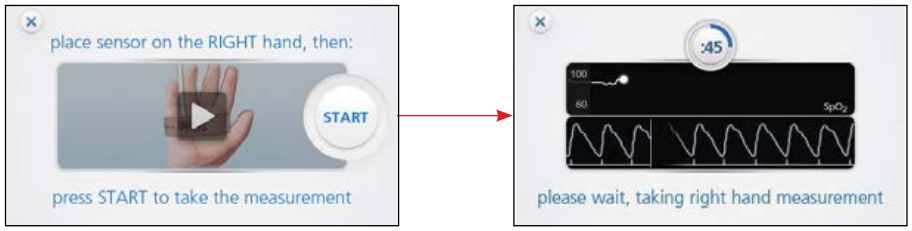
** Referred to as "CCHD Mode" in Radical-7*

*** In no-motion condition*

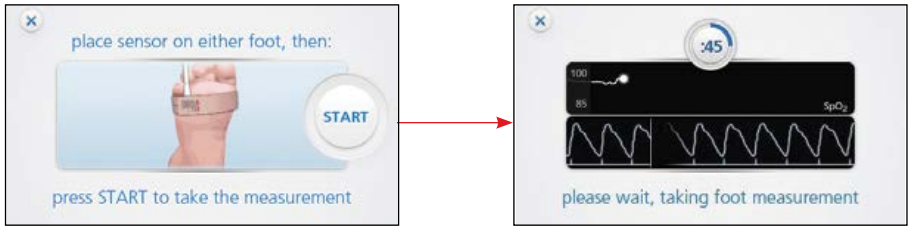
STEP-BY-STEP INSTRUCTION ENABLES CONSISTENCY, ACCURACY, AND EFFICIENCY

Eve screenshots on Radical-7

STEP 1: Sensor Placement on Right Hand



STEP 2: Sensor Placement on Either Foot



STEP 3: Two Possible Screening Results***

CUSTOMISATION

The screening protocol recommended by the CCHD workgroup is the default setting but can be customised to align with institution policy.

"Failing to follow and interpret a proper screening protocol, as well as being able to read measurements in newborns who are often in motion and have low perfusion are factors that can make CCHD screening with pulse oximetry a challenge. The data and study evidence show that having the right pulse oximetry technology for CCHD screening is critical - and it's very exciting to see the introduction of new tools that offer nurses a clearer, safer, more efficient way to conduct newborns screening and protect newborn lives."

Annamarie Saarinen, Co-Founder and CEO of the Newborn Foundation, and the mother of Eve, who was diagnosed at 48 hours old with CCHD

[1] Kemper, et al. *Pediatrics*. 2011. [2] de-Wahl Granelli A., et al. *BMJ*. 2009 Jan 8;338. [3] Ewer AK et al. *Lancet*. 2011 Aug 27;378(9793):785-94. [4] Zhao Q-m et al. *The Lancet*, Early Online Publication, 23 April 2014. doi:10.1016/ S0140-6736(14)60198-7. [5] de-Wahl Granelli A et al. *Acta Paediatr*. 2007 Oct;96(10):1455-9.

*** *CCHD screening result is based on the protocol recommended by Kemper et al., Pediatrics, 2011. The screening result is not a definitive assessment of the patient's CCHD condition. The result should be evaluated in conjunction with the patient's clinical status and confirmed with additional diagnostic tests consistent with each hospital's policy.*

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Regulatory Notice: Eve Newborn Screening Application* is CE Mark and not currently available for sale in the United States.

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