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FDA clears first MRI device for neonates

by from the Food and Drug Administration Center for Devices and Radiological Health, Office of Pediatric Therapeutics and Division of Pediatrics and Maternal Health

On Thursday, the Food and Drug Administration cleared the first MRI device specifically intended for use in neonatal intensive care units (NICUs). The Embrace Neonate MRI System is a 1.0 Tesla permanent magnet MRI designed specifically for imaging of the neonatal head in patients with a head circumference up to 38 centimeters (cm) and body weight between 1 and 4.5 kilograms (kg).

The Embrace system can be placed inside a NICU environment due to the system's fully-enclosed design that requires neither a safety zone nor a radiofrequency shielded room. The potential to place this system in the NICU helps to reduce the amount of travel required for a head MRI, which potentially expands access to safe imaging for both preterm infants and other patients who would not be considered stable enough to be transported out of the NICU.

The system is designed so that the patient bed is a temperature-controlled infant incubator, which is placed directly into the MRI scanner, minimizing movement of the baby and reducing the risk for hypothermia. In the event of a medical emergency, neonates can be removed from the MRI system in under 30 seconds. Use in neonates heavier than 4.5 kg or with a head circumference greater than 38 cm as well as infants with metallic or electronic implants is contraindicated.

To avoid putting vulnerable patients at risk, the efficacy of the Embrace system was demonstrated primarily based on nonclinical testing, including images of phantoms simulating an infant brain that were determined to be of sufficient quality for diagnostic use by an independent board-certified radiologist.

Resources

- FDA news release
- MRI benefits and risks
- FDA information on MRI