

# FDA approves first neonatal MRI device

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(HealthDay)—The first magnetic resonance imaging (MRI) device designed specifically for neonatal brain and head imaging in intensive care units has been approved by the U.S. Food and Drug Administration.

The Embrace Neonatal MRI System device is designed expressly for taking images of the neonatal head. The system includes a temperature-controlled incubator placed directly into the MRI system, the FDA said.

To avoid putting vulnerable infants at risk, the device was tested using simulated infant brains, the agency added. The device shouldn't be used on infants weighing more than 4.5 kilograms (about 9.9 pounds) or with a head circumference of more than 38 centimeters (about 15 inches).

"Although we can use traditional MRI scanners to image neonates, taking babies outside of the neonatal [intensive care unit](#) to MRI suites presents great challenges," Vasum Peiris, M.D., M.P.H., chief medical officer of pediatrics and special populations at the FDA's Center for Devices and Radiological Health, said in a statement. "Having a system in the [neonatal intensive care](#) unit enables safer imaging for this vulnerable patient population."

Approval for the device was granted to the Israeli firm Aspect Imaging.

**More information:** [More Information](#)

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