Medtronic News

Medtronic INVOS™ 7100 Cerebral/Somatic Oximetry System receives 510(k) clearance for pediatric indications

FDA clearance expands use of the INVOS™ 7100 system, helping clinicians better monitor organ-specific oxygen levels and identify warnings signs for neonates and children earlier

DUBLIN, Dec. 14, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for its INVOS™ 7100 cerebral/somatic oximetry system for children from birth through age 18. The INVOS system picks up key signals to inform time-critical decisions by pediatric clinicians related to hemodynamic management, ventilation, and resuscitation for premature infants, neonates, children, and other patients treated by pediatric clinicians.

"Timing is critical for vulnerable pediatric patients, and the INVOS™ 7100 system can alert clinicians to changes in patient condition before traditional monitored parameters even react,"[1, 2] said Frank Chan, president of the Patient Monitoring business, which is part of the Medical Surgical Portfolio at Medtronic. "The INVOS™ 7100 system can help clinicians decide if intervention is necessary — a core component in successful outcomes. And our technology consistently enables users to determine if they need to intervene sooner."[1-6]

The INVOS™ near-infrared spectroscopy monitoring system has been previously cleared for use in adult patients and is the clinical reference standard for regional oximetry.[7] The real-time measures of tissue perfusion and oxygenation provided by the INVOS™ 7100 system provide early alerts to changes in perfusion before other vital sign measurements.[1, 2] This data may indicate to clinicians that a patient is becoming critical — providing them the crucial time needed to treat newborns and young patients.

"There are so many time-critical conditions clinicians face when treating some of our youngest patients in intensive care units, from RSV to complex heart conditions and beyond. We see this as an opportunity to equip providers with technology that can help improve outcomes among the most vulnerable populations," said Sam Ajizian, MD, FAAP, FCCM, CPPS, and chief medical officer of the Patient Monitoring business at Medtronic. "We are thrilled that the INVOS™ 7100 system has been cleared for pediatric indications."

The technology inside the INVOS™ 7100 system delivers first-alert performance with its unique algorithms that measure acute alterations in hemodynamics, regional oxygen saturation, and oxygen metabolism.[1, 2] The system provides continuous, noninvasive readings of organ-specific regional blood oxygen levels in up to four site specific areas chosen by the care team and oxygen saturation from vascular beds to assess organs individually, or in combination to track brain/body perfusion shifts.

The INVOS™ 7100 system with the pediatric indications will be available worldwide for commercial use in spring 2022.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies

treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

The INVOS™ monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

1. Lu Y, Di M, Li C, Chen M, Yuan K, Shangguan W. Comparing the response of pulse oximetry and regional cerebral oxygen saturation to hypoxia in preschool children. *Exp Ther Med*. Jan 2020;19(1):353-358. doi:10.3892/etm.2019.8199
2. Tobias JD. Cerebral oximetry monitoring with near infrared spectroscopy detects alterations in oxygenation before pulse oximetry. *J Intensive Care Med*. Nov-Dec 2008;23(6):384-8. doi:10.1177/0885066608324380
3. Alderliesten T, Lemmers PM, van Haastert IC, et al. Hypotension in preterm neonates: low blood pressure alone does not affect neurodevelopmental outcome. *J Pediatr*. May 2014;164(5):986-91. doi:10.1016/j.jpeds.2013.12.042
4. Bonestroo HJ, Lemmers PM, Baerts W, van Bel F. Effect of antihypotensive treatment on cerebral oxygenation of preterm infants without PDA. *Pediatrics*. Dec 2011;128(6):e1502-10. doi:10.1542/peds.2010-3791
5. Chock VY, Kwon SH, Ambalavanan N, et al. Cerebral Oxygenation and Autoregulation in Preterm Infants (Early NIRS Study). *J Pediatr*. Dec 2020;227:94-100.e1. doi:10.1016/j.jpeds.2020.08.036
6. Pichler G, Urlesberger B, Baik N, et al. Cerebral Oxygen Saturation to Guide Oxygen Delivery in Preterm Neonates for the Immediate Transition after Birth: A 2-Center Randomized Controlled Pilot Feasibility Trial. *J Pediatr*. Mar 2016;170:73-8.e1-4. doi:10.1016/j.jpeds.2015.11.053
7. Yu Y, Zhang K, Zhang L, Zong H, Meng L, Han R. Cerebral near-infrared spectroscopy (NIRS) for perioperative monitoring of brain oxygenation in children and adults. *Cochrane Database Syst Rev*. Jan 17 2018;1(1):Cd010947. doi:10.1002/14651858.CD010947.pub2

Contacts:

Ellen Lupfer	Ryan Weispfenning
Public Relations	Investor Relations
+1-508-212-9845	+1- 763-505-4626

SOURCE Medtronic plc

Additional assets available online: Photos (3)

https://news.medtronic.com/2021-12-14-Medtronic-INVOS-TM-7100-Cerebral-Somatic-Oximetry-System-receives-510-k-clearance-for-pediatric-indications