



Novii+ Wireless Maternal and Fetal Monitoring Solution Cleared by the FDA for Monitoring Approximately 95% of All Eligible Births in the United States¹

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- GE HealthCare receives FDA clearance for expanded indication for Novii+ maternal and fetal monitoring solution for pregnant patients ≥ 34 weeks.
- Novii+ noninvasively measures and displays fetal heart rate, maternal heart rate and uterine activity, while providing patient comfort and mobility in the hospital.

CHICAGO--(BUSINESS WIRE)--Feb. 1, 2024-- GE HealthCare (Nasdaq: GEHC) today announced it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for NoviiTM+ Wireless Patch Solution. The antepartum and intrapartum maternal and fetal monitor noninvasively measures and displays fetal heart rate, maternal heart rate and uterine activity, so care teams can have a real-time view of patient data. Through its belt-free and wireless design, Novii+ enables mobility and freedom for mothers to support the laboring experience. Additionally, studies have shown upright positions and walking may help decrease the length of labor.²

"Novii+ allows moms to move around and stay active during labor while providing reliable monitoring for their care teams," said Lisa Allen, BSN, RN, senior clinical development specialist, maternal infant care, GE HealthCare. "This freedom of movement can help moms have a more comfortable labor experience."

Novii+ is an expanded indication from the Novii Maternal and Fetal Monitoring Solution that utilizes an updated algorithm (Cross Check artifact reduction) to improve reliability and accuracy. Novii+ can be used for both antepartum and intrapartum pregnant patients 34 weeks and greater, which extends usage before the previously defined use of 37 weeks and greater of pregnancy. The expanded indication is based on data submitted to the FDA to determine Novii+ Wireless Patch Solution's equivalence to doppler fetal heart rate, tocodynamometer uterine activity and pulse oximetry maternal heart rate devices for preterm patients (≥ 34 weeks) in terms of accuracy and reliability. In the United States, Novii+ is a first-of-its-kind patch-based antepartum and intrapartum monitoring solution for preterm patients (≥ 34 weeks).

Monitoring is crucial to check on health status for both pregnant patients and their fetuses particularly for preterm and high-risk pregnancies.³ Novii+ provides a personalized view of the mother and fetus' statuses, and alerts care teams for changes to heart rate and contraction pattern during labor, so they can proactively intervene.

"One in ten newborns in the United States is born prematurely, a rate that has not changed significantly in over 60 years.⁴ At the same time, maternal morbidity and mortality have increased, especially for women of color,"⁵ said Kurt R. Wharton, MD, FACOG, a professor and obstetrician-gynecologist.¹ "New technologies and approaches are crucially needed to improve maternal and newborn outcomes. With the expanded indication for Novii+, care teams can now use the fetal and maternal monitoring solution for a larger number of patients faced with high-risk pregnancies," adds Wharton.

¹ Dr. Kurt R. Wharton is a paid consultant for GE HealthCare. The statements by Dr. Wharton described here are based on his own opinions and on results that were achieved in his unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Intrapartum monitoring provides care teams with the data needed to care for their patients confidently and efficiently.³ Nearly all respondents (97%) of GE HealthCare's [The State of Flexible Healthcare Delivery](#) survey reported visual dashboards for monitoring patient status is moderately or critically important. By connecting to other monitors in the hospital, Novii+ allows data to flow seamlessly to existing surveillance and archival systems. The Novii+ Wireless Patch Solution will be available to customers in the United States later this year.

GE HealthCare designs solutions to meet the needs of providers, families, and patients to support care that can help send moms and babies home healthy. For more information on our fetal and maternal monitoring solutions, please visit: <https://www.gehealthcare.com/products/maternal-infant-care/fetal-monitors>

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GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from prevention and screening, to diagnosis, treatment, therapy, and monitoring. We are an \$18 billion business with 50,000 employees working to create a world where healthcare has no limits.

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¹Nativity, 2016-2022 expanded Request. Centers for Disease Control and Prevention. Group By: Plurality; OE Gestational Age Weekly. Accessed January 31, 2024.

<https://wonder.cdc.gov/nativity-expanded-current.html>

²Lawrence A, Lewis L, Hofmeyr GJ, Dowswell T, Styles C. Maternal positions and mobility during first stage labour. Cochrane Database Syst Rev. 2009 Apr 15 ; (2) : CD003934

³Ayres-de-Campos, D., Spong, C.Y., Chandrachan, E. and (2015), FIGO consensus guidelines on intrapartum fetal monitoring: Cardiotocography. International Journal of Gynecology & Obstetrics, 131: 13-24. <https://doi.org/10.1016/j.ijgo.2015.06.020>

⁴Preterm birth. Centers for Disease Control and Prevention. October 24, 2023. Accessed December 29, 2023. <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm>

⁵Hoyert D. Maternal Mortality Rates in the United States, 2021. www.cdc.gov. Published March 16, 2023. <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm>

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GE HealthCare Media Contact:

Jennifer Purdue

M +1 267 593 9735

jennifer.purdue@gehealthcare.com

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