✦ DELIVERY DATE AI· FDA DE NOVO GRANTED · DEN250007

Supporting consistent delivery timing assessment across the maternity service line.

Delivery Date AI™ is an FDA De Novo Granted adjunctive decision-support tool that analyzes routine ultrasound images to generate a **Predicted Delivery Date** (PDD) for singleton pregnancies without a reliable estimated delivery date[1]. Designed to support more consistent delivery timing assessment across the maternity service line.

01 WHY DELIVERY TIMING CONSISTENCY MATTERS

10.4%

of U.S. births were preterm in 2024 — the primary population where delivery timing certainty matters most

March of Dimes PeriStats, 2024

58%

reduction in prediction error vs. Hadlock in the FDA pivotal study (N=247, GA 14-36 wks)

UAI Clinical Validation Study, 2026

25.3%

NTSV cesarean national average (2024) vs. Healthy People 2030 target of 23.6% — a quality benchmark linked to delivery timing consistency

Leapfrog Group Maternity Care Report, 2025

02 MATERNITY PROGRAMS INCREASINGLY DEPEND ON DELIVERY TIMING CONSISTENCY

Health systems are increasingly evaluated on maternity quality performance, operational consistency, and standardized documentation across providers and sites. In pregnancies without a reliable estimated delivery date, delivery timing uncertainty can complicate surveillance planning, eligibility review, retrospective documentation, and care coordination.

WHERE TIMING CONSISTENCY AFFECTS MATERNITY OPERATIONS

Maternity quality reporting

Standardized delivery timing documentation supports more **consistent** eligibility classification, retrospective quality review, and maternity reporting workflows across providers and sites.

CMS maternity measures, Joint Commission perinatal metrics, and NTSV benchmarking all depend on consistent documentation practices.

Provider and site variability

Variation in delivery timing assessment across clinicians and locations contributes to inconsistent surveillance planning and documentation review. **Standardized inputs support more consistent workflows across employed groups and sites.**

Enterprise maternity operations

More consistent delivery timing assessment may support cleaner care coordination, documentation alignment, and operational predictability across maternity service lines and network locations.

More consistent delivery timing assessment supports standardized documentation, cleaner retrospective review, and more aligned care coordination across the maternity service line.

03 WHERE DELIVERY TIMING UNCERTAINTY AFFECTS MATERNITY OPERATIONS

Documentation and eligibility consistency

Delivery timing uncertainty affects NTSV/LRCD eligibility classification, PC-01 elective documentation, surveillance timing, and cesarean threshold assessment. In later-presenting pregnancies, conventional methods become less dependable, increasing variability across providers and care settings.

Downstream maternity resource utilization

Prematurity and delivery timing uncertainty are associated with substantial downstream maternity and neonatal resource utilization. More consistent delivery timing assessment may support clearer care coordination and retrospective review across the maternity service line.[2]

Operational integration

No new hardware. No protocol changes. No additional patient visits. Delivery Date AI integrates into existing obstetric ultrasound workflow via secure DICOM cloud processing. Compatible with most ultrasound systems. Structured PDD output returns alongside standard study reporting.

Staffing & operational planning

Variability in delivery timing assessment across providers may contribute to inconsistent scheduling patterns, escalation timing, and care coordination. Standardized Predicted Delivery Date outputs may support more aligned maternity workflows across employed groups and sites.[3]

04 DELIVERY DATE AI — PRODUCT OVERVIEW & INTEGRATION

No new hardware · Compatible with most standard ultrasound systems · HIPAA-compliant · SSL/TLS encrypted · 2FA supported

Consistent output across your service line

Returns a structured Predicted Delivery Date alongside standard study reporting — consistent across every provider, group, and site. Role-based access supports institutional oversight and user management.

No disruption to existing workflow

No new equipment. No protocol changes. No additional patient visits. DICOM files transfer directly from existing equipment or PACS into a secure cloud platform.

Meets institutional security requirements

HIPAA-compliant. Encrypted data transmission. Two-factor authentication supported. Full technical specifications available on request.

05 CLINICAL FOUNDATION

SOURCE	PERFORMANCE & POPULATION DETAIL
FDA De Novo Pivotal (N=247)[1]	Suboptimally dated singletons, GA 14 0/7–36 6/7 wks. AI MAE 15.22d (95% CI 13.67–16.77) vs. Hadlock 36.41d (CI 32.88–39.94), p<0.001 — 21.19-day improvement, 58% error reduction. Vendor: GE 90.5%, Philips small N.
PAIR Study (N=5,714)[4]	Patel et al., J Matern Fetal Neonatal Med 2025;38(1):2532099. 19,940 exams, up to 2,042,759 images. R^2=0.92 all births; term R^2=0.95 (V4); MAE 12.90d all / 10.76d term. Single-institution academic medical center.
Important distinction	PAIR validates the underlying AI across all pregnancies. The FDA De Novo Granted device (N=247) is specifically validated for suboptimally dated singletons.

U.S. regulatory note (DEN250007): Delivery Date AI™ is FDA De Novo Granted as an aid to clinical judgment for women 18+ with singleton pregnancies at 14 0/7–36 6/7 weeks gestation lacking a reliable EDD. Per FDA labeling, the output is not intended to predict or assess the risk of preterm birth. Pipeline modules referenced herein are not FDA-authorized and not for clinical use. Brazil (ANVISA) operates under separate local authorization; Chile is R&D only — no ISP registration.
[1] **FDA Pivotal (N=247):** Suboptimally dated singletons only; do not generalize. Vendor: GE 90.5% of cohort; Philips N=24 (wider CI). [2] **Association, not causation.** Industry statistics are peer-reviewed associations between delivery timing and outcomes — not causal claims for Delivery Date AI. [3] **Staffing framing is directional** — institutional FTE impact data is emerging. [4] **PAIR Study:** Patel N, O'Brien J, Bunn R, Schanbacher B, Bauer J, Lam GK.J Matern Fetal Neonatal Med. 2025;38(1):2532099. Single-institution academic medical center; generalizability not established. Dr. Lam has stock interest in Ultrasound AI; Robert Bunn is President & Founder.