Delivery Date AI™

Ultrasound AI

Stronger delivery date prediction. Validated in peer-reviewed research.

Delivery timing shapes nearly every consequential decision in obstetric care, from antenatal surveillance and steroid timing to induction planning and escalation. Yet many pregnancies present without a reliable estimated delivery date, particularly in women who present later in gestation, have had limited prenatal care, or where early dating was not performed. For these cases, **Delivery Date AI™** analyzes routine ultrasound images to generate a **Predicted Delivery Date**, providing an additional image-based data point to support clinical judgment.

INDICATIONS FOR USE

Delivery Date AI™ analyzes routine ultrasound images to provide healthcare practitioners with a Predicted Delivery Date (PDD) in women without a reliable estimated delivery date. Indicated for singleton pregnancies from 14 0/7 to 36 6/7 weeks gestation. Intended users: board-certified or board-eligible OB/GYNs and Maternal-Fetal Medicine specialists.

VALIDATED ACROSS TWO INDEPENDENT STUDIES

PAIR Study (peer-reviewed, published)

$R^2 = 0.92$

Overall delivery timing correlation across all births — term and preterm (V4 model)

In the PAIR Study (N=5,714 pregnancies; 19,940 studies), the underlying AI demonstrated strong correlation with delivery timing outcomes across diverse pregnancy presentations. For term births: $R^2 = 0.95$, MAE 10.76 days.

Patel N, O'Brien J, Bunn R, Schanbacher B, Bauer J, Lam GK. *J Matern Fetal Neonatal Med.* 2025;38(1):2532099. *Single-institution study.*

FDA Pivotal Study (De Novo cleared device, N=247)

58% reduction

In prediction error vs. the Hadlock biometric formula

in women without a reliable estimated delivery date

In the FDA pivotal study of suboptimally dated singleton pregnancies (N=247, GA 14–36 weeks):

- AI MAE: 15.22 days (95% CI 13.67–16.77) vs Hadlock MAE: 36.41 days (95% CI 32.88–39.94)
- p<0.001 — exceeding the pre-specified 7-day superiority margin
- 62.8% of AI predictions fell within ±14 days of actual delivery, vs. 25.5% for Hadlock.

CLINICAL INTEGRATION · NO CHANGE TO YOUR SCANNING PROTOCOL

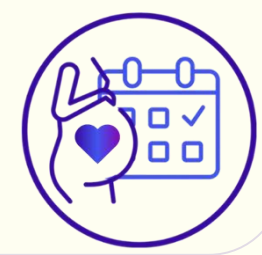
01
Standard ultrasound scan
Routine obstetric imaging. No protocol changes. No new hardware.

→

02
Automated AI analysis
DICOM images are rapidly processed by Delivery Date AI, via secure cloud post-processing.

→

03
Predicted Delivery Date
A structured report is delivered alongside standard study outputs for clinical review.



SUPPLEMENTARY REAL-WORLD DATA

Additional observational findings (not yet peer-reviewed) In a head-to-head observational analysis of 2,350 studies presented at SMFM 2026, Delivery Date AI demonstrated lower prediction error compared with the Hadlock formula across the study population. AI MAE: 11.1 days vs. Hadlock MAE: 15.7 days (p<0.0001). These findings have not undergone peer review and should be interpreted as preliminary.

FDA De Novo

FDA De Novo Granted · DEN250007 · February 11, 2026 · Software as a Medical Device (SaMD), Class II · Product Code SHE · Rx Only · U.S. patents issued and pending · Full clinical evidence and study data on reverse.

Adjunctive use. Delivery Date AI™ is an adjunctive decision-support tool designed for use by board-certified or board-eligible OB/GYNs and MFM specialists. The Predicted Delivery Date should be used as an aid in clinical judgment, distinct from standard methods for assessing gestational age. Not intended for multiple gestations, known fetal anomalies, first trimester (<14 0/7 weeks), term pregnancies (≥37 0/7 weeks), or the prediction/assessment of preterm birth risk. Federal law restricts this device to sale by or on the order of a physician or other licensed healthcare professional.

PAIR Study disclosures: single academic medical center; generalizability to all practice settings has not been established. Dr. Lam has a stock interest in Ultrasound AI; Robert Bunn is President and Founder of Ultrasound AI.

Validated where delivery timing matters most.

14.82d

AI MAE · BMI ≥30 · N=155

62.8% of the pivotal cohort had BMI ≥30 — where Hadlock biometry is most challenged by maternal habitus.

Hadlock MAE, same subgroup: 33.15d. AI 95% CI 12.71–16.93.

11.44d

AI MAE · 28–36 wks · N=117

Third-trimester accuracy — when induction timing, antenatal steroids, and delivery planning decisions are most consequential.

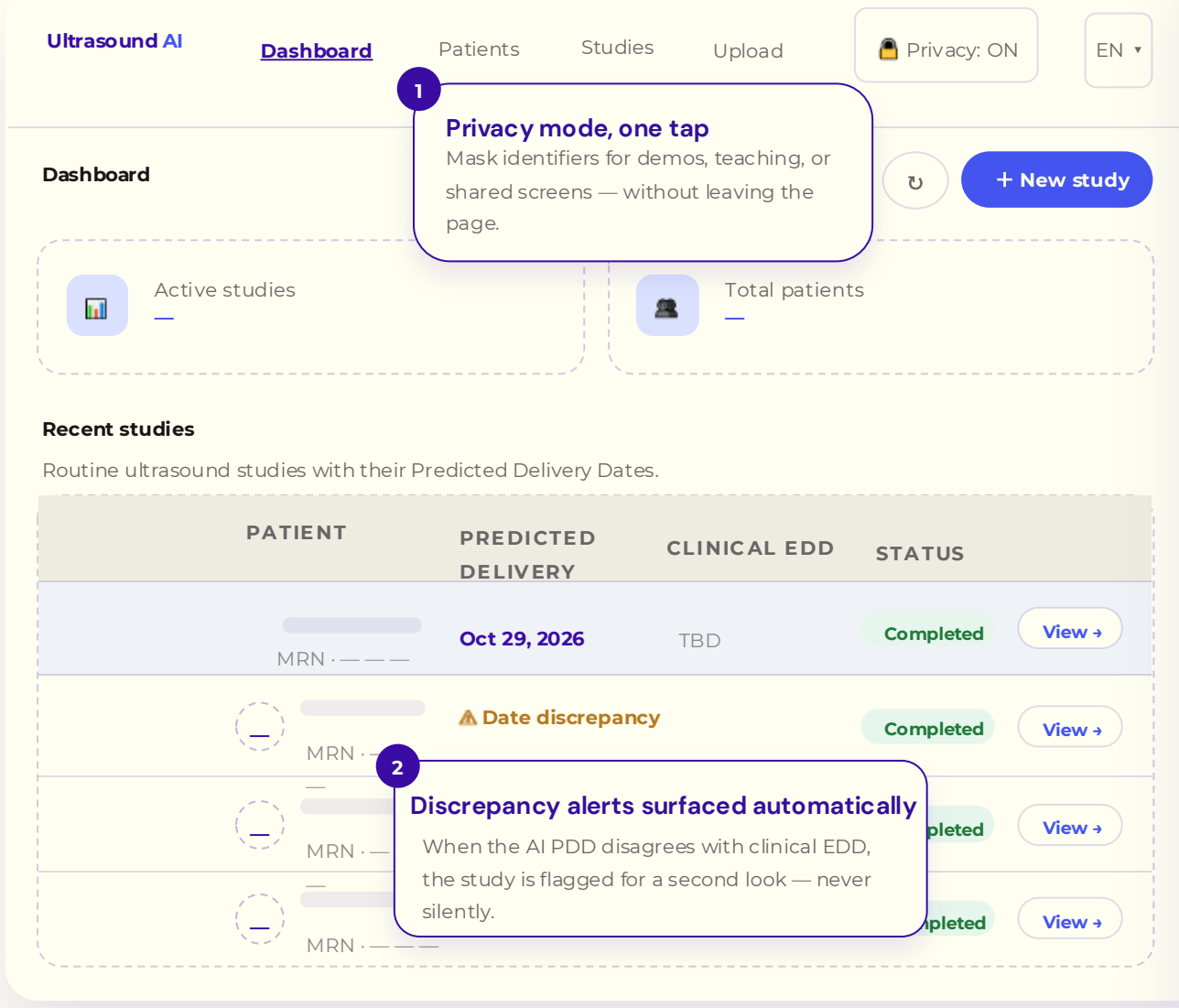
Hadlock MAE, same window: 26.52d.

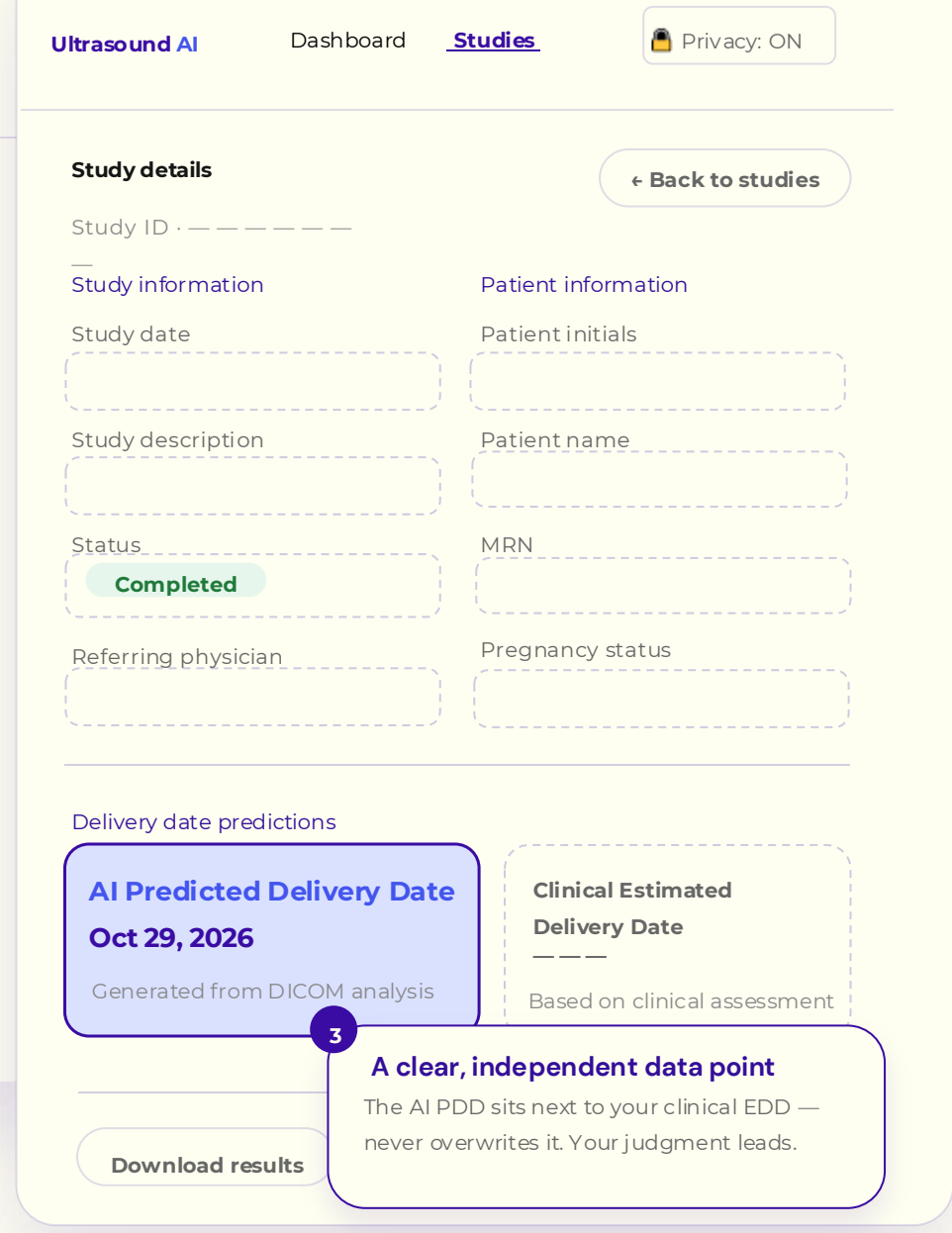
SUBGROUP PERFORMANCE · PIVOTAL STUDY (N=247)

Subgroup	N	AI MAE	HADLOCK
Gestational Age at Scan (weeks)			
28-36	117	**11.44d**	26.52d
20-27	89	**17.02d**	48.31d
14-19	41	**22.22d**	34.10d

Asian and Hispanic populations were under-represented in the validation cohort; results may be less characterized for these groups.

WHAT THE CLINICIAN RECEIVES





Patient study view · AI Predicted Delivery Date alongside the Clinical Estimated Delivery Date. Privacy mode masks identifiers; structured report integrates into standard study outputs.
Illustrative mockup. Final UI, colors, copy, and data presentation are subject to change.

KEY CONSIDERATIONS FOR YOUR PRACTICE

Does this replace my biometry?

No. The PDD is an adjunct to clinical judgment, distinct from standard biometry-based dating.

Will it change my workflow?

No new protocols, no additional views, no extra patient visits.

Who is it for?

Board-certified or board-eligible OB/GYNs and MFM specialists.

How should I use the PDD?

It sits alongside your clinical EDD as an additional data point.

Bring an additional data point to your most uncertain cases.

Start a clinical evaluation at ultrasound.ai or reach us at connect@ultrasound.ai

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Sources: FDA De Novo DEN250007 (Feb 2026). Patel N, et al. PAIR Study. *J Matern Fetal Neonatal Med.* 2025;38(1):2532099. Single-institution study; generalizability to all practice settings has not been established. Dr. Lam has a stock interest in Ultrasound AI; Robert Bunn is President and Founder of Ultrasound AI.