✦ INDUSTRY FIRST · FDA DE NOVO GRANTED · DEN250007

The first FDA De Novo Granted AI that predicts actual delivery timing from routine ultrasound images

Delivery Date AI™ uses routine ultrasound images to predict actual delivery timing — helping clinicians identify pregnancies that may require earlier intervention, surveillance, or delivery planning.
Validated across 5,714 pregnancies with $R^2 = 0.92$ for delivery timing prediction.

01 THE PROBLEM · NO RELIABLE DELIVERY TIMING

Incorrect or uncertain delivery dating can delay interventions, impair fetal surveillance, increase NICU utilization, and contribute to avoidable maternal and neonatal complications. **Delivery Date AI was built to provide an additional Predicted Delivery Date from routine ultrasound.**

10.4%
OF U.S. BIRTHS ARE PRETERM
March of Dimes PeriStats, 2024

$71,158
AVG NICU ADMISSION COST
In employer insured populations
Health Care Cost Institute (HCCI), 2021 data — published 2023

18.07% vs 13.25%
NICU admission rate, poorly dated vs well-dated pregnancies
Not a causal claim for Delivery Date AI.
Source: Reis et al. 2020.

02 THE SOLUTION Delivery Date AI™

FDA De Novo–granted (DEN250007) AI for image-based delivery prediction. Image-only — no extra views, no blood draw, no new hardware.

58%
REDUCTION IN PREDICTION ERROR vs. current methods
(FDA Pivotal Study, N=247)

$R^2 = 0.92$ / 1.0
OVERALL DELIVERY TIMING CORRELATION
(PAIR Study, N=5,714, V4 model)

2026
FDA De Novo GRANTED

6
ISSUED PATENTS ACROSS 3 COUNTRIES

03 HOW IT WORKS · ECONOMICS

01 · SCAN
Standard scan
Routine ultrasound, performed as normal.

02 · UPLOAD
Secure DICOM
Images sent via encrypted cloud transfer.

03 · ANALYZE
Secure image analysis
Runs in seconds, no human handoff.

04 · REPORT
PDD delivered
Structured report alongside study output.

~8.7×

Base-case payer ROI (modeled scenario)
In a modeled 10,000 birth population:
$3M screening spend → ~$23.1M net savings on a 10K-birth population.
Modeled estimate; actual results will vary by population and institution.

04 ABOUT ULTRASOUND AI

FOUNDED	2019
EVIDENCE	PAIR Study · 5,714 pregnancies · R^2 = 0.92[1]
U.S. FDA	De Novo Granted Feb 11, 2026 · DEN250007 · code SHE
MARKETS	U.S. (FDA), Brazil (ANVISA 82499100004) · Chile: R&D only, no ISP registration
IP	6 patents issued across 3 countries (U.S., Israel, Singapore); EU/CN/KR pending
TEAM	R. Bunn (Founder) · M. Davis (CEO) · A. Newhouse (COO/GC) · Dr. R. Dardik (CMO)

05 WHY THIS CATEGORY IS

Proprietary data moat

One of the largest proprietary obstetric ultrasound AI datasets assembled globally. Exceptionally difficult to replicate. Every new clinical scan widens the gap.

FDA De Novo Granted

The first FDA-cleared software category for image-based delivery date prediction. Establishes a regulatory moat competitors must navigate to enter this market.

Platform Vision

AI prediction of future clinical outcomes directly from medical imaging.

06 MARKET OPPORTUNITY · MATERNAL-HEALTH IMAGING

TAM
$8B
Global obstetric AI

SAM
$3–4B
Global addressable markets

2-5-YR SOM
~$1B
Plan target capture

07 2026 INITIATIVES

01
Market land-grab

Direct enterprise sales to top-50 U.S. health systems; target run-rate ARR within 24 months.

02
OEM platform embedding

Integrations with global ultrasound OEMs for scaled distribution.

03
Reimbursement pathway

Health-economic studies with payers to convert 8.7× ROI into reimbursement codes.

04
Future investigational modules (not FDA-authorized)

Future investigational modules may evaluate additional maternal-health applications. These modules are not FDA-authorized and not for clinical use.

08 THE RAISE

RAISING
$25M
Series A

USE OF FUNDS

Market land-grab	**50%**
Reimbursement & evidence	**20%**
Pipeline expansion	**15%**
Operations, quality & G&A	**15%**

Learn more.

Fundraise discussion · product demo · diligence materials

ultrasound.ai · bob@ultrasound.ai · 720.545.8055

DEN250007 · UN AI for Good · PAIR Study, JMFNM 2025

U.S. regulatory note (DEN250007): In the United States, Delivery Date AI™ is authorized 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 requirements, the output is not intended to predict or assess the risk of preterm birth. Preterm AI and other pipeline modules referenced herein are **not FDA-authorized** and not for clinical use. Product availability, indications, and permitted claims vary by jurisdiction; Brazil (ANVISA) operates under separate local authorization. Chile is R&D only — no ISP registration has been obtained.

[1] **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 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. [2] **Proprietary dataset** reflects total internal training corpus across studies; PAIR validation set comprised 877,141 de-identified images. Population statistics: CDC / March of Dimes (2024).