



Obstetric Innovation that transcends care settings

KEEPING PATIENTS CLOSE FROM AFAR

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Disclaimer:

- ▶ This independent presentation is not part of the official program as planned by the SMFM Pregnancy Meeting™ Program Committee. The content of this session is not endorsed by or recommended by SMFM

Disclosure(s):

I am an advisor/consultant and/or paid speaker for the following companies

- ▶ Nuvo
- ▶ Natera
- ▶ Hologic

Role of Fetal Surveillance



INTERIM UPDATE

ACOG PRACTICE BULLETIN

Clinical Management Guidelines for Obstetrician–Gynecologists

NUMBER 229

(Replaces Practice Bulletin Number 145, July 2014)

Committee on Practice Bulletins—Obstetrics. This Practice Bulletin was developed by the Committee on Practice Bulletins—Obstetrics with the assistance of Dwight J. Rouse, MD.

INTERIM UPDATE: The content in this Practice Bulletin has been updated as highlighted (or removed as necessary) to reflect a limited, focused change to align with American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 828, *Indications for Outpatient Antenatal Fetal Surveillance*, and provide updated information regarding fetal kick counts.

Antepartum Fetal Surveillance

The goal of antepartum fetal surveillance is to reduce the risk of stillbirth. Antepartum fetal surveillance techniques based on assessment of fetal heart rate (FHR) patterns have been in clinical use for almost four decades and are used along with real-time ultrasonography and umbilical artery Doppler velocimetry to evaluate fetal well-being. Antepartum fetal surveillance techniques are routinely used to assess the risk of fetal death in pregnancies complicated by

Indications for Outpatient Antenatal Fetal Surveillance Committee Opinion Number 828 June 2021

Table 1 Factors Associated With an Increased Risk of Stillbirth and Suggested Strategies for Antenatal Fetal Surveillance After Viability

The guidance offered in this table should be construed only as suggestions, not mandates. Ultimately, individualization about if and when to offer antenatal fetal surveillance is advised.

Factor	Suggested Gestational Age to Begin Antenatal Fetal Surveillance	Suggested Frequency of Antenatal Fetal Surveillance
Fetal		
Growth restriction ¹		
UAD: normal or with elevated impedance to flow in umbilical artery with diastolic flow present; with normal AFI and no other concurrent maternal or fetal conditions	At diagnosis ²	Once or twice weekly
UAD: AEDV or concurrent conditions (oligohydramnios, maternal comorbidity [eg, preeclampsia, chronic hypertension])	At diagnosis ²	Twice weekly ³ or consider inpatient management
UAD: REDV	At diagnosis ²	Inpatient management ³
Multiple gestation		
Twins, uncomplicated dichorionic	36 0/7 weeks	Weekly
Twins, dichorionic, complicated by maternal or fetal disorders, such as fetal growth restriction	At diagnosis ²	Individualized
Twins, uncomplicated monochorionic-diamniotic	32 0/7 weeks ⁴	Weekly
Twins, complicated monochorionic-diamniotic (ie, TTTS)	Individualized	Individualized
Twins, monoamniotic	Individualized	Individualized
Triplets and higher order multiples	Individualized	Individualized
Decreased fetal movement	At diagnosis ³	Once ⁵
Fetal anomalies and aneuploidy	Individualized	Individualized

Indications for Outpatient Antenatal Fetal Surveillance Committee Opinion Number 828 June 2021

Maternal

Hypertension, chronic		
Controlled with medications	32 0/7 weeks	Weekly
Poorly controlled or with associated medical conditions	At diagnosis ²	Individualized
Gestational hypertension/preeclampsia		
Without severe features	At diagnosis ^{2,3}	Twice weekly
With severe features	At diagnosis ^{2,3}	Daily
Diabetes		
Gestational, controlled on medications without other comorbidities	32 0/7 weeks	Once or twice weekly
Gestational, poorly controlled	32 0/7 weeks	Twice weekly
Pregestational	32 0/7 weeks ⁶	Twice weekly
Systemic lupus erythematosus		
Uncomplicated	By 32 0/7 weeks	Weekly
Complicated ⁷	At diagnosis ²	Individualized
Antiphospholipid syndrome	By 32 0/7 weeks ⁸	Twice weekly
Sickle cell disease		
Uncomplicated	32 0/7 weeks	Once or twice weekly
Complicated ⁹	At diagnosis ²	Individualized
Hemoglobinopathies other than Hb SS disease	Individualized	Individualized
Renal disease (Cr greater than 1.4 mg/dL)	32 0/7 weeks	Once or twice weekly
Thyroid disorders, poorly controlled	Individualized	Individualized
In vitro fertilization	36 0/7 weeks	Weekly
Substance use		
Alcohol, 5 or more drinks per week	36 0/7 weeks	Weekly
Polysubstance use	Individualize	Individualized

Indications for Outpatient Antenatal Fetal Surveillance Committee Opinion Number 828 June 2021

Prepregnancy BMI		
Prepregnancy BMI 35.0–39.9 kg/m ²	37 0/7 weeks	Weekly
Prepregnancy BMI 40 kg/m ² or above	34 0/7 weeks	Weekly
Maternal age older than 35 years	Individualized ¹⁰	Individualized
Obstetric		
Previous stillbirth		
At or after 32 0/7 weeks	32 0/7 weeks ¹¹	Once or twice weekly
Before 32 0/7 weeks of gestation	Individualized	Individualized
History of other adverse pregnancy outcomes in immediately preceding pregnancy		
Previous fetal growth restriction requiring preterm delivery	32 0/7 weeks	Weekly
Previous preeclampsia requiring preterm delivery	32 0/7 weeks	Weekly
Cholestasis	At diagnosis ²	Once or twice weekly
Late term	41 0/7 weeks	Once or twice weekly
Abnormal serum markers ¹²		
PAPP-A less than or equal to the fifth percentile (0.4 MoM)	36 0/7 weeks	Weekly
Second-trimester Inhibin A equal to or greater than 2.0 MoM	36 0/7 weeks	Weekly
Placental		
Chronic placental abruption ¹³	At diagnosis ²	Once or twice weekly
Vasa previa	Individualized	Individualized
Velamentous cord insertion	36 0/7 weeks	Weekly
Single umbilical artery	36 0/7 weeks	Weekly
Isolated Oligohydramnios (single deepest vertical pocket less than 2 cm)	At diagnosis ^{2,3}	Once or twice weekly
Polyhydramnios, moderate to severe (deepest vertical pocket equal to or greater than 12 cm or AFI equal to or greater than 30 cm)	32 0/7–34 0/7 weeks ¹⁴	Once or twice weekly

Stillbirth

Stillbirth occurs in families of all races, ethnicities, and income levels, and to women of all ages. However, stillbirth occurs more commonly among certain groups of people including women who

- Are 35 years of age or older
- Are of low socioeconomic status
- Smoking (cigarettes, other substances) during pregnancy
- Have certain medical conditions, such as high blood pressure
- Are pregnant with more than one baby (such as twins or triplets)
- Have had a stillbirth in the past

cdc.gov/stillbirth

Stillbirth

More often to women in certain racial or ethnic groups

In 2020 Stillbirths occurred in non-Hispanic Black women 2x more than non-Hispanic White and Asian or pacific Islander women

Disparities are not rooted in biological or genetic difference but can be attributed to many underlying causes

- ▶ Access to quality health care
- ▶ Pre-existing health conditions
- ▶ Structural discrimination

Health Disparities



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 586 • February 2014

(Reaffirmed 2016. Replaces Committee Opinion Number 429, March 2009)

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Health Disparities in Rural Women

ABSTRACT: Rural women experience poorer health outcomes and have less access to health care than urban women. Many rural areas have limited numbers of health care providers, especially women's health providers. Rural America is heterogeneous where problems vary depending on the region and state. Health care professionals should be aware of this issue and advocate for reducing health disparities in rural women.

Health Disparities

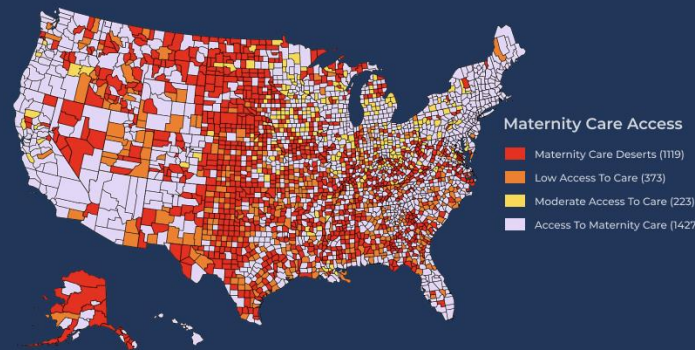
► [Birth](#). 2024 Jun;51(2):363-372. doi: 10.1111/birt.12792. Epub 2023 Nov 15.

Health care use and health consequences of geographic lack of access to abortion and maternity care

Maeve E Wallace ¹, Dovile Vilda ¹, Lauren Dyer ¹, Iman Johnson ¹, Lillian Funke ²

of counties in the
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46% OF WOMEN IN THE U.S. HAVE ZERO TO LOW ACCESS
TO OBSTETRIC HOSPITALS OR BIRTH CENTERS



Health Disparities

Fetal mortality rate: United States, 1990–2021

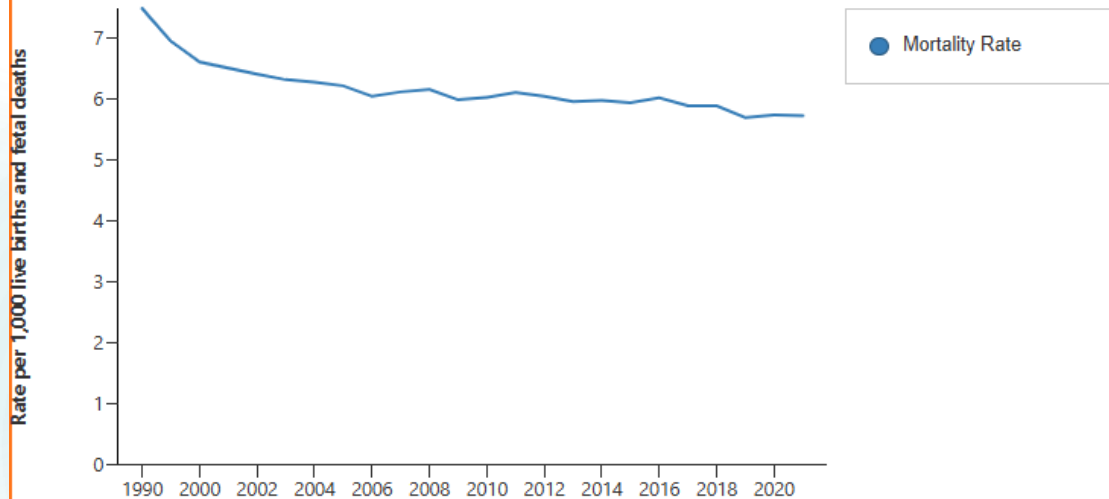
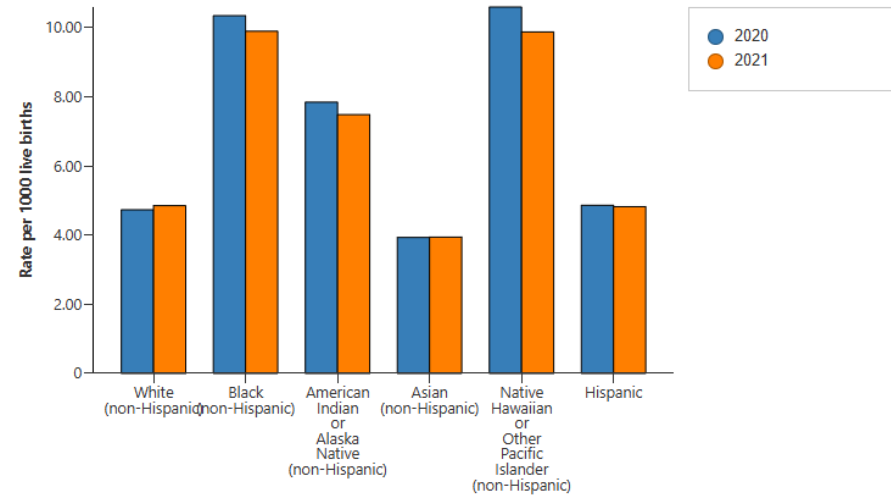


Figure 2. Fetal mortality rates, by race and Hispanic origin of mother: United States, 2020 and 2021



Adrian's story

“My son Adrian was stillborn due to complications from undiagnosed preeclampsia. Preeclampsia is a condition that can happen after 20 weeks of pregnancy. No one mentioned the risk of stillbirth, and none of my providers seemed concerned about my symptoms. The night before I hit my 41st week of pregnancy, I went to bed with my son actively kicking in my belly. By the time I woke up the following morning, he was dead. I wish I had known stillbirth is as common as it is. I wish I had known that having symptoms of preeclampsia was a big deal. Most of all, I wish more people talked about stillbirth. My son should be here, and he isn't.”

cdc.gov/stillbirth

Stillbirth

Women who have previously had a stillbirth have higher risks of having pregnancy complications and of having another stillbirth – and are, therefore, tested more frequently, require more monitoring and come to the hospital more frequently out of concern – than women who have had a live birth. They are also five times more likely to develop anxiety, more than four times more likely to have post-traumatic stress disorder, and two times more likely to have depression than women who have had a live birth.

TeleHealth: Yes or No

- ▶ Evidence suggests that telehealth provides comparable health outcomes when compared with traditional methods of health care delivery without compromising the patient–physician relationship, and it also has been shown to enhance patient satisfaction and improve patient engagement. For example, investigators compared perinatal outcomes in 117 women opting for a regimen of nine in-person prenatal visits and five virtual prenatal visits to 941 women receiving up to 12 in-person prenatal visits. There were no significant differences in rates of cesarean birth, preterm birth, neonatal intensive care unit admissions, or birth weight despite a higher rate of preeclampsia in the virtual visit cohort. Patient satisfaction was significantly higher among women having virtual visits, although the absolute differences between in-person and virtual visits were so small as to be of questionable clinical significance

Why Make NSTs Remote?

BARRIERS TO CARE

- ▶ Employment
- ▶ Child Care
- ▶ Transportation
- ▶ Mental Health

BENEFITS (patients)

- ▶ Increased compliance
- ▶ Patient Preference
- ▶ Reduced Anxiety
- ▶ OB-ED Mitigation

OPTIONS on How to Make NSTs Remote

INVU



Pregnabit



Sense4Baby



BioRithm



Monica by GE



Nemo



Hera Beat



BloomLife



Some of the remote monitoring systems in development or on the market

Why Make NSTs Remote?

OFFICE (OUTPATIENT) MODEL

- ▶ Increasing number of complicated cases (~25% are HIGH RISK)
- ▶ Increased maternal age, obesity, hypertension and diabetes
- ▶ Decreased access
 - ▶ ~40% of women drive >30 minutes for OB care
 - ▶ ~7 million women in low access geographies

Trends in Pregnancy and Childbirth Complications in the U.S. Blue Cross Blue Shield. June 17, 2020.
https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/HoA_Maternal_Health.pdf

PregSense MD U.S. Market Opportunity. LEK. Sept 2018

Nowhere to go: Maternity care deserts across the U.S. March of Dimes. 2022

Roa L, Uribe-Leitz T, Fallah PN, Williams W, Jarman MP, Bergmark RW, Boatín AA, Molina RL. Travel Time to Access Obstetric and Neonatal Care in the United States. *Obstet Gynecol*. 2020 Sep;136(3):610-612. doi: 10.1097/AOG.0000000000004053. PMID: 32769634.

Why Make NSTs Remote?

Staff Complaints

- ▶ Setting up/cleaning
- ▶ Managing late and add-on patients. High volume of patients
- ▶ Noise and interference from multiple simultaneous patients
- ▶ Not enough time to focus on any individual patient's needs
- ▶ Coordinating testing with other appointments
- ▶ Pressure to get the patient off the monitor (even if non-reactive) and managing prolonged monitoring (refer to L&D?)
 - ▶ Non-reactivity rates decrease from: 25% at 20min → 5% at 40min → 1% at 80 minutes

How Can We Make NSTs Remote?

WHAT IS REQUIRED TO MAKE IT A REALITY – SOLO PRACTICE

- ▶ Clinically validated 👍 and supported by academic institutions (AFI)
- ▶ Regulatory approved 👍
- ▶ Easily self-administered by patients 👍
- ▶ Able to be used regardless of patient to shape/size/BMI 👍
- ▶ Easy-to-use for patients & providers with integration into clinical work-flow 👍
- ▶ Reimbursable with existing (or new) CPT codes 👍
- ▶ Scalable across the practice/system
- ▶ Monitoring sessions viewed synchronously 👍

The REACTIVE trial:

Remote Pregnancy Monitoring to Improve Access

NIH RO1 PI: Nadav Schwartz

Trial PI: Sam Parry; **Co-PI:** Rebecca Feldman

Objectives:

1. Effectiveness of remote NSTs on testing completion rates overall, and in Black vs non-Black patients
2. Impact on obstetric outcomes and resource utilization
3. Identify key facilitators and barriers to implementation of a wide-scale remote fetal monitoring program

Study Design: Type 1 hybrid RCT

- 400 high risk singletons being randomized to in-office NSTs vs remote NSTs.
- Enrollment began: 5/25/2023
- **As of 4/3/2024: 118 patients enrolled**
- **Goal Completion Date June 2025**

Funded by NICHD RO1-HD105446



Case 1

- ▶ IG is a 42yo G1P0 with a demanding job
- ▶ Risk factors included AMA >40yo, CHTN, BMI >40
- ▶ Recommended 2x/wk fetal testing from 32 weeks GA
- ▶ Pt did not feel that she would be able to perform 2x/week testing but would compromise with weekly testing alternating between her 1' OB and MFM
- ▶ Prior to virtual fetal monitoring this would have been a challenge. However, patient was eager to be able to monitor remotely at her convenience and was able to choose to do at work or at home

Why Make NSTs Remote?

INPATIENT (OUTPATIENT) MODEL – De-HOSPITALIZATION

▶ SOCIAL

- ▶ Separation from family
- ▶ Loss of income
- ▶ Increased in mental health concerns (depression/anxiety)

▶ MEDICAL

- ▶ Nosocomial Infections
- ▶ Thromboembolic risk
- ▶ Iatrogenic interventions

▶ FINANCIAL

- ▶ Daily hospital costs vs home care
- ▶ ~10 billion maternity hospitalization costs annually

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- ▶ Retrospective cohort on 400 high risk patients in Denmark
- ▶ Included 179 patients with indications generally managed as an inpatient in the US
 - ▶ Preeclampsia with FGR (N=94)
 - ▶ PPROM (N=85)
- ▶ Overall fetal death rate was 1% (4/400)
- ▶ No fetal/neonatal deaths attributed to the remote monitoring
- ▶ No cord prolapse or emergent deliveries from home

Home telemonitoring versus hospital care in complicated pregnancies in the Netherlands: a randomised, controlled non-inferiority trial (HoTeL)

Mireille N Bekker, Maria P H Koster, Willem R Keusters, Wessel Ganzevoort, Jiska M de Haan-Jebbink, Koen L Deurloo, Laura Seeber, David P van der Ham, Nicolaas P A Zuithoff, Geert W J Frederix, Josephus F M van den Heuvel, Arie Franx

2023

- ▶ Multi-site RCT comparing hospitalization vs daily telemonitoring with home NST and BP (N=200)
- ▶ Primary outcome was a composite of adverse perinatal outcomes assessed after delivery: mortality, 5' Apgar <7 or a UC pH <7.05, maternal morbidity, NICU admission, C/S rate
- ▶ Primary outcome was LOWER in the telemonitoring group (31% vs 40%)
- ▶ LOWER preterm birth in the telemonitoring group (56% vs 65%)
- ▶ Single IUFD in the telemonitoring group (aneuploidy and FGR)
- ▶ Telemonitoring group had better patient satisfaction and quality of life scores on post-partum surveys at 4 weeks
- ▶ Telemonitoring decreased antenatal costs by a mean of 2774 euro

Case 2

- ▶ MG is a 37yo G3 P2002
- ▶ History of 2 prior uncomplicated pregnancies
- ▶ Current pregnancy with admission to the hospital for bleeding placenta previa @ 27 weeks with discharge home after 48 hours without bleeding. Returned @ 30 weeks with 2nd bleed and after 4 days in the hospital without bleeding, she wanted to go home but was concerned about her fetal safety
- ▶ Prior to virtual fetal monitoring this would have been a challenge. However, patient was excited to be able to monitor the fetus and contractions remotely and decrease her need to travel to her outpatient office visits



Additional Slides (INVU)

Introducing Philips Remote Fetal Monitoring

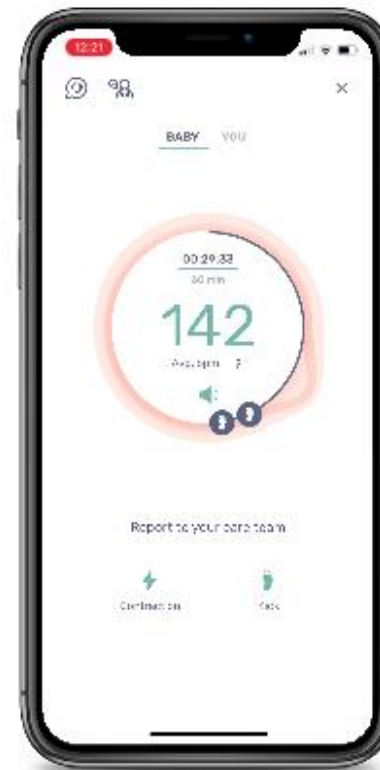
Per-pregnancy service to hospitals that enable
remote NST monitoring

Included in the Remote Fetal Monitoring pay-per-use
(per pregnant patient) service:

- **Virtualization of patient NST*** visits without changing the current clinical workflow.
- **Self-applied INVU** by Nuvo fetal monitoring belt *shipped directly* to patient.
- **Seamless integration of Patient scheduling directly from EMR** through secure data integration via Philips IntelliBridge Enterprise (IBE).
- **Comfort and convenience for the pregnant patient**, who applies the device at home with guidance and feedback from the patient app.
- **Hospital workflow support.**



INVU Mobile App – Patient Views



INVU as a self-administered pregnancy sensor belt



Mhajna et al. Wireless, remote perinatal monitoring. *AJOG MFM* 2020.

- Biopotential sensors
- Acoustic sensors
- Accelerometer and gyroscope for motion detection

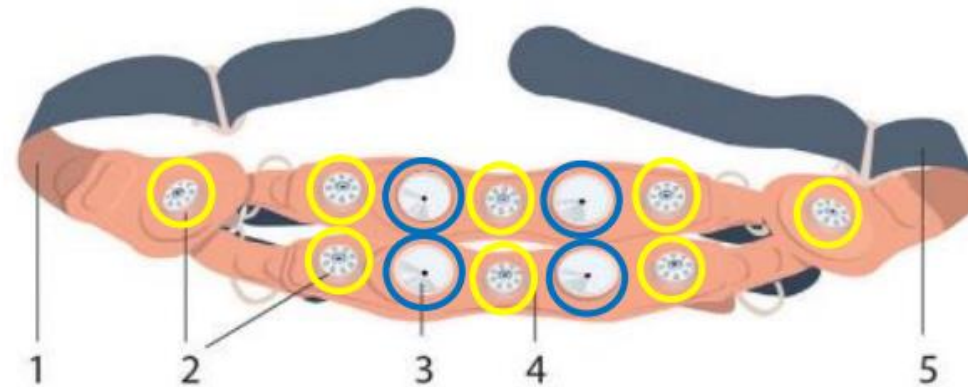


FIGURE 2 | INVU sensor band™ inner-side view (the side facing the abdominal skin) is shown, detailing the (1 and 5) rear-closing buckle; (2) electrocardiogram sensors, eight in total; (3) acoustic sensors, four in total; and (4) textile band (this figure was published in N. Schwartz et al., "Novel Uterine Contraction Monitoring to Enable Remote, Self-administered Non-stress Testing," *Am. J. Obstet. Gynecol.*, 2021)

About the INVU device and apps

INVU by Nuvo self-applied fetal monitoring belt

- Monitors FHR, MHR, and contractions
- 32 weeks gestation and above
- FDA cleared for NST ¹
- FDA cleared for self-application for remote (home) use ¹
- Comfortable wearable sensor band
- 8 bio-potential surface sensors for fetal/maternal ECG and 4 acoustic sensors for phonocardiogram (PCG)

INVU Patient app

- Easy to learn with self-paced training
- Self-reported kick counts

INVU Pro Clinician web app

- Clinician-initiated patient chat feature
- HIPAA compliant
- Cloud-based



How INVU looks to the patient



Belt is delivered to the patient's home



App goes "live" during a scheduled appointment



User training is provided within the app



Patient can see some but not all data



Patient can text with provider during the session

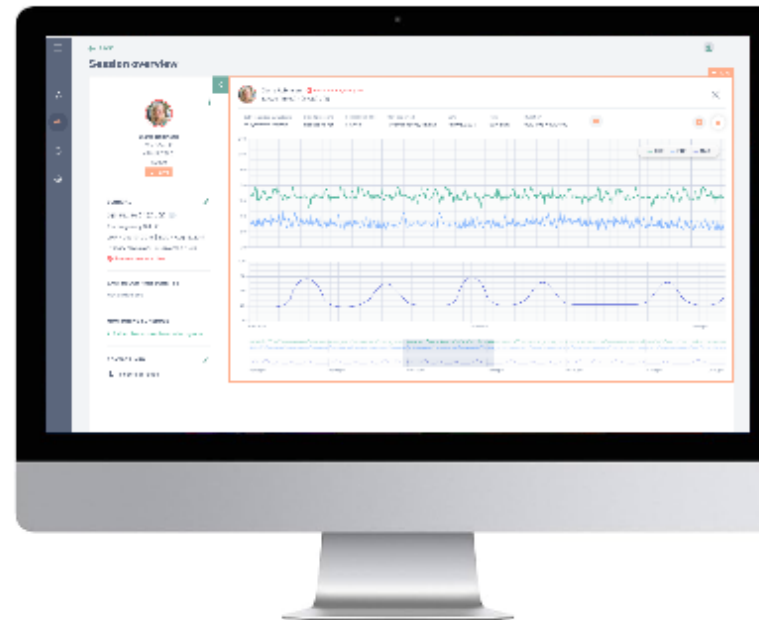


How INVU looks to the provider

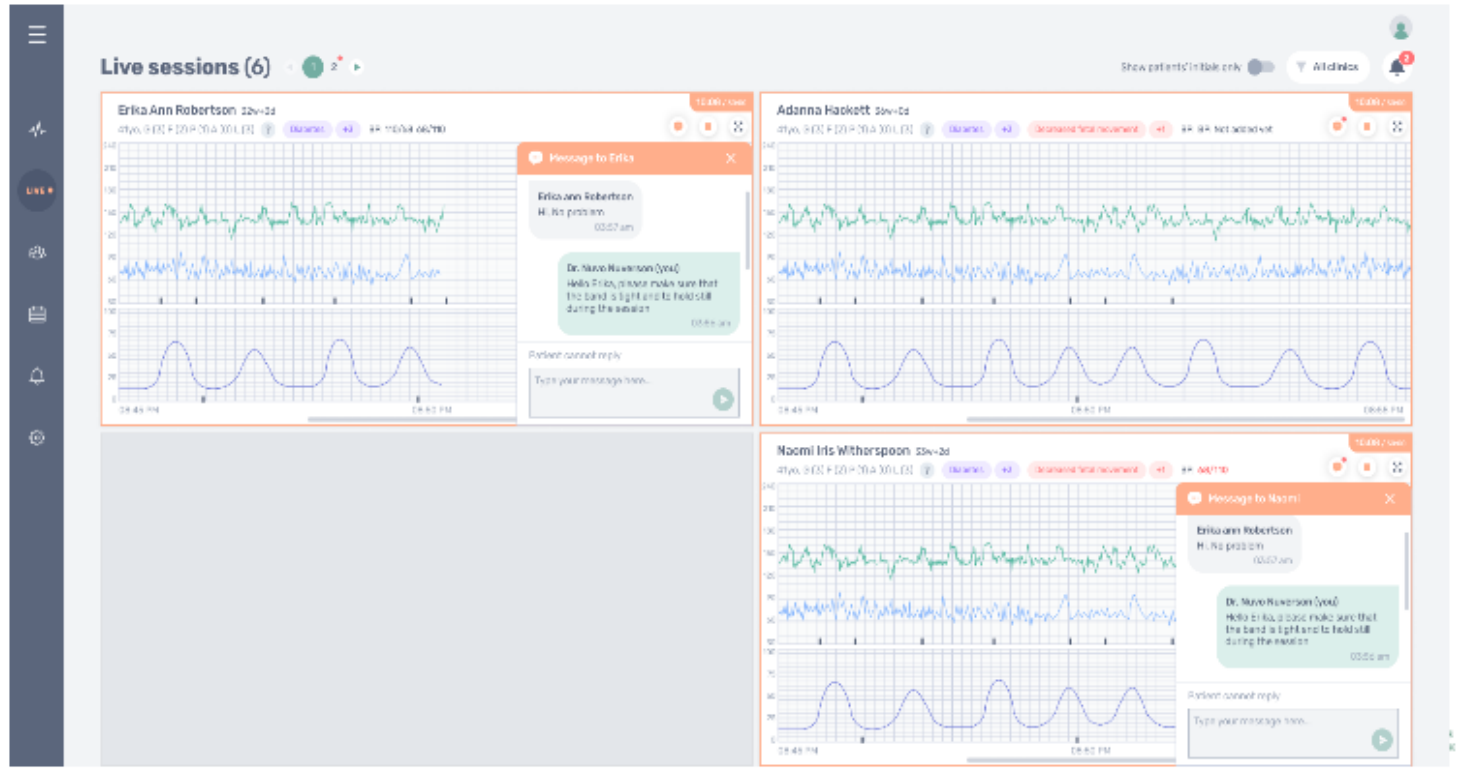


Live traces can be viewed by providers through a Clinician Web App.

Data is **automatically transferred into the EMR** via IBE and, if available, ISP.



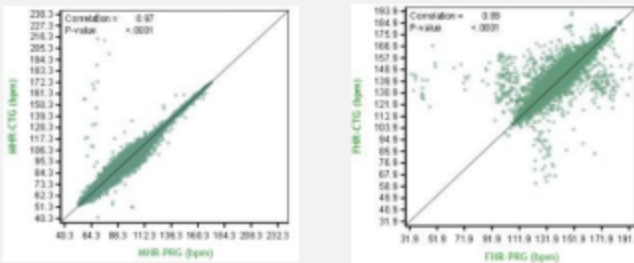
INVU Pro – Simultaneous Remote NST Sessions



Nuvo has built strong clinical and scientific validation

Validation of FHR & MHR: Efficacy and Safety

- Clinical safety and efficacy were successfully validated in multi-center clinical trial
- 148 subjects, over 40K datapoints



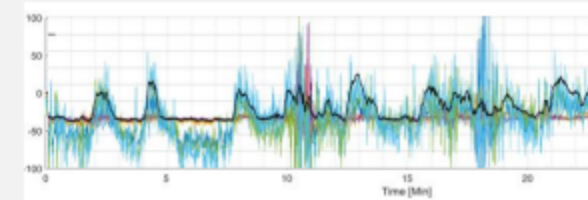
Excellent results: Correlation > 0.92, $p < 0.0001$

Validation of Self Administration for Remote Pregnancy Monitoring

- The ability to self-administer the INVU Sensor Band was successfully validated in FDA-recognized Human Factors center: Medstar Health
- Tested on multiple eligible end users – used the device without assistance
- Excellent results: indicate the design, implementation and instructive materials for INVU platform facilitate safe remote use.

Scientific Breakthrough: Maternal Uterine Activity (MUA)

- Current technology has high failure rate and suffers from many limitations (TOCO)
- Scientific breakthrough – a new non-invasive method based on ECG-derived robust electrical signal was successfully developed.



- Sensitivity > 90%: comparison of INVU to Gold Standard IUPC.