

## Wireless, remote solution for home fetal and maternal heart rate monitoring



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**BACKGROUND:** Access to prenatal care can be challenging due to physician shortages and rural geography. The multiple prenatal visits performed to collect basic fetal measurements lead to significant patient burden as well. The standard of care tools for fetal monitoring, external fetal heart rate monitoring with cardiotocography, as used today, must be applied by a medical professional in a healthcare setting. Novel tools to enable a remote and self-administered fetal monitoring solution would significantly alleviate some of the current barriers to care.

**OBJECTIVE:** To compare maternal and fetal heart rate monitoring data obtained by 'Invu system' (a wireless, wearable, self-administered, fixed-location device containing passive electrical and acoustic sensors) to cardiotocography, toward a true remote fetal monitoring solution.

**MATERIALS AND METHODS:** A prospective, open-label, multi-center study evaluated concurrent use of Invu and cardiotocography in pregnant women, aged 18 to 50 years, with singleton pregnancies  $\geq 32+0$  weeks' gestation (NCT03504189). Simultaneous recording sessions from Invu and cardiotocography lasted for  $\geq 30$  minutes. Data from the 8 electrical sensors and 4 acoustic sensors in the Invu belt were acquired, digitized, and sent wirelessly for analysis by an algorithm on cloud-based servers. The algorithm validates the data, preprocesses the data to remove noise, detects heartbeats independently from the two data sources (electrical and acoustic), and fuses the detected heartbeat arrays to calculate fetal heart rate (FHR) and maternal heart rate (MHR). The primary performance endpoint was Invu FHR limit of agreement within  $\pm 10$  beats per minute (bpm) of FHR measured with cardiotocography.

**RESULTS:** A total of 147 women were included in the study analysis. The mean (SD) maternal age was  $31.8 \pm 6.9$  years, and the mean gestational age was  $37.7 \pm 2.3$  weeks. There was a highly significant correlation between FHR measurements from Invu and cardiotocography ( $r = 0.92$ ;  $P < 0.0001$ ). The 95% limits of agreement for the difference, the range within which most differences between the two measurements will lie, were  $-8.84$  bpm to  $8.24$  bpm. Invu measurements of MHR were also very similar to cardiotocography and were highly significantly correlated ( $r = 0.97$ ;  $P < 0.0001$ ). No adverse events were reported during the study.

**CONCLUSION:** Although captured by very different methods, the FHR and MHR outputs wirelessly obtained by the Invu system through passive methods were very similar to those obtained by the current standard of care. The limits of agreement for FHR measured by Invu were within a clinically acceptable  $\pm 8$  bpm of cardiotocography FHR. The Invu device uses passive technology to allow for safe, non-invasive and convenient monitoring of patients in the clinic and remotely. Further work should investigate how remote perinatal monitoring could best address some of the recent challenges seen with prenatal care and maternal and fetal outcomes.

**CLINICAL TRIAL INFORMATION:** Registration date: April 20, 2018; First participant enrollment: February 28, 2018; [ClinicalTrials.gov](https://clinicaltrials.gov/registration/NCT03504189) registration NCT03504189; <https://clinicaltrials.gov/ct2/show/NCT03504189>

**Key words:** fetal heart rate, fetal monitoring, passive, remote prenatal monitoring, wireless monitoring

Prenatal care has experienced recent challenges, with reduced availability of obstetric services due in large part to a growing shortage of obstetrician-gynecologists as well as higher-risk women pursuing pregnancy.<sup>1,2</sup> Pregnant women may have a difficult time obtaining quality perinatal care because of the need for serial clinic visits to acquire fetal measurements, and the

increasing difficulty in accessing expert perinatal care, especially in rural locations.

Cardiotocography (CTG) is the current standard of care for external monitoring of a fetus during a non-stress test (NST) and a contraction stress test (CST), as well as during labor.<sup>3</sup> At present, CTG can be applied only by a medical professional because CTG Doppler sensors must be placed accurately for a robust signal and may need to be repositioned with fetal or maternal movement.<sup>4</sup> In addition, CTG uses Doppler ultrasound, which actively deposits energy into the tissue, to record fetal and maternal signals.<sup>4</sup> Other limitations of CTG include episodic measurement in the clinic or hospital, lack of automated analysis, and lower utility in

pregnant women with high body mass index (BMI).<sup>5,6</sup>

Remote monitoring could improve the ability of pregnant women to obtain prenatal care. Remote monitoring has shown benefits in high-risk pregnancies, including in women with gestational hypertensive disorders and gestational diabetes,<sup>7-9</sup> and in low-risk pregnancies.<sup>10-12</sup> Additional potential benefits of remote monitoring could include increased compliance with prenatal healthcare, increased access to prenatal healthcare for women in rural locations, and connected care between multiple providers.

For a remote, outpatient fetal monitoring program to be successfully implemented, the monitoring device must do the following: (1) be designed

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## AJOG MFM at a Glance

**Why was this study conducted?**

True remote, self-administered maternal and fetal heart rate monitoring has not been widely implemented with available technologies. Remote fetal heart rate (FHR) monitoring may improve access to prenatal care, reduce the burden of clinic visits for pregnant women, and allow for connected care.

**Key findings**

Remote, passive, wireless FHR monitoring with electrical and acoustic sensors in the 'Invu system' showed measurements that were highly correlated with cardiocotography. Maternal heart rate measured with the Invu system was also highly correlated with that measured by cardiocotography.

**What does this add to what is known?**

Reliable FHR measurements can be obtained from a remote, wireless abdominal belt self-applied by a pregnant woman who can remain mobile during monitoring. The Invu system provides a beat-to-beat calculation of heart rate.

for self-application by the patient and without the need for device repositioning by a healthcare professional; (2) acquire valid data that accurately distinguish between maternal heart rate (MHR) and fetal heart rate (FHR); (3) continuously monitor FHR during a pregnancy; (4) have a very low rate of false-positive results (ie, detecting a fetal heartbeat when there is none) to prevent false reassurance outside of a clinical environment; and (5) be comfortable. However, currently available technology does not allow for true remote prenatal FHR monitoring.

"Invu" was designed to be a fully remote, medical-grade maternal–fetal monitoring solution that addresses each of the aforementioned challenges. Invu is composed of a wearable, self-administered, fixed-location device containing passive bio-potential (electrical) sensors and acoustic sensors (Figure 1). The Invu belt contains multiple sensors to acquire a consistent and robust signal that overcomes variability in body habitus or changes in fetal position. The FHR and MHR outputs are based on underlying fetal and maternal electrocardiography (ECG) data, respectively, which allow for beat-by-beat precision of heart rate (HR) calculations. This, in turn, enables robust discrimination of FHR and MHR, separating the data into 2 corresponding channels for calculation and visualization.

As a first step toward validating data obtained by the Invu system, the objective of this study was to compare maternal and fetal heart rate monitoring data obtained by Invu to those obtained by the standard of care, CTG.

**Materials and methods**

A prospective, open-label, multicenter study (NCT03504189) evaluated concurrent use of Invu and CTG in pregnant women. The study was conducted in accordance with the principles set forth in the Declaration of Helsinki and in compliance with International Conference on Harmonisation-Good Clinical Practice standards. The local Institutional Review Board at each study site approved the protocol (Hadassah-Hebrew University Medical Center: EC # HMO-0116-17, MoH# 20174697; Heidelberg University: CIV-17-05-019406; University of Pennsylvania IRB: PROTOCOL#: 828202; EVMS: Chesapeake IRB Pro00022598).

The Invu (Nuvo-Group, Ltd, Tel Aviv, Israel) wearable belt contains 8 electrical sensors and 4 acoustic sensors. The acoustic sensors are highly sensitive microphones that transduce sound waves into an analog electrical signal. The biopotential sensors measure small potential or voltage changes on the skin that arise from physiological signals, including the cardiac electrical signals generated during each heartbeat. Raw

data from each sensor are sent to an analog-to-digital (A/D) conversion module, which samples the analog signals at 250 Hz and sends packets by Bluetooth to a mobile device, which transmits the signal securely to the cloud for processing (Figure 2a). After the data are acquired, they are digitized and sent wirelessly for analysis on cloud-based servers by an algorithm (Figure 2a-e). The goal of the algorithm is to fuse the independent information gathered from the acoustic sensors (phonocardiogram [PCG]) and electric sensors (electrocardiogram [ECG]) to obtain FHR and MHR.

The algorithm consists of the following: (1) data validation; (2) data preprocessing to remove noise; (3) heartbeat detection independently from electrical signals and acoustic signals; and (4) fusion of the detected heartbeats from electrical and acoustic signals to calculate the FHR and MHR curves.

**Data validation**

Each channel of raw data is examined to determine whether it contains valid data. The electrical channel is determined to contain a valid signal if the maternal ECG can be detected, because the maternal ECG has a large enough amplitude to appear with adequate quality in all electrical channels. Acoustic signals are examined for their validity using a linear support vector machine trained on the root mean square of the PCG signals. Acoustic channels that are suspected of containing only noise are considered invalid. If the data are valid, they are passed to the next step; if they are not valid, the algorithm discards the data from that channel for the next steps of the analysis.

**Data preprocessing**

Acoustic signals and electrical signals are independently filtered using several prespecified digital filters optimized to capture the relevant physiological signals and to reduce unwanted signals or noise (Figure 2b). The electrical signal filtering includes the following: (1) high-pass filtering using an inverse moving-average filter with a duration of 201 milliseconds; (2) low-pass filtering with

a 12th-order Butterworth filter, with a cut-off frequency of 85 Hz; and (3) powerline filtering using a notch filter centered at the powerline frequency (for this study, 60 Hz in the United States, and 50 Hz in Germany and Israel). An additional inverse moving median filter (101-millisecond duration) is used to eliminate low-frequency noise in signals with high levels of noise. Acoustic signals are preprocessed with multiple bandpass filters of varying bandwidth, in the range of 10–95 Hz. Signals are then equalized in magnitude and enhanced for their peaks.

### Heartbeat detection

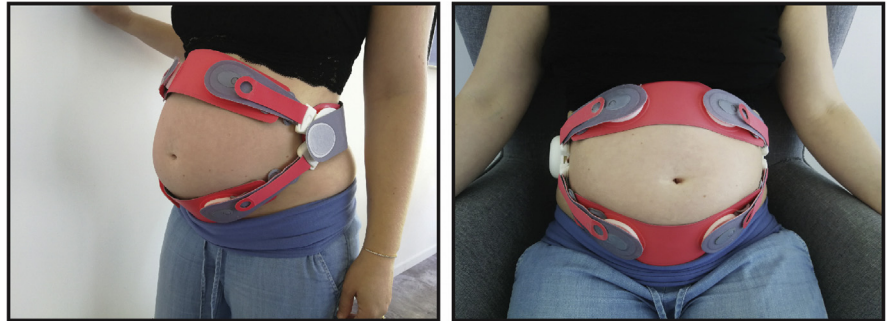
#### Electrical signals

The electrical signals are analyzed 1 channel at a time. The maternal QRS complexes are detected on each channel using a peak detection algorithm and are cross-correlated between multiple channels to obtain a single array of QRS timepoints. After identifying the location of maternal QRS complexes, which define the maternal heartbeats, an adaptive maternal ECG template is constructed based on cross-correlation analysis of adjacent beats. This is performed for each of the detected heartbeats, enabling extraction of the maternal ECG signals from the electrical signals. Once the maternal ECG is extracted from the signal, it is then subtracted from each channel of electrical data, leaving the fetal ECG data and noise not eliminated in the preprocessing step.

The remaining data are processed to enhance the fetal ECG. The signal is bandpass filtered using a Butterworth filter with cutoff frequencies of 15 Hz and 85 Hz. The signal is further enhanced by using a sliding window median-absolute-deviation operator. Independent component analysis is then performed on the signal. The resulting signals (Figure 2c) are processed for fetal QRS detection. This step involves similar techniques applied in the detection of the maternal QRS complexes, such as peak detection and cross-correlation. The end result is a data stream with annotations of maternal and fetal QRS occurrences.

#### FIGURE 1

The Invu wearable belt is a self-administered device consisting of 8 electrical sensors and 4 acoustic sensors worn by the pregnant woman. The accompanying monitoring system also contains an algorithm that remotely analyzes the data for fetal heart rate (FHR) and maternal heart rate (MHR), and a data visualization layer, which can be accessed through 1 of 2 mobile apps that provide tailored information to either the healthcare provider or to the pregnant woman



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#### Acoustic signals

Each channel is examined to determine whether PCG signals are contained within the data. The algorithm determines whether the acoustic signals are “true” heart sounds, for example, S1 (when the atrioventricular valve closes at the beginning of systole) and S2 (when the aortic valve and pulmonary valve close at the end of systole), by performing peak detection on the filtered data. This is achieved by calculating a slow envelope of the analytic Hilbert transform of the signal, finding all of the zero crossings of the derivative of the signal (corresponding to locations of peaks in the signal), discarding peaks that are not prominent, and grouping peaks into 2 groups according to shape and size using a Gaussian mixture models clustering algorithm. An initial estimate of the beat-to-beat interval of each PCG group is calculated. Missing beats are identified and added as appropriate. In parallel, an autocorrelation function is calculated for the envelope of the PCG signal. The algorithm then determines whether or not the heart sounds are coming from the same source, and segments the data into 2 streams to represent the 2 sources (S1, S2). After the segmentation, the acoustic signals

are classified as either maternal or fetal (Figure 2d) using the maternal QRS positions detected by the ECG processing algorithm as a reference. If the cross-correlation of the PCG data and the maternal QRS data is high, then the PCG data stream is classified as maternal. If the cross-correlation of the PCG data with the maternal QRS is low, then cross-correlation is performed with the fetal heartbeats calculated from the ECG algorithm. If this correlation is high, the PCG data stream is classified as fetal. If neither correlation is high, the acoustic signal and the respective detected heartbeats are discarded.

#### Data fusion

The results from the independent analyses of electrical and acoustic signals are grouped to extract the final maternal and fetal heart rates. The time-stamped annotations of detected heartbeats of electrical data and acoustic data are combined, recognizing that the electrical signal annotations are shifted earlier in time from the acoustic annotations of the same heartbeat. A local score is calculated per annotation to measure the local variation in time differences between nearby electrical signal and acoustic

signal annotations. The algorithm finds the most uniform heart rate vector by modulating the time difference between electrical and acoustic annotations. Missing electrical annotations or acoustic annotations can be added if there is a corresponding signal in the other data stream, as long as the addition increases the global score of the annotations. The annotations are fused into 1 data stream of 1 annotation per heartbeat, and heart rate is calculated as beats per minute.

**Study population**

Women between the ages of 18 and 50 years were eligible to participate in this study if they had a singleton pregnancy  $\geq 32+0$  weeks' gestation. Exclusion criteria included the following: a pre-pregnancy body mass index of  $\geq 45$  kg/m<sup>2</sup> or  $\leq 15$  kg/m<sup>2</sup>; multiple gestation; presence of a fetal anomaly; uncontrolled maternal hypertension; an implanted electronic device (eg, pacemaker, defibrillator); or a skin condition in the abdominal area (eg, wound, skin rash). All patients provided written informed consent to participate in the study.

**Recordings**

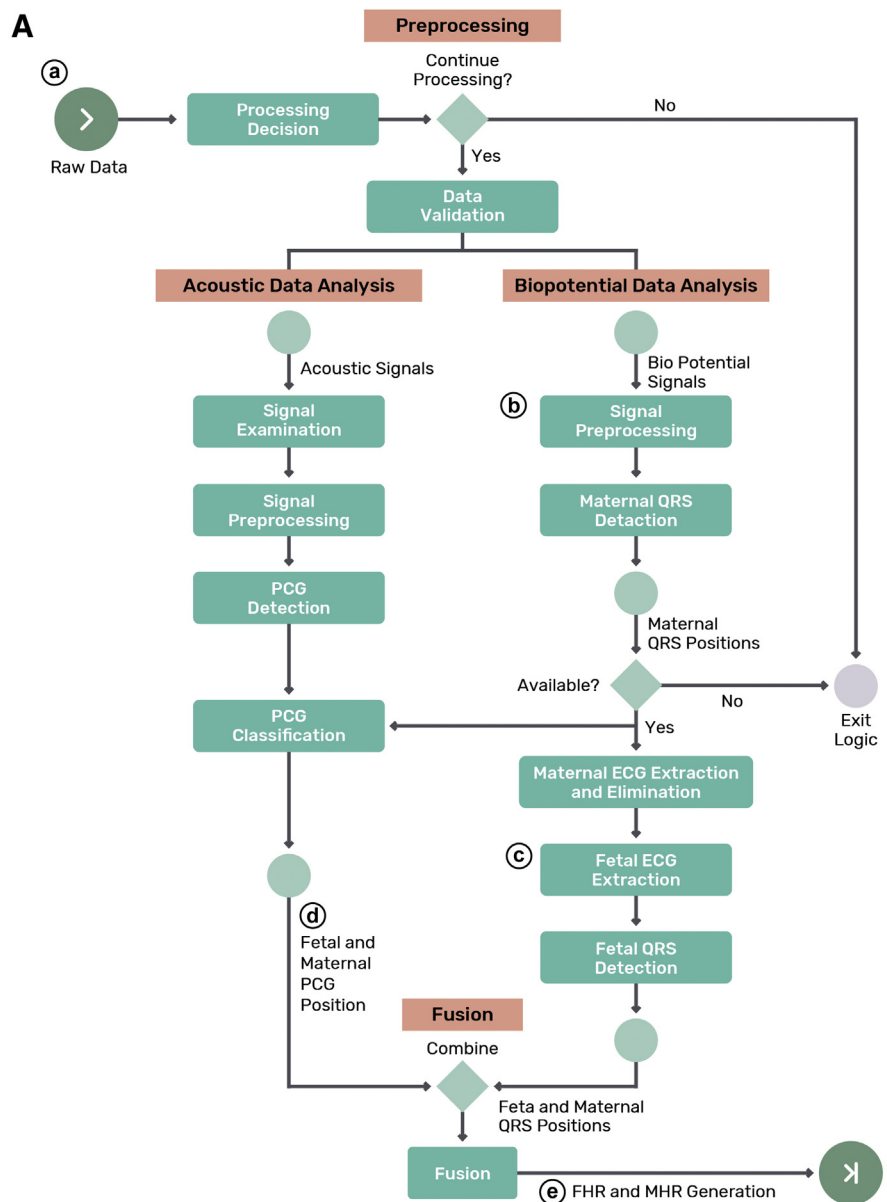
An Invu belt and an Avalon FM-30 Fetal Monitor CTG device (Philips Healthcare, Andover, MA) were placed on the woman's abdomen concurrently. MHR was also recorded by the CTG device's pulse oximeter. The Invu belt was placed on the woman's abdomen first, a validated signal was obtained, and then the CTG sensors were placed in between the 2 straps of the Invu belt. Signals were acquired and fetal and maternal heart rate were measured simultaneously using both instruments. Each recording session lasted at least 30 minutes, according to current clinical practice guidelines.<sup>6</sup>

**Endpoints**

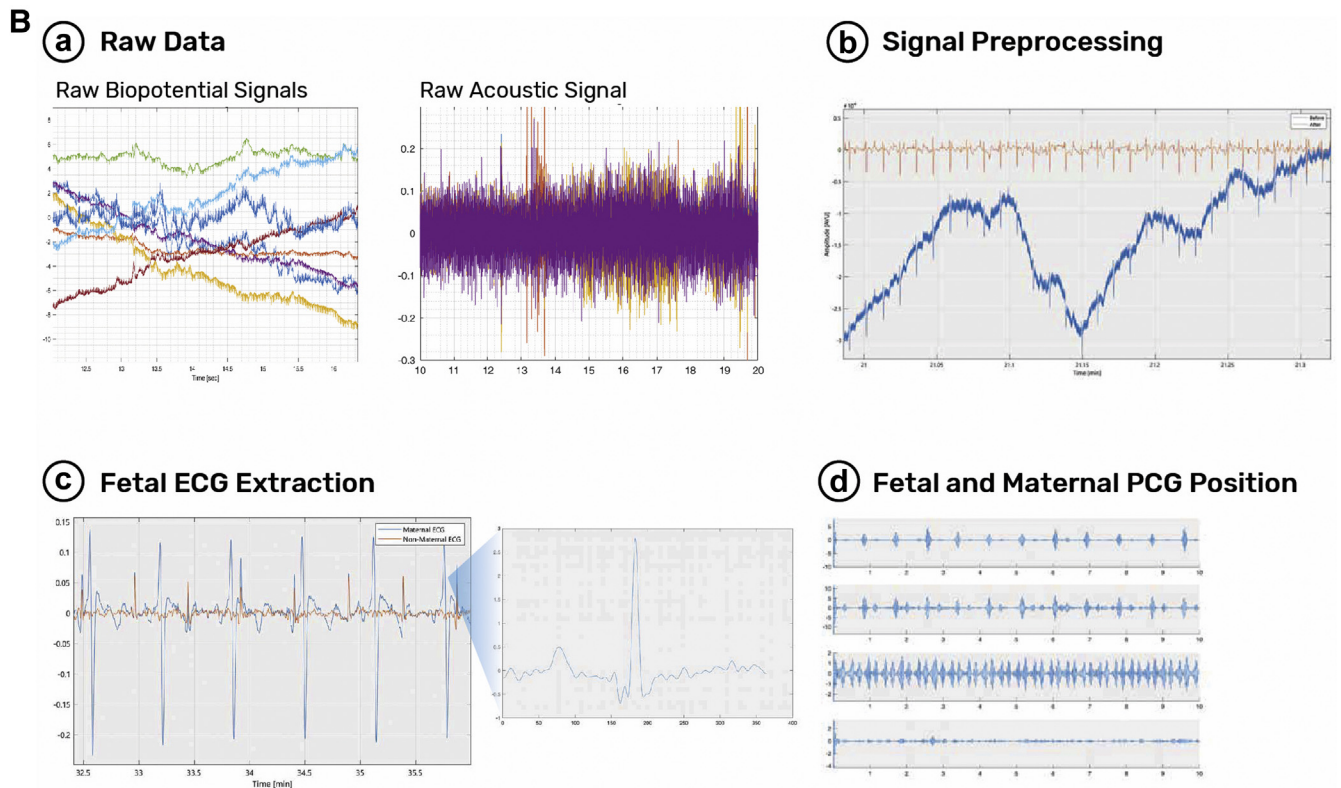
The primary performance endpoint was Invu FHR limit of agreement (LOA) within  $\pm 10$  beats per minute (bpm) of FHR measured with CTG. A co-primary

**FIGURE 2**

**Diagram of the Invu algorithm that separately analyzes (a) the biopotential and acoustic signals collected from the wearable sensor belt in a series of signal-processing steps described in the diagram. b, Signals are preprocessed to capture the relevant physiological signals and to reduce unwanted signals or noise. c, The algorithm separates 1 input data stream into 2 groups: a maternal electrocardiogram (ECG) and a nonmaternal ECG. In the fetal ECG, detailed information can be made available to providers, including QRS morphology, and P-R, S-T, and Q-T intervals. d, After segmenting, the acoustic signals are classified as either maternal or fetal, using the maternal QRS positions detected by the ECG processing algorithm as a reference. e, See Figure 3 for detailed fetal heart rate and maternal heart rate generation**



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**FIGURE 2**  
**Continued**


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performance endpoint was Invu MHR LOA within  $\pm 7$  bpm of MHR measured with CTG. Safety was assessed by reports of adverse events.

### Statistical analysis

Descriptive statistics (eg, mean, standard deviation [SD]) were calculated for continuous variables. The correlation and mean difference (95% confidence interval [CI]) between Invu and CTG measures of FHR and MHR were calculated. Bland–Altman plots were generated to show the agreement between the 2 monitoring methods by plotting the difference in measurement between the 2 methods vs the average in measurement of the 2 methods. All statistical analyses were performed with SAS v9.4 (SAS Institute, Cary, NC)

### Results

A total of 147 women were included in the performance analysis set (2

participants who enrolled in the study were excluded from the analysis because of a technical failure during the procedure). Two patients who were screened for the study did not enroll (1 patient withdrew consent, and 1 patient was pregnant with twins). The mean (SD) maternal age was 31.8 (6.9) years, and the mean (SD) pre-pregnancy BMI was 26.1 (6.2) kg/m<sup>2</sup>. The mean gestational age was 37.7 (2.3) weeks.

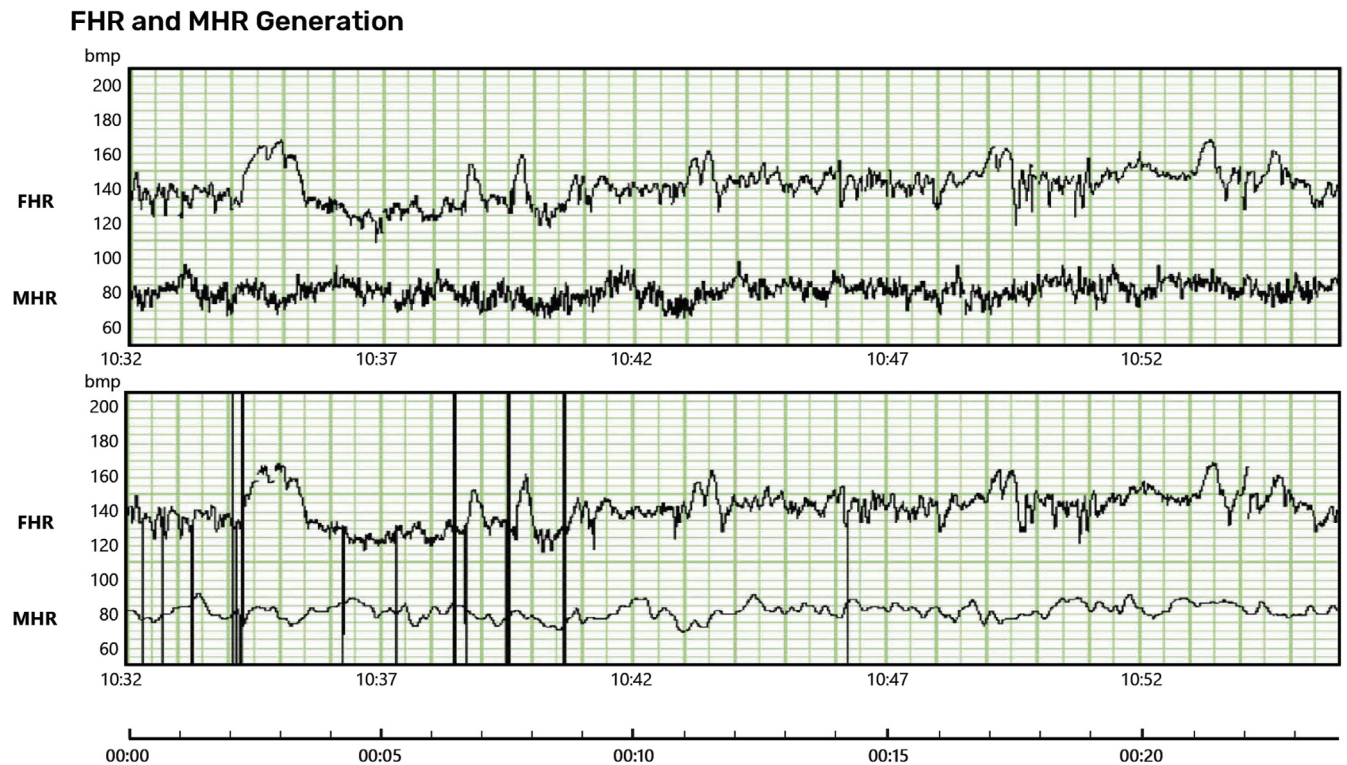
An illustrative sample of the FHR and MHR tracings obtained by Invu and CTG are shown in Figure 3. In this example, a baseline FHR of approximately 140 bpm was measured by both devices, with moderate FHR variability in highly similar patterns. It should be noted that in contrast to CTG, Invu FHR and MHR are not averaged signals, they are displayed as beat-to-beat measurements of HR. This is evident in the higher variability and temporal resolution of the data.

There was a highly significant correlation between FHR measurements from Invu and CTG (0.92;  $P < .0001$ ; Figure 4A). The mean bias (95% CI) between Invu and CTG FHR measurements was  $-0.30$  ( $-0.77, 0.18$ ) bpm. The 95% limits of agreement for the difference, the range within which most differences between the 2 measurements will lie, were  $-8.84$  bpm (95% CI,  $-10.05, -7.63$ ),  $8.24$  bpm (95% CI,  $7.03, 9.45$ ) (Figure 4B).

The Invu measurements of MHR were also very similar to those of CTG (Figure 5A). The measurements were highly significantly correlated (0.97;  $P < .0001$ ). The mean bias (95% CI) between Invu and CTG MHR measurements was  $0.28$  (0.24, 0.33) bpm (Figure 5B). The 95% limits of agreement for the MHR difference were  $-5.30$  bpm (95% CI,  $-6.09, -4.51$ ),  $5.86$  bpm (95% CI,  $5.07, 6.65$ ). No adverse events were reported during the study.

**FIGURE 3**

Fetal heart rate (FHR) and maternal heart rate (MHR) over time show highly similar measurements of baseline heart rate and variability between (top) Invu and (bottom) cardiocotography (CTG). Note the lack of movement artifacts in FHR traces from Invu



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## Comment

### Principal findings

Although captured by very different methods, the FHR and MHR outputs obtained by Invu were very similar to those obtained by the current standard of care. The fusion of data from wireless, passive electrical and acoustic sensors and the unique placement of the sensors enabled the measurement of FHR in a reliable manner.

### Results

The limits of agreement for FHR measured by Invu were within  $\pm 8$  bpm of the CTG FHR, a clinically acceptable range to recognize common clinical phenomena including bradycardia, tachycardia, accelerations, and decelerations.<sup>13</sup> Most FHR clinical phenomena are defined as an increase/decrease of 15 bpm from baseline, which could be detected given a  $\pm 8$  bpm limit

of agreement.<sup>13</sup> Clinical practice guidelines state that moderate FHR variability, between 5 and 25 bpm, is considered normal.<sup>6,13</sup> Baseline HR variability can range from 3–12 bpm as measured with standard CTG, and which increases with gestational age.<sup>14,15</sup> Moreover, FHR calculations derived from CTG have previously been shown to have a high degree of inaccuracy when compared with those derived from fetal ECG-based measurements.<sup>16</sup> Thus, given the known limitations of CTG, some of variability quantified by the limits of agreement in this study may be due to error in CTG measurements and not Invu measurements.

### Clinical implications

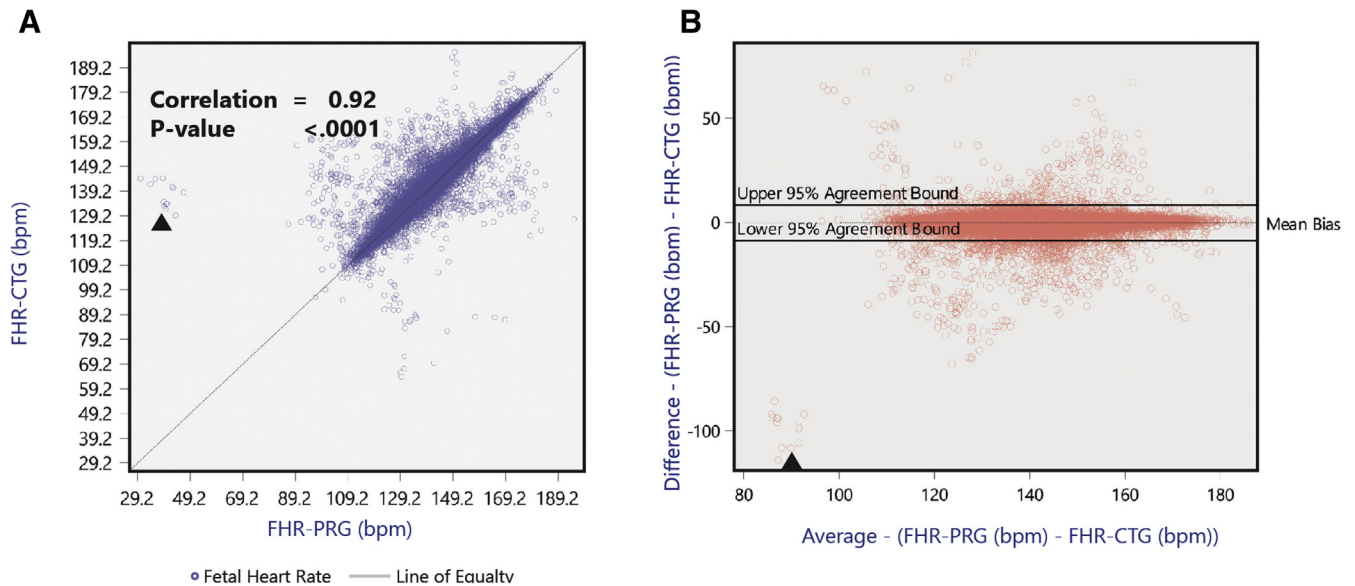
Routine implementation of remote FHR monitoring could significantly reduce healthcare use and the burden on the pregnant woman of traveling to the

clinic for prenatal monitoring. True remote monitoring with a passive device that can accurately present fetal ECG and maternal ECG has the potential to improve access to obstetrical services, including for women in rural areas and those affected by the shortage of obstetrician-gynecologists. In addition, wireless, remote monitoring can allow a pregnant woman to be mobile during labor, which may improve the woman's labor experience, shorten the labor time, and decrease the risk of cesarean delivery.<sup>17</sup>

Doppler-based and fetal electrode-based methods to measure FHR differ in their core technology. Because of the underlying technology, Doppler-based methods cannot provide true beat-by-beat heart rate calculations but, rather, an approximation. Fetal electrode-based methods can provide accurate timing of each beat, and compute the RR interval

FIGURE 4

**A, Fetal heart rate (FHR) values from Invu and cardiocotography (CTG) were highly significantly correlated with each other. B, Bland – Altman plot shows the mean bias (–0.30 bpm) and the upper and lower 95% limits of agreement (–8.84 bpm [95% confidence interval, –10.05, –7.63], 8.24 bpm [95% confidence interval, 7.03, 9.45]) for Invu FHR, relative to CTG FHR**



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and derive a beat-by-beat heart rate accordingly. This reduced resolution of information available from Doppler-based methods may account for differences seen in indices and measures derived from FHR when recorded in the 2 different methods, potentially leading to misinterpretations and poor clinical decisions in the last minutes of labor.<sup>18</sup> Obtaining true beat-by-beat heart rate is important when analyzing heart rate variability, as it may provide additional information on the well-being of the fetus.<sup>19,20</sup> The Invu device uses the FECG to calculate a true beat-by-beat FHR, which can provide an accurate measure of FHR variability, improving upon the indirect method of measuring FHR using CTG.<sup>21</sup> The same phenomenon applies to MHR recording, which is usually monitored using photoplethysmography (PPG). For example, heart rate variability indices derived from PPG differ from those recorded simultaneously from ECG.<sup>22</sup> Interestingly, there are data linking MHR variability to maternal mental health, raising the prospects for accurate and remote MHR tracings

serving as biomarkers of disease.<sup>23,24</sup> Therefore, the ability to provide true beat-to-beat FHR and MHR measurements remotely and noninvasively may expand the clinical toolbox of obstetrics in the future.<sup>13</sup>

Another limitation of traditional CTG-based FHR measurements relates to the impact of MHR artifacts, which can result in potentially dangerous consequences for the fetus.<sup>25</sup> Although a noninvasive system to measure FHR will inherently capture maternal recordings, the large amplitude of the maternal signal ensures that it can be captured with sufficient signal-to-noise ratio to validate it and eliminate it from the raw signal. In contrast to strategies that rely on a single or a few biosensors to capture FHR and MHR signals, the use of data from multiple biosensors (8 ECG and 4 acoustic) in the Invu system allows the algorithm to remove the maternal ECG from contaminating the fetal ECG, essentially performing signal ambiguity detection, thereby reducing artifacts and the likelihood of errors in FHR calculation and interpretation.<sup>26</sup>

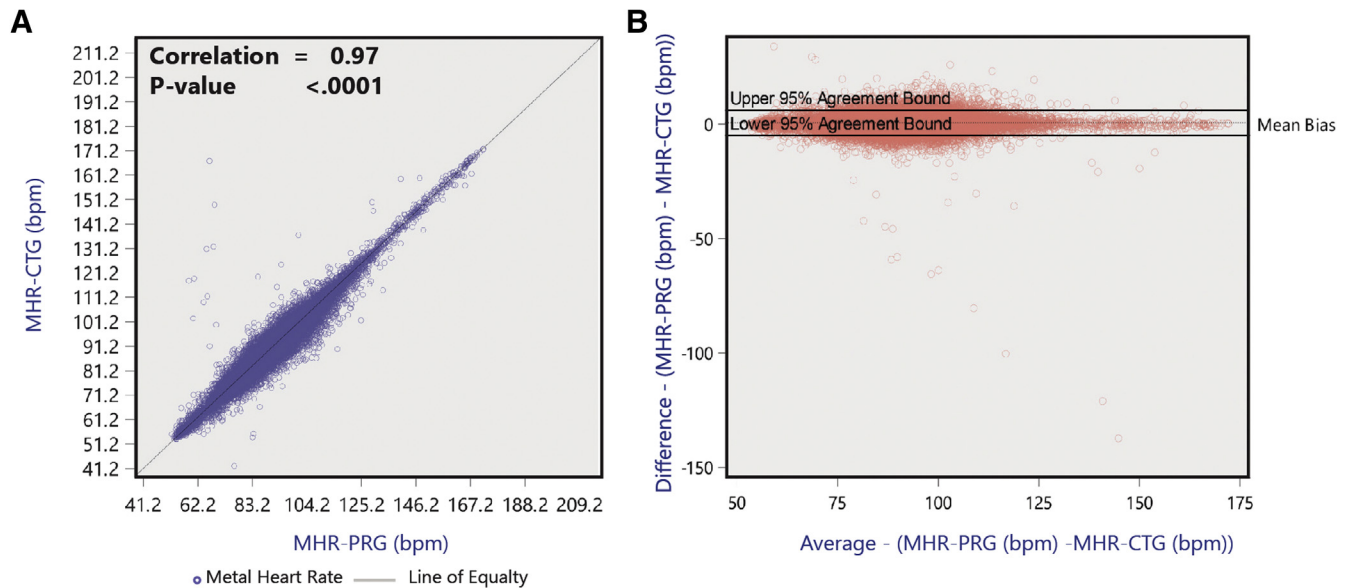
## Research implications

The FHR obtained from the Invu system is based on a true fetal RR interval, calculated from the fetal ECG (Figure 2c), allowing for high temporal data resolution and potentially for advanced analysis of FHR variability such as phase-rectified signal averaging, which may enable potentially superior diagnostic capabilities based on FHR variability as compared to CTG.<sup>27,28</sup> Furthermore, noninvasively recording fetal ECG is challenging, but important as it allows healthcare providers to identify abnormalities in the fetal ECG.<sup>29</sup> Future versions of the Invu system may present maternal ECG and fetal ECG information, such as the QRST waveform, to healthcare providers after studies have validated the ECG output of Invu, which could be explored as a means of assessing both fetal and maternal cardiovascular disease.

In addition to reliably obtaining MHR and FHR tracings, there is also the potential to build on the multiple sensors, automated algorithm, and

FIGURE 5

**A**, Maternal heart rate (MHR) values from Invu and cardiocotography (CTG) were highly significantly correlated with each other. **B**, Bland – Altman Plot shows the mean bias (0.28 bpm) and the upper and lower 95% limits of agreement (–5.30 bpm [95% confidence interval, –6.09, –4.51], 5.86 bpm [95% confidence interval, 5.07, 6.65]) for the Invu MHR, relative to the CTG MHR



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digitized data to incorporate the use of machine-based learning to identify novel biomarkers of maternal and fetal well-being. This would set the stage for developing novel tools in an effort to improve prenatal care and pregnancy outcomes.

### Strengths and limitations

The strengths of the study are the large study population used to validate the device, and the inclusion of women with high BMI.

One limitation of this study was that the Invu belt was administered by research staff in a medical setting and not self-administered in the pregnant woman's home. However, the primary objective in this study was to demonstrate the ability to reliably obtain MHR and FHR tracings that are similar to those obtained with CTG, which must be applied by a healthcare professional. Invu is indeed designed to be self-administered by a lay person without the need for sensor repositioning. Importantly, these capabilities were tested in a human factors

usability study, which demonstrated successful self-administration without the assistance of a medical professional (in preparation), potentially overcoming 1 of the major limitations of CTG for fetal monitoring. Future investigations are warranted to demonstrate at-home monitoring by the device in a real-world setting. The study enrolled only pregnant women without pathology before labor, which may not adequately represent complicated FHR patterns, such as those found in active, awake fetuses and during the second stage of labor, and which need further study using the Invu system.<sup>13,30</sup> In addition, maternal uterine activity was not reported concurrently in this article. The Invu system can measure maternal uterine activity and results will be reported in a separate publication.

The present study was limited to women presenting from 32 weeks to term; future investigations will need to include women from 24 weeks onward, the gestational age range at which CTG is currently performed.

### Conclusion

Invu's FHR and MHR measurements, derived from fetal ECG and maternal ECG, respectively, correlated highly with CTG measurements of FHR and MHR. Importantly, Invu is designed to be self-administered by a lay person (the pregnant woman or her partner) and to provide fetal monitoring with 1 placement of the belt (ie, no sensor repositioning needed). The system uses passive, wireless technology to allow for safe, noninvasive, mobile monitoring of patients in the clinic and remotely. The current standard of care for fetal monitoring does not currently allow for remote or at-home monitoring, and requires a medical professional to apply and interpret. Remote perinatal monitoring could address some recent challenges seen with prenatal care and maternal and fetal outcomes. ■

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