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ORIGINAL RESEARCH ARTICLE

Evaluation and patient experience of wireless noninvasive fetal heart rate monitoring devices

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Abstract

Introduction: In clinical practice, fetal heart rate monitoring is performed intermittently using Doppler ultrasound, typically for 30 minutes. In case of a non-reassuring heart rate pattern, monitoring is usually prolonged. Noninvasive fetal electrocardiography may be more suitable for prolonged monitoring due to improved patient comfort and signal quality. This study evaluates the performance and patient experience of four noninvasive electrocardiography devices to assess candidate devices for prolonged noninvasive fetal heart rate monitoring.

Material and methods: Non-critically sick women with a singleton pregnancy from 24 weeks of gestation were eligible for inclusion. Fetal heart rate monitoring was performed during standard care with a Doppler ultrasound device (Philips Avalon-FM30) alone or with this Doppler ultrasound device simultaneously with one of four noninvasive electrocardiography devices (Nemo Fetal Monitoring System, Philips Avalon-Beltless, Demcon Dipha-16 and Dräger Infinity-M300). Performance was evaluated by: success rate, positive percent agreement, bias, 95% limits of agreement, regression line, root mean square error and visual agreement using FIGO guidelines. Patient experience was captured using a self-made questionnaire.

Results: A total of 10 women were included per device. For fetal heart rate, Nemo performed best (success rate: 99.4%, positive percent agreement: 94.2%, root mean square error 5.1 BPM, bias: 0.5 BPM, 95% limits of agreement: −9.7 – 10.7 BPM, regression line: $y = -0.1x + 11.1$) and the cardiotocography tracings obtained simultaneously by Nemo and Avalon-FM30 received the same FIGO classification. Comparable results were found with the Avalon-Beltless from 36 weeks of gestation, whereas the Dipha-16 and Infinity-M300 performed significantly worse. The Avalon-Beltless, Nemo and Infinity-M300 closely matched the performance of the Avalon-FM30 for maternal heart rate, whereas the performance of the Dipha-16 deviated more. Patient experience scores were higher for the noninvasive electrocardiography devices.

Abbreviations: BPM, beats per minute; CTG, cardiotocogram; DU, Doppler ultrasound; ECG, electrocardiogram; FHR, fetal heart rate; Hz, Hertz; MHR, maternal heart rate; NI-FECG, noninvasive fetal electrocardiography; PPA, positive percent agreement; RMSE, root mean square error; TOCO+MP, tocodynamometer with integrated maternal pulse oximeter.

Conclusions: Both Nemo and Avalon-Beltless are suitable devices for (prolonged) noninvasive fetal heart rate monitoring, taking their intended use into account. But outside its intended use limit of 36 weeks' gestation, the Avalon-Beltless performs less well, comparable to the Dipha-16 and Infinity-M300, making them currently unsuitable for (prolonged) noninvasive fetal heart rate monitoring. Noninvasive electrocardiography devices appear to be preferred due to greater comfort and mobility.

KEYWORDS
Doppler ultrasound, fetal heart rate monitoring, fetal monitoring, noninvasive fetal electrocardiography, prolonged fetal monitoring

1 | INTRODUCTION

In current practice, fetal heart rate (FHR) monitoring is performed intermittently over a 30-minute period. Because of the intermittent nature, earlier or later FHR abnormalities may go undetected. In the presence of a non-reassuring pattern, monitoring is usually prolonged. Prolonged FHR monitoring is hypothesized to be better able to detect these signs of deterioration.[1] It probably enables detection of subtle changes in FHR frequency and variability over time and could provide opportunities for early prediction of clinical deterioration and more accurate timing of delivery in case of complications during pregnancy. On the other hand, there is a risk that prolonged FHR monitoring may lead to overdiagnosis of fetal distress.

Conventionally, the FHR is measured noninvasively using a wired Doppler ultrasound (DU) transducer and the uterine contractions and maternal heart rate (MHR) are measured noninvasively using a wired tocodynamometer with integrated maternal pulse oximeter (TOCO+MP). The transducers are attached to the abdomen with elastic belts. DU monitors cardiac activity by detecting the movement of cardiac structures. The FHR is determined every 250 milliseconds using autocorrelation, following a sample-and-hold method. This method can produce duplicates and beat-to-beat information is lost. DU devices seem less suitable for prolonged FHR monitoring, as signal quality degrades with increasing maternal body mass index or with incorrect positioning or movement of the DU transducer relative to the fetal heart.[2,3] In addition, fetal movements during the registration period can cause signal loss.[4] Poor signal quality may affect the predictive capability of prolonged FHR monitoring.[5] The wires and belts limit patient mobility, which, together with the need to reposition the DU transducer in case of maternal or fetal movements, may affect maternal comfort. Also, DU emits high frequency sound waves and although the exposure does not cause a thermal effect, safety regulations require it to be as low as reasonably achievable.[6]

Technological innovations have led to alternative FHR monitoring solutions based on noninvasive fetal electrocardiography (NI-FECG). Electrodes placed on the abdomen passively record the electrical activity of the fetal heart, maternal heart and uterus at microvolt level. The amplitude of the fetal electrocardiogram (ECG) ranges from 2 to 50 microvolts. The time interval between consecutive fetal R-peaks is used to determine the FHR, resulting in an irregularly sampled beat-to-beat FHR. This provides insights into cardiac morphology and its relationship to fetal wellbeing. With NI-FECG, signal quality is not affected by maternal body mass or fetal movement.[2,4] Also, the electrodes do not require repositioning. The devices appear to be preferred because of improved mobility and comfort. Our hypothesis is that NI-FECG technology is more suitable for prolonged FHR monitoring since NI-FECG devices are wireless and beltless, which improves mobility and comfort. As a first step, we wanted to evaluate whether NI-FECG devices performed as well as a conventional DU device in antepartum FHR monitoring during a 30-minute recording period.

Key message

The Nemo Fetal Monitoring System and Philips Avalon-Beltless are suitable candidate devices for introducing prolonged noninvasive fetal heart rate monitoring within their intended use, given their reliable and accurate performance and the improved comfort and mobility experienced by women.

The aim of the study was to determine performance and patient experience of four NI-FECG devices compared with a conventional DU device, from 24 weeks of gestation, in order to assess candidate devices for the introduction of prolonged noninvasive FHR monitoring.

2 | MATERIAL AND METHODS

This prospective, single-center, observational study was conducted at the Department of Obstetrics and Gynecology of the Erasmus MC Sophia Children's Hospital. Women over 24 weeks pregnant, not critically sick and with a singleton pregnancy were eligible for inclusion. Exclusion criteria were: congenital anomalies, fetal growth restriction, oligohydramnios, signs of fetal distress, active blood loss, abdominal discomfort, proven rupture of membranes, use of an externally or internally implanted stimulator, a lack of language proficiency in Dutch or English, in labor, or in source isolation. All

participants provided written informed consent. Women were equally assigned to one of five FHR monitoring groups, based on device availability.

2.1 | Data collection and analysis

Maternal age, pre-pregnancy body mass index and gestational age were collected. During standard care, FHR monitoring was performed with only a DU device, Avalon-FM30 (Royal Philips NV) or simultaneously this DU device with one of four NI-FECG devices: Avalon-Beltless (Royal Philips NV), Nemo Fetal Monitoring System (Nemo Healthcare BV), Dipha-16 (Demcon), Infinity-M300 (Dräger Medical). The NI-FECG devices are shown in Figure 1. The Avalon-FM30, Avalon-Beltless and Nemo are commercial FHR monitoring devices. Nemo is approved for use from 21 weeks of gestation and Avalon-Beltless for use from 36 weeks; however, in this study it was also being used study prior to 36 weeks. The Dipha-16 and Infinity-M300 are physiological amplifiers that can potentially monitor FHR, but are designed to monitor diaphragm activity and pediatric and adult heart rate, respectively. Clinical decisions were based solely on the DU device.

FHR monitoring was performed according to clinical protocol. The women were instructed to lie in half-sitting or left lateral tilt position and to limit their movements during the approximately 30-minute recording period. Before attaching the NI-FECG device, the abdomen was washed with soapy water, dried with a towel and abraded with medical tape (3M Red Dot Trace Prep-2236, 3M Canada) at electrode placement sites. The electrodes were placed on the abdomen in a fixed configuration and the main device was connected to the electrodes. For the Avalon-Beltless and Nemo, the electrode configuration from the user manual was used. For the Dipha-16 and Infinity-M300, electrodes (3M Red Dot 2250–50, 3M Canada) were placed following a near-term configuration.[7] A trained nurse attached the DU and TOCO+MP transducers. In some cases, based on clinical protocol, a finger pulse oximeter (Philips-M119B, Royal Philips NV) was used instead of the TOCO+MP to measure MHR. FHR monitoring was performed for as long as required by the clinical protocol. Afterwards, women completed a questionnaire assessing their experience with the application, measurement and removal of the device and they rated their experience with the device on a scale of 1–10. The questionnaire is provided in Appendix S1 and was developed by the authors.

Data were collected in-hospital. The Avalon-FM30, Avalon-Beltless, and Nemo transmitted the MHR and FHR in beats per minute (BPM) at 4 Hertz (Hz) using a Series-50 protocol. A data logger was built following the digital interface protocol for a Series-50 fetal monitor using LABVIEW software (LABVIEW 2017, National Instruments). Data were transmitted from the fetal monitor to the computer via an RS232 interface. The Dipha-16 and Infinity-M300

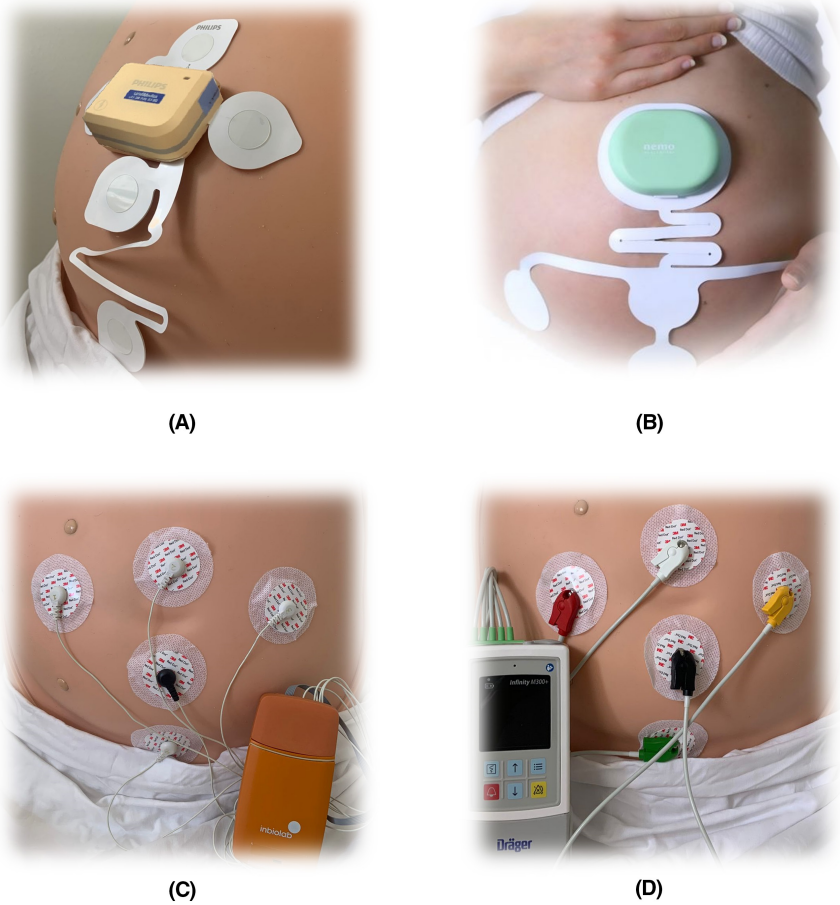

FIGURE 1 Included noninvasive fetal heart rate monitoring devices: (A) Avalon-Beltless, (B) Nemo Fetal Monitoring System, (C) Dipha-16, (D) Infinity-M300. All devices are CE-certified and have been used in clinical settings.

measured electrical activity in microvolts at 500 Hz and 200 Hz, respectively. Data were transmitted wirelessly to the computer. The following offline signal processing techniques, retrieved from the literature and online, were applied to determine MHR and FHR from the electrical signal using MATLAB software (MATLAB 2021b, The MathWorks Inc.). The noise components in the electrical signal were suppressed[8] and the locations of the R-peaks in the maternal ECG were determined.[9] The maternal ECG signal was predicted and suppressed, resulting in an estimate of the fetal ECG signal. Two different methods were used for maternal ECG suppression because its performance determines the accuracy of the estimated fetal ECG signal: an average template subtraction method and a blind source separation method.[10,11] The fetal R-peaks were detected.[11] The maternal ECG compression and FHR extraction algorithm by Varanini et al.[11] is available online.[12] The maternal and fetal R-peak intervals were used to determine the MHR and FHR in BPM. The irregularly sampled output was standardized at 4 Hz so that every 250 milliseconds an output from NI-FECG could be compared with DU. Therefore, beat-to-beat variability information was lost. The Results section shows the results of the Dipha-16 and Infinity-M300 using the blind source separation method. Internal data processing and output times varied between devices. To synchronize the 4 Hz output of the DU and NI-FECG devices, the discrete time sequences were cross-correlated.

2.2 | Statistical analyses

Baseline characteristics were reported as mean ± standard deviation or median (range), depending on data distribution. The performance of each NI-FECG device was evaluated for FHR and MHR. The performance of the Avalon-Beltless was also evaluated for all measurements from 36 weeks of gestation to assess the performance in its intended use. The following performance measures were used: success rate, positive percent agreement (PPA), bias, 95% limits of agreement, regression line, root mean square error (RMSE) and visual agreement. Additionally, for FHR, success rate, PPA and RMSE were analyzed separately for five different gestational age intervals (in weeks): $24^{0/7}$ to $27^{6/7}$, $28^{0/7}$ to $31^{6/7}$, $32^{0/7}$ to $35^{6/7}$, $36^{0/7}$ to $39^{6/7}$, $\geq 40^{0/7}$. Patient experience was captured using a questionnaire.

Success rate was defined as the percentage of time that the device provided a non-zero value and was only determined for the Avalon-FM30, Avalon-Beltless and Nemo because the offline signal processing technique for the Dipha-16 and Infinity-M300 always provided a value. PPA was defined as the percentage of time the NI-FECG devices generated a non-zero value within 10 BPM of a non-zero value from the DU device. Both the success rate and the PPA were aggregated over the total measurement time and all measurements. The mean, standard deviation and 95% confidence intervals were reported. Bland–Altman analysis was used to evaluate the agreement between the NI-FECG and DU device, correcting for multiple observations per woman.[13] The difference per sample point between the NI-FECG and DU device was plotted against their mean, as proposed by Bland and Altman[14] The bias, defined as the mean difference between the two devices, and the 95% limits of agreement, defined as the interval in which 95% of the differences between the two devices lie, were calculated. A regression line was plotted from each pair and the y-intercept, slope, RMSE and *P*-value were given. RMSE was defined as the square root of the mean square difference between the data points and regression line. Visual agreement of the FHR was measured for the Avalon-Beltless and Nemo. Two trained and blinded maternal-fetal medicine specialists classified the corresponding cardiotocogram (CTG) tracings from the Avalon-FM30 and Avalon-Beltless, and from the Avalon-FM30 and Nemo according to modified FIGO guidelines, including baseline FHR, accelerations, decelerations and variability.[15] The classifications of the simultaneously recorded tracings were compared. All analyses were performed using MATLAB software.

3 | RESULTS

A total of 58 women were enrolled in the study between September 2020 and February 2022. Eight women were excluded due to insufficient MHR or FHR registration. Two women had less than 30 minutes of registration with Dipha-16, one woman had insufficient MHR acquisition with the TOCO+MP, and five women did not have a simultaneous heart rate registration; in four cases the Avalon-Beltless did not provide an output, and in one case the Nemo suppressed the output due to quality requirements. Baseline characteristics are summarized in Table 1. Gestational age ranged from $24^{6/7}$ weeks to $41^{2/7}$ weeks (Figure 2). Data analysis revealed that some data samples were lost due to a time synchronization error between the data logger and the commercial devices. The average data loss was 1.3% ± 0.8%, (0.0–2.9). Also, the actual sample rate of the Dipha-16 was found to be 494.4 Hz, which is lower than the sample rate in the specifications.

3.1 | Fetal heart rate

The success rate per FHR monitoring group is summarized in Table 2. The Avalon-Beltless was less successful than the Avalon-FM30 in providing a non-zero FHR value as output. This was also true when only the measurements from 36 weeks were considered, although the difference was much smaller. The Nemo was more successful than the Avalon-FM30 in providing a non-zero FHR as output. The success rate of the FHR for Nemo was always close to 100% across the different gestational age intervals. For the Avalon-Beltless, this was only true within its intended use (Table 4). Table 3 summarizes the PPA per FHR monitoring group. Nemo had the highest agreement within 10 BPM and the Infinity-M300 had the lowest agreement within 10 BPM at times when both the Avalon-FM30 and the NI-FECG device of interest provided a non-zero FHR value. The PPA

TABLE 1 Baseline characteristics per FHR monitoring group.

Characteristic	FHR monitoring group					
	Avalon-FM30, $n=10$	Avalon-Beltless + Avalon-FM30, $n=10$	Avalon-Beltless* + Avalon-FM30, $n=6$	Nemo + Avalon-FM30, $n=10$	Dipha-16 + Avalon-FM30, $n=10$	Infinity-M300 + Avalon-FM30, $n=10$
Maternal age, years	32.2 ± 5.1	33.0 ± 4.4	33.2 ± 5.1	34.5 ± 4.8	32.8 ± 3.6	30.4 ± 6.7
Maternal pre-pregnancy BMI, kg/m^2	25.6 ± 6.0	26.2 ± 4.9	25.0 ± 4.6	25.7 ± 3.6	28.5 ± 6.4	26.0 ± 5.1
Gestational age, weeks	$33^{0/7}$ ($28^{4/7}$ to $36^{3/7}$)	$36^{2/7}$ ($30^{0/7}$ to $37^{0/7}$)	$36^{6/7}$ ($36^{4/7}$ to $39^{5/7}$)	$35^{3/7}$ ($33^{4/7}$ to $37^{2/7}$)	$36^{1/7}$ ($31^{2/7}$ to $36^{3/7}$)	$33^{5/7}$ ($30^{2/7}$ to $36^{6/7}$)
Duration of monitoring, minutes	40.5 (34.9–57.7)	50.4 (40.3–66.0)	55.3 (40.3–67.7)	41.5 (35.6–64.7)	41.6 (31.7–55.4)	41.2 (30.4–45.2)

Note: Data presented as mean ± SD or median (range), depending on the distribution of the data.

Abbreviations: BMI, body mass index; kg/m^2, kilogram/meter^2; Nemo, Nemo Fetal Monitoring System; SD, standard deviation.

*Subanalysis for the Avalon-Beltless including all measurements from 36 weeks of gestation, which is within the intended use of the device.

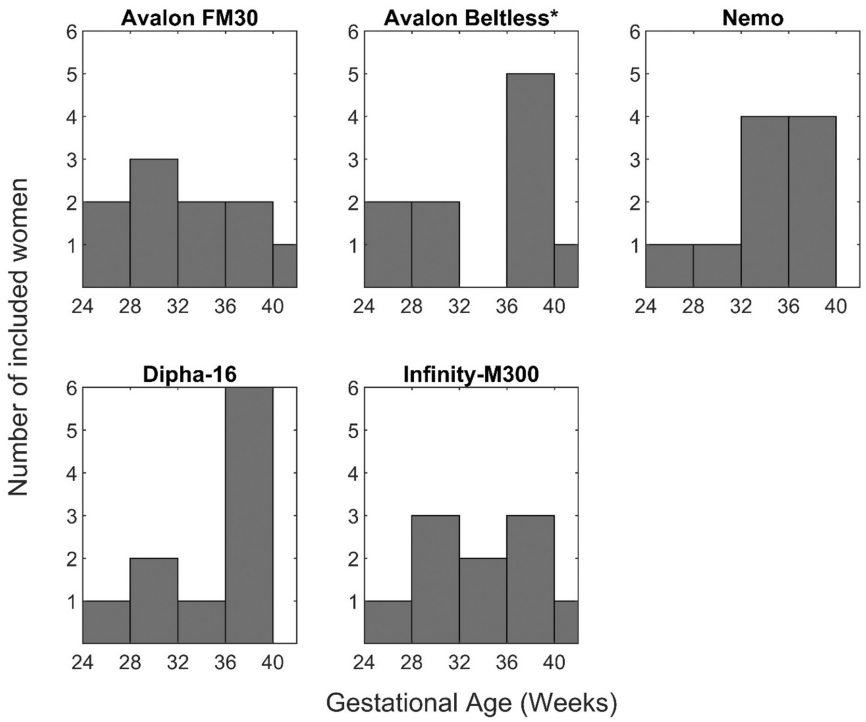

FIGURE 2 Histogram with the distribution of included women per gestational age interval for each FHR monitoring group. *Avalon-Beltless is intended to be used from 36 weeks of gestation and is also used within this study outside its intended use. FHR, fetal heart rate; Nemo, Nemo Fetal Monitoring System.

TABLE 2 Success rate per FHR monitoring group.

		FHR monitoring group					
		Avalon-Beltless + Avalon-FM30, $n=10$		Avalon-Beltless* + Avalon-FM30, $n=6$		Nemo + Avalon-FM30, $n=10$	
		Avalon-Beltless	Avalon-FM30	Avalon-Beltless*	Avalon-FM30	Nemo	Avalon-FM30
Fetal heart rate	Mean ± SD	70.8 ± 39.7	94.4 ± 8.0	96.8 ± 6.9	97.9 ± 3.3	99.4 ± 1.2	96.7 ± 3.2
	CI	46.2–95.4	89.5–99.4	91.3–100.0	95.2–100.0	98.6–100.0	94.7–98.7
Maternal heart rate	Mean ± SD	99.9 ± 0.1	76.6 ± 27.1	100.0 ± 0.0	64.6 ± 29.6	100.0 ± 0.0	88.0 ± 18.9
	CI	99.9–100.0	59.8–93.4	100.0–100.0	40.9–88.2	100.0–100.0	76.3–99.7

Note: 95% CI is used. The CI is truncated at 100.0%. The success rate is aggregated over the total measurement duration and all women.

Abbreviations: SD, standard deviation; CI, confidence interval, Nemo, Nemo Fetal Monitoring System.

*Subanalysis for the Avalon-Beltless including all measurements from 36 weeks of gestation, which is within the intended use of the device.

TABLE 3 Positive percent agreement per FHR monitoring group.

		FHR monitoring group				
		Avalon-Beltless + Avalon-FM30, $n=10$	Avalon-Beltless* + Avalon-FM30, $n=6$	Nemo + Avalon-FM30, $n=10$	Dipha-16† + Avalon-FM30, $n=10$	Infinity-M300† + Avalon-FM30, $n=10$
Fetal heart rate	Mean ± SD	70.8 ± 39.1	95.3 ± 5.5	94.2 ± 6.7	62.4 ± 37.6	31.0 ± 27.1
	CI	46.5–95.0	90.9–99.7	90.1–98.4	39.1–85.7	14.2–47.8
Maternal heart rate	Mean ± SD	97.1 ± 4.2	96.5 ± 5.2	97.4 ± 6.1	90.7 ± 25.7	97.0 ± 4.2
	CI	94.5–99.8	92.3–100.0	93.6–100.0	74.8–100.0	94.4–99.6

Note: 95% CI is used. The CI is truncated at 100.0%. The positive percent agreement is aggregated over the total measurement duration and all women.

Abbreviations: BSS, blind source separation; CI, confidence interval; Nemo, Nemo Fetal Monitoring System; SD, standard deviation.

*Subanalysis for the Avalon-Beltless including all measurements from 36 weeks of gestation, which is within the intended use of the device.

†BSS method is used.

TABLE 4 Success rate, positive percent agreement and root mean square error for different gestational age intervals.

			Gestational age intervals				
			$24^{0/7}$ to $27^{6/7}$	$28^{0/7}$ to $31^{6/7}$	$32^{0/7}$ to $35^{6/7}$	$36^{0/7}$ to $39^{6/7}$	≥$40^{0/7}$
Success rate	Avalon	No. of patients	2	2	0	5	1
	Beltless*	Mean ± SD	45.3 ± 53.0	18.1 ± 14.9	-	96.2 ± 7.5	99.8
		CI	0.0–100.0	0.0–38.8	-	89.6–100.0	-
	Nemo	No. of patients	1	1	4	4	0
		Mean ± SD	97.6	100	99.0 ± 1.6	100 ± 0	-
		CI	-	-	97.4–100.0	100–100	-
Positive percent agreement	Avalon	No. of patients	2	2	0	5	1
	Beltless*	Mean ± SD	62.9 ± 35.3	5.1 ± 6.3	-	94.6 ± 5.9	99.2
		CI	14.0–100.0	0.0–15.8	-	89.5–99.8	-
	Nemo	No. of patients	1	1	4	4	0
		Mean ± SD	98.8	98.5	90.6 ± 7.2	95.5 ± 7.1	-
		CI	-	-	83.6–97.7	88.6–100.0	-
	Dipha-16†	No. of patients	1	2	1	6	0
		Mean ± SD	8.5	87.3 ± 4.2	86.8	59.1 ± 39.8	-
		CI	-	81.5–93.1	-	27.3–90.9	-
	Infinity-M300†	No. of patients	1	3	2	3	1
		Mean ± SD	29.6	44.7 ± 23.0	4.6 ± 1.9	37.0 ± 41.4	26.1
		CI	-	18.7–70.7	2.0–7.2	0.0–83.9	-
RMSE	Avalon Beltless*	No. of data points	11 837	3021	-	55 676	14 983
		RMSE	8.3	25.3	-	6.6	3.5
	Nemo	No. of data points	11 305	18 064	32 013	47 176	-
		RMSE	4.1	2.9	5.9	5.5	-
	Dipha-16†	No. of data points	22 251	19 316	7439	52 051	-
		RMSE	17.8	7.6	6.7	18.8	-
	Infinity-M300†	No. of data points	9529	23 678	23 913	29 548	7769
		RMSE	11.3	13.3	16.4	22.0	13.0

Note: For Avalon-Beltless, 95% CI is used. The CI is truncated at 100.0%. The success rate, positive percent agreement and RMSE are aggregated over the total measurement duration and all women. The number of data points represents the number of sampling points.

Abbreviations: BPM, beats per minute; BSS, blind source separation; CI, confidence interval; Nemo, Nemo Fetal Monitoring System; No, number; RMSE, root mean square error; SD, standard deviation.

*Avalon-Beltless is intended to be used from 36 weeks of gestation but within this study is also used outside its intended use.

†BSS method is used.

of the Avalon-Beltless was higher when only measurements from 36 weeks were included. Across the different gestational age intervals, the PPA of the FHR was highest for Nemo (Table 4). Figure 3 provides Bland–Altman plots for each device including the bias, 95% limits of agreement, regression line and RMSE. The bias, 95% limits of agreement, slope, intercept and RMSE of the FHR were lowest

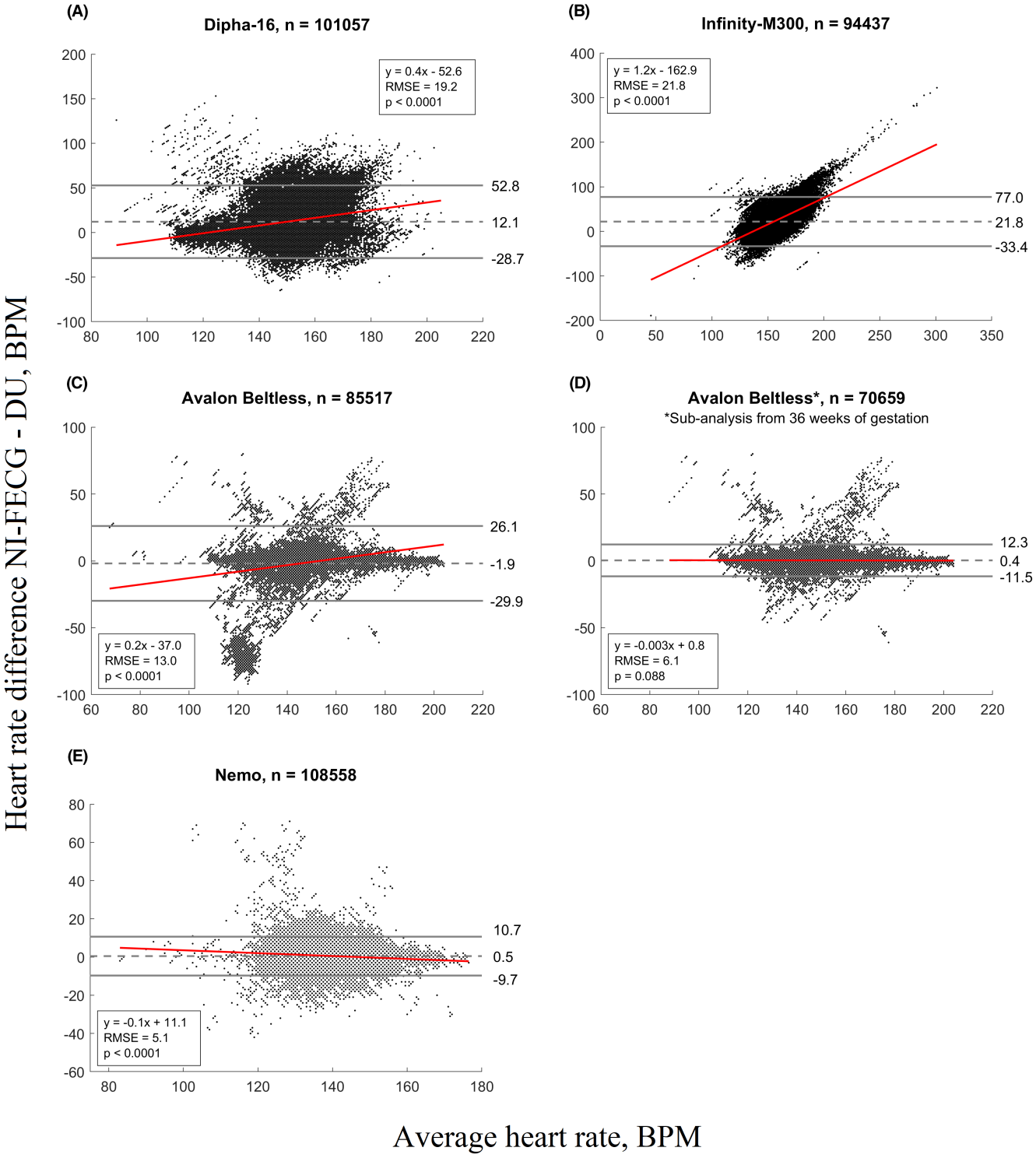

FIGURE 3 Bland-Altman plot between fetal heart rate measurement per sample point obtained with the Avalon-FM30 and (A) Dipha-16†, (B) Infinity-M300†, (C) Avalon-Beltless, (D) Avalon-Beltless* and (E) Nemo. The agreement is presented as bias (striped gray) with the upper and lower 95% limits of agreement (light gray) in BPM. The linear regression is plotted (red) and the regression equation and RMSE are given. *Subanalysis for the Avalon-Beltless including all measurements from 36 weeks of gestation, which is within the intended use of the device. †BSS method is used. BPM, beats per minute; BSS, blind source separation; DU, Doppler ultrasound; Nemo, Nemo Fetal Monitoring System; NI-FECG, noninvasive fetal electrocardiography; RMSE, root mean square error.

for the Nemo and highest for the Infinity-M300. The RMSE of the FHR across the different gestational age intervals was lowest for the Nemo (Table 4). No differences were found between the FHR classifications of the simultaneously registered tracings by Nemo and Avalon-FM30. For the simultaneously registered tracings by Avalon-Beltless and Avalon-FM30, two tracings were classified differently by one of the maternal-fetal medicine specialists. In the first case, FHR was measured at $26^{2/7}$ weeks. The Avalon-FM30 measurement was classified as normal, whereas the Avalon-Beltless measurement was classified as suboptimal due to a partial saltatory pattern and signal loss with possible a complicated variable deceleration. In the second case, the FHR was measured at $36^{0/7}$ weeks. The Avalon-FM30 measurement was classified as suboptimal due to a baseline FHR of 155 BPM, whereas the Avalon-Beltless measurement was classified as normal with a baseline FHR of 150 BPM. In addition, both maternal-fetal medicine specialists were unable to classify three tracings by Avalon-Beltless due to a high level of signal loss. These tracings were obtained at $26^{6/7}$, $30^{0/7}$ and $30^{6/7}$ weeks of gestation.

3.2 | Maternal heart rate

Unlike the Avalon-FM30, Nemo always provided a non-zero MHR value as output (Table 2). The Avalon-Beltless outperformed the Avalon-FM30 in providing a non-zero MHR value as output, with a 100% success rate when only measurements within its intended use were considered. All NI-FECG devices achieved a PPA >90% for the MHR (Table 3). Nemo had the highest PPA and Dipha-16 had the lowest. The Avalon-Beltless had a slightly lower PPA when only the measurements from 36 weeks were included. Figure 4 provides Bland–Altman plots of the MHR for each device including the bias, 95% limits of agreement, slope, intercept and RMSE. The bias, 95% limits of agreement, slope, intercept and RMSE of the MHR were lowest for the Avalon-Beltless and highest for the Dipha-16. When only the measurements from 36 weeks were considered for the Avalon-Beltless, the bias decreased and the 95% limits of agreement, slope, intercept and RMSE slightly increased.

3.3 | Patient experience

Women who had FHR monitoring performed with a NI-FECG device rated their FHR monitoring experience higher than did women who had FHR monitoring performed with a DU device alone (Avalon-FM30 7.2 ± 2.1, Avalon-Beltless 8.4 ± 1.4, Nemo 7.9 ± 1.1, Dipha-16 9.4 ± 0.6, Infinity-M300 8.9 ± 1.0). Eight of 40 women who had FHR monitoring performed with a NI-FECG device reported skin irritation from the electrodes (Avalon-Beltless $n = 4$, Dipha-16/Infinity-M300 $n = 3$, Nemo $n = 1$). Three of 10 women who had FHR monitoring performed with only the DU device reported discomfort due to movement restrictions.

4 | DISCUSSION

This study compared the performance and patient experience of four NI-FECG devices with that of a conventional DU device, as an initial step to assess candidate devices for the introduction of prolonged noninvasive FHR monitoring.

It was demonstrated that all devices were capable of measuring FHR and MHR. The difference in FHR measurement with the DU device was smallest for the Nemo and was greater for the Avalon-Beltless, Dipha-16, and Infinity-M300. According to FIGO guidelines, FHR should be clearly readable at least 80% of the time. This criterion was met by the Nemo (99.4%) and by the Avalon-Beltless (96.8%) when only including the measurements from 36 weeks of gestation. We considered differences from the DU device of up to 10 BPM to be clinically acceptable. The 10 BPM limit was exceeded 5.8% of the time with the Nemo, 29.2% of the time with the Avalon-Beltless, 37.6% of the time with the Dipha-16 and 69.0% of the time with the Infinity-M300. When only the measurements from 36 weeks of gestation were considered, the Avalon-Beltless exceeded this limit 4.7% of the time. The visual agreement metric showed that for Nemo this did not result in any differently classified CTG tracings and therefore would not affect clinical management. For Avalon-Beltless, however, it would affect clinical management because outside its intended use, four CTG tracings were classified differently and within its intended use, one CTG tracing was classified differently. Bland–Altman analysis revealed that the 95% limits of agreement of the FHR for the Avalon-Beltless, Dipha-16 and Infinity-M300 devices were multiples (nearly 3–8 times) of our 10 BPM limit. For the Dipha-16 and Infinity-M300 the bias already exceeded our 10 BPM limit. If the difference in output for these devices were as extreme as the 95% limits of agreement, this could affect the interpretation of the CTG and clinical management. For example, a baseline FHR measured by DU within the normal range (110–150 BPM) could result in a suboptimal or abnormal baseline FHR. Also, acceleration or deceleration patterns may be lost. Therefore, we consider the quality of the FHR measurement of the Dipha-16, Infinity-M300, and Avalon-Beltless outside its intended use currently inadequate.

An advantage of the NI-FECG technology is that the sensor simultaneously measures the MHR, eliminating the need for a TOCO+MP or finger pulse oximeter to measure MHR. The NI-FECG devices were more successful in providing a non-zero MHR value than the conventional device was. For the Avalon-Beltless, Nemo and Infinity-M300, the PPA was greater than 97% and the 95% limits of agreement were around ±10 BPM. Therefore, these devices performed at least as well as the conventional device when MHR was measured. In contrast, the performance of the Dipha-16 was lower than that of the conventional device. The higher patient experience scores for the NI-FECG devices reported in this study are promising for the use of a NI-FECG device in a prolonged FHR monitoring protocol.

Previous studies on late preterm and term NI-FECG monitoring have reported reliable and accurate FHR registrations. These studies

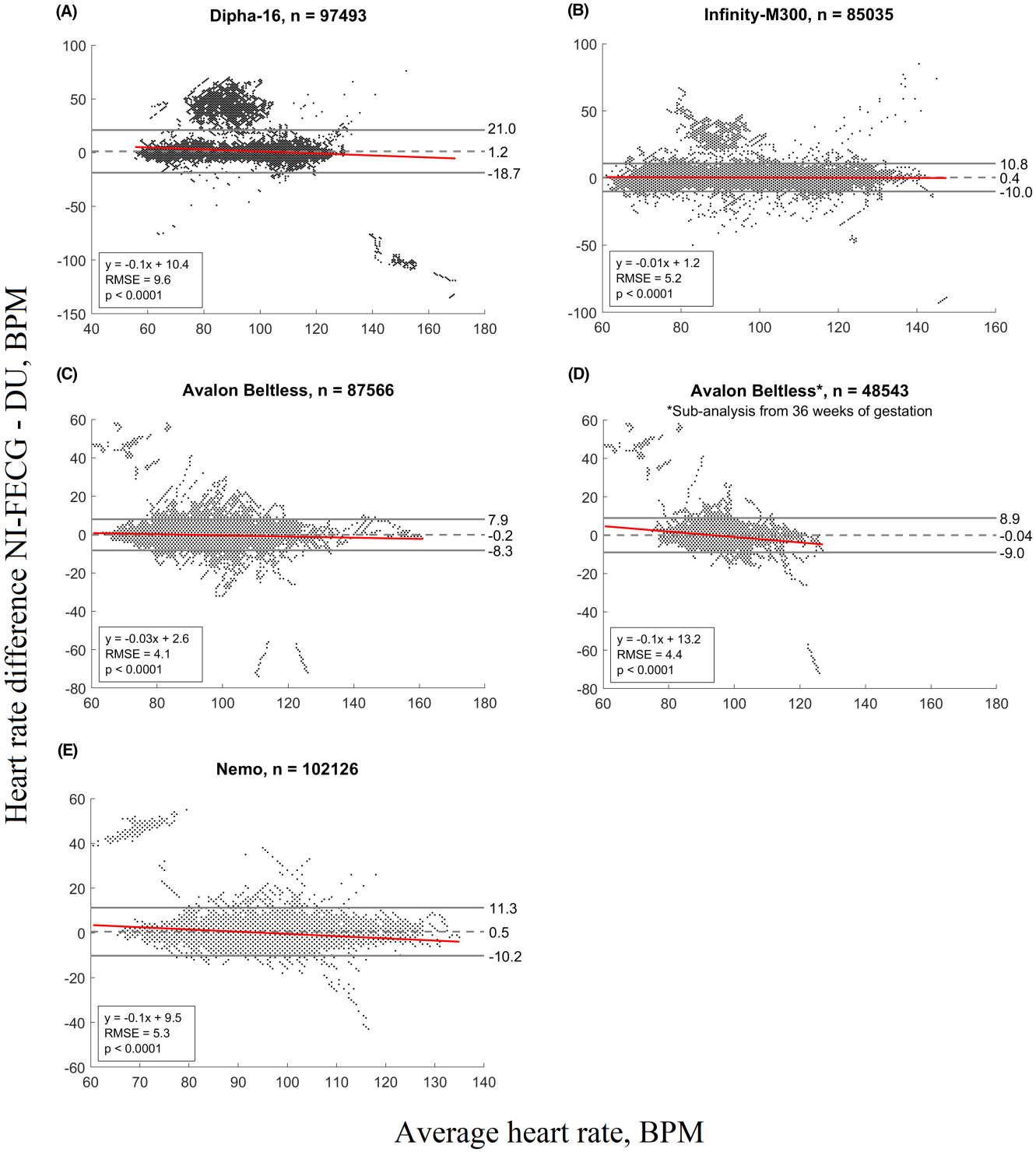

FIGURE 4 Bland-Altman plot between maternal heart rate measurements per sample point obtained with the Avalon-FM30 and (A) Dipha-16†, (B) Infinity-M300†, (C) Avalon-Beltless, (D) Avalon-Beltless* and (E) Nemo. The agreement is presented as bias (striped gray) with the upper and lower 95% limits of agreement (light gray) in BPM. The linear regression is plotted (red) and the regression equation and RMSE are given. *Subanalysis for the Avalon-Beltless including all measurements from 36 weeks of gestation, which is within the intended use of the device. †BSS method is used. BPM, beats per minute; BSS, blind source separation; DU, Doppler ultrasound; Nemo, Nemo Fetal Monitoring System; NI-FECG, noninvasive fetal electrocardiography; RMSE, root mean square error.

used either DU or invasive fetal scalp electrode as reference standard.[4,16–24] In contrast, conflicting results on performance have been reported in the literature for preterm NI-FECG monitoring.[20,25,26] Our study also showed conflicting results in preterm monitoring between NI-FECG devices. It is important that the performance of the NI-FECG device is high in both preterm and term monitoring,

as prolonged FHR monitoring can be used throughout pregnancy to detect clinical deterioration. Reliable and accurate performance of NI-FECG devices for MHR measurements has been reported previously.[19,23] Previous research has shown that women prefer the comfort of the NI-FECG device over the DU device.[18,26] In addition, reported skin irritation from the electrodes does not prevent women from reusing the NI-FECG.[20,27] The aforementioned studies evaluated several NI-FECG devices: Avalon-Beltless,[27] Femom,[4] Monica-AN24,[17,20,21,25,26] Monica-Novii[18,19] and Nemo.[23,24] Other commercial NI-FECG devices known to the authors are: Fetal Lite and Meridian-M110.

This study included two amplifiers repurposed as FHR monitors: the Dipha-16 and Infinity-M300. The performance of both devices deviated from the DU device. The greater deviations may be explained by the technical specifications, the electrode configuration used and the algorithms employed. First, the sample rate for both devices was <1000 Hz recommended for NI-FECG monitoring, which is considered necessary for accurate R-peak detection in the maternal and fetal ECG signal.[28] Secondly, the Infinity-M300 applied its own signal filtering that is based on adult ECG monitoring and, as a result, the fetal ECG may have been suppressed.[29] Thirdly, the electrode configuration used is recommended for near-term pregnancies,[7] whereas the measurements were taken from 24 weeks, when the fetus has more room to move. Fetal movement changes the orientation of the heart relative to the electrodes and alters signal morphology and amplitude. Consequently, the fetal ECG signal-to-noise ratio may be reduced, making the extraction more difficult.[28] Fetal orientation is unknown beforehand, therefore an electrode grid is used to capture the electrical signal from different directions. The configuration is a trade-off between patient comfort and the accuracy needed to assess fetal health. More electrodes provide a more complete picture and may be used to assess morphological parameters that can discriminate between healthy and pathologic fetuses (eg growth restriction). Commercial NI-FECG devices have a fixed electrode configuration that ensures accurate FHR detection throughout pregnancy and does not require additional education on positioning. The signal-to-noise ratio may also explain the varying performance of NI-FECG devices in our study during preterm monitoring. In preterm monitoring, the signal-to-noise ratio is lower because a smaller heart produces a smaller electrical signal, and the formed vernix acts as an electrical insulator, which challenges fetal ECG extraction and may result in signal loss. Our study found no effect of gestation on signal loss for Nemo, but the PPA decreased at 32–36 weeks compared with 28–32 weeks (90.6% vs 98.5%). In contrast, for Avalon-Beltless, signal loss was higher and PPA lower for gestation at <32 weeks compared with gestation from 36 weeks. The DU device used a TOCO+MP sensor for the MHR measurement. The high signal loss from the TOCO+MP sensor may be caused by motion artifacts, low pulse rates or the pulse signal quality on the skin.[30] A stable MHR measurement is important to identify MHR-FHR ambiguity.

This study appears to have a number of important strengths. First, the study evaluated the performance of the NI-FECG for a broad range of gestational ages ($24^{6/7}$–$41^{2/7}$ weeks). Secondly, the study included four different NI-FECG-based devices, providing an overview of the performance of different NI-FECG-based devices and allowing comparison between devices. Last, the study determined the visual classification of CTG tracings used in clinical practice and discussed the implications of the difference in visual classification on clinical management.

Several limitations of this study need to be addressed. First, the sample size of the study was small, allowing potential outliers to have a greater negative influence on the results. The sample size was a trade-off between the goal of providing initial insights into NI-FECG monitoring devices and their suitability for prolonged monitoring, and the feasibility of the study. Secondly, no intrapartum measurements were performed. It is important to determine the performance of the devices intrapartum, as intrapartum monitoring presents new challenges for FHR extraction due to uterine activity and the second phase of labor. Thirdly, intermittent monitoring was performed in the study, according to the clinical protocol.

The results of the study cannot be directly extrapolated to prolonged FHR monitoring, as prolonged monitoring introduces additional elements that may affect performance, such as more body movement by the women. However, we believe that the results provide a good indication of the potential of the devices for prolonged noninvasive FHR monitoring. This study compared MHR and FHR per sample and the visual interpretation of FHR patterns. Visual interpretation is the gold standard for assessing fetal wellbeing in our hospital. However, it has high inter- and intra-variance. An objective alternative is computerized CTG, which uses algorithms to measure FHR indices such as short-term variation. Future studies could evaluate agreement between computerized CTG indices derived from DU and NI-FECG. In addition, future studies are recommended to include a larger sample size, intrapartum FHR monitoring and prolonged FHR monitoring.

5 | CONCLUSION

Dedicated FHR monitoring devices, in the form of Nemo and Avalon-Beltless, perform significantly better than repurposed amplifiers, in the form of Dipha-16 and Infinity-M300. The latter are currently unsuitable for (prolonged) noninvasive FHR monitoring. Below its intended use limit of 36 weeks of gestation, the Avalon-Beltless is also currently unsuitable for (prolonged) noninvasive FHR monitoring, due to its inferior performance compared with conventional DU. For their intended use, both the Nemo and the Avalon-Beltless are suitable devices for (prolonged) noninvasive FHR monitoring. NI-FECG devices are preferred by women for (prolonged) noninvasive FHR monitoring because of the greater ease of movement and comfort.

AUTHOR CONTRIBUTIONS

Chantal Eenkhoorn, Tom G. Goos and Alex J. Eggink designed the study and interpreted results. Chantal Eenkhoorn performed measurements, analyzed data, prepared figures and wrote the draft.

Tom G. Goos, Jenny Dankelman, Arie Franx and Alex J. Eggink edited and revised the paper. All authors approved the final version of the paper.

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CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

ETHICS STATEMENT

The study is registered under FHR monitoring pilot and approved by the Daily Board of the Medical Ethics Committee Erasmus Medical Center (Rotterdam, The Netherlands) (MEC-2019-0637, October 15, 2019), in accordance with the Research Involving Human Subject Act (WMO).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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