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Clinical Investigation Plan Summary

Title	A cross-sectional, interventional, single-arm clinical study for validating the equivalence of Bloomlife MFM-Pro to clinical standard-of-care for fetal heart rate and maternal heart rate when performing antepartum fetal monitoring
Acronym	NST
Protocol Number	NST-01-2021-US
Version	3.0 – 23FEB2022
Reference number (IRB)	*Pro00049843*
Funding	This study is funded by Bloomlife Inc (study sponsor)

Study Synopsis	Population	Non-laboring pregnant women with singleton pregnancy, at 32 weeks of gestation or more, monitored with Bloomlife MFM-Pro and Cardiotocograph (CTG).
	Investigational Device	Bloomlife MFM-Pro is indicated for monitoring of maternal and fetal physiological parameters during the antepartum period. It is to be used by healthcare professionals in hospitals, clinics, physicians' offices, antepartum rooms, and in the patients' home on the order of a physician. Bloomlife MFM-Pro is a non-invasive, wireless, external monitoring system used to measure fetal heart rate (fHR), maternal heart rate (mHR), and uterine activity during antepartum (non-stress) testing on pregnant women with a singleton pregnancy. The system acquires biopotential signals from abdominal surface electrodes and measures the fetal electrocardiography, maternal electrocardiography and electrohysterography. The sensor also acquires motion data through an accelerometer. It transmits the measured data to the Bloomlife Mobile App and to the Cloud for storage/processing.
	Comparison	Reference device: Cardiotocograph (Philips Avalon FM30 or equivalent)

	Objectives	Primary objective: ● To demonstrate equivalence of Bloomlife MFM-Pro to clinical standard-of-care for fetal heart rate and maternal heart rate when performing antepartum fetal monitoring. Secondary objective: ● To establish the safety of Bloomlife MFM-Pro. Exploratory objectives: ● To compare measurement reliability of Bloomlife MFM-Pro and CTG in measuring fetal heart rate. ● To compare measurement reliability of Bloomlife MFM-Pro and CTG in measuring maternal heart rate. ● To study the Bloomlife MFM-Pro performance when compared to standard-of-care (CTG) for uterine activity. ● To study the correlation between the Bloomlife MFM-Pro signal quality check result and fetal heart rate quality
	Endpoints	Primary endpoints: ● Extent of agreement between Bloomlife MFM-Pro and CTG in fetal heart rate (FHR) and maternal heart rate (MHR): ○ 95% LoA for FHR within +/- 10 bpm ○ 95% LoA for MHR within +/- 7 bpm ● Regression analysis of MFM-Pro vs CTG for fetal heart rate and maternal heart rate determining if the bias is constant across the range of the measurements. Secondary endpoints: ● Summary tables of recorded adverse events, serious adverse events, adverse device effects, device deficiencies. Exploratory endpoints: ● Percentage of a recording with a FHR for Bloomlife MFM-Pro and for CTG. ● Percentage of a recording with a MHR for Bloomlife MFM-Pro and for CTG. ● Sensitivity and False Event Rate for uterine contractions annotated by experts based on uterine activity traces measured with Bloomlife MFM-Pro and with CTG.

		• Confusion matrix between the signal quality check result (pass or fail) and the recording quality (for the MFM-Pro fetal heart rate signal, over the complete measurement)
	Design	National, prospective, cross-sectional, interventional, single-arm study.
	Number of subjects	Pilot phase: up to 200 enrolled subjects Pivotal phase: up to 60 enrolled subjects
	Inclusion criteria	• Pregnant woman ≥ 18 years old • Gestational age ≥ 32 weeks and 0 days • Singleton pregnancy • Ability to read and understand English or Spanish • Willingness to participate in the study
	Exclusion criteria	• Implanted pacemaker or any other implanted electrical device • Plurality higher than 1 • History of allergies to skin adhesives • Irritated or lesioned skin at the Bloomlife MFM-Pro electrodes locations • Contraindication to the use of CTG (e.g. due to preterm contractions)
	Enrolment criteria	A participant is considered enrolled when their eligibility is confirmed, and the signal validation screening test (performed by the Bloomlife MFM-Pro) gives a successful result.
	Study duration	Q1 2021 – Q2 2022
	Study Procedures	<u>Informed consent:</u> Eligible participants will be asked to sign an informed consent form before any study-specific procedure is performed. <u>MFM-Pro electrodes connection check & signal quality check:</u> Once the informed consent is signed, participants are asked to sit on a reclined (NST) chair (or lie on a hospital bed).

		The researcher prepares the patient's skin by cleaning it and by using medical skin-prep tape on her belly. The researcher proceeds with setting up the Bloomlife MFM-Pro system, in parallel with the CTG. The researcher instructs the participant to annotate perceived contractions by pressing a button. With this setup, data is collected with both devices, while the Bloomlife MFM-Pro performs an electrode connection check and signal quality check (screening test). This step may take up to 15 minutes. If the electrode connection check fails or the CTG does not capture the MHR/FHR signals, the measurement setup is adjusted as needed (up to three attempts are allowed). <u>Study measurement:</u> If the electrodes connection check and the CTG setup are successful, data is collected with both the Bloomlife MFM-Pro and the CTG monitor for 45 minutes. A video of the belly and a picture of the setup may also be taken. During the data collection, the researcher uses a custom data visualization interface to visualize data from the CTG and the Bloomlife MFM-Pro, to identify issues with the measurement setup and annotate relevant events in the data collection process. At the end of the data collection, the Bloomlife MFM-Pro and CTG tracings are stored in a digital format for analysis. After the Bloomlife MFM-Pro data collection, relevant information pertaining to the subject's pregnancy and medical history is collected from her medical records and entered in the eCRF. Any adverse event observed during the data collection (signal quality check and measurement) will be recorded by the researcher. Information about other adverse events will be collected from the participant's medical records for 7 days after the measurement.
	Statistical Data Analysis	**Limits of Agreement:** For assessing the agreement between the Bloomlife MFM-Pro fetal heart rate (FHR) and a standard of care

		Cardiotocograph (CTG), we plan to estimate the 95% limits of agreement (LoA) according to Bland-Altman, together with 95% confidence intervals (95%CI). 95% limits of agreement objectives: 1. Fetal heart rate the 95% limits of agreement lie within +/- 10 bpm 2. Maternal heart rate the 95% limits of agreement lie within +/- 7 bpm. **Linear regression analysis:** A linear regression analysis assessing the relationship between the bias and the magnitude of measurements will also be performed**.**
	Timeline	Subjects are asked to participate in one data collection performed at the clinic. The data collection requires up to 1.5 hours. A follow-up period of 7 days (after the measurement) is used to collect safety information.

Sponsor	Name	Bloom Technologies NV (a daughter company of Bloomlife Inc)
	Address	Schiepse Bos 6, 3600 Genk (Belgium)
	Key personnel	Elisa Rossetti, Clinical Studies Manager Melissa Ingersoll, Clinical Research Associate Violaine Emonard, Clinical advisor Julien Penders, COO

During the study, the Sponsor keeps a separate document with an updated list of the Principal Investigator(s) and investigation site(s). The PI and site information is submitted to the IRB at study submission.