January 26, 2025

Pulsenmore™
Home Ultrasound

Clinical Studies
Pulsenmore ES

- Study index completed and ongoing
- Claims
- Publication list
- Quiz

Key publications

1. Mobile Self-Operated Home Ultrasound System for Remote Fetal Assessment During Pregnancy
2. Feasibility and Acceptance of Self-Guided Mobile Ultrasound among Pregnant Women in Routine Prenatal Care
3. Integrating technologies to provide comprehensive remote fetal surveillance: A prospective pilot study
4. The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial
5. Validation of Pulsenmore ES M-mode Fetal Heart Rate (FHR) and Maximal Vertical Pocket(MVP) Measurement tools.

Mobile self-operated home ultrasound system for remote fetal assessment during pregnancy

Year	2021
Medical Center	Helen Schneider Hospital for Women, Rabin Medical Center, Israel
PI	Prof. Eran Hadar
# of Patients	100
Status	Completed

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Study design	An observational feasibility study Population: Pregnant women, singleton fetus, 14-40GW, Participants received the device for a self-use period of 7–14 days and performed 1-3 scans a day. Participants completed a self-assessment questionnaire to evaluate safety and user experience and satisfaction
Objective	To evaluate the use of remote fetal ultrasound assessment during pregnancy
Results	100 women completing 1,360 self-scans, used the device for 8.1 ± 1.5 days, performing an average of 13.6 ± 6.2 scans each. No device-related serious adverse events were found. 95.3% success in detection of fetal heart activity, 88.3% for body movements, 69.4% for tone, 92.2% for normal amniotic fluid volume, 23.8% for breathing movements. Self-assessed user experience was rated at 4.4/5, whereas device satisfaction was rated at 3.9/5.

Feasibility and acceptance of self-guided mobile ultrasound among pregnant women in routine prenatal care

Year	2023
Medical Center	Department of Obstetrics and Gynecology, Universitätsklinikum Erlangen, 91054 Erlangen, Germany
PI	Prof. Constanza A. Pontones
# of Patients	46
Status	Phase I completed & published; Phase 2 ongoing

Uniklinikum Erlangen

Study design	Prospective, single-center, interventional study, Women with singleton pregnancies between 17 + 0 and 29 + 6 GW were included in two cohorts, using two different mobile ultrasound systems (Pulsenmore ES and Butterfly iQ). The participants examined the fetal heartbeat, fetal profile and amniotic fluid. Feasibility and acceptance were evaluated using a questionnaire. Success rates in relation to image and video quality were evaluated by healthcare professionals
Objectives	Evaluation of the benefits and possible risks of self-guided ultrasound examinations conducted by pregnant women remotely. Aspects of feasibility, acceptance, and success rates.
Results	The results show wide acceptance of self-examination using mobile systems for fetal ultrasonography during pregnancy. Image quality was adequate for assessing the amniotic fluid and fetal heartbeat in most participants. Phase II study is currently ongoing to determine whether ultrasound self-examinations can be implemented in prenatal care and

Integrating technologies to provide comprehensive remote fetal surveillance: A prospective pilot study

Year	2023
Medical Center	Department of Obstetrics and Gynecology, Sheba Medical Center, Israel
PI	Prof. Abraham Tsur
# of Patients	10
Status	Completed - published

SHEBA Tel HaShomer City of Health

19th World Congress in Fetal Medicine

Study design	Prospective pilot study, with low-risk pregnant participants who were recruited at the time of their first full-term in-person visit. Patients were scheduled for a follow-up telemedicine visit, using novel self-operated fetal monitoring and Pulsenmore ES ultrasound devices. Fetal heart monitoring and amniotic fluid volume measurements were obtained to complete a modified biophysical profile (mBPP). Total visit length was measured for both the in-person first visit and the subsequent telemedicine encounter. A patient satisfaction survey form was obtained.
Objectives	To determine the feasibility of extending remote maternal-fetal care to include fetus well-being.
Results	10 women between 40 + 1 and 40 + 6 GW participated in telemedicine encounters.9 women (90%) completed remote mBPP assessment. For 1 participant, fetal assessment was not completed due to technically inconclusive fetal monitoring. Another participant was referred for additional assessment in the delivery room. Satisfactory amniotic fluid volume measurements were achieved in 100% of participants. The telemedicine encounter was significantly shorter (93.1 ± 33.1 min) than the in-person visit (247.2 ± 104.7 min; $P < 0.001$). High patient satisfaction was reported.

The effect of home ultrasound on maternal anxiety in patients with previous recurrent pregnancy loss: A randomized control trial

Year	2023
Medical Center	Edith Wolfson Medical Center, Holon, Israel
PI	Prof. Eran Weiner
# of Patients	50
Status	Completed

Study design	Randomized controlled study, enrolling women with a history of pregnancy loss after 20 weeks. Participants were randomized into two groups: Control group receiving routine high-risk prenatal care, Study group receiving additional telemedicine visits, including home-ultrasound scans. Maternal anxiety was assessed using the State-Trait Anxiety Inventory Scale (STAI-S). Maternal attachment was evaluated using the Maternal Antenatal Attachment Scale (MAAS-2), at four time points during pregnancy.
Objective	To evaluate the impact of twice-a-week telemedicine visits, including home-ultrasound, on maternal anxiety and antenatal attachment in women with a history of pregnancy loss.
Results	50 patients completed the follow-up,(25 in each group). No significant differences in demographics or pregnancy outcomes between the groups. STAI score at the last visit was significantly lower in the device group compared to the control group (34.8 ± 12.9 vs. 45.0 ± 15.9, p = 0.016). In addition, the study group exhibited a greater reduction in STAI scores between the first and last visits (-13.6 ± 15.0 vs. -1.5 ± 11.3, p = 0.015), and a significant increase in MAAS scores from the beginning to the end of the follow-up period in the study group compared to the control group (1.8 ± 14.9 vs. -3.8 ± 13.6, p = 0.013).
Conclusion	Integrating routine home-ultrasound telemedicine visits into prenatal care of women with previous pregnancy loss, can significantly reduce maternal anxiety during pregnancy and contribute to greater maternal attachment

Validation of Pulsenmore ES M-mode Fetal Heart Rate (FHR) and Maximal Vertical Pocket(MVP) Measurement tools.

Year	2023
Medical Center	Helen Schneider Hospital for Women, Rabin Medical Center, Israel
PI	Dr. Anat Pardo
# of Patients	30
Status	Completed

RABIN MEDICAL CENTER
BEILINSON • HASHARON

Study design	An observational study compared FHR and MVP measurements obtained from ultrasound clips, generated by participant's self-scanning using Pulsenmore (PNM) ultrasound, with those from In-Clinic conventional ultrasound. Each participant underwent four scans, comprising two pairs: (1) Self-scan using AG mode followed by an In-Clinic conventional scan (INC1), and (2) Self-scan using CG mode followed by an In-Clinic conventional scan (INC2). Scans were reviewed by three independent blinded readers, with agreement defined for differences in average measured values for FHR (< 32BPM) and MVP (within 20%) between modalities. 32% of cases have abnormal amniotic fluid volume, to assess the Pulsenmore ES capability to identify abnormal MVP.
Objectives	To validate the accuracy of Pulsenmore ES M-mode FHR and MVP measurements compared to these measurements in real-time and on MP4 clips generated by conventional US device by a healthcare professional
Results	28 participants completed the study, 9 (32%) with previous diagnosis of abnormal AFV. Fetal heartbeat and AFV were visualized in > 94% of scans with adequate image quality score for diagnosis (3.44 of 5). FHR and MVP measurements were obtained in 85% and 92% of AG scans, respectively, and in 95% of CG scans. The FHR average absolute differences, between Pulsenmore ES scans and In-clinic scans, was 10.8±7.5 bpm for AG vs INC1 (7.3% percent error [PE]), and 5.8±5.1 bpm for CG vs. INC2 (4% PE) (both p< 0.001). The MVP average difference, between Pulsenmore ES scans and In-clinic scans, was 1.3±1.4 cm (p<0.16) for AG vs. INC1 (22% PE), and 0.9±0.8 cm (p<0.002) for CG vs. INC2 (14.5% PE). Subjective evaluation of AFV as normal or abnormal revealed sensitivity of 66.7% for both AG and CG modes, and specificity of 86.7% and 78.3% for AG and CG, respectively. Evaluation of AFV as normal or abnormal based on MVP measurements (2cm<MVP< 8 cm is considered as normal, MVP<2cm or MVP>8cm is considered as abnormal), revealed sensitivity of 87.5% and 100% for AG and CG, respectively, and specificity of 95% for both operation modes. **Conclusions**: The Pulsenmore home ultrasound, operated by lay users, provides high-quality and accurate evaluation of AFV and FHR, non-inferior to standard assessments.

Abstract

Real-world study: Self operated remote ultrasound and remote expert review enabling continuity of antenatal care

Year	2022
Medical Center	Helen Schneider Hospital for Women, Rabin Medical Center, Israel
PI	Prof. Eran Hadar
# of Patients	2000
Status	Completed

RABIN MEDICAL CENTER
BEILINSON • HASHARON

ECPM: 28th European Congress of Perinatal Medicine 2022

Study design	Retrospective study of deidentified real-world data from the service center of Clalit: evaluation of self-performed scans by pregnant women using the Pulsenmore system. Scans were reviewed by physicians for asynchronous review, interpretation, and feedback.
Objectives	To evaluate the performance and adequacy of the service for remote fetal ultrasound using the Pulsenmore system.
Results	Out of 20,153 scans performed, 98.4% were classified as "adequate," with the ultrasound professional able to identify and evaluate all three designated variables: fetal pulse, movements, and amniotic fluid volume. Following the first adequate scan, 95.3% were normal and 3.1% were abnormal. For abnormal scans, women were guided to repeat the scan (2.47%) or referred to an in-person visit (2.23%). Repeat scans resulted in an additional 1.78% normal scans, leading to a total of 97.08% scans considered normal.

Hybrid remote and In-Clinic maternal-fetal surveillance for women with gestational diabetes - A Prospective Pilot Study

Year	2023
Medical Center	The Josef Buchmann Gynecology and Maternity Center, Sheba Medical Center, Tel Hashomer, Israel
PI	Prof. Abraham Tsur
# of Patients	20
Status	Completed – In preparation for Submission

SHEBA
Tel HaShomer
City of Health

Study design	20 women with gestational diabetes ≥32 GW participated in a 4-week prospective study of alternating remote and in-clinic visits. During the in-clinic visits the patients had a meeting with a nurse including anamnesis, vital signs, urinalysis, a modified biophysical assessment combining non-stress test and sonographic assessment by an ultrasound technician and a physician evaluation including ongoing glycemic control. The remote assessment included video anamnesis, vital signs, ongoing glycemic control, urinalysis, and modified biophysical assessment combining non-stress test and sonographic maximal vertical pocket. We examined remote visit feasibility, comparison of the duration of in-clinic and remote visits, assessment of compliance to glucose documentation during and after the study and patient satisfaction.
Objective	To investigate the feasibility and effects of hybrid comprehensive maternal-fetal care for gestational diabetes.
Results	Hybrid maternal-fetal care is feasible, saves time, improves patient satisfaction, and improves maternal compliance with glycemic control.

Feasibility of additional telemedicine and home- ultrasound visits in reducing maternal anxiety during pregnancy subsequent to stillbirth.

Year	2023
Medical Center	Edith Wolfson Medical Center, Holon, Israel
PI	Prof. Eran Weiner
# of Patients	50
Status	Ongoing

Study design	Randomized controlled study, enrolling women with a history of stillbirth. Participants are randomized into two groups: the Control group receiving routine high-risk prenatal care, and the Study group receiving additional telemedicine visits with a maternal-fetal medicine specialist, including home-ultrasound scans. Maternal anxiety was assessed using the State-Trait Anxiety Inventory Scale (STAI-S), Maternal attachment was evaluated using the Maternal Antenatal Attachment Scale (MAAS-2), at four time points during pregnancy.
Objective	To evaluate the impact of twice-a-week telemedicine visits, including home-ultrasound, on maternal anxiety and antenatal attachment in women with a history of stillbirth.
Results	Analysis

Pulsenmore's claims

Claim	Reference
Feasible and accepted solution for remote prenatal care	Hadar E. et al 2022, Pontones et al. 2023, Nir et al. 2024, Clalit Real World data
Adequate imaging that enables reliable evaluation	
Safety	
Good user experience and satisfaction	Clalit survey, Pontones et al. 2023, Nir et al. 2024,
Accurate measurement of FHR and MVP parameters	Pardo A. et al 2024
Reduced anxiety and improved pregnancy experience	Mor. L et al. 2024, Clalit survey
Enhanced care of specific high-risk pregnancy monitoring (GDM, recurrent pregnancy loss)	Axelrod et al. 2025, Mor. L et al. 2024
Feasibility of remote mBPP and BPP	Nir O. at al. 2024, Pardo A. et al 2024
Biofeedback pre -labour maternal training	Prof. Perlman & Dr. Hendin