PROTOTYPE PRODUCT/
NEWLY COMMERCIALIZED

2022

Fetal monitor

Country of origin | India
Primary function | Monitoring
Category | Medical device

Commercial information

List price (USD): 2000
Year of commercialization: 2019
Number of units distributed: 0-100
Currently marketed in: Commercially available in India. Under evaluation in Poland, Israel, ASEAN, Ghana
Brand: InnAccel
Model: Fetal Lite

Product description

Fetal Lite (FL) is based on non-invasive aECG/EMG signal capture and analysis, a next-gen technology in fetal monitoring. FL uses patented hi-sensitivity electrodes for data capture, and machine learning algorithms to derive fetal & maternal heart rate and uterine activity with high accuracy. FL is designed for low-resource settings, being portable, battery-powered, cloud-enabled for remote monitoring, with an AI-driven risk detection engine to detect fetal distress, and requires minimal user skill.

Product details

Consumables: Electrodes
Warranty duration: 1 year
Lifetime: 5-10 years
Energy requirements: Rechargeable battery, DC, 5V, 5W, 4-hour battery recharge cycle, 8-hour battery life
Facility requirements: Specific temperature and/or humidity range, Storage: 0 to 50 C°, Operation: 10 to 50 C°, Dry storage

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

WHO assessed some newly commercialized products as a prototypes considering they had limited production, availability and evidence.

Clinical assessment

In 2019, an estimated 1.9 million babies were stillborn at 28 weeks or later, with a global stillbirth rate of 13.9 stillbirths per 1,000 total births and three-quarters of all cases occurring in sub-Saharan Africa and South Asia. With better monitoring during pregnancy and access to obstetric care, a large proportion of these deaths could be prevented.

The Fetal Lite electronic fetal monitor is designed for non-invasive intermittent monitoring of fetal heart rate, maternal heart rate, and uterine contractions during labor in singleton pregnancies at term and should be used by a qualified healthcare professional. The fetal heart rate pattern aids in identifying fetuses that do not tolerate the recurrent transitory disruptions of fetal oxygenation caused by uterine contractions. The sensor unit of the device is a single portable, wireless probe with six ECG electrodes that need to be positioned over the umbilicus to capture both fetal heart rate and uterine activity. This concept could partly circumvent the limitations of a conventional cardiotocograph, which requires fetal heart localization and does not allow for mother's movements. However, before utilizing it, the user should know whether the woman has multiple pregnancies, which raises some concerns about its applicability in resource-limited settings.

WHO specification comparison

The Fetal Lite device complies with the "Foetal Cardiac Monitor" WHO technical specifications currently available.

Non-compliances:. None. Specific features such as headphones, additional probes and extended warranty can be provided as "options".

Not possible to be verified/not specified: Not clear if the optional probe that could be provided and claimed to be a "probe for pre 36 weeks monitoring in singleton pregnancies" is compliant with the 10-12 weeks foetus required. Not clear if the following accessories required can be provided with the equipment: compatible headphones. Not clear which is the ultrasound working frequency (required in the range 2MHz -10% to 3MHz +10%). Not clear if other probes with compliant MHz specifications could be available since the requirement is to have "at least two high sensitivity equipment compatible probes provided: 2 and 3 MHz".

Regulatory assessment

Pre-market assessment
Post-market assessment
Quality system assessment

Proceed with caution
Not acceptable
Proceed

Pre-market – The product has an EC certificate. The manufacturer provided software validation and electrical safety test reports. An IEEE article was provided to demonstrate clinical performance. However, other significant pre-market assessment data and documents were missing.

Post-market – No documents were provided.

A current ISO 13485:2016 certificate was provided.

The following data and documents were not provided and should be included for the pre-market assessment and to demonstrate the safety and efficacy of the device:

- IEC 60601-1-2:2014
- IEC 60601-1-11;2015

FDA Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices or equivalent wireless validation

- Use Life Testing
- Battery Life Testing
- Battery Indicator Testing
- Acoustic output measurement methodology as recommended in FDA

Cleaning and Disinfection of a reusable medical device validation referencing :

- AAMI TIR12 ,AAMI TIR30,ASTM D543 ,ASTM EI 837-96 ,ISO 17664-1:2021

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	→	→
Safety	→	→
Economy	!	!
Organizational	→	→
Legal	→	→
Social	→	→
Ethical	→	→
Green environment	!	!

The device is already commercialized in India as non-invasive intermittent monitoring of Maternal Heart Rate (MHR), Fetal Heart Rate (FHR), and Uterine Activity (UA) during labour. It is still under evaluation in several other countries. The device is portable, easy to use for trained clinicians and nurses, and has a multilingual interface. The submitted documentation on safety confirmed a high accuracy of the device compared to CTG for FHR and CTG for UA. In LMICs usability tests, in hospital settings were performed. Affordability may be an issue based on cost data submitted. Cost-benefit analyses in LMICs were not submitted. The manufacturer does not provide information on handling twin pregnancies. Nevertheless, in summary, the device can be recommended with caution.

Summary

Innovation

Technology readiness level 9

Technology evidence assessment Recommend with caution

Fetal monitor

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	✗	Ease of cleaning	→
Ease of Use	!	Ease of maintenance	!
Positive impact on clinical outcomes	!	Infrastructure requirements	!
Affordability	✗	Local access to sales support	✗
Engineering resources minimization	→	Local access to technical support	✗
Cultural and social acceptability	N/A	Local access to training	✗
Environmental conditions	→	Local access to spare parts	✗
Aesthetics	→	Locations of use within target setting	!

Target settings: Primary, Secondary & Tertiary level

Submission of portable fetal monitoring product that is commercially available in India. Presently undergoing clinical trials (Israel and Ghana), but no technical data was provided other than a paper presented at an Indian conference. In that paper, a total of 1053 fetal heart rate samples were compared with conventional fetal heart monitoring and estimated to be at almost 94% accurate. Similar data for comparison of the mother's contraction measurement during motion is missing. The product is powered by a rechargeable battery with a life of 8 hrs. It wirelessly connects to a detachable tablet to display results and archiving. Submitter claims benefit from A.I. deployment, however no evidence for benefits over conventional fetal heart monitors are described. User interface experience, the effect of mother/fetal movement, or when mother carries multiple fetuses on product performance, are missing. So is data on sensors resistance to product drops and user abuse. Product contains software and should have a start-up test and error code reporting, but none were identified. Use data is also missing about battery life/charging/replacement, error code interpretation of operational issues such as device dropped, loss of wireless communication, sensor failure alarm, and loss of data during use. Recommendation inclusion with caution.

Intellectual property and local production

Technology transferability	!
Openly access intellectual property	✗
Local production	!

Intellectual property – The device has proprietary software and patent protection. The status of the patent application is pending. Clearance to use this technology is required. Caution advised due to pending patent applications.

Local production – Contract manufacturers are likely to have manufacturing know-how. Electronics assembly, manufacturing and related QMS experience are required. Existing manufacturing line is currently in a region suitable for low volume production, hence local production is less likely to provide further commercial benefits.

WHO related guidance material

- Maternal mortality: evidence brief - https://apps.who.int/iris/handle/10665/329886
- Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division - https://apps.who.int/iris/handle/10665/327595
- Managing complications in pregnancy and childbirth: a guide for midwives and doctors – 2nd ed. - https://apps.who.int/iris/handle/10665/255760
- WHO recommendations on antenatal care for a positive pregnancy experience - https://apps.who.int/iris/handle/10665/250796
- WHO recommendations on maternal health: guidelines approved by the WHO Guidelines Review Committee - https://apps.who.int/iris/handle/10665/259268
- Recurrence of adverse perinatal outcomes in developing countries - https://dx.doi.org/10.2471/BLT.12.111021