

Fetal monitor - wireless, mobile

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

Commercial information

List price (USD): 8000
Year of commercialization: 2019
Number of units distributed: 101-1,000
Currently marketed in: South East Asia Region
Brand: Melody International Ltd.



Product description

The fetal monitor iCTG ensures proper care of pregnant women and their fetuses. iCTG graphically displays the fetal heart rate and uterine contractions in 20 minutes to several hours. The iCTG is comparable in performance to conventional CTGs but is ultra-compact, completely wireless, and mobile. The widespread use of this device will enable the early transfer of pregnant women to secondary or tertiary hospitals in areas where there is a shortage of doctors or poor access to medical care.

Product details

Consumables: Ultrasound gel, 2 x CTG belts
Warranty duration: 5 year
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, AC, 110V, 220V, 1-hour battery recharge cycle, 6-hour battery life
Facility requirements: Access to a cellular phone network, Storage temperature -10 to 45°C, relative humidity 10-90%, atmospheric pressure 700-1060hPA

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In 2017, around 295,000 women died during and after pregnancy and delivery, with the vast majority of deaths (94%) occurring in low-resource settings. In 2019, an estimated 1.9 million babies were stillborn at 28 weeks or later, with three-quarters of all cases occurring in Sub-Saharan Africa and South Asia. With better monitoring and availability of emergency obstetric care, a large proportion of these deaths could be avoided.






Cardiotocography enables the evaluation of fetal health during pregnancy by examining fetal heart rate patterns. The primary goal of antepartum and intrapartum fetal monitoring is to identify fetuses at risk of hypoxia and allow for a timely intervention to lower the risk of hypoxic injury or death while also avoiding unneeded interventions in well-oxygenated fetuses.

The manufacturer's iCTG offers a paperless, wireless, portable solution for both antepartum and intrapartum monitoring, which should only be used by a trained healthcare provider. It is intended to enable real-time visualization of relevant clinical data and facilitate remote diagnosis. The device does not support fetal heart rate measurement in multiple pregnancies, despite of the possibility of monitoring more than one foetus, caution must be exercised in the use of this device in low-resource settings, as it is not clear how it behaves in unidentified multiple pregnancies.

WHO specification comparison

The Melody International CTGi - Cardiotocograph MI1001A device is claimed to be a "Foetal heart detector" and not a "Monitor". Consequently, at the time of report creation, WHO technical specifications are not available to perform a compliance evaluation with this type of technology.

























Regulatory assessment

 Pre-market assessment	 Proceed with caution
 Post-market assessment	 Not acceptable
 Quality system assessment	 Proceed

Pre-maket - A safety and EMC report, as well as a usability assessment based on IEC 60601-1-6/IEC 62366, was provided, but no protocol or test report was submitted. Report on biocompatibility and clinical performance or ultrasound testing and wireless and alarm validation were not included. The software validation is based on JIS T 2304:2017 certificate.

Post-maket - Documents were not provided. The ISO 13485 certificate expires in 2023. It has a MHLW manufacturing certificate.

Technology evidence assessment

Domains	Evidence assessment		
	Risk/benefit ratio	Impact	
 Medical			<p>Melody-i is already commercially available as a cardiotocography device that detects fetal heart rate using an ultrasound Doppler method and uterine contraction using a strain gauge from mid-pregnancy to birth. The device can be used in areas with unstable power supplies since it has a built-in battery that provides 6-10 hours of usage. The battery can be charged using a small solar charger. It is durable, easy to produce and maintain. There is a high medical need. High implementation costs prevent the device from being affordable for low-resource settings. If the costs cannot be reduced significantly, the device is not recommendable.</p>
 Safety			
 Economy			
 Organizational			
 Legal			
 Social			
 Ethical			
 Green environment			

Summary

Innovation



Technology readiness level

9

Technology evidence assessment

Not recommended

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target settings:
Durability		Ease of cleaning		Primary, Secondary & Tertiary level, Ambulance
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		Local access to training		
Environmental conditions		Local access to spare parts		
Aesthetics		Locations of use within target setting		

This product, available commercially, offers added observation of expecting mother and their baby condition while away from the hospital. Although it is not a replacement for a clinically acceptable fetal monitoring system, it delivers information that can help manage mother and baby vital conditions during pregnancy. The sensors, to be placed on the mother's abdomen, detect the baby's heart movement using ultrasound detectors (doppler effect) and convert the information into a heart rate while a second force-based sensor detects the mother's contractions. Since the baby heartbeat sensing sensor uses quartz substance to create and sense changes in the ultrasound wave pitch - the handling of the iCTG must be gentle in order to prevent damage to the quartz (i.e. from dropping).

The product is powered by a rechargeable Lithium battery that must be charged after 6 hours of operation. The charging time is an hour. This condition may require patients to obtain an additional backup unit for use during the battery depletion or charging period, which may increase the cost of the overall product. Additionally, the submission notes that an iPhone or iPad is required, while the Android devices have not yet been tested for connectivity.

Intellectual property and local production

Technology transferability		Intellectual property - It is patent-protected and the design is registered. There are registered trademarks for the device. Clearance to use this technology is required.
Openly access intellectual property		Local production - Innovator does not want to consider producing locally. There is also a high dependency on imports for local production.
Local production		

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>