

## Fetal Heart Rate Monitor

FOR INTRAPARTUM DETECTION OF HYPOXEMIA

### Condition

Fetal heart rate (FHR) is monitored to detect variations that may indicate a distressed fetus. Variations in FHR may signal complications including intrauterine hypoxia, placental abruption, uterine rupture, or constriction of the umbilical cord.

### Mechanism of Action

Electronic fetal monitoring (EFM), doppler ultrasound, and Pinard stethoscopes are all commonly used to assess FHR. EFM provides continuous monitoring either using a doppler sensor on the mother's abdomen or a fetal scalp electrode. Doppler devices use a handheld ultrasonic transducer (coupled to the mother's abdomen with a gel), to transmit and detect reflected 2-3MHz sound waves from the moving fetal heart. Many devices provide a digital read out; virtually all provide an audible representation of the heart beat. Pinard stethoscopes are simple plastic or metal cones used to auscultate the FHR directly. By placing the larger opening firmly on the mother's abdomen, the user can listen for the baby's heartbeat from the smaller end. The electronic methods can detect FHR after about 10 weeks gestation; the Pinard after approximately 20 weeks.

### Current use in high-resource settings

Electronic fetal monitoring is used in approximately 85% of all US births, providing a continuous record of FHR throughout labor and delivery. Use of EFM is associated with increased cesarean section and instrumental delivery, but not necessarily improved perinatal outcomes relative to intermittent auscultation with Doppler ultrasound. Prior to delivery, Doppler is commonly used at each prenatal appointment after 10 weeks.

### Application in low-resource settings

Pinard stethoscopes are the most common method of monitoring FHR in low-resource settings. They do not require power, are highly portable, and typically cost around \$2. Doppler devices have been associated with more favorable outcomes, more reliable measurement, and greater patient and caregiver comfort. Cost remains an issue for the penetration of these devices, although when available, their utilization and efficacy appear to be satisfactory.

### DIAGNOSTIC



PREVENTION DIAGNOSTIC TREATMENT



Representative Product

### DEATHS ASSOCIATED WITH FETAL AND NEONATAL ASPHYXIA:

	PERCENT (%)	NUMBER
Maternal	N/A	N/A
Neonatal	22%	814,000
Stillbirth	5-20%	160,000-640,000

### REPRESENTATIVE DEVICES

MAKE	MODEL	PRICE*	STATUS	NOTES
Freeplay	FHRM	\$300	Piloted	Hand cranked device, no battery required
Sonicaid FD1	Dopplex II FD2	\$600-700	Marketed	Digital readout and waterproof probe
HiBebe	BT-200	\$100	Marketed	Digital readout plus audio
AngelSounds	JPD 100S	\$25-50	Marketed	Consumer product, audio only
Generic	Pinard	\$2	Marketed	Highly portable, accuracy subject to user skill

\* Prices are approximated. Actual pricing can, and will vary by marketplace and market conditions.

## CHARACTERISTICS OF REPRESENTATIVE PRODUCT (HIBEBE BT-200)

	TECHNOLOGY CHARACTERISTICS	OPERATIONAL PARAMETERS	POTENTIAL OPPORTUNITIES FOR IMPROVEMENT
<b>SKILLS REQUIRED</b>	Intended end user	Physician, Nurse	Training may be required to translate the numerical FHR and FHR trend over time into an action plan to improve the outcome of pregnancy.
	Training required	Hours	
	Time required per use	Minutes	
<b>ENVIRONMENT / INFRASTRUCTURE</b>	Power required	Two 1.5V batteries	Battery supply has been a problem for this class of device. While the Freeplay FHRM operates without batteries (using a crank mechanism) the incremental \$200 in price may still be too high for wide deployment.
	Waste collection	None	
	Complementary technologies required	Coupling gel	
	Temperature and storage	N/A	
	Maintenance	N/A	
<b>COST</b>	Product Cost (Approx)	\$100	Doppler will never be price competitive with the \$2 Pinard stethoscope, but most caregivers prefer the comfort and accuracy of doppler.
	Cost/use (Approx)	<\$0.10	
<b>OTHER</b>	Portability	<500g	
	Regulatory	FDA and CE approved	
	Efficacy	Intermittent auscultation with fetal doppler has been shown to have similar outcomes to continuous EFM	

Additional devices required for impact: Instrumental delivery, cesarean section, or other interventions may be required depending on the severity of FHR abnormalities

Sources: WHO Technology Summary - GMDN #35068 Fetal heart detector, ultrasonic, UMDNS #11696 Detectors, Fetal Heart, ultrasonic Infant Formula.

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