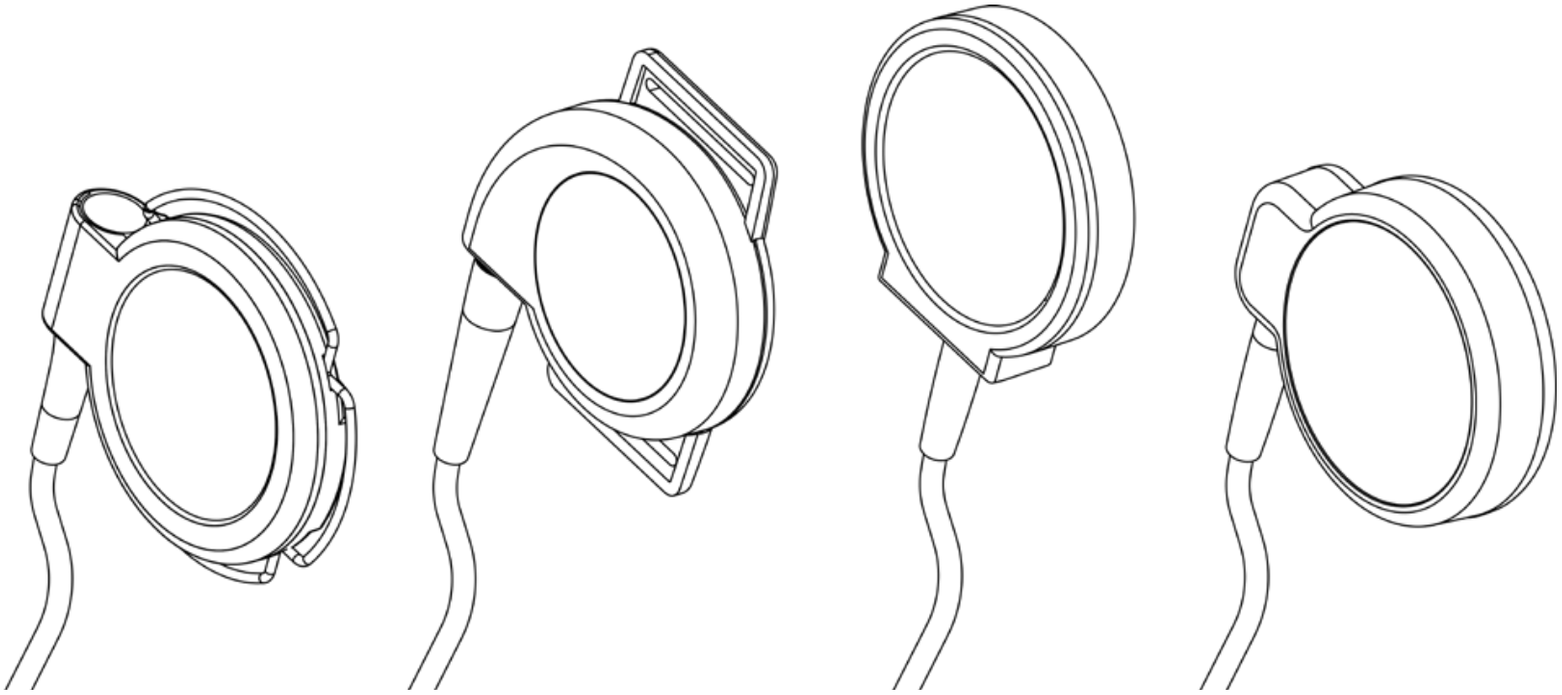
Drantech

The **difference** you can **sense**

CE 0123



Fetal Ultrasound Transducers

User Manual

Intended Use & Indications for Use

These transducers are intended to be used as replacement accessories to fetal monitors to measure fetal heart rate in the gravid patient from 25th week of gestation.

Operation Procedures

Before fetal heart rate monitoring, read the user manual of the monitor and prepare the setup of the monitor such as configuration settings, power, etc.

- Clipping a transducer to the belt.
- Make sure the compatibility of the transducer. See the attached the compatible label to ensure the device used with is compatible with the transducer.
- Make sure the transducer plug matches the connector on the device. Then fully plug the transducer into the device's socket.
- Fastening a belt around the patient.
- Find the fetal heart position by auxiliary means such as palpation, auscultation or ultrasound imaging.
- Apply a small amount of ultrasound gel in a thin layer to the transducer.
- Apply the transducer to the patient, working it in a circular motion to ensure the gel layer makes good contact.
- When you have a good signal, clip the transducer in position on the belt.
- At the bedside monitor, ensure that the tracing is recording FHR, not MHR.

Use in Shower or Tub

Note: When using watertight transducers for monitoring in a watery environment, it is recommended that the buttontop transducer and reusable buttonhole belts be used for the best results.

- Use transducers in a watery environment only when connected to a telemetry system. Do not allow the telemetry system to get wet.
- Do not use the transducer in a watery environment when connected directly to a fetal or

maternal/fetal monitor that is directly connected to AC line power.

Performance & Reliability

The ultrasound transducers with its compatible ultrasonic doppler fetal monitor has been validated and tested for compliance with IEC 60601-2-37.

Operating Mode	Pulsed Waveform(PW) Doppler
Pulse Repetition Rate	2000Hz
Ultrasound Frequency	Dependent upon monitor specifications
FHR Measurement Range	Dependent upon monitor specifications
Resolution	1 bpm
*Accuracy	±2 bpm
Acoustic Output	<20 mW cm-2
Input Voltage	Dependent upon monitor specifications
Power Rating of Monitor	Dependent upon monitor specifications
Electrical Classification of Monitor	Class I
NOTE: The essential performance is marked with an asterisk *.	

Degree of Protection against Electric Shock: Type BF applied part
Degree of Protection against the Ingress of Water: IPX2

Cleaning & Disinfecting

- **Attention**

- Do not expose the connector pins to the cleaning solutions as this may cause permanent

damage to both the transducer and the monitor.
- When cleaning or disinfecting, disconnect the transducers from the monitor.
- Remove any ultrasound gel or residue from the transducer before cleaning.

• **Cleaning**

- With a soft cloth moistened with 70% isopropyl alcohol, wipe the exterior surface of the transducer.
- Wipe within the grooves of the transducer.
- When there is no visible contamination, allow the transducer to dry at room temperature.

• **Disinfection**

The recommended disinfectants include: 70% ethanol, 70% isopropanol, or 2% glutaraldehyde-based liquid disinfectants.

Do not use undiluted bleach (5% ~ 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.

- Saturate a clean, dry gauze pad with the cleaning solution.
- Wipe all surfaces of the transducer with this gauze pad.
- Saturate another clean, dry gauze pad with sterile or distilled water.
- Wipe all surfaces of the sensor and cable with this gauze pad.
- Dry the transducer by wiping all surfaces with a clean, dry gauze pad.

Storage & Handling

When not in use, transducers should be loosely coiled and stored in room temperature. Don't wrap transducers around equipment cases to avoid damaging internal wires.

Operating Conditions

- Ambient temperature: 0°C to +35°C
- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~ 106 kpa

Storage & Packaging

Each transducer is individually packaged.
Transducers must be stored in its original packaging and within the storage conditions to maximize the storage life.
Storage conditions are as follows:

- Ambient temperature: -10°C to +40°C
- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~106 kpa

Shelf Life

5 years.

Warranty & Liability

Orantech offers 12 months warranty against defects in material or workmanship from the date of purchase. But does not include the damage or breakage due to the abusive use or negligent care of the transducers.
Orantech reserves the right to perform warranty service at its own facility. We guarantee that the products conform to the specifications of the safety and performance standards currently in force and applicable to it.

⚠Warning

- ⚠Transducers are designed for use with specific monitors.
- ⚠The operator is responsible for checking the compatibility of the monitor, transducer and cable before use.
- ⚠Incompatible components can result in degraded accuracy and performance.
- ⚠Consult the operation instructions for the equipment concerned and the related accessories before operating equipment to ensure their compatibility.
- ⚠Portable and mobile RF communications equipment can be affect equipment.

- ⚠Disposal of the transducers shall comply with local regulation.
- ⚠Do not use the transducer during MRI scanning. Conducted current may cause burns. Also, the transducer may affect the MRI image, and the MRI unit may affect the accuracy of measurements.
- ⚠Do not immerse transducer or transducer connector ends in cleaning solution(s).
- ⚠Do not allow service or maintenance the transducer while used in patient.
- ⚠No modification of this equipment is allowed.
- ⚠Do not use damaged transducers.
- ⚠Route cables to avoid risk of strangulation.
- ⚠Patient movement will affect the measurement accuracy, please do not move when monitoring.

⚠ Caution

⚠Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

Waste Disposal

Please refer to your local laws and regulations for information on how to dispose of fetal Ultrasound transducers.

Title of Symbol

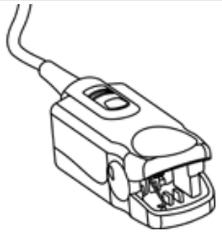
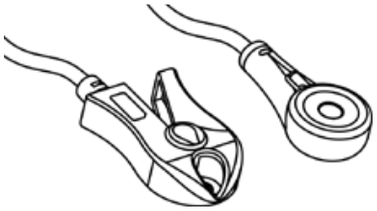
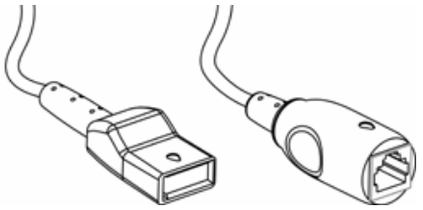
	Manufacturer
REF	Catalogue number
LOT	Batch code
SN	Serial number
	Not made with natural rubber latex
	Refer to instruction manual/ booklet
	Non-sterile
Rx only(U.S.)	U.S. federal law restricts this device to sale by or on the order of a physician.
EC REP	Authorized Representative in the European Community
	Caution

	Warning
	Date of manufacture
	Crossed out wheelie bin indicates separate treatment from general waste at end of life. Waste of Electrical and Electronic Equipment Directive (WEEE)
IPX2	Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
CE 0123	CE Mark
	Type BF Applied Part
MD	Medical device
UDI	Unique Device Identifier

Support

To get the support, please contact the representative of manufacturer or local distributor.

The categories shown below are available for sale through the local distributors or e-commerce.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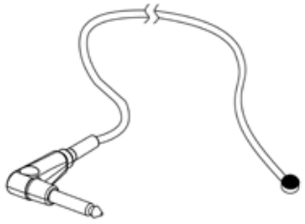	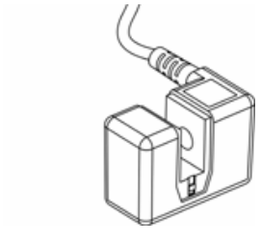	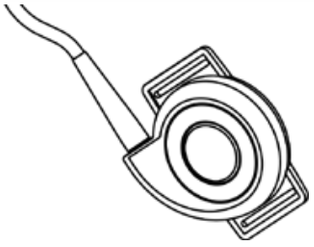	
TEMP	$EtCO_2$	FETAL	EEG

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EC REP

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