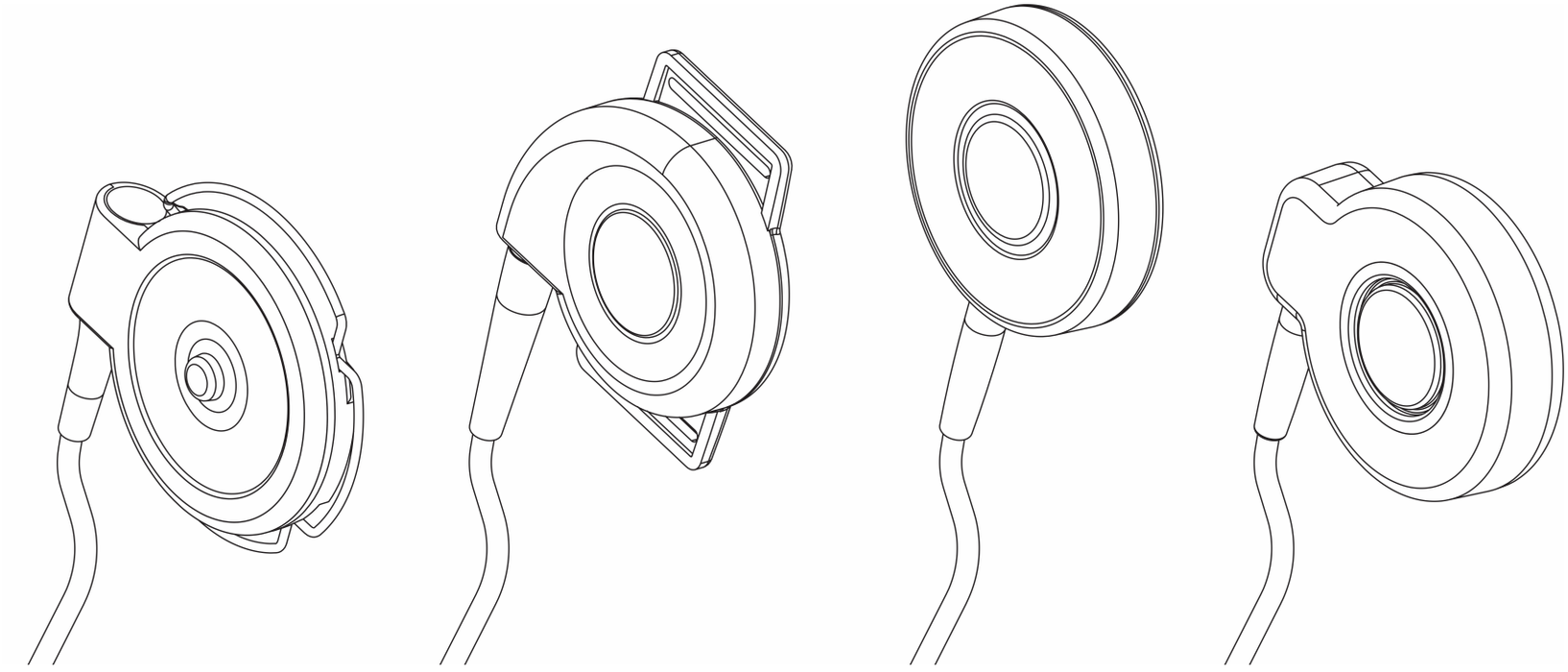
Drantech

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

CE 0123



Fetal TOCO Transducers

User Manual

Intended Use & Indications for Use

These transducers are intended to be used as replacement accessories for fetal monitors to measure uterine contractions in the pregnant patient from the 25th week of gestation.

Operation Procedures

Before uterine activity monitoring, read the user manual of the monitor and prepare the setup of the monitor such as configuration settings, power, etc.

- Make sure the compatibility of the transducer. See the attached the compatible label to ensure the device used with is compatible with the transducer.
- Fasten the abdominal transducer belt around the patient.
- Make sure the transducer plug matches the connector on the device. Then fully plug the transducer into the device's Toco socket.
- Place the transducer on the patient's fundus to ensure the optimum recording of uterine activity.
- When you have a good signal, clip the transducer in position on the belt.

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

*TOCO Range	Dependent upon monitor specifications
Resolution	1 relative unit
*Sensitivity	44 relative units/100 gm
*Sensitivity Error	±5 relative units

Repeatability	≤1 relative unit/100 gm
Hysteresis	≤1 relative unit/100 gm
Zero Set Temperature Drift	≤1 relative unit/10°C
Temperature Sensitivity Drift	≤1 relative unit/10°C
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 transducer 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 transducer 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.

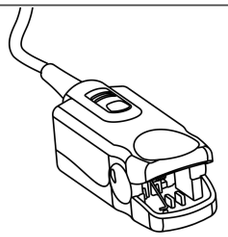
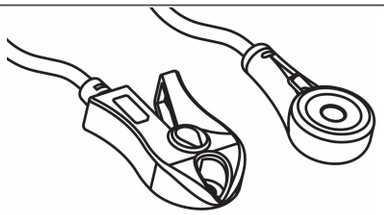
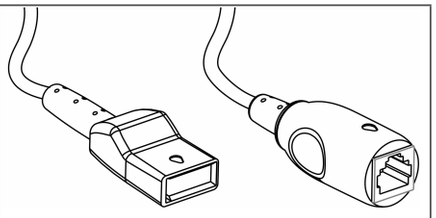
Title of Symbol

	Manufacturer
REF	Catalog number
LOT	Batch code
SN	Serial number
	Not made with natural rubber latex
	Refer to instruction manual/ booklet
	Non-sterile
Rx only(U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician
	Type BF Applied Part

	Caution
	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)
EC REP	Authorized Representative in the European Community
CE 0123	CE Mark
IPX2	Protection against vertically falling water drops when ENCLOSURE tilted up to 15^0

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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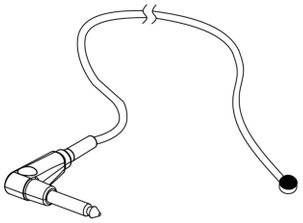	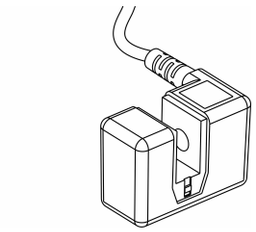	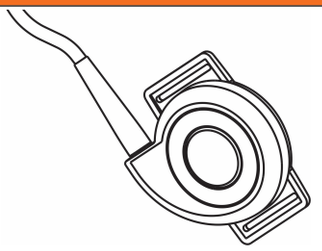	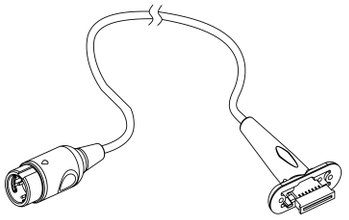
TEMP	$EtCO_2$	FETAL	EEG

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