The Koala™ intrauterine pressure monitoring system is a sterile, single-use device designed for measurement of intrauterine contraction pressure. Koala™ is easy to insert and helps confirm placement in the amniotic space.

- Soft, flexible tip makes it comfortable and safe for both mother and child.
- No electronic components in the disposable catheter.
- Transparent catheter tubing for positioning
- Double lumen for amnio infusion

**Description**

The IUP measurement uses an advanced technology, Atmospheric Isolating Monitoring (AIM). This means atmospheric pressure is separated from the transducer. AIM uses a micro column of air which communicates intrauterine pressure from a cylindrical diaphragm at the center tip to an external transducer. The diaphragm is housed inside a perforated transparent catheter tube. The perforations let amniotic fluid flow freely around the diaphragm while the tube protects it from tissue contact. Connection of the catheter to the transducer cable automatically charges an exact amount of air into the diaphragm.

Intrauterine pressure is imparted directly by the amniotic fluid surrounding the diaphragm to the air inside. This is naturally relayed by the micro column of air in the catheter to the externally located transducer.

**Setup:**

This system has a simple four-step setup:

1. Insert adapter cable into fetal monitor.
2. Insert catheter.
4. Attach the catheter to the connector cable. This automatically charges the diaphragm with an exact amount of air.

**Zeroing**

It is an important aspect of AIM technology to zero the monitor before the catheter is connected. Pressure in the amniotic fluid pushes out all air trapped by the diaphragm. Since the transducer is exposed to atmospheric pressure when the cable and catheter are disconnected, this provides a naturally true zero - even though the catheter is in utero. Connecting the reusable cable isolates the diaphragm from atmospheric pressure and automatically charges it with a specified volume of air. To re-zero the monitor, simply disconnect the catheter from the cable to re-expose the transducer to atmospheric pressure.

**Safety**

The transparent catheter tube surrounding the diaphragm automatically fills with amniotic fluid on correct insertion into the amniotic space. Extraovular placement (outside the amniotic membranes) is marked by lack of fluid and/or endometrial tissue and blood traces. The transparent catheter tube ensures that amniotic fluid can be visually checked for myconium and amniotic fluid consistency.

- An ergonomically designed introducer provides added stiffness during insertion.
- Markings on the catheter indicate correct depth.
- Most importantly the small tip is covered by a soft flexible plastic cap diminishing the risk of accidental perforations.
- All materials are latex-free to avoid allergic reactions.

**Readings Unaffected by Physical Contact**

Unwanted artifact readings resulting from direct physical tissue contact with either baby or uterus are avoided because of the mechanical protection of the diaphragm offered by the catheter tube.
Amniotic Infusion Capability

A second lumen in the catheter tube allows amniotic infusion. A port on the connector allows for convenient infusion of saline solution or other sterile fluids up to a rate of 20 ml/min and/or easy sampling of amniotic fluid.

Cable Cleaning

The reusable connector cable can be wiped cleaned with soap and water or alcohol, provided that cables are well rinsed afterwards. The reusable connector cable may also be sterilized with gas. Do not immerse the connectors in liquid as this would impair their function. Swabs of minimal sizes of 5.5 mm may be used to clean the interior connector.

Specifications:

- **Transducer Type**: Piezoresistive bridge, Silicon diaphragm, passive device.
- **Sensitivity**: 5 µV/V/mmHg ± 2%
- **Non-linearity and Hysteresis**: < ± 1% of reading or ± 1 mmHg, whichever is greater
- **Sensitivity Thermal Effect**: < ±0.1%
- **Operating Temperature**: 10°C to 43°C (50°F to 109°F)
- **Zero Thermal Effect Max**:
  - < ± 0.3 mmHg/°C
  - < ± 0.166 mmHg/°F
- **Zero Drift with Time**: < 1.0 mm Hg/8 hours
- **Leakage Current**: < 5 µA @ 115 VACrms
- **Input Impedance**: 1800-4500 Ω
- **Output Impedance**: 310 Ω ± 10%
- **Overpressure Protection**: -400 mmHg/+1200 mmHg
**Excitation Voltage and Frequency:** 2 to 10 Vdc or Vacrms from DC to 5 kHz (sines and squarewave)

**Catheter Size:** 3.5mm (.13") Diameter
82cm (32.2") Length

**Ammio Port/Lumen:** At a pressure of 65 mmHg the flow rate is 20 ml per minute minimum

**Tip Size:** Nominal (Approx)
5 mm (.19") Diameter
2 cm (.78") Length

**Relative Humidity:** < 90% of catheter

**Sterilization of Catheter:** Sterilized by g irradiation

**Shelf Life:** 6 months minimum

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<table>
<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
<th>Use with Philips Fetal Monitor</th>
<th>Qty/Box</th>
<th>Weight/Box</th>
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<tr>
<td>M1333A</td>
<td>Disposable Koala IUP Catheter (Single Patient Use)</td>
<td>8040A M13350A M13350B M13350C M13353A M13310A</td>
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<td>Reusable Koala IUP Cable (63cm)</td>
<td>M2703A</td>
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</table>

**Connection to Monitors**

For Philips Avalon Fetal Monitors:

FM30 using a patient module

![Diagram of FM30 with patient module](Image)

FM30 using a Toco+ transducer

![Diagram of FM30 with Toco+ transducer](Image)

For Philips (HP/Agilent) Series 50 Fetal Monitors:

50 IX/XM/XMO (M1350A/B/C)
50 IP/IP-2 (M1353A)
50 T (M1310A)
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