



## **Accuracy & Reliability**

### Koala & Intran Dual Catheter Test

As the manufacturer of the Koala IUP-5000E catheter, we have been asked about the accuracy of the Koala tracings and the reliability of the system.

#### Competition

As Koala sales have escalated each year since its' introduction in 1996, the efforts by our competition to discredit Koala have increased each year as well. The competition continues to make unsubstantiated claims about the accuracy and reliability of Koala. These claims are not based on any scientific data but are composed of hypothetical, prevaricatory rhetoric.

At Clinical Innovations, it is not our policy to employ deceptive tactics in an attempt to discredit the competition and sell our products. We let our products speak for themselves, do our testing in the clinic, and provide factual data.

#### Accuracy

The Koala design features a sensing membrane in the tip of the catheter that communicates through a sealed micro-tube to the electronic transducer located in the reusable cable. The Koala technology is similar to non-invasive blood pressure monitoring which clinicians use to make critical decisions every day.

The Koala helps improve accuracy through proper placement. The purpose of an IUPC is to measure the fluid pressure in the amniotic space. When IUPCs are placed outside the amniotic membranes between the chorion and the endometrial lining or in an isolated pocket within the amniotic space, accuracy is compromised by tissue contact force error.

By taking care on placement to obtain amniotic fluid flashback in the Koala clear amniolumen, clinicians can be sure of proper placement in the amniotic fluid space and that the general fluid pressure is being monitored.

Koala electronics are not inserted into the uterus where they are subject to more hostile conditions and are not affected by electronic distortions such as unbalance, thermal sensitivity (warming of the transducer), contact pressure or force.

By disconnecting the catheter from the cable the clinician can not only verify a true zero, but can also confirm that the electronics are functioning correctly and accurately independent from the catheter.

#### Reliability

The Koala cable, which houses the transducer, is state-of-the-art technology designed for multiple uses. The cable is rugged to withstand shock, vibration, mechanical forces, etc., and can be cleaned with soap and water or gas sterilized if needed.

The Koala's silicon-chip piezo-resistive pressure transducer technology is one of the most stable, reliable pressure sensing technologies available today and is used in medical, space, automotive, and industrial applications.

Koala cables can be tested at any time, before, during or after use, simply by disconnecting and verifying true zero on the monitor. Likewise, the transducer in the cable can be checked for specification and accuracy at any time by biomedical engineering with a pressure reference.

The Koala electronics (transducer and cable) provide the only system that can be verified at any time such as when the catheter is in the uterus.

### Clinical Testing

Clinical testing was conducted in which a Koala IPC-5000E and an Intran Plus IUP-400 were attached together with heat shrink and inserted together into the uterus.

Since the catheter tips were tied together, they were inserted into the same patient in the same uterine location and hence should read the same pressures. Two fetal monitors were used; one on each catheter-calibrated the same, to record the tracings. The tracings were compared and analyzed to document baseline, contraction peak, peak minus baseline, and contraction duration.

Attached are three of many cases performed with excerpts from the strip charts. As can be seen from the strips, the two catheters compared favorably throughout the studies.

### Demonstration

Each Koala product specialist can demonstrate Koala accuracy with a uterine model created from an IV bag. Please call to request a demonstration.

### Track Record

The Koala catheter was introduced to the market over four years ago; it has been used hundreds of thousands of times in hundreds of hospitals. The Koala has been widely accepted for its accuracy and reliability.

At Clinical Innovations, we take pride in producing the safest, most accurate and clinically acceptable IPC catheter on the market. We strive to address all clinical concerns in the design and servicing of our products.

Thank you for your interest in Koala.

Please contact us if we can answer any additional questions.

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