



Atmos Air Charged Urodynamics Catheters

Instructions for Use

Please read the instructions before use

This box contains:

Ten (10) Sterile Disposable Air-Charged Catheters Labeled according to the following SKUs.

SKU	Description	Luer Color Identification
1A-AC	Single Sensor Abdominal Air-Charged Urodynamics Catheter	Blue – Abdominal (Rectum or Vagina)
1B-AC	Single Sensor Bladder Air-Charged Urodynamics Catheter	Yellow – Bladder Clear - Infusion
1CB-AC	Single Sensor Coudé Bladder Air-Charged Urodynamics Catheter	Yellow – Bladder Clear - Infusion
2BU-AC	Dual Sensor Bladder/Urethral Air-Charged Urodynamics Catheter	Yellow – Bladder Green - Urethra Clear - Infusion
1RB-AC	Single Sensor Radiopaque Bladder Air-Charged Urodynamics Catheter	Yellow – Bladder Clear - Infusion
2RBU-AC	Dual Sensor Radiopaque Bladder/Urethral Air-Charged Urodynamics Catheter	Yellow – Bladder Green - Urethra Clear - Infusion

Product Description

Atmos Air-Charged Catheters are single use catheters used in conjunction with commercially available Urodynamics Diagnostic Equipment and air-catheter charging/pressure sensing cables.

Each Atmos Catheter is sterile and individually pouched.

Intended Use

To be used by healthcare professionals knowledgeable on Urodynamic studies for measurement of urodynamic parameters in patients with potential incontinence, voiding dysfunction, and pelvic floor dysfunction. Abdominal catheters are used to measure abdominal pressure during cystomanometry, urethrocystomanometry, and flow-pressure studies. Bladder catheters are used to perform urodynamic procedures for measurement of the intravesical pressure during cystomanometry by inserting the catheter into the bladder and connecting it to a pressure transducer.

Contra-indications

The devices must be used only for their intended use. Should not be used if the patient has a known allergic reaction to polyurethane.

Important

Insert gently using aseptic technique. Abrupt or forced insertion may cause patient discomfort, pain, or trauma.

Precautions

- Known current Urinary Tract Infection (UTI)

- Urethral injury and stricture.
- Recent urethral or bladder surgery.
- Prior transurethral resection of the prostate with a large tissue defect.
- Significant symptoms of urinary obstruction prior to treatment.
- History of abdominoperineal resection for rectal cancer, rectal stenosis, or other major rectal pathology.

Catheter Insertion and Study Preparation

- Position Patient in right lateral or semi lithotomy position.
- Secure cables to thigh according to Local Policies.
- Ensure transducer switch is in open position per equipment manufacturer instructions/labeling.
- Note - luer color coding from chart above and follow steps E-G matching proper luer to cable or tubing.
- Partially open pouch, only exposing luer and keeping distal end in sterile field.
- Remove protective caps from catheter luers and cables.
- Connect catheter luer to cable by twisting until snug and repeat until all catheters and luers are connected.
- Urethral Catheter Insertion (1B-AC, 1CB-AC, 2BU-AC, 1RB-AC, 2RBU-AC)
 - Remove catheter from pouch.
 - Coat catheter with water-based gel or lubricant according to local Clinical Policies
 - Female Urethral
 - Single Sensor (1B-AC, 1RB-AC) – insert catheter 8-10cm and tape to thigh.
 - Dual Sensor (2BU-AC, 2RBU-AC) – insert 12-14cm and tape to thigh.


















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- Male Urethral
 - Single Sensor (1B-AC, 1RB-AC, 1CB-AC) – insert 8cm plus penile length and tape to thigh.
 - Dual Sensor (2BU-AC, 2RBU-AC) – insert 12cm plus penile length and tape to thigh.
- I. Abdominal Catheter Insertion (1A-AC)
 - Remove catheter from pouch.
 - Coat catheter with water-based gel or lubricant according to local Clinical Policies
 - Female Abdominal (either vaginal or rectal)
 - Insert into vagina just behind the cervix to the posterior fornix or to vaginal apex if the patient has had a prior hysterectomy.
 - Insert into the rectum 10-15cm along the anterior wall.
 - Male Abdominal
 - Insert into the rectum 10-15cm along the anterior wall.
- J. Zero equipment per manufacturer instructions
- K. Charge transducer per equipment manufacturer instructions/labeling.

Please Note

- Only use water-based lubricants or gels.
- Clean cables prior to each use according to local Clinical Policies.

Sterilization: Do Not Re-sterilize

	Catalogue Number – Reference Number		Do not use if package is damaged.
	Batch code		Keep Dry
	Date of manufacture		Keep away from sunlight
	Use by date		Consult instructions for use
	Manufacturer		Prescription use only
	Sterilized using ethylene oxide		Caution
	Temperature limit		Non-pyrogenic
	Do not re-sterilize		Does not contain natural rubber latex
	Do not Reuse		



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Catheter has been sterilized by EO. The expiry date can be found on the sterile pouch and the box. Damaged or open products may not be used.

Warning

Are for single use only. Do not re-sterilize or re-use.

Storage and Operating Environmental Conditions

Should be stored in their original packaging in a dry place away from direct sunlight. Store the product at a temperature between +5°C and +35°C.

Disposal

Should be disposed of in line with your local Clinical Policies.

Additional Warnings & Precautions

- Prior to catheter removal ensure transducer switch is in open position per equipment manufacturer instructions/labeling.
- Do not use ointments or lubricants with a petroleum base.
- Do not use sharp instruments – sharp instruments could damage the catheter and cause it to malfunction.
- Instructions for Use shall be read and abided by carefully.
- Medical advice shall always be followed depending on patient's clinical symptoms.
- Strict adherence to aseptic technique and hand hygiene are essential to minimize the risk of Catheter-Associated Urinary Tract Infections.
- Report adverse events to manufacturer.