



Atmos Air-Charged Urodynamics Catheters

Instructions for Use - Please read all instructions carefully before use.

SKU	Description	Color Identification
1A-AC	Single Sensor Abdominal Air-Charged Catheter	Blue – Abdominal
1B-AC	Single Sensor Bladder Air-Charged Catheter	Yellow – Bladder Clear – Infusion
1CB-AC	Single Sensor Coudé Bladder Air-Charged Catheter	Yellow – Bladder Clear – Infusion
2BU-AC	Dual Sensor Bladder/Urethral Air-Charged Catheter	Yellow – Bladder Green – Urethra Clear – Infusion

Device Description

Atmos® Air-Charged Urodynamics Catheters are sterile, single-use air-charged catheters intended for use with urodynamic measurement systems and air-charged pressure sensing cables.

Each catheter is individually pouched and sterilized using ethylene oxide (EO).

Atmos® Air-Charged Catheters are not made with natural rubber latex.

Intended Use

Atmos® Air-Charged Urodynamics Catheters are intended for use by trained healthcare professionals during urodynamic studies for physiologic pressure measurement within the bladder, urethra, rectum, or vagina.

Bladder catheters are intended for intravesical pressure measurement and fluid infusion during cystometric procedures.

Abdominal catheters are intended for measurement of abdominal pressure during urodynamic testing via rectal or vaginal placement.

Indications for Use

Atmos® Air-Charged Urodynamics Catheters are indicated for use in adult and pediatric patients undergoing urodynamic evaluation of lower urinary tract symptoms (LUTS), including suspected:

- urinary incontinence,
- voiding dysfunction,
- neurogenic bladder dysfunction,
- pelvic floor dysfunction,
- bladder storage disorders,
- bladder emptying disorders.

These devices are intended to provide physiologic pressure measurements during cystometry, pressure-flow studies, urethrocystometry, and related urodynamic procedures.

Clinical Benefits

When used with a compatible urodynamic system, Atmos® Air-Charged Catheters provide physiologic pressure measurements that may assist healthcare professionals in the evaluation and classification of lower urinary tract dysfunction and support clinical decision-making.

Performance Characteristics

Atmos® Air-Charged Catheters utilize an air-charged pressure sensing system to transmit physiologic pressure measurements from the bladder, urethra, rectum, or vagina during urodynamic testing.

Contraindications

Do not use:

- in patients who are not candidates for urodynamic testing,
- in patients with known hypersensitivity to polyurethane materials,
- in the presence of active urinary tract infection unless the potential clinical benefit outweighs the risk in the judgment of the healthcare professional.

Warnings

- For single use only. Do not reuse, reprocess, or re-sterilize.

- Reuse, reprocessing, or re-sterilization may compromise device integrity and performance and may result in device malfunction, cross-contamination, infection, or patient injury.
- These devices are intended for use only by trained healthcare professionals knowledgeable and experienced in urodynamic procedures and aseptic catheterization technique.
- Strict adherence to aseptic technique and institutional infection control policies is essential to minimize the risk of urinary tract infection and cross-contamination.
- Use only sterile, water-based lubricants. Do not use petroleum-based ointments or lubricants.
- Do not use if packaging is opened, damaged, or compromised, or if product sterility may have been affected by handling or storage conditions.
- Forced insertion may result in patient discomfort, urethral trauma, bleeding, false pressure measurements, or device malfunction.
- Do not bend, kink, cut, stretch, compress, or excessively manipulate the catheter, as damage may impair device performance.
- Do not use sharp instruments with the catheter system, as damage to the catheter or sensing components may occur.
- Verify appropriate catheter placement using clinical judgment, patient anatomy, and physiologic waveform assessment prior to and during testing.
- In pediatric patients, catheter insertion depth and positioning should be determined using clinician judgment, patient anatomy, procedural goals, and waveform confirmation rather than fixed insertion depths.
- Urodynamic testing should be performed according to institutional protocol and accepted clinical practice standards.
- If abnormal resistance is encountered during insertion, discontinue advancement and evaluate catheter positioning and patient anatomy before proceeding.

Precautions

Use caution in patients with:

- urethral stricture,
- recent urethral or bladder surgery,
- recent pelvic surgery,
- history of traumatic catheterization,
- significant bladder outlet obstruction,
- rectal pathology,
- rectal stenosis,
- history of abdominoperineal resection,
- altered pelvic anatomy.

The use of prophylactic antibiotics is at the discretion of the healthcare professional and institutional policy.

Patient Preparation

1. Position patient according to institutional protocol.
2. Secure cables per institutional policy.
3. Ensure transducer switches are in OPEN position according to urodynamic system instructions.

Atmos Air-Charged Urodynamics Catheters

Catheter Connection

- Partially open pouch while maintaining catheter sterility. Do not remove the catheter from the pouch.
- Remove protective caps from catheter luers and corresponding cables.
- Connect matching luer connections by twisting clockwise until secure.
- Zero and prepare equipment according to urodynamic system manufacturer instructions.
- Charge transducers according to system labeling and instructions.

Catheter Insertion

NOTE:

Insertion depths are provided as general guidance only and may vary based on patient anatomy, clinical condition, procedural goals, and clinician judgment. Appropriate catheter placement should always be confirmed by physiologic waveform assessment and clinical evaluation.

- Remove catheter from pouch.
- Apply sterile water-based lubricant.
- Gently insert catheter using aseptic technique to the depths noted below
- Secure catheter according to institutional protocol.

Bladder Catheters (1B-AC, 1CB-AC, 2BU-AC)

Typical **Adult** insertion depth guidance:

SKU	Female	Male
1B-AC, 1CB-AC	8–10 cm	8 cm plus penile length
2BU-AC	12–14 cm	12 cm plus penile length

Pediatric Patients

- Insert catheter gently using clinician judgment based on patient anatomy, procedural goals, and physiologic waveform verification.
- Avoid forced advancement.

Abdominal Catheters (1A-AC)

Typical **Adult** insertion guidance:

SKU	Female	Female & Male
1A-AC	Vaginal placement: insert to posterior fornix or vaginal apex if post-hysterectomy	Rectal placement: approximately 10–15 cm along the anterior rectal wall

	Medical Device
	Manufacturer
	Date of manufacture
	Use by date
	Batch code
	Catalogue Number – Reference Number
	Consult instructions for use
	Sterilized using ethylene oxide
	Do not Reuse
	Do not re-sterilize

Pediatric Patients

- Insert gently using clinician judgment and confirm placement using appropriate physiologic waveform assessment.

During Study

- Confirm physiologic pressure signals prior to testing.
- Follow equipment manufacturer instructions for zeroing and charging.
- Monitor patient comfort throughout procedure.

After Procedure

Prior to catheter removal:

- Ensure transducer switch is returned to OPEN position per system instructions.
- Remove catheter gently.
- Dispose of catheter according to institutional biohazard waste procedures.

Sterility

Sterilized using ethylene oxide (EO).

Do not use after the expiration date shown on packaging.

Do not use if sterile barrier is damaged or compromised.

Storage and Handling Conditions

Store in original packaging in a clean, dry environment away from direct sunlight.

Recommended storage temperature:

+5°C to +35°C

Protect from excessive heat, freezing, and moisture.

Disposal

Dispose of used devices in accordance with local, state, federal, and institutional biohazard waste regulations.

Adverse Event Reporting

Report serious incidents or adverse events to Gemini Medical Technologies and applicable regulatory authorities according to local regulations.

Traceability

Each catheter package includes a lot number for product traceability.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

	Do not use if package is damaged.
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Keep Dry
	Keep away from sunlight
	Temperature limit
	Prescription use only
	Does not contain natural rubber latex
	Caution
	Non-pyrogenic



Manufactured for:
Gemini Medical Technologies, LLC
8211 Ulmerton Road
Largo, FL 33771-3975

Phone: +1-833-943-6464
www.geminimedtech.com