Form 05: Baseline Urodynamic Studies, Version 07/25/03 (C)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit # Baseline Assessment.....BASE

SECTION B: NON-INSTRUMENTED UROFLOWMETRY (NIF)

B1. Maximum flow rate: ____ ____ . ____ **ml/sec**

B2. Mean flow rate: ____ ____ . ____ **ml/sec**

B3. Classify the flow pattern of the urine stream:

Normal (continuous, smooth, arc-shaped signal with high amplitude) 1

Abnormal 2

B4. Time to maximum flow: ____ ____ ____ . ____ **sec**

B5. Voided volume: ____ ____ ____ **ml**

(If voided volume is < 150 ml, NIF must be repeated at another time.
Data recorded in B1-B5 should be from the NIF with the greater voided volume.)

B5a. Is the NIF from a spontaneous or a mechanical fill? Spontaneous fill 1

Mechanical fill 2

B6. Post void residual: ____ ____ ____ **ml**

INELIGIBLE IF STRESS TEST PVR AND UDS PVR > 150 ml WITH POP-Q STAGE 0 OR I

B7. Are any NIF data points invalid or missing?

YES.....1

NO.....2 ➔ **SKIP TO B8**

B7a. Describe: _____

_____

B8. Date NIF completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B9. NIF Tester's initials: ___ ___ ___

B10. Date review completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B11. UITN MD Reviewer's initials: ____ ____ ____
(REVIEWER MUST = UITN CERTIFIED SURGEON.
IF REVIEWER = TESTER, CODE –3)

B12. Equipment BCC Registration ID#: ___ ___ ___ / ___ ___

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SECTION C: CYSTOMETROGRAM (CMG) AND LEAK POINT PRESSURES (LPP)

C1. In what position was the CMG completed?

Freestanding, weight bearing (required by protocol) ..... 1 ➔ **SKIP TO C2**

Leaning..... 2

Supine..... 3

Sitting upright..... 4

Sitting at 45º angle 5

C1a. Why not freestanding? _____

C2. Catheter diameter: < 8 French ..... 1 ➔ **SKIP TO C3**

8 French ..... 2 ➔ **SKIP TO C3**

> 8 French 3

C2a. Specify catheter diameter: ____ ____ **F**

C2b. Why not ≤ 8 French? _____

C3. P**ves** at baseline: ____ ____ ____ **cm H_2O**

C4. P**abd** at baseline: ____ ____ ____ **cm H_2O**

C5. Bladder volume at first desire to void: ____ ____ ____ **ml**

C6. Bladder volume at strong desire to void: ____ ____ ____ **ml**

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PROLAPSE STATUS

C7. Is there a Stage III or IV anterior prolapse? YES ..... 1 ➔ **SKIP TO C10**

NO 2

LPP MEASURES FOR PATIENT <u>WITHOUT</u> ANTERIOR PROLAPSE STAGE III OR IV

C8. Did leakage occur with Valsalva? * YES.....1

NO .....2 ➔ **SKIP TO C15**

** To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

C9. At what volume? ____ ____ ____ ml

C9a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

C9b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

C9c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ **SKIP TO C17** if leakage occurs at least twice at the same volume with Valsava maneuvers

LPP MEASURES FOR PATIENT <u>WITH</u> ANTERIOR PROLAPSE STAGE III OR IV

C10. Did leakage occur with Valsalva **without reduction**? * YES..... 1

NO ..... 2 ➔ **SKIP TO C12**

** To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

C11. At what volume? ____ ____ ____ **ml**

C11a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

C11b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

C11c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ Leakage must occur at least twice with Valsalva maneuvers at the same volume

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MEASURES COMPLETED AFTER PROLAPSE REDUCTION

C12. Specify how the prolapse was reduced:

Gauze vaginal packing ..... 1 ➔ **SKIP TO C13**

Sponge stick ..... 2 ➔ **SKIP TO C13**

Pessary..... 3 ➔ **SKIP TO C12a**

Speculum..... 4 ➔ **SKIP TO C12c**

Other..... 99 ↓

Specify: _____ ➔ **SKIP TO C12c**

C12a. Specify pessary size: _____

C12b. Specify pessary type: _____

C12c. Why wasn't gauze vaginal packing or sponge stick used? _____

_____

C13 Did leaking occur with Valsalva **with reduction? *** YES..... 1

NO ..... 2 ➔ **SKIP TO C15**

** To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

C14. At what volume? ____ ____ ____ **ml**

C14a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

C14b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

C14c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ **SKIP TO C17** if leakage occurs at least twice at the same volume with Valsalva maneuvers

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C15. Why were LPPs not obtained? _____

_____

C16. Did leaking occur with cough at MCC? YES 1

NO 2

C17. Bladder volume at MCC: ____ ____ ____ **ml** **INELIGIBLE IF BLADDER VOLUME < 200 ml**

C18. P**ves** at MCC: ____ ____ ____ **cm H_2O**

C19. P**abd** at MCC: ____ ____ ____ **cm H_2O**

C20. Was there detrusor overactivity? YES 1

NO ..... 2 ➔ **SKIP TO C21**

Record volume at each occurrence of detrusor overactivity and indicate if overactivity was associated w/ leakage.

	Occurrence	**Recorded Volume**		**Leakage?**	
C20a.	Occurrence 1:	____ ____ ____ ____ **ml**		YES.....1	NO.....2
C20b.	Occurrence 2:	____ ____ ____ ____ **ml**		YES.....1	NO.....2
C20c.	Occurrence 3:	____ ____ ____ ____ **ml**		YES.....1	NO.....2

C21. Are any CMG data points invalid or missing or are any required annotations missing? YES.....1

NO .....2 ➔ **SKIP TO SECTION D**

C21a. Describe: _____

_____

_____

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SECTION D: PRESSURE FLOW STUDY (PFS)

D1. **Did the patient cough before voiding** to confirm proper placement of the catheters and a dynamic response of the pressure channels?

YES..... 1

NO..... 2

D2. Maximum flow rate: ____ ____ . ____ **ml/sec**

D2a. P**ves** at maximum flow: ____ ____ ____ **cm H_2O**

D2b. P**abd** at maximum flow: ____ ____ ____ **cm H_2O**

D2c. P**det** at maximum flow: ____ ____ ____ **cm H_2O**

D3. Time to maximum flow: ____ ____ . ____ **sec**

D4. Voided volume: ____ ____ ____ **ml**

D5. Did the urethral sphincter relax during voiding?

YES 1

NO 2

CANNOT DETERMINE; PERINEAL SURFACE EMG ELECTRODES WERE NOT USED 3

CANNOT DETERMINE; PERINEAL SURFACE EMG ELECTRODES WERE USED, BUT NOT FUNCTIONING OR RESULTS WERE NOT CONCLUSIVE 4

D6. Voiding Mechanism:

Detrusor.....1

Abdominal.....2

Mixed 3

Other.....4

Uninterpretable.....5

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D7. **Did the patient cough at the end of the PFS** to confirm proper placement of the catheters and a dynamic response of the pressure channels?

YES..... 1

NO..... 2

D8. Are any PFS data points invalid or missing or are any required annotations missing?

YES 1

NO .....2 ➔ **SKIP TO D9**

D8a. Describe: _____

_____

_____

D9. Date CMG completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D10. CMG Tester's initials: ___ ___ ___

D11. Date PFS completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D12. PFS Tester's initials: ___ ___ ___
(IF PFS TESTER = CMG TESTER, CODE -3)

D13. Date review completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D14. UITN MD Reviewer's initials: ___ ___ ___
(REVIEWER MUST = UITN CERTIFIED SURGEON
IF REVIEWER = TESTER, CODE –3)

D15. Equipment BCC registration ID#: ___ ___ ___ / ___ ___

Affix ID Label Here

SECTION E: ELIGIBILITY SUMMARY

DETERMINE IF THE PATIENT IS STILL ELIGIBLE BASED ON THE UDS.

THE PATIENT IS <u>NOT ELIGIBLE</u> IF:

- **Her MCC is < 200 ml (C17);**
- **She has a POP-Q Stage 0 or 1 and demonstrates obstructed voiding defined as:**
  - **a maximum flow rate of < 12 ml/sec on both the NIF (B1) and the PFS (D2)**
    <u>or</u>
  - **a Pdet at maximum flow > 50 cm H_2O by PFS (D2c);**
- **Her UDS PVR (B6) <u>and</u> Stress Test PVR (FM13, B4) > 150 ml with POP-Q Stage 0 or I**

E1. Does the patient meet all eligibility criteria as required in this form?
Review items **B1**, **B6**, **C17**, **D2**, & **D2c.**

YES ..... 1 ➔ **CONTINUE SCREENING**

NO ..... 2 ➔ **INELIGIBLE**

E2. Date eligibility determination completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

E3. Initials of person completing eligibility determination: ____ ____ ____