



Question by Question Specifications Guide
Form 13: Baseline Stress Test
Version 10/21/02 (A)

I. Purpose

A provocative stress test will be performed on all women participating in the UITN trial pre-operatively at baseline to determine eligibility for the trial and subsequently at the 6-month, 12-month, 24-month, 36-month and 48-month follow-up visits to ascertain treatment success. The standard procedures established by the UITN Steering Committee are described in detail in the Stress Test Procedures Manual.

II. Administration

A. Order of Administration

Examiners are obliged to follow the Stress Test procedures described in the Stress Test Procedures Manual.

B. Certification of Examiners and Testers

Stress Test examiners must be certified by and registered with the BCC. The obligations of certification for examiners are documented in the QA Plan. Results of these measures conducted by non-certified clinicians may not be entered in the UITN DMS. In such cases, measures would need to be repeated by a certified clinician.

III. Section by Section Review

Section A: General Study Information

- A1. **Study ID number:** Affix the patient ID label in the spaces provided in the A1 field and in the upper right hand corner of each page of the Data Form. Avoid handwriting ID numbers. Transcription errors are common when transcribing long numbers, and errors in an eight-digit ID usually cannot be corrected. Furthermore, handwritten numbers are often illegible. Most research studies will not accept handwritten IDs, making the data gathered on such Data Forms unusable.
- A2. **Visit number:** The visit number is pre-coded for Data Form 05 which will always be Visit **BASE**. This Data Form is to be completed at the baseline visit.

Section B: Baseline Stress Test

Refer to the Stress Test Procedures Manual for details of how to perform this procedure.

- B1. **Did the patient demonstrate SUI at a bladder volume ≤ 300 ml during the Stress Test?:** Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form. If the patient did not demonstrate SUI during the stress test, she is ineligible.
- B2. **Negative Stress Test:** If the patient did not demonstrate SUI, record the **highest** bladder volume at which the Stress Test was performed in milliliters.
- B3. **Positive Stress Test:** If the patient did demonstrate SUI, record the **lowest** bladder volume at which SUI occurred in milliliters.

- B3a. **When did SUI occur?:** Record yes (code 1), no (code 2), or not tested (code 3) to indicate the occurrence of SUI at this **lowest** bladder volume with each of the maneuvers/positions listed.
- B4. **Post void residual:** Record PVR in milliliters. Patients POP-Q Stage 0 or I are ineligible if both the Stress Test PVR and UDS PVR are >150 ml.
- B4a. **Did SUI occur at this PVR in the post-void supine Stress Test?:** Record yes (code 1) or no (code 2) to indicate the occurrence of SUI at the PVR in the post-void supine position with Valsalva or cough. The response option of “Not Tested” was not included because SUI at the patient’s PVR in the post-void supine position should always be tested with Valsalva and with cough.
- B5. **Was it necessary to reduce a Stage III or IV anterior prolapse to complete this Stress Test?:** Circle yes (code 1) or no (code 2) to indicate whether or not it was necessary to reduce the patient’s prolapse.
- B6. **Date Stress Test Completed:** Record the date on which the Stress Test was completed. All dates must be in the format of mm/dd/yyyy.
- B7. **Stress Test Examiner’s Initials:** Enter the initials of the examiner who conducted the Stress Test. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the examiner doesn’t have a middle initial, strike a dash in the second space. If the examiner’s last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.
- B8. **Date Abstract Completed:** Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.
- B9. **Abstractor’s Initials:** Enter the initials of the person abstracting the data. If the examiner is filling out this form, code –3 for this item. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the abstractor doesn’t have a middle initial, strike a dash in the second space. If the abstractor’s last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section C: Eligibility Summary

- C1. **Is the patient still eligible?:** Review the completed Data Form, specifically items B1, B2 and B4 to determine if the patient meets all Stress Test eligibility criteria. Circle yes (code 1) or no (code 2). If the answer is no, the patient is ineligible.
- C2. **Date Eligibility Determination Completed:** Record the date on which the eligibility summary was completed. All dates must be in the format of mm/dd/yyyy.
- C3. **Data Collector’s Initials:** Enter the initials of the data collector who coded C1. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the examiner doesn’t have a middle initial, strike a dash in the second space. If the examiner’s last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.