



Stress Test Procedures Manual Version 10/22/08

BASELINE

Patients will have a Stress Test at baseline to determine eligibility by the criterion of leakage on provocative Stress Test at any volume. There are no standardized stress testing procedures at baseline.

12 MONTH FOLLOW-UP

OVERVIEW: A provocative Stress Test and measure of PVR is performed at the 12 month follow-up visit. Provocative stress testing is performed as a surgical treatment outcome measure and a PVR is obtained to assess bladder emptying capability. Each Stress Test should be recorded “positive-yes” if there is observed leakage from the urethral meatus coincidental with the Valsalva or cough maneuver. The overall Stress Test outcome will be considered “positive” if a “yes” response is recorded in any position or maneuver at a bladder volume of 300mL or less. The overall Stress Test will be considered “negative” if there is no observed leakage from the urethral meatus at all tested volumes, positions, and maneuvers.

Testing steps should be completed sequentially in the order prescribed below. NOTE: As stated on protocol page 11, to minimize potential bias, the examiner cannot be the surgeon. Any other qualified examiner registered as certified with the DCC may perform the test.

TESTING PROCEDURES:

1. Instruct the subject to **void** in a toilet hat or uroflowmetry chair prior to stress testing and measure the **voided volume**.
2. Perform an **Empty Bladder Stress Test: (EBST)** with the subject in the dorsal lithotomy position. Perform Valsalva maneuver first, followed by cough.
3. Place catheter in the bladder and determine the **volume of the PVR** which is also the volume of the EBST. If the Empty Bladder Stress Test is positive, then a fill with a catheter is not required and the PVR may be obtained by bladder scan.

Testing is complete if the EBST Stress Test is positive. Otherwise proceed to #4.

4. **Retrograde fill:** Perform retrograde fill to 300mL or bladder capacity, whichever is less.
5. **Full Bladder Stress Test (FBST):** Perform the Full Bladder Stress Test in the following sequence:
 - a. Valsalva in dorsal lithotomy position
 - b. Cough in dorsal lithotomy position
 - c. Valsalva in standing position
 - d. Cough in standing position

NOTE: Stop the FBST at any point in the sequence if the test is positive and then record “Not Tested” for the subsequent positions or maneuvers.

6. **Test Documentation:** All test data must be recorded in a source document and abstracted onto ValUE Data Form 553.