UITN: The TOMUS Protocol
UDS Reviewer Interpretive Guidelines
Version 03/29/06

Definition of Terms:

"Tester" is the UITN certified clinician performing the UDS.

"UITN MD Reviewer" is the UITN SISTEr certified surgeon interpreting the UDS for the study Data Forms. This cannot be the same surgeon who performed the TOMUS surgical procedure as TOMUS surgeons will remain blinded to UDS data.

In General:

Electronic or paper printout signals can be reviewed. However, if annotations are missing, misplaced, or incorrect, the reviewer (or tester) should correct these annotations electronically and the corrected signals should be reviewed.

Record values if they are **legible, plausible, and annotated**. If you record a value on a UITN Data Form you are saying that the value belongs in the urodynamics database. In some circumstances, when an annotation is not present but can be inferred with confidence (e.g. baseline, MCC), values may be accepted following the specific guidelines below.

Do not leave data fields blank on any of the UDS Data Forms, because the data manager will not know if the value was reviewed or inadvertently overlooked.

- If the values do not meet the criteria described in these Guidelines, write the word "***invalid***" in the data field and describe why the data should not be used.
- Write the word "***missing***" in the data field if the data are missing for any other reason.

Requirements for entering specific values are as follows:

NIF

Maximum Flow Rate/Qmax: (Expected range 5 to 50ml/s)

- For traces with smooth curves with no significant artifacts affecting Qmax values, the original value given by the equipment will be accepted as the result. Traces where the Qmax is influenced by artifact should be smoothed. Only peaks that last 2 seconds will be considered as true Qmax values. (Lewis, Abrams BJU Int, 2000)

  Follow "*Good Urodynamic Practices*" (Schafer, N&U, 2002) for "smoothing" by hand (p. 264) using a sliding average over 2 seconds to remove positive and negative spike artifacts.

Voided Volume: (Expected ranges: 150-666mL)

Do not abstract values from an NIF if the voided volume is <150mL.

Flow Patterns: Classify non-instrumented flow patterns using ICS definitions, i.e. continuous, smooth; vs. continuous, fluctuating; vs. intermittent.

UPP (Urethral Pressure Profile)

MUCP expected range: 10 – 120 cm/ H_20

Functional Urethral Length (FUL) expected range: 10- 50 mm

Evaluate the UPP signals for validity. The UPP should be continuous, bell-shaped, and without spike artifacts. If numerous spike artifacts or irregularities of the signal prevent interpretation of the Maximum Urethral Closure Pressure (MUCP) the MUCP must be considered invalid. If the reviewer determines one or more of the three withdrawals to be invalid, the word "invalid" should be written in the MUCP data field next to that withdrawal and a description for the invalidity should be written in the space provided above.

Review the UPP Signal and determine if the "UPP start" and "UPP stop" annotations are correctly placed. Move annotations if necessary. To obtain an accurate calculated FUL measurement the "UPP start" annotation should be placed at the start (inflection point) of the p_{clo} signal as soon as the signal starts to increase above baseline. The "UPP stop" annotation should be placed at the end of the UPP curve when the pressure is decreasing and $p_{clo} = p_{clo}$ at UPP start. The FUL (length) data should be extracted from the UPP event summary. If there is a spike artifact in the UPP signal, move the cursor (annotation) to the real MUCP portion of the curve or the best representative area of the MUCP and record this as the MUCP.

CMG

Prior to the start of the fill look for evidence/annotations of zeroing of catheters to atmosphere, establishment of an interpretable CMG baseline and evidence of properly functioning catheters.

CMG pressure measurement validity screening questions

CMG pressure measurements will be considered invalid for several reasons including illegible signals, failure to zero catheters to atmosphere prior to the start of the fill, and improperly functioning pressure catheters at the CMG baseline. You may also determine CMG pressure values invalid for other reasons. If you conclude the CMG pressure measurements are invalid for any other reason record "Yes" to the final validity question and provide a brief description in the text field.

If the CMG is invalid, indicate all the reasons for the invalid study and write the word '*invalid*" in the data fields for the CMG pressure measurements .Even if the CMG is invalid, you should record the non-pressure measurements on the data form, i.e. sensation parameters, volumes of VLPP and MCC, leak with cough at MCC, and presence and volume of detrusor overactivity.

If the baseline annotation is missing, Reviewers should record values from the most representative stable baseline before the 100 mL cough annotation.

Pves and Pabd @ baseline (Expected range +10 to +60)

- The UITN SISTEr data demonstrated that 95% of Pves and Pabd baseline values should fall in the 12 to 60 cm H_20 range. Pves and Pabd values of <10 and >60 will prompt an edit report for your confirmation.

Pdet @ baseline (Expected range 0 to +5)

- Ideally, baseline Pdet values should be between 0 and +5 and therefore values outside this range should be immediately evaluated by the tester prior to proceeding with filling. Pdet values <-5 or >+8 cm will prompt an edit report for your confirmation.

Volume of VLPP's: (Expected range: 190 - 750)

- Record the actual volume at which VLPP's were obtained, realizing that this volume is often not an exact 100 ml multiple.
- Write N/A in the VLPP data field(s) if there are no VLPPs annotated on the signals.

VLPP: (Expected range: 50 -205)

- Baseline should meet plausibility rules, i.e., baseline Pves values should fall between 10-60cm.
- Tracings should appear "live" (e.g. responds to cough, Pabd increases, etc.)
- Pves lead is not blunted (reaches 80 % of Pabd for all Valsalva events). If Pves does not reach 80% of Pabd, Reviewers should code the value as invalid. Pves may exceed Pabd during Valsalva.
- Recorded VLPP's should be read from the lowest volume during which at least two values were obtained.
- In some instances the VLPP is annotated **after** the peak. This most likely represents a tester "late on the trigger" when marking leakage. When the annotation falls **after** the peak, the VLPP annotation should be moved to the peak of the Valsalva effort and the pressure measurements should be taken from the peak of Pves. The annotation **should not** be moved if it falls before the peak.
- It is recognized that some patients or Testers "overshoot" with initial aggressive, rapid Valsalva attempts and then more than three values are performed by the Tester. If more than three VLPP's are annotated, the Reviewer should record the first three "representative," "typical" annotated VLPP's.
- Testers are instructed to obtain three VLPP at the same volume to allow maximize test precision and evaluate reproducibility. (A mean value for VLPP will be calculated in analyses at the BCC.) In the event that three VLPPs are not obtained, two VLPP values will be accepted. If this occurs, record "NA" for the 3rd VLPP.

Leak with cough @MCC

- This maneuver is only required if urodynamic stress incontinence was not documented earlier in the study. Record "Yes" (code 1) only if "Cough/Leak" is annotated on the signal. Record "No" (code 2) if "Cough/**No Leak**" is annotated on the signal. Reviewers should write "**missing** cough maneuver for SUI @ MCC" on the data form if there is no evidence of SUI earlier in the study and there is no evidence the required cough maneuver was performed at MCC.
- Code this item N/A (code -1), even if the maneuver was performed, if there is evidence of SUI earlier in the study making this maneuver 'not applicable.

Pressures at MCC

Pves at MCC: (Expected Range 21-66)

Pabd at MCC: (Expected range: 10-60)

- If MCC is not annotated, the reviewer should pick the maximum infused volume and record pressure values from the most representative stable area at this maximum infused volume.

Detrusor Overactivity

- Detrusor Overactivity (DO): The Reviewer should record the volume at which DO occurred and indicate if it was with or without leakage if it is annotated on the signal as such. If strong suspicion for DO is noted by the Reviewer which is not annotated on the signal, Reviewers should record the volumes at which DO occurred in the volumes data field.

PFS

At the start of the PFS, the Reviewer should look for evidence/annotations for the change in position to sitting, adjustment of transducers, concordant response of both the Pabd and Pves signals to cough, and establishment of an interpretable PFS baseline. In certain circumstances, when annotation is not present, but can be inferred, PFS values may be accepted (e.g. change in position or transducer adjustment not annotated, but tracing implies it occurred).

PFS pressure measurement validity screening questions

PFS pressure measurements should be considered invalid if the signals are not legible, catheters were not zeroed to atmosphere prior to the start of filling, the patient did not sit to void, transducers were not adjusted after the patient changed position, the patient could not void, the PFS baseline is not interpretable, or the Pves and Pabd measuring systems were not functioning properly when baseline and/or Qmax pressure values were obtained. You may also conclude PFS pressure values are invalid for other reasons. If you conclude the pressure measurements in the PFS are invalid for any other reason, record "Yes" to the final validity screening question and provide a brief description in the text field

If the PFS is invalid, indicate all the reasons the study is invalid. Even if the PFS is invalid, you should still record all non-pressure measurements from the PFS, i.e. Qmax, time to Qmax, and voided volume.

Was there at least 70% concordance between the Pves and Pabd pre-void cough spike:

This maneuver is performed to confirm proper placement of the catheters and a dynamic response of the pressure channels. Carefully note the peak value of both the vesical and abdominal prevoid cough spikes. Note that because of transmission delay differences, an annotation at the peak of one pressure measurement may not match the peak of the second pressure cough peak. It is the maximum value of each cough spike that should be compared. If the smaller cough peak is ≥70% of the larger cough peak then record "yes" to the concordance question. If more accuracy is needed to make this determination, and you are reading the signals electronically, use the slide bar at the bottom of the electronic UDS signal and read the numerical values on the right side of the screen while sliding the pressure spikes thru the right side of the screen. This prevoid cough maneuver should be considered as one of the tools to assess a functioning pressure system, but lack of a pre void cough or lack of 70% concordance for this measure alone does not automatically invalidate the PFS pressure measurements.

Pves and Pabd @ PFS baseline (Expected range +10 to +70)

Pdet @ PFS baseline (Expected range -4 to +15)

The baseline pressure measurements should be annotated after the position change to void, after the prevoid cough, and from a stable, flat Pves and Pabd signal. Typically this measurement occurs a few or several seconds before flow and prior to any vesical or abdominal pressure increase associated with the beginning of the void. If a PFS baseline is not annotated, measurements should be taken from the prevoid signal that best approximates the above description.

Pves at Qmax: (Expected range 23-150)

Pabd at Qmax: (Expected range: 8-150)

Pdet at Qmax: (Expected range: -5 - +50)

Qmax: (Expected range: 5-50)

- Guidelines are the same as NIF Qmax. For traces with smooth curves with no significant artifacts affecting Qmax values, the original value given by the equipment will be accepted as the result. Traces where the Qmax is influenced by artifact should be smoothed. Only peaks that last 2 seconds will be considered as true Qmax values. (Lewis, Abrams BJU Int, 2000)

Follow "*Good Urodynamic Practices*" (Schafer, N&U, 2002) for "smoothing" by hand (p. 264) using a sliding average over 2 seconds to remove positive and negative spike artifacts.

- If there are two identical Qmax values, the recorded value should be the one with the lowest Pdet (Lewis, Abrams BJU Int, 2000).

Record Pabd, Pves from the tracing. Do not adjust Pabd or Pves values for perceived insufficient releveling of the transducers or for perceived imbalances in Pves and Pabd caused by position changes or for a Pabd decrease with void initiation.

Voiding Mechanism

- Record "Pure or predominant **detrusor**" (code 1) if the dominant voiding force was detrusor.
- Record "Pure or predominant **abdominal**" (code 2) if the dominant voiding force was an abdominal or Valsalva force.
- Record "Mixed" (code 3) if there is evidence of significant contributing detrusor and abdominal forces and neither could be considered predominant.
- Record "Indeterminate /Uninterpretable" (code 5) if you are unable to assess, or if poor concordance prevents assessment, or if the study is sufficiently invalid to preclude interpretation.

Did the patient cough after the void?
Was the Pves measuring system functioning during the post void cough?
Was the Pabd measuring system functioning during the post void cough?

The cough maneuver at the end of void is performed to confirm proper placement of the catheters and a dynamic response of the pressure channels. The Reviewer should note and record if a post void cough was performed and then assess, based on this cough, if the systems were functioning during this cough. Concordance measurements are not taken. This post void cough should be considered as one of the tools used to assess a functioning pressure system, but lack of a post void cough or lack of concordance for this measure alone does not invalidate the PFS pressure measurements.

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Expected ranges for UDS data points

(Based on 2.5-97.5th percentile data from SISTEr UDS)

FYI: Values outside this range will generate an edit report for Reviewer confirmation.

NIF

Max flow rate: **5-50**

Mean flow rate: **4.0-29.0**

Time to max flow: **2.0-40.0**

Voided volume: **149-666**

PVR: **0-120**

INVALID= (-66)

MUCP

MUCP: **10-120mm**

Functional urethral length: **10-50mm**

INVALID= (-66)

CMG

Pves at baseline: **10-60**

Pabd at baseline: **10-60**

Pdet at baseline: **-5 - +8**

Bladder volume at first desire: **30-387**

Bladder volume at strong desire: **68-600**

VLPP volume: **190-750**

Raw Pves at 1st , 2nd, 3rd leakage: **48-200**

- Pves must reach 80% of Pabs
- If >3VLPPs, pick 1st 3 most representative/typical VLPPs

Bladder volume at MCC: **195-750**

Pves at MCC: **21-66**

INVALID= (-66)

PFS

Pves at PFS baseline: **10-70**

Pabd at PFS baseline: 10-**70**

Pdet at PFS baseline: **-4 and +15 and (Pves minus Pabd)**

Pves at Qmax: **23-150**

Pabd at Qmax: **8-150**

Max flow rate: **5-50**

Time to max flow: **3-80**

Voided volume: **110-772**

INVALID= (-66)