



Question by Question Specifications Guide
Form 06: Baseline Pad Test and Voiding Diary Summary
Version 07/01/02 (A)_revised 01/21/03

I. Purpose

A. Voiding Diary

For purposes of this trial, a 3-Day Voiding Diary will be used to assess the frequency of voluntary micturitions and involuntary episodes of urine loss at baseline and at several time points post intervention. A mean micturition of ≥ 12 times per day (the average of the three Voiding Diary days) has been established as an exclusion criterion for the trial. The recommended duration for keeping a voiding diary ranges from 3 –14 days (Burton, 1984; Robb, 1985). The Steering Committee has selected a 3-Day Voiding Diary based on the results of reliability testing by Nygaard and Holcomb (2000) in women with genuine SUI. They reported a high correlation between the first 3 days of the diary and the last 4 days, suggesting that a 3-day diary is an appropriate outcome measure for clinical trials evaluating treatment for SUI.

B. Pad Testing

Pad testing will be used in the UITN trial to quantify the amount of urine involuntarily lost. The 24-Hour Pad Test will be used to reflect everyday incontinence. This test, standardized by the International Continence Society, correlates well with UI symptoms, and has good reproducibility.

II. Administration

The Voiding Diary and the Pad Test will be completed at baseline and at the 6-month, 12-month and 24-month visits.

The two measures will always be completed together. It is essential that the Voiding Diary and the Pad Test be conducted in a standardized manner as both measures are considered primary outcome measures of treatment success. An instructional video explaining the measures has been developed for patients' use to prevent/minimize error in the conduct of the measures. Ideally, patients will view the videotape at the Continence Treatment Center (CTC) and review the procedures with a Study Nurse to maximize compliance with the at-home procedures. Additionally, patients should be allowed to take a videotape home to review at other times as questions might arise during the 3-day measurement period. The text of the videoscript is included here as Attachment A.

In addition, a summary of patient instructions for each of the measures appears in the Voiding Diary and in the Pad Test reminder insert. These summaries are included here as Attachments B and C.

A. Window for Re-Screening of Patients:

The results of these measures expire 6 months following their completion; therefore, if more than 6 months transpires between the date either measure is completed and the date of the planned UITN surgery, the measure(s) must be repeated to ensure current eligibility status (Voiding Diary) as well as to obtain 'current' baseline values that would be subject to change over a 6-month period.

B. Timing

The timing of completion of these measures is very precise. The Voiding Diary is a 3-day diary, with each day representing a complete 24-hour period. The start of a day is midnight or 12:00 AM, and the end of a day (exactly 24-hours later) is 11:59 PM.

The pad test is completed for one, and only one day, that is, one complete 24-hour period starting at the patient's waking time and ending **exactly** 24 hours later.

Patients who still menstruate should avoid completing either measure during their menstrual period. Primarily, it would be troublesome for patients to complete the measures during a period; but, for study purposes, the results would be complicated by the difficulty of separating urine loss from blood loss. Investigators realize that this may be a difficult prediction for UITN patients to make, but every effort should be made to avoid this time. For similar reasons, we ask patients to avoid the use of vaginal creams, jellies, suppositories or douche treatments during the conduct of the measures. We also ask patients to avoid intercourse during the conduct of the measures. Finally, since some woman have reported tampon use reduces the number of urinary accidents they have, we are asking woman to avoid the use of tampons while completing the Pad Test, whether they are menstruating or not.

Our goal is to collect data that represent "typical days", so we are asking patients to plan for 2 of the 3 Diary days to be weekdays. We are also asking patients to schedule the Pad Test on a typical weekday when they would expect to be busy with normal or typical daily activities. In other words, we do not want them to avoid certain days of the week or to change activities that would usually cause them to have urinary accidents; we want measurements from typical days.

Patients with pelvic organ prolapse should complete the measures in their "typical" state. If the patient typically wears a pessary, then a pessary should be worn during the conduct of the Voiding Diary and Pad Test.

Finally, it is best if patients complete the Pad Test one or two days before they're next scheduled study visit. In general, patients will see the merits of this rule, as it limits the number of days they have to hold onto 'used' pads! Second, and more importantly for our purposes, it eliminates/minimizes the potential for urine evaporation from the "used" pads. Third, the longer the time period between completion of the Pad Test and the date of the study visit, the more likely it is that patients will return for the visit without bringing the used Pads with them.

With all of these objectives in mind we ask patients to:

- Avoid using the Voiding Diary on any of the days that they might have their period;
- Complete the Voiding Diary just prior to their next scheduled study visit, i.e. complete the 3rd day of the Voiding Diary no later than midnight of the night before the next study visit;
- Start the Voiding Diary on any day from Sunday to Thursday;
- Begin using the Voiding Diary at 12 midnight and use it for 3 complete days in a row;
- Complete the Pad Test on Day 2 or 3 of the Voiding Diary days and complete it one or two days before the next scheduled study visit;
- Avoid the use of vaginal creams, jellies, suppositories or douche treatments during the conduct of the measures;
- Do not use tampons while completing the Pad Test, whether you are menstruating or not; and,
- Avoid having intercourse while completing the Pad Test.
- Complete the measures in your "typical" state (with or without a pessary)

In light of all of these essential restrictions, it is best if the Study Nurse works with the patient to schedule the date of the next study visit and select the actual days for completion of the Voiding Diary and Pad Test using a calendar

as reference. Do not forget to consider the possibility of a menstrual period when selecting the dates for the measures.

C. Source of Data

No source documents, other than the Data Forms 06 and 06A, will be expected for these 2 measures. The patient completes both the Voiding Diary and the Pad Test. The patient will be instructed to keep precise records of her voiding habits and pad use in the Voiding Diary (Form 06A) and return to the CTC with her completed Voiding Diary and used Pad Test Kit. All pre- and post-use pad weights completed by the Study Nurse will be recorded directly onto the UITN Data Form 06, see Section B. This forms is considered the primary recording site for these measures. Other data required for the completion of Form 06 will be abstracted from the Voiding Diary (Form 06A).

D. Certification of UITN Interviewers and Data Collectors

Interviewers and data collectors must be certified by and registered with the BCC as a UITN Interviewer / Data Collector. The obligations of certification are documented in the QC Plan in the Manual of Operations. Data gathered by non-certified persons should not be entered into the UITN DMS.

E. Materials / Space Needed

- Instructional Video for the 3-Day Voiding Diary and the 24-Hour Pad Test
- A TV monitor and VCR
- A private room for viewing the Video
- A 3-Day Voiding Diary with a patient ID label attached
- The Pad Test Reminder insert including an abbreviated version of the Pad Test procedures and a reminder of the Pad Test start date
- A Pad Test Kit including the number of Poise™ protective pads specific to each patient's needs
- Prescribed, zip-lock biohazard bags; one bag for each pad
- A larger, teal colored plastic bag for all the Kit materials
- Pad Test labels pre-printed with the patient's confidential ID number, one per pad (Avery Label 1" x 2 5/8", # 5260)
- Blank gram weight Pad Test label for recording the pad weights (same Avery label, size 1" x 2 5/8"; # 5260)
- A calendar as reference to select the dates/days for completing the Voiding Diary and the Pad Test and for scheduling the next study visit
- UITN Data Form # 06 with patient ID labels attached
- Standard scale for weighing each pad before and after use: Model GX-2000 Multi-Function Balance (A&D Engineering, Milpitas, CA). This scale (balance) is a study-required piece of equipment.
- Stapler

F. Care and Calibration of the Scale

Daily care and maintenance of the scale is important to maximize the accuracy of the Pad Test. A scale that is accurate to .01 gram has been selected to maximize precision for this primary outcome measure. See Attachment D for UITN guidelines. A complete manual is included with the scale you purchase.

G. Preparing the Pad Test Kit

The following steps are listed in logical sequence:

1. First, determine the number of pads needed for the 24-hour test. Show the patient the type of pad you will give her and ask her how many of these pads she would expect to use if the day selected were to be one of

her worst. Include one and a half that specified amount of pads in the kit you prepare for her. Patients with large prolapses may report that “Poise” pads are insufficient in managing their incontinence. These patients are permitted to complete the Pad Test (pre-randomization) using an alternative product appropriate to their incontinence needs. If this situation occurs, request the patient bring in a sufficient number (1½ times the amount needed on one of her worst days) of the alternative product for pre-weight measurements. Then, proceed to follow all other weighing guidelines listed below. In the latter case of use of an alternative “Pad”, please contact the BCC.

2. Next, make arrangements for the patient to watch the video somewhere in the CTC. The video lasts 15 minutes.
3. While the patient watches the video, the Study Nurse should prepare the patient’s Pad Test Kit making certain that all of the pads are weighed and labeled correctly.
4. Using clean technique (wash hands, wear clean gloves, work in a clean field) remove the commercial outer wrapper of the pad(s).
5. Place each pad in a regulation biohazard zip-lock bag and seal the bag.
6. **Then, staple the bag at the top, above the bag’s zip-lock seal. Remember to staple the bag prior to weighing the pad. Since most pads will be returned with the staple still attached to the bags, we have decided to include the staple in the pre-weight measure. Therefore, the weight recorded on the label will now include the weight of the staple.**
7. Next, weigh each single pad in its biohazard bag following the weighing procedures described in Attachment D. Don’t forget to
 - remove the metal ring that surrounds the weighing pan to reduce weighing error and
 - roll the biohazard bag around the Pad a few times to be certain that no part of the biohazard bag falls off the weighing pan or touches any area of the scale other than the weighing pan. The weight can vary significantly if this occurs.
8. Hand-write the weight of the pad (in gram weight to the .01 measure) on a prescribed blank gram weight label and place the label on the outside of the biohazard bag. It is important to always weigh the pad, in the biohazard bag without the label(s) attached.

This much of the procedure can be completed in advance in batches for many pads.

9. When you prepare the personalized Pad Test Kit for the patient, first hand write a sequential pad # onto each of the patient’s pre-printed confidential ID labels that you will use for this patient’s Kit. The labels include a specific space for you to record the Pad #. For example, if you are giving the patient 6 pads you will write a number “1” on the first ID label, a number “2” on the second ID label, a number “3” on the third ID label and so on, until you have 6 confidential ID labels each with a pad # written on the label. Then, place these labels on the outside of each of the biohazard bags included in the patient’s Kit. Remember, you must use the pre-printed, Pad Test ID labels so that each pad will be labeled with the patient’s pre-printed confidential ID number and a sequential pad number attached to the outside of the biohazard bag.

NOTE: The weight of the two study specific “Avery” labels is equal to the weight of one pad adhesive paper that the patient will remove and discard when she uses the pad. Therefore, when a used pad is returned and reweighed only the weight of the urine loss will be measured.

10. Complete Section A and items B1-B6 of data Form 06. The pre-weight values for each of the pads included in the patients Pad Test Kit must be recorded on the form before you give the Kit to the patient. The rest of the form will be completed when the patient returns the Kit.
11. Finally, put all of the pads into the larger, teal colored plastic bag prescribed for Pad Test use.

H. Completing the Measures

1. When the patient finishes viewing the video, the Study Nurse should meet with her to answer any procedural questions she might have regarding either the Voiding Diary or the Pad Test.

2. Then, using the patient's calendar, identify the time of her next period and determine the appropriate dates and days to complete the Voiding Diary, the Pad Test, and next study visit.
3. Next, the Study Nurse gives the patient the Pad Test Kit, prepared to the patient's personal specifications, reviews the contents of the Kit with the patient, and gives the patient a business card. The Study Nurse should encourage the patient to call with any question or concerns.
4. As a reminder, the Study Nurse should make arrangements to contact the patient one day prior to the start of the Voiding Diary to remind her to complete the Diary and Pad Test as planned. The Nurse should schedule with the patient a convenient time to talk for the reminder call. This will provide a good opportunity for the Nurse to answer any final questions the patient might have prior to the start of the measures.

I. Recording the Data

1. When the patient returns with the completed Voiding Diary and the Pad Test Kit (including all used and unused pads) the Study Nurse weighs each of the Pads in the Kit per protocol and completes all the remaining sections of Data Form 06 at that time.
2. Patients will frequently make errors when documenting in the Voiding Diary. For example, times of voids/accidents are often recorded incorrectly or in the wrong columns; written comments will contradict the markings in the "Toilet"/"Accident" columns; start and stop times of the Pad Test will be missing; etc. Because the total number of voids is an eligibility criterion, no interpretation of the voiding diary data is allowed. All times or markings documented in the "Toilet" column will be counted as voids and all times or markings documented in the "Accident" column will be counted as accidents. When an accident and a void are recorded at the same time, both incidents will be counted (i.e. one void and one accident). Any confusing or illegible elements on the Diary must be clarified with the patient and documented in C13.
3. The Nurse or an assigned CTC staff member completes any required QC procedures (see guidelines forthcoming in the QC Plan Section of the Manual of Operations).

Section A: General Information

- A1. Study ID Number:
- A2. **Visit Number:** The visit number is pre-coded for Form 06, which will always be Visit **BASE**. This Data Form is to be completed at the baseline visit.
- A3. **Date Form Completed:** Enter the date that the form is completed. This date should be the date when all post-weight measures have been recorded and the Voiding Diary data has been abstracted. All dates must be in the format of mm/dd/yyyy.
- A4. **Is this a repeat measure?:** These measures may be repeated for various reasons. If more than 6 months transpires between completion of these measures and the planned date of surgery, the measures must be repeated. A measure may also be repeated if a previously completed measurement was invalid. Circle code yes (1) or no (2) and follow the skip pattern on the Data Form.
- A4: **Reason for repeat measure:** Indicate the reason the measure is being repeated. Circle code 1 if measures completed earlier have expired; circle code 2 if measures completed earlier were invalid.

Section B: Pad Test

- B1. **Are there Pad Test measures to record on this form?:** There will be occasions when you will complete one of these test alone, i.e. one of the measures may be invalid on first measure and will need to be repeated. For example, if you are repeating the Voiding Diary (but not the Pad Test) because a previous Diary was invalid, you can circle code 2 for this item and skip to Section C.

- B2. **Date Pad Test Kit distributed:** Record the date you complete the patient education procedures and give the Pad Test Kit to the patient.
- B2a. **Initials of person who distributed the Pad Test Kit:** This must be a UITN certified data collector. This should be the same person who completes all required patient education procedures for the Pad Test including video viewing, review of the patient's Pad Test Kit materials and at-home patient procedures after video viewing, completing the follow-up phone contact, etc.
- B3. **Number of Pads in the Kit:** Record the number of pads included in this patient's Pad Test Kit.

Pad Weights

- B4. **Date pre-weights are recorded:** Record the date when pre-weight measurements are documented on the Data Form.
- B5. **Initials of the person recording the pre-weight measures:** Enter the initials of the person who records the pre-weight measurements in B6. In most instances, this will be the same person who distributes the Kit to the patient (B2a above).
- B6a-b. **Pad #:** Record in sequential order, the number assigned to each pad included in the Kit. If 4 pads are included in the kit, record the number 1 in the B6.1.a field, record the number 2 in the B6.2.a field and so on. **Pre-weight:** Weigh each Pad following procedures described in Attachment D. For each pad included in the Kit, record the pad weight in grams to the .01 weight.

No other data can be recorded until the patient returns with the Pad Test Kit and the Voiding Diary.

- B7. **Date post-weights are recorded:** Record the date when post-weight measurements are documented on the Data Form.
- B8. **Initials of the person recording the post-weight measures:** Enter the initials of the person who records the post-weight measurements in B8. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided.
- B9a-b: **Post-weight:** Weigh each used pad following procedures described in Attachment D. Record the pad weight in grams to the .01-gram weight. **Contamination Code:** Ask the patient and inspect each used pad to determine and record a contamination code. Do not weigh unused pads; instead, record the words "*not used*" in this space in lieu of a gram weight measure. If the pad was not used, you do not need to list a contamination code for that pad. If a Pad is missing, write the words "*missing pad*" in this space in lieu of a weight measurement and record the appropriate contamination code in the contamination code field. See contamination codes 10 and 11.

Contamination Codes: Record the appropriate code for each used pad.

Code	Description
Record 01	if the pad is not contaminated with anything other than urine.
Record 02	if the pad is soaked through with urine.
Record 03	if the pad is contaminated with blood.
Record 04	if the pad is contaminated with stool.
Record 05	if the pad is soaked through with urine and contaminated with blood.

- Record 06 if the pad is soaked through with urine **and** contaminated with stool.
- Record 07 if the pad is soaked through with urine **and** contaminated with blood **and** stool.
- Record 08 if you cannot identify the contaminant.

If Kits are returned with some pads missing:

- Record 10 if the pad is missing and the patient reports that she **DID NOT USE** the pad during the 24-hour testing period.
- Record 11 if the pad is missing and the patient reports that she **DID USE** the pad during the 24-hour testing period. This error will invalidate the test and may necessitate that the test be repeated. Call the BCC for direction.

- B10. **Date Kit Returned:** Record the date the Pad Test Kit is returned. This should be the same date as the date the post-weight measurements are completed (B7).

Abstracted from the Voiding Diary

- B11. **Date pad test started:** Review the Voiding Diary and record the date that the patient started the Pad Test. The patient has been instructed to record the start time of the Pad Test by writing a “**P**” in the Toilet column adjacent to the hour of the day she begins the test. Record the date that appears at the top of the page.

B11a-d. **Start and end of Pad Test:** Record the start and end time of the Pad Test in these fields.

- B12. **Was the patient menstruating when the Pad Test was completed?:** Record yes or no for this item.

Protocol Compliance

- B13. **Was the Pad Test completed per protocol requirements?:** Record yes or no and follow the skip pattern on the data form. If the Pad Test measure is completed alone circle code 2 (No) and follow the skip pattern on the form.
- B13a-b. **Describe the protocol deviation:** Identify if it was a patient error or a research staff error and provide a description of the protocol deviation. If the start and end times of the Pad Test are > two hours apart, this is considered a protocol deviation.
- B14. **Is this a valid measure?** Based on your knowledge of the Pad Test protocol, was the measure completed in a manner sufficient to obtain a valid measure? Repeat the Pad Test if you judge the measure to be invalid. Although the Pad Test is not an eligibility measure, it is best if the patient completes a valid baseline Pad Test.

Section C: The Voiding Diary

- C1. **Are there Voiding Diary data to record on this Data Form?:** There will be occasions when you will complete one of these test alone, i.e. one of the measures may be invalid on first attempt and will need to be repeated. For example, if you are repeating the Pad Test (but not the Voiding Diary) because a previous Pad Test was invalid, you can circle code 2 for this item and skip to section D.
- C2. **Date Voiding Diary distributed:** Record the date you complete the patient education procedures and give the Voiding Diary to the patient.

- C2a. **Initials of person who distributed the Voiding Diary:** This must be a UITN certified data collector. This should be the same person who completes all required patient education procedures for the Voiding Diary including video viewing, review of the patient's Voiding Diary and at-home patient procedures after video viewing, completing the follow-up phone contact etc.

Day One

C3. **Date of Voiding Diary Day 1:** Record the date as mm/dd/yyyy.

C3a. **Day of the week:** Record the day of the week that the patient circled at the top of Diary Day 1.

C3b. **Number of accidents:** Count the number of accidents recorded in the Accident column of the Diary for Day 1. Note: more than one accident may occur in any given hour.

C3c. **Voids during waking hours:** Count the number of voids recorded in the Toilet column of the Diary for Day 1 during **waking** hours. Ascertain the waking hours by referring to the Awake Time and Bed Time recorded on the bottom of the page.

C3d. **Voids during bedtime hours:** Count the number of voids recorded in the Toilet column of the Diary for Day 1 during **bedtime** hours. Ascertain the bedtime hours by referring to the Awake Time and Bed Time recorded on the bottom of the page.

Be sure that your totals for C3c and C3d add up to the total number of all voids recorded in the Toilet column for the day.

C4. **Total number of voids for Day 1:** Record the total number of voids in the 24-hour period for Day 1. This should be equal to the sum of the numbers recorded in the C3c and C3d data fields. Be sure that this total adds up to the total number of all voids recorded in the Toilet column for the day.

Day Two

C5. **Date of Voiding Diary Day 2:** Record the date as mm/dd/yyyy.

C5a. **Day of the week:** Record the day of the week circled by the patient at the top of the Diary Day 2.

C5b. **Number of accidents:** Count the number of accidents recorded in the Accident column of the Diary for Day 2. Note: more than one accident may occur in any given hour.

C5c. **Voids during waking hours:** Count the number of voids recorded in the Toilet column of the Diary for Day 2 during **waking** hours. Ascertain the waking hours by referring to the Awake time and Bed Time recorded on the bottom of the page.

C5d. **Voids during Bed Time hours:** Count the number of voids recorded in the Toilet column of the Diary for Day 2 during **bedtime** hours. Ascertain the bedtime hours by referring to the Awake Time and Bed Time recorded on the bottom of the page.

C6: **Total number of voids for Day 2:** Record the total number of voids in the 24-hour period for Day 2. This should be equal to the sum of the numbers recorded in the C5c and C5d data fields. Be sure that this total also adds up to the total number of all voids recorded in the Toilet column for the day.

Day Three

- C7. Date of Voiding Diary Day 3:** Record the date as mm/dd/yyyy.
- C7a. Day of the week:** Record the day of the week circled by the patient at the top of the Diary Day 3.
- C7b. Number of accidents:** Count the number of accidents recorded in the Accident column of the Diary for Day 3. Note: more than one accident may occur in any given hour.
- C7c. Voids during waking hours:** Count the number of voids recorded in the Toilet column of the Diary for Day 3 during **waking** hours. Ascertain the waking hours by referring to the Awake time and Bed Time recorded on the bottom of the page.
- C7d. Voids during Bed Time hours:** Count the number of voids recorded in the toilet column of the Diary for Day 3 during **bedtime** hours. Ascertain the bedtime hours by referring to the Awake Time and Bed Time recorded on the bottom of the page.
- C8. Total number of voids for Day 3:** Record the total number of voids in the 24-hour period for Day 3. This should be equal to the sum of the numbers recorded in the C7c and C7d data fields. Be sure that this total also adds up to the total number of all voids recorded in the Toilet column for the day.

Total Toilet Voids in the 3-Day Diary period / Eligibility Determination

Total Toilet Voids Worksheet: The Worksheet is provided to simplify your work in the determination of total voids over the 3-Day Diary Period. Record the results of the total number of voids per day in the appropriate boxes in the worksheet; use items C4, C6 and C8. (NOTE: These data will not be data entered again from this field, as they are already captured at the C4, C6 and C8 fields.)

- C9. Total Voids in the 3-Day period:** Ascertain the total number using the worksheet and record the total in C9. The formula for calculating the total is: $C4 + C6 + C8 = C9$
- C10. Determine eligibility:** If the total number of Toilet Voids over the three-Day Diary period recorded in C9 is ≥ 36 , the patient is ineligible to participate in the trial.

Protocol Compliance

- C11. Was the Voiding Diary completed per protocol requirements?:** Record yes or no and follow the skip pattern on the Data Form. If the Voiding Diary is completed alone, circle code 2 (No) and follow the skip pattern on the form.
- C11a-b. Describe the protocol deviation:** Identify if it was a patient error or a research staff error and provide a description of the protocol deviation.
- C12. Is this a valid measure?:** Based on your knowledge of the Voiding Diary protocol, was the measure completed in a manner sufficient to obtain a valid measure? If you judge the measure to be invalid the Voiding Diary must be repeated. Eligibility cannot be determined if the Voiding Diary measurement is invalid.
- C13. Patient provided information:** If the patient provided you with any information that clarified the data documented in the Voiding Diary, please provide this information in the space provided. It is important to document any clarifications made by the patient about her voiding diary.

Section D: Summary of Eligibility Status

Review codes to items C9, C10 and C12 to ascertain if the patient is still eligible to continue with the screening measures. If the patient meets all eligibility criteria in this data form, continue with the screening measures. If not, no further measurements should be completed. If the Diary was determined to be invalid and eligibility cannot be determined, have the patient repeat the Voiding Diary.

ATTACHMENT A: SCRIPT FOR THE VOIDING DIARY AND PAD TEST VIDEO

PART 1: Introduction and Instructions for the 3-Day Voiding Diary

Hello, I'm Sharon Tennstedt, a Research Scientist and Nurse from the New England Research Institutes in Watertown Massachusetts. I'm also one of several Principal Investigators for the Urinary Incontinence Treatment Network. Thank you for participating in this very important study.

In this video, I will be explaining the procedures we would like you to follow for the completion of 2 important measures or tests for the Urinary Incontinence Treatment Study; specifically the 3-Day Voiding Diary and the 24-Hour Pad Test. These measures are important to help us understand the nature and the extent of your urinary incontinence symptoms. In addition, the results of these measures, completed both before surgery and at selected time points **after** surgery, will help us to evaluate how effective the surgery is in treating or curing your incontinence.

We made a video of these instructions so that we are certain that all the patients who participate in the Study receive the same instructions and complete the measures in the same way. In this way, we can be certain that none of the procedures are left out. In addition, having the instructions on a video makes it possible for you to review the instructions, on your own, in the privacy of your own home at the beginning of the measurement period, and at any other time over the course of the 3-day period.

The best way for you to complete this review is to have the forms and related materials that you will be using to complete these measures in front of you. Let's begin with a review of **The 3-Day Voiding Diary**. You should have your copy of the Diary handy to follow along as I review these procedures.

The 3-Day Voiding Diary

A Voiding Diary is used commonly by doctors and nurses, to get an **accurate** or precise picture of the problems you are having with urinary incontinence. We are asking all the patients who participate in the UITN study to keep a Voiding Diary for three full days before surgery and at several time points after their surgery.

The first thing you need to do is to plan **when** you will start and end the 3-Day Voiding Diary. If you still get your menstrual period, you'll need a good prediction of when your next period will begin and end. Mark these dates on a calendar and then consider the following points:

- You should start the Diary on any day from Sunday to Thursday, but begin using it at 12 midnight and use it for 3 complete days in a row. We want to get information about your typical days, so we want 2 of the 3 days to be weekdays.
- Start your Diary as soon as possible, but whenever you start it, you should complete all three days just prior to your next study visit. That means you must complete the 3rd day of your Diary no later than midnight of the night before your next study visit.
- Avoid using the Diary on any of the days that you might have your menstrual period. First, we realize that it would be troublesome for you to complete the Diary and Pad Test during this time. But also, for the purposes of this Study, the results would be complicated by the difficulty of separating urine loss from blood loss.

Once you decide **when** you will use the Diary, remember these points:

- Get prepared the night before because you need to start keeping your records at midnight on Day 1. It's best if you keep your notes in the Diary as the day goes on. Don't wait until the end of the day and then try to remember everything that happened. It only takes a few seconds to do and the information is much more accurate if you do it as you go. Your record keeping doesn't have to be neat as long as it contains the essential information.
- Once you start keeping the Diary, record the date for Day 1 in the top left hand corner of the page. Next, circle a letter next to the date to tell us the **day** of the week that corresponds with the date. Do this at the top of each page for each of the 3-days that you use the Diary. Look on the example page of your own Diary to see how to do this. The example Diary was kept on April 24th, 2001; that was a Tuesday. See--- the T is circled.
- Now let's review what we want you to keep track of. You'll see that the Diary has 4 columns; the column headings are **Hour of the Day**, **Toilet**, **Accident** and **Reason for Accident / Notes**.
- **COLUMN 1: HOUR OF THE DAY:** We'll review the columns one-by-one starting with the first column, labeled **Hour of the Day**. We have already recorded each of the day's 24-hours in this column. We pre-recorded these rows for your easy reference; we want to make sure that all the patients participating in the study remember to keep the Diary for the full 24-hour cycle for each of the three Diary days. As you can see, the first hour of the day starts at 12 midnight and ends just a minute before 1 AM. So all of the information that you record in that **row** (across) will represent whatever happens for you in that hour of the day. The next hour (row) starts at 1 AM and ends just one minute before 2 AM. This continues to the bottom of the page with each row representing one hour of the day. The last hour of the day starts at 11:00 PM and ends at 11:59 PM, or one minute before 12 midnight when the **next** Diary day begins.
- **COLUMN 2: TOILET:** The next column is labeled **Toilet**. In this column we want you to record the **approximate time** when you urinate in the toilet. Let's look at the example in the Sample Diary at the entry recorded at 3:05 am. In this example, you can see that the woman keeping this Diary recorded that she urinated in the **toilet** at 3:05 am.
- **COLUMN 3: ACCIDENT:** In the next column, labeled **Accident** we want you to record the approximate time you accidentally lose or leak urine without getting to the toilet. Any leakage of urine at all should be counted as an accident. Even a small accident that might be just a few drops of urine in your underpants or in a protective Pad should be counted as an accident. When in doubt, count it as an accident. Now let's look at the example in the Sample Diary at the entry recorded at 7:00 am. In this example you can see that the woman keeping this Diary recorded that she had an "accident" at 7:00 am.
- **COLUMN 4: REASON FOR ACCIDENT / NOTES:** You can also see in this example, the woman records some remarks about the accident in the next column. This last column in the Diary is labeled, **Reason for Accident/Notes**. For each accident, we would like you to record what you think might be the reason for the accident in this last column. For example, if you accidentally lose urine with physical activity, coughing, or laughing, write this in the **Reason for Accident / Notes** column. You should also record any physical feelings that you might have had at the time of the accident, for example, you might write, "*sudden urge when walking, couldn't make it to the BR.*" If you had no urge prior to an accident, you should record any event or physical activity that you might have been doing at the time just prior to the leakage, e.g. "*with a sneeze,*" "*lifting groceries,*" "*doing the dishes,*" or "*jogging.*" As you can see in the Sample Diary, for the 7:00 AM accident, this woman recorded: *Woke up, strong urge, couldn't hold it.* If there seems to be no reason for the accident, please record what you were doing when the leakage occurred. If you did not feel the leakage when it happened and just found yourself damp or wet, note this in the last column.

For the three days that you keep this Diary, please change your clothes or your protective pad(s) whenever you feel yourself leaking or find yourself damp. Changing your clothes or your pad whenever you are wet will increase your awareness of when you are leaking (especially the smaller leaks) and improve the accuracy of your diary. For example, if you always wear a pad but usually only change it when the pad gets very wet, it will be harder to know how many accidents/ leakages occurred in that period. For the purposes of this study, it is important that we get a good measure of the total number of accidents / leakages that you are having in this three days period.

BOTTOM OF PAGE: At the bottom of each page there is a **comment section** for you to record any special circumstances that occurred or any helpful observations that you have that you think might help us understand more about your problem for that day, for example you might record, “*I drank more coffee than usual today,*” or “*Have a cold, coughed all day.*”

AWAKE TIME / BED TIME / # OF PADS USED: Also at the bottom of the page we would like you to record the **time you wake up** and the **time you go to bed for the night** for each of the three days you keep the Diary. Also write in the **number of pads** that you used for the day.

PART 2: Instructions for the 24-hour Pad Test

The next measure or ‘test’ that we would like you to complete is called the **24-Hour Pad Test**. Like the Voiding Diary, doctors and nurses frequently ask their patients to complete a Pad Test to get a precise assessment of their problems with urinary incontinence. These 2 tests (The Voiding Diary and the Pad Test) will always be completed at the same time throughout the course of your participation in the UITN study. We are asking all UITN patients to complete a Pad Test over the course of a complete 24-hour period starting on Day 2 or Day 3 of the 3-Day Voiding Diary.

First, let’s review all the materials you will need to complete the 24-Hour Pad Test. For the Pad Test.

3-Day Voiding Diary:you will be using the 3-Day Voiding Diary to write down certain notes and ...

UITN Pad Test Kit:you will be using **special** protective pads that the study nurse will give you in a kit. We realize that you may prefer to use another type of pad or product for your urine leakage. However, for this one-day test, we ask you to use **only** the pads that are in the kit. We also ask that you return all of the pads in the kit whether you use them or not. We will weigh the whole kit before we give it to you, and then we will weigh the kit again when you return it to us after you complete the test. The change in the weight of your kit will give us a very good estimate of how much urine you lost in that 24-hour period. This measurement will help us decide if the surgery is effective in treating or curing your urinary incontinence. We have included more than enough pads in each kit for this one-day test. You might not use all the pads in the kit, but you must return all of the pads--- both the pads you use and the pads you do not use--- for the measurement to be accurate. If any of the pads are missing, the test will be considered incomplete.

A UITN Protective Pad: Each protective pad in the kit will be enclosed in it’s own zip-lock bag. Each of these bags will have a UITN Study label on it. This label will be marked with your unique confidential study ID number. Your name will not be on the label. All the pads will be enclosed in a larger, discrete, sealable bag for your convenience on the day of the test. All the pads should be returned to the study nurse in this larger bag.

Like with the Voiding Diary, the first thing that you need to do is **pick the day** that you will complete the Pad Test. Most of the work of picking this day is complete when you decide when you will complete the Voiding Diary. We ask you to complete the Pad Test on either Day 2 or Day 3 of your Voiding Diary Days. In addition, the Pad Test should be completed on a typical **weekday** when you expect to be busy with normal or typical daily activities. In other words, don’t avoid days or situations that usually cause you to have urinary accidents. We want a measure of a typical day. Finally, you should complete the Pad Test just one or two days before your next study visit.

Once you decide **when** to complete the Pad Test, remember these important points:

- Complete the Pad Test on Day 2 or 3 of your Voiding Diary Days and complete it just one or two days before you come in for your next study visit. The Study Nurse will work with you to pick the best days for the Pad Test and your next study visit.
- Think about this test the night before, and get prepared. We want you to start the Pad Test as soon as you wake up in the morning. Even though you might use your own protective pads through the night before you start the Pad Test, remember to start using a **Study Pad** the first thing in the morning when you wake up. If you shower the **very** first thing in the morning, use a Study Pad right after your shower. However, if you usually get up and do other things before your shower, like eat breakfast, read the paper or help others get prepared for the day, then use a Study Pad **as soon as you get up**.
- Please record in the Voiding Diary the hour that you start the Pad Test. Let's look at a sample form. As I have done on this form, write a "P" in the Toilet column the hour you *start* the Pad Test. You should also write a comment in the Notes column of the Diary as is shown here: ***'started Pad Test'***.
- On the next day when you complete the Pad test, write a "P" in the Toilet column in the hour you *end* the Pad Test. Also write a comment in the Notes column: ***'ended Pad Test'***.
- We want you to tell us specifically about any accidents that you have when a Pad becomes ***'soaked through'***. Write this information in your Diary along with the reason for the accident in the last column. When you return your Pad Test Kit and the Diary to the study nurse, she will ask how many of the Study Pads were ***'soaked through'*** on the Pad Test Day. If you keep accurate records on your Diary, this information will be easy to get.
- Please change the pad whenever you feel yourself leaking or find yourself damp. This will improve the accuracy of the Test by minimizing the chances of a Pad becoming ***'soaked through'***. If you have a large accident and a pad becomes ***"soaked through"***, change the pad and write a note in your Diary to let us know about it. And, of course, be sure to put the used Pad in the zip-lock bag, and use another Study Pad from the Kit.
- Be sure to use a Study Pad through the night of the Test. The last Study Pad of the test will be the Pad you take off when you wake up the following morning. **Remember; do not use a Study Pad from the Pad Test Kit after the end of this 24-hour period. This will invalidate the test.**
- If you have any questions, please call the Study Nurse.

This covers all of the important information for these two tests. Your Study Nurse can review this information with you and answer all of your questions. We want you to have a clear understanding of these two measures. So please, do not hesitate to ask questions. No question is too simple or silly. We want to make sure you understand what to do and to make it as easy as possible for you to complete these important measures.

On behalf of all the investigators in this study, thank you for participating in this important study on surgical treatments for urinary incontinence.

ATTACHMENT B: Abbreviated Voiding Diary Procedures

Instructions for the 3-Day Voiding Diary

Please use this Diary to record information about your pattern of urination and urinary accidents covering a complete 24-hour period for each of three days in a row. See the Sample Diary on the right.

1. You can start the Diary on any day from Sunday to Thursday, but begin using it at 12 midnight (i.e., late Saturday night to late Wednesday night) and use it for 3-days in a row. Please be sure to complete the Diary before you return for your next study visit.
2. Do not complete the Diary (or the Pad Test) during a menstrual period.
3. Write the date and circle a letter at the top of the Diary to indicate the dates and days of the week that you keep the Diary.
4. Every time you urinate in the Toilet or have an Accident, please record the approximate time of day that the event occurred in the appropriate box next to the hour of day. You may write multiple times in the same box. (See the 8:00 pm hour in the Sample Diary.)
 - Record each time you urinate in the toilet by writing the approximate time you urinated in the Toilet column next to the hour of day that the event occurred.
 - Likewise, record each time you accidentally lose or leak urine by writing the approximate time in the Accident column next to the correct hour of day. Remember, even a small amount of accidental leakage should be recorded each time it occurs.
5. For each accident, record what you think might be the reason for the accident in the last column. For example, if you accidentally lose urine with physical activity, coughing, or laughing, write this comment in the Reason for Accident / Notes column. If there seems to be no reason for the accident, please record what you were doing when the leakage occurred. If you did not feel the leakage when it happened and just found yourself damp or wet, note this in the last column.
6. You can record any observations for the day that you think might be important in the Comments section at the bottom of each page.
7. In addition, please complete a "Pad Test" on Day 2 or Day 3 of your Diary days. A Pad Test should be completed for an entire 24-hour period, starting the first thing in the morning when you wake up on Day 2 or Day 3. Record a "P" in the Toilet column in the hour of the day you start the Pad Test and another "P" for the hour of day you end the Pad Test. See the Pad Test Instructions for more complete directions.

ATTACHMENT C: Abbreviated Pad Test Procedures

Use as a single, brightly colored page as a reminder insert for the Voiding Diary Booklet.

Instructions for the 24-Hour Pad Test

1. Prepare yourself the night before. Remember to start using a Study Pad the first thing in the morning when you wake up, even if you used your own protective pads through the night before you start the Pad Test. If you shower the very first thing in the morning, use a Study Pad right after your shower. But, if you usually get up and do other things before your shower, like eat breakfast, read the paper or help others get prepared for the day, use a Study Pad as soon as you get up.
2. Avoid using a tampon or vaginal creams, jellies, suppositories or douche treatments during the 24-hour Pad Test. And avoid having intercourse.
3. Write a "P" in the Toilet column of the Voiding Diary the hour you *start* the Pad Test. You should also write a comment in the Notes column of the Diary, '*started Pad Test*'.
4. On the next day when you complete the Pad test, write a "P" in the Toilet column in the hour you *end* the Pad Test. Also write a comment in the Notes column: '*ended Pad Test*'.
5. We want you to tell us specifically about any accidents that you have when a Pad becomes '*soaked through*'. Write this information in your Diary along with the reason for the accident in the last column. When you return your Pad Test Kit and the Diary to the Study Nurse, she will ask how many of the Study Pads were '*soaked through*' on the Pad Test Day. If you keep accurate records on your Diary, this information will be easy to remember.
6. Please change the pad whenever you feel yourself leaking or damp. This will improve the accuracy of the Test by minimizing the chances of a Pad becoming '*soaked through*'. Be sure to put the used Pad back into the zip-lock bag it came out of, and proceed to use another Study Pad from the Kit.
7. Be sure to use a Study Pad through the night of the Test. The last Study Pad of the test will be the Pad you take off when you wake up the following morning. Remember, do not use a Study Pad from the Pad Test Kit after the end of this 24-hour period. This will invalidate the test.
8. Please remember to bring back all Pad Kit supplies (used and unused Pads) given to you when you return for your next visit.

If you have any questions, please call the Study Nurse.

Attachment D: Weighing Pads for the 24-Hour Pad Test

Equipment: Model GX-2000 Multi-Function Balance (A & D Engineering, Milpitas, CA).

Installation:

Location: The balance should be installed in an environment with minimal changes in temperature and humidity and with no exposure to direct sunlight or drafts from heaters, air conditioners or open windows. It should be on a solid table, as level as possible, not subject to vibration or shock, and away from magnetic fields (eg., computer monitors). Corners of rooms on the first floor are best, as they are less prone to vibration.

Leveling: Level the balance using the leveling feet on either side near the front corners. Adjust the feet by turning clockwise to raise, counter-clockwise to lower, until the bubble in the level (front left corner of the balance) is in the center of the ring. When properly installed, the balance rests on three points: the two leveling feet and on a third point in the middle of the back.

Caution: Never place anything on the balance that is heavier than the weighing capacity of the balance (2100 grams, or about 4.5 pounds).

Each day the balance is used:

Warm up the machine. Press the ON/OFF key to turn on. The balance should be on for 30 minutes before being used. **Before 30 minutes it may give inaccurate measurements.**

Calibrate using the internal mass. Press CAL key. The balance should display "CAL in", then perform the calibration using the internal mass, then display "End" and return to weighing mode. It is particularly important to recalibrate when first setting up the scale, if the scale is moved and if there is a change in the ambient environment.

Set response adjustment and perform self-test. Hold down MODE key until RESPONSE blinks. The balance will perform a self-test. When done, it should display a response mode (SLOW, MID or FAST) and OK should blink for a little while. If MID or SLOW is displayed the scale can be used but there may be vibration or draft that can be reduced. If, instead of OK the balance displays "CH nO" (small n, big O) the weight scale should not be used because the weight value is unstable. Check ambient conditions such as vibration, draft, magnetic fields and try again. If it displays "CH no" (small n, small o) there is an internal error requiring repair of the balance.

Each time a pad is weighed. .

Set units. Make sure the balance is expressing weight in grams. If there is not a "g" at the right side of the display, press the MODE key repeatedly until you see "g".

Preparing the pad to be weighed. After discarding the pad's plastic outer cover, place a single "Poise" pad into a study specific biohazard, zip-lock bag. Staple the top of the biohazard bag above the bag's zip-lock seal. Fold the zip lock bag around the Pose pad two times, to minimize the actual size of the bag.

Remove the metal ring. Removing the metal ring that surrounds the weighing pan will prevent weighing error that may occur if any part of the weighed item is touching the ring.

Re-zero the balance. Zero the balance with just the empty weighing pan. Press the RE-ZERO key and wait for the display to read "0.00 g" with a little "o" appearing on the left of the screen.

Weigh each biohazard bag/pad separately. Gently place the biohazard bag/pad onto the balance; do not drop. Place the bag/pad in the center of the weighing pan. Be sure 100% of the bag is on the weighing pan, and no part of the bag is touching any area off of the weighing pan. Wait for the little "o" at the left of the display to appear. If the reading fluctuates up and down by 0.01 g, use the higher value.

Record the reading. Record the reading onto a blank study specific “Avery” label. Remove the bag from the balance and stick the weight identification label onto the bag. Now, the biohazard bag and pad are ready for patient assignment. When assigned, a pre-printed patient identification label will also be placed onto the biohazard bag.

NOTE: The weight of two study specific “Avery” labels is equal to the weight of the removable pad adhesive paper. Therefore, the additional weight of two “Avery” labels to the weight of the biohazard bag (with pad), minus the weight of the pad adhesive paper results in an approximate net 0.00 g change. Therefore, when used pads are returned and reweighed, only the weight of the urine loss will be measured.