



TOMUS

Procedure Manual for Administration of the Pad Test and Voiding Diary

Version 10/27/06 (A)

I. Overview

A. Purpose

For purposes of this trial, a Voiding Diary will be used to assess the frequency of voluntary micturitions and involuntary episodes of urine loss over a three day period. A Pad Test will be used to quantify the amount of urine involuntarily lost in 24-hours. The Pad Test will be used to reflect everyday incontinence.

B. Schedule and Methods

Both measures will be completed pre-operatively at baseline and post-operatively at the 6-month, 12-month and 24-month visits. These two primary outcome measures will be completed together, in a standardized manner in accordance with the procedures described herein. Baseline Pad Test and Voiding Diary Teaching Points are included in this document as Attachment A and posted as an independent document on the TOMUS website. In addition, a summary of instructions for completion of the measures is also provided with the Voiding Diary; the instructions for the Diary are written on the inside cover of the Voiding Diary, and instructions for completion of the Pad Test are provided on a loose leaf page that fits neatly into the Voiding Diary. The Teaching Points should be reviewed with each patient, point-by-point, prior to the completion of the measures. The Teaching Points tool is being used in lieu of the video that was used in the SISTER trial.

The goal is to collect data that represent “typical days”, so we ask 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 subjects 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 who use a pessary (always or sometimes) should use the pessary during completion of the measures in accordance with her typical routines.

Patients who still menstruate should be instructed to avoid completing the measures 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. Every effort should be made to avoid this time when scheduling dates for completion of the measures. For similar reasons, patients will be instructed to avoid the use of vaginal creams, jellies, suppositories or douche treatments during the conduct of the measures. Patients will also be instructed to avoid intercourse during the conduct of the measures. Finally, since some women have reported tampon use reduces the number of urinary accidents they have, patients should be instructed to avoid the use of tampons while completing the Pad Test, whether they are menstruating or not.

Finally, it is best if patients complete the Pad Test one or two days before their 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.

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.

The Voiding Diary: 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.

With all of these objectives the patient will be instructed to:

- Avoid completing the measures when she is menstruating and do not use tampons whether she is menstruating or not;
- Avoid the use of vaginal creams, jellies, suppositories or douche treatments, and avoid having intercourse;
- Complete measures on ‘typical’ days; i.e. start the Voiding Diary on any day from Sunday to Thursday and complete measures with or without a pessary per typical routines;
- 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 both measures 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.

In light of all of these essential restrictions, the Interviewer/Data Collector should negotiate with the patient to schedule the date of the next study visit and select the actual days for completion of the measures using a calendar as reference. Do not forget to consider the possibility of a menstrual period when selecting the dates for the measures.

C. Expiring Measures

Both measures are considered expiring measures, i.e. if 6 months or more transpires between the date either measure is completed and the date of randomization, the measure(s) must be repeated to ensure collection of ‘current’ baseline values that would be subject to change over a 6-month period.

II. Required Materials

- Baseline Pad Test/Voiding Diary Teaching Points
- 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 the 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 2⁵/₈”, # 5260)
- Blank gram weight Pad Test label for recording the pad weights (same Avery label, size 1’ x 2⁵/₈”; # 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 306 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

III. Pad Test / Voiding Diary Procedures

A. 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 provided to all CTC to maximize precision for this primary outcome measure. See Attachment B for Procedures for the Care and Calibration of the Scale for Weighing Pads. A complete manual was included with the scale at the time of purchase.

B. Weighing Pads prior to Pad Testing

B.1. Supplies needed:

Pads may be weighed in advance of the patient teaching day and a small inventory of pre-weighed pads can be maintained at the CTC. The following materials should be assembled to weigh a batch of Pads:

- Standard scale for weighing each pad: Model GX-2000 Multi-Function Balance (A&D Engineering, Milpitas, CA). This scale (AKA balance) is a study-required piece of equipment.
- Clean work environment and gloves.
- A supply of Poise™ protective pads;
- Prescribed, zip-lock biohazard bags; one bag for each pad;
- Sheet of blank gram weight Pad Test labels for recording the pad weights (Avery label, size 1' x 2⁵/₈"; # 5260)
- Stapler

B.2. Procedures for Preparing the Scale

1. **Warm up the machine:** Press the ON/OFF key to turn the scale on and allow it to warm up for at least 30 minutes. Readings are considered inaccurate if pads are weighed prior to the full 30 minutes warm up period.
2. **Calibrate the scale using the internal mass.** Press the CAL key. The scale should a) display "CAL in", b) then perform the calibration using the internal mass, c) then display "End" and d) return to weighing mode. [It is particularly important to calibrate/recalibrate when first setting up the scale, if the scale is moved or whenever there is a change in the ambient environment.]
3. **Set response adjustment and perform a self-test.** Hold down the MODE key until RESPONSE blinks. The scale will perform a self-test. When complete, the scale should display a response mode (SLOW, MID or FAST) and OK should blink for a little while. If SLOW or MID 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 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.
4. **Set the unit of measure:** Each time a pad is weighed make sure the scale 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".
5. **Remove the metal ring.** Removing the metal ring that surrounds the weighing pan to prevent weighing errors that may occur if any part of the weighed item or plastic biohazard bag touches the ring.
6. **Zero the balance.** Zero the scale 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.

B.3 Procedures for Preparing and Weighing Pads

1. Select your work location and prepare it for clean technique (wash hands, wear clean gloves, work in a clean field)
2. Remove and discard the commercial plastic outer wrapper of the Poise™ pad.
3. Place the single pad in a regulation biohazard zip-lock bag and seal the bag.
4. 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.]

5. Repeat Step 2-4 for several pads prior to moving to the actual weighing procedures.
6. Weigh each biohazard bag/pad separately. Fold the zip lock bag around the pad twice to minimize the actual size of the bag.
7. Gently place the biohazard bag/pad onto the scale; do not drop the bag/pad on the scale. 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.
8. Recording the weight: Hand-write the weight of the pad (in gram weight to the .01 measure) on a prescribed blank gram weight label.
9. Remove the bag/pad from the scale 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.

C. Assembling the Patient’s Pad Test Kit and Completing Patient Teaching for Both Measures

C.1. Supplies needed:

You will need the following supplies to prepare the patient’s Voiding Diary and Pad Test Kit.

- Baseline Pad Test/Voiding Diary Teaching Points
- A 3-Day Voiding Diary with the patient’s unique ID label attached
- The Pad Test patient instructions reminder insert
- Pre-weighed Poise™ protective pads in the prescribed zip-lock biohazard bags with a pre-weight measure recorded on a prescribed gram weight Pad Test label stuck to outside of the biohazard bag
- A patient specific pad test labels sheet pre-printed with the patient’s confidential ID number (Avery Label 1” x 2½”, # 5260)
- A larger, teal colored plastic bag for all the Kit materials
- A calendar as reference to select the dates/days for completing the measures and for scheduling the next study visit
- UITN Data Form 306 with patient ID labels attached

C.2. Procedures for Assembling the Patient’s Pad Test Kit

1. Determine the number of pads the patient will need to complete the Pad Test. Show the patient a Poise pad and ask her how many of ‘this type’ of pads she would expect to use if she completed the Pad Test on one of her **worst** days. Then give her one and a half times that number of pads in her Pad Test Kit.¹
2. Handwrite a sequential pad # onto each of the pre-printed Pad Test labels. (The Pad Test label is the pre-printed label with the patient’s confidential ID # and a space for recording the sequential pad #). For

¹ A patient with a large prolapse may report that the Poise pads will be insufficient for her incontinence. These patients will be permitted to complete the baseline Pad Test 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 as outlined above. If an alternate product is used, notify the BCC and document the deviation on the Data Form.

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. The labels are attached to the outside of the bio-hazard bags.

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.

3. Complete A1, A2, A4, A5, and B1-B6 of F306. The pre-weight values for each of the pads included in the patients Pad Test Kit must be recorded on F306 before the Kit is given to the patient. Write the sequential pad number in B6a and the corresponding weight recorded on the same label in B6b. Repeat this for each pad you plan to give the patient. The rest of the form will be completed when the patient returns the Kit.
4. Finally, put all of the pads into the larger, teal colored plastic bag prescribed for Pad Test use.

C.3. Patient Teaching for Measurement Completion

1. Review the Baseline Pad Test/Voiding Diary Teaching Points and the actual Voiding Diary and Pad Test Kit with the patient, and answer any procedural questions she might have regarding either measure.
2. Then, using an actual calendar, schedule the day and date of the patient’s next study visit and determine the appropriate dates and days to complete the measures. If the patient is pre or peri-menopausal, schedule measurement completion accordingly.
3. As a reminder, 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. Schedule a ‘best time’ to talk for the reminder call. This will provide a good opportunity to answer any final questions the patient might have prior to the start of the measures.

D. Reviewing Completed Measures to Determine Validity

1. When the patient returns with the completed measures, review the Diary and returned pads while the patient is still present and clarify illegible, illogical or incredible documentation.
 - Is the date and day recorded for each day?
 - Is the bedtime and wake time recorded for each day?
 - Are events recorded from 12 midnight on and are they credible in relation to the wake times and bedtimes?
 - Are event times recorded for both voids and accidents?
 - Are there notes in the last column for each accident?
 - Is the start and end times for the Pad Test written in the last column of Day 2 and 3?
 - Does the number of pads used recorded on the Diary match the number of used pads returned?
 - Was the patient menstruating when she completed the measures?
 - What is the contamination status for each used pad?

Patients will frequently make incomplete or inaccurate notes when documenting events in the Diary. For example, times of voids/accidents are often recorded incorrectly or in the wrong columns; written comments might contradict the markings in the “Toilet”/“Accident” columns; start and stop times of the Pad Test or bed or wake times may be missing; etc. Any confusing or illegible elements on the Diary must be clarified with the patient and documented in C8.

You may prompt the patient to recall actual bed or wake times if notes made in the Diary are otherwise complete and the recalled bed and wake times are credible in relation to all other notes recorded. The window of time between the date of the missing recording and the Diary Review date can not exceed 14 days. Clarifications cannot be provided by the patient in a telephone conversation as the patient cannot ‘see’ her own notes.

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 events will be counted (i.e. one void and one accident).

Inspect both used and not used pads. Check to see if all the pads given to the patient are returned. Check pads for contamination and look for pads soaked through with urine. The biohazard contamination bag will contain liquid urine outside the pad if the pad is soaked through.

2. Inspect and weigh each of the used pads in the Kit. Follow the pad weighing procedures documented above for pre-weight measurements. Take appropriate precautions to clean the weighing pan after weighing used pads.
3. Record a post-weight and a contamination code for each used pad. If a pad is not used, write the words ‘not used’ in the post-weight data field that corresponds to that pad.
4. **Determine if the BASELINE Pad Test is valid** A valid Pad Test meets the following criteria:
 - Exact start and stop times are reported by the patient,
 - The test is completed for 24 hours (a window of ± 2 hours is allowed at a baseline visit.)
 - All used pads are returned,
 - The number of study pads used as reported by the patient, matches the number of “used” study pads returned in the Pad Test Kit,
 - The Pad test is not completed while the patient is menstruating,
 - Pads are not contaminated with anything other than urine, i.e. contamination codes 01 and 02.
NOTE: A pad that is ‘soaked through,’ contamination code 02, invalidates a Pad Test completed at a follow-up visit,
 - Returned used pads are weighed soon after the Pat Test is completed but never more than 14 days following completion of the test.

The following observations won’t invalidate a Pad Test but should be reported as a deviation on F306:

- Not completed from wake time to wake time;
- Not completed just prior to the date of the next scheduled study visit,
- Not completed on Day 2 or 3 of the Voiding Diary.

The Pad Test must be repeated if the measure is invalid. A valid Pad Test should not be repeated.

Although the Pad Test is not an eligibility measure, it is a primary outcome measure so the patient must be capable of completing a valid Pad Test at baseline to participate in the trial. The patient should not be asked to complete more than 3 Pad Tests, i.e. if the patient returns a third invalid Pad Test, she is ineligible to participate in the trial.

5. **Determine if the Voiding Diary is valid:** A valid Voiding Diary meets the following criteria:
 - Completed for 3 consecutive days from midnight to midnight, i.e. 72 hours (3 consecutive days, 2 nights);
 - Credible evidence that all accidents are reported;
 - Completed on ‘typical’ days,

- started on a Sunday through Thursday unless weekend days are determined to be more typical for the patient and so noted in C8;
- Completed in the patient's typical state with / without a pessary for patients who use a pessary;

The following observations won't necessarily invalidate a Voiding Diary but should be reported as a deviation:

- Patient indicates void or accident events with credible markings other than the exact time of day,
- Bedtimes or wake times are missing.

The Voiding Diary must be repeated if the measure is invalid. A valid Voiding Diary should not be repeated. Although the Voiding Diary is not an eligibility measure, it is a primary outcome measure so the patient must be capable of completing a valid Voiding Diary at baseline to participate in the trial. The patient should not be asked to complete more than 3 Voiding Diaries, i.e. if the patient returns a third invalid Voiding Diary, she is ineligible to participate in the trial.

Attachment A: Baseline Pad Test and Voiding Diary Teaching Points

3-Day Voiding Diary

- You should start the Diary on any day from Sunday to Thursday, but begin using it at 12 midnight (i.e., early Sunday morning to late Wednesday night) and use it for 3 complete days in a row (i.e., 3 consecutive days must be filled in for each entire day).
- We want to get information about your typical days, so we want 2 of the 3 days to be weekdays. You **should not begin** the 3-day diary **on Friday or Saturday**. However, if you work on the weekends, please let your Study Staff know and they will help you figure out when to complete the Diary.
- 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. Study Staff will help you choose a good day to start the Diary.
- 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.
- Complete the measures in your “typical” state (with or without a pessary).
- 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. Writing your notes 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.
- 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 25th, 2006; that is a Tuesday. See - the T is circled.
- At the bottom of the diary, write the time that you woke up, went to bed, and the total number of study pads used.

Every time you urinate in the Toilet or have an Accident, please record the 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 10:00 am hour and the 8:00 pm hour in the Sample Diary.)

- Record each time you urinate in the toilet by writing the time you urinated in the Toilet column next to the hour of day that the event occurred.
- 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 / Pad Test Times** 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.
- You can record any observations for the day that you think might be important in the Comments section at the bottom of each page.

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 Day**, **Toilet**, **Accident** and **Reason for Accident / Pad Test Times**.

- **COLUMN 1: HOUR OF DAY:** We’ll review the columns one-by-one starting with the first column, labeled **Hour of Day**. We have already recorded each of the day’s 24-hours in this column. We pre-recorded these rows for your 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 consecutive 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 **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 time you accidentally lose or leak urine. 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 some examples in the Sample Diary. Look at the entry recorded at 2:15 pm. In this example you can see that the woman keeping this Diary recorded that she had an "accident" at 2:15 pm. Also see the entry recorded at 7:00 am. In this example, you can see that the woman had an accident and then voided at 7:00 am.
- **COLUMN 4: REASON FOR ACCIDENT / PAD TEST TIMES:** 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 / Pad Test Times**. 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 / Pad Test Times** 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; leaked on the way to the toilet*". 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 **Comments** section for you to record any special circumstances or any helpful observations from that day you think might help us understand more about your voids/accidents 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 total **number of study pads** that you used for the day.

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

24-HOUR PAD TEST

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

- Avoid using a tampon or vaginal creams, jellies, suppositories or douche treatments during the 24-hour Pad Test. Avoid having intercourse.
- Remember to begin the 24-hour Pad Test when you wake up on either the second or third day of the Voiding Diary. End the pad test exactly 24 hours later, on the next day. Continue to keep the diary for the rest of the third day if that is the day the pad test ends. The Pad Test should be completed one or two days before the next scheduled study visit. The Study Staff will work with you to pick the best days for the Pad Test. Please use **study pads** only.
- 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** 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 exact time at which you start the Pad Test by writing a comment in the **Reason for Accident / Pad Test Times** column of the Diary, “*started Pad Test at XX :XX*”.
- 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. We specifically want you to tell us 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 changing Pads, 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. Be sure to use the pads in numerical order.
- 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.**
- Please record in the Voiding Diary the exact time at which you *end* the Pad Test by writing a comment in the **Reason for Accident / Pad Test Times** column: “*ended Pad Test at XX:XX*”.
- When you return your Pad Test Kit and the Diary to the Study Staff, 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.
- Please remember to bring back all Pad Kit supplies (used and unused Pads) given to you when you return for your next visit. Put all biohazard bags into the green bag along with your completed diary.
- If you have any questions on the 24-Hour Pad Test, reference the pink instruction sheet or call the Study Staff.

Attachment B: Procedures for the Care and Calibration of the Scale for Weighing Pads

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

Installation:

Location: The scale (AKA 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 scale 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 scale 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 scale that is heavier than it's weighing capacity of 2100 grams, or about 4.5 pounds.

Each day the scale is used:

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

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

Set response adjustment and perform self-test. Hold down MODE key until RESPONSE blinks. The scale 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), do not use the scale to weigh pads, there is an internal error requiring repair of the scale.

Each time a pad is weighed. .

Set unit of measure. Make sure the scale 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".

Remove the metal ring. Remove the metal ring that surrounds the weighing pan to 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.

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.

Weigh each biohazard bag/pad separately. Gently place the biohazard bag/pad onto the scale's weighing pan; 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 weight of the pad onto a blank study specific "Avery" label. Remove the bag from the scale 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.