BE-DRI

Question by Question Specifications Guide
Form 206: Baseline Bladder Diary Summary
Version 11/05/04 (A)_revised 08/05/05

I. Purpose

Data from the patient's Baseline Bladder Diary (F206A) will be abstracted onto the Baseline Bladder Diary Summary Data Form (F206). Diary data will be used to determine voiding frequency, frequency and severity of urinary incontinence, urinary incontinence type, severity of urge sensation, and nocturia. Data from the patient's Diary will be abstracted onto the BE-DRI Bladder Diary Summary Data Form and the Randomization Data Form.

See the Evaluation Bladder Diary Procedures for a complete description of this measure. Here follows a Question by Question specification guide for abstracting the patient's Diary onto F206.

II. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the spaces provided in the A1 field and in the upper right-hand corner of each page of the Data Form.

A2. **Visit Number:** The visit number is pre-coded for F206, as it will always be Visit **SCRN**.

A3. **Date Abstract Completed**: Record the date in the format of mm/dd/yyyy.

A4. **Abstractor's Initials**: The abstractor should record her initials in this field. Enter first initial in the first space provided, middle initial in the second space provided, and last initial in the third space provided. If there is not a middle initial to record, strike a dash in the second space. If the abstractor's last name is hyphenated or if she has 2 last names, enter the initials of her first last name in the third space. Abstractors must be certified in the Bladder Diary measure.

A5. **Date Diary Distributed:** Record the date the Diary was distributed. This should be the same as the date the patient teaching for Diary completion was conducted. Record the date in the format of mm/dd/yyyy.

A6. **Distributor's Initials**: Enter the initials of the person who gave the Diary to the patient and completed the patient teaching. Follow the convention described in A4 above. Distributors must be certified in the Bladder Diary Measure.

A7. **Is this a repeat Diary?** If the Diary is invalid, it must be repeated. If this Diary is a repeat Diary, circle code 1 (Yes).

Section B: Overall Validity

B1. **Is the Diary valid or invalid?** See the Evaluation Diary Procedures for details regarding assessment of validity. If the Diary is valid, circle code 1 (valid) and skip to C1. If the Diary is invalid, circle code 2 and complete the remaining items in Section B.

B2. **Why is the Diary invalid?** If you conclude the Diary is invalid overall, record the reason here. Code the reason and follow the skip pattern as directed.

Code	Description
Circle code 1:	if there are less than 5 valid days
Circle code 2:	if the 5 valid days fall outside a 7-day window
Circle code 3:	if the patient had a UTI during Diary completion. The patient should not be asked to complete another Diary unless the UTI has been treated.
Circle code 4:	if more than 3 months transpires between the date of Diary Day 1 and the date of the planned randomization visit. Write the date of Diary Day 1 in the space provided.
Circle code 5	if the Diary is deemed invalid for any other reason and describe the reason in the text field provided.

B3. Code all the reasons why any Diary **day** was considered invalid. There may be more than one reason why days were considered invalid. **You must circle code 1 (Yes) or 2 (No) for every item.**

a. **Less than 24 hours**: Circle code 1 (Yes), if the patient did not keep her Diary for the entire day or missed one or more days completely. Otherwise, circle code 2 (No).

b. **Illegible entries for accidents**: Circle code 1 (Yes), if it is impossible to confirm with certainty that a patient's illegible markings represent a true accident. Otherwise, circle code 2 (No).

c. **Some accidents not credible / not in real time**: Circle code 1 (Yes), if accidents recorded on the Diary seem implausible or unlikely, and the patient cannot provide credible clarification. Otherwise circle code 2 (No).

d. **Patient reported some accidents not recorded:** If the patient reports that she forgot / failed to record one or more accidents, circle code 1 (Yes). Other wise, circle code 2 (No).

e. **Patient wearing a urethral occlusion pad:** Circle code 1 (Yes), if the patient was wearing a urethral occlusion pad during the day. Otherwise, circle code 2 (No).

f. **Some other reason:** Circle code 1 (Yes), if you classified a day invalid for some other reason and write the reason in the text field below.

B4. **Will the patient repeat the Diary to allow eligibility determination?**

Circle code 1:	if the patient will repeat the Diary. This form is complete. Another F206 should be completed when the patient returns with the next Diary.
Circle code 2:	if the patient won't repeat the Diary. You must also complete a F280 to end participation in BE-DRI.
Circle code 3:	if the patient won't repeat the Diary at this time but you think she will before any other Baseline measure is due to expire. Until you complete a F280 for the patient, her ID will remain active and DMS reports will show her Baseline Forms as expected. If more than 3 months pass or if any other Baseline measure expires

before the Diary is repeated, the patient must be completely re-screened under a new ID.

Section C: The Diary Window and Fluid Intake

C1. Record the dates of the first and last valid days you will abstract on this F206.

C1a. **First valid day**: Record the date in the format of mm/dd/yyyy.

C1b. **Last valid day:** Record the date in the format of mm/dd/yyyy.

C2. **How many valid Diary days will you be recording on this F206?** Circle the number of valid days you will record on this F206. Ideally, you will record 7 days. If some days are classified as invalid, you might be recording as few as 5 days. Start abstracting the Diary from the first valid day. Record up to 7 valid days. If more than 7 days are recorded in the Diary, the days abstracted must fall within a 7-day window. If more than 7 valid days are sequential, abstract the first 7 days.

C3. **Were any Diary days invalid?** Refer to the Evaluation Diary Procedures for validity rules. If there are 7 valid days, circle code 2 (No) and follow the skip directive. If any days are classified as invalid or if there were fewer than 7 valid days, circle code 1 (Yes) and complete C4.

C4. Code all the reasons why any Diary day was considered invalid. **You must circle code 1 (Yes) or 2 (No) for every item.**

a. **Less than 24 hours**: Circle code 1 (Yes), if the patient did not keep her Diary for the entire day or missed one or more days completely. Otherwise, circle code 2 (No).

b. **Illegible entries for accidents**: Circle code 1 (Yes), if it is impossible to confirm with certainty that a patient's illegible markings represent a true accident. Otherwise, circle code 2 (No).

c. **Some accidents not credible / not in real time**: Circle code 1 (Yes), if accidents recorded on the Diary seem implausible or unlikely, and the patient cannot provide credible clarification. Otherwise circle code 2 (No).

d. **Patient reported some accidents not recorded:** If the patient reports that she forgot / failed to record one or more accidents, circle code 1 (Yes). Otherwise, circle code 2 (No).

e. **Patient wearing a urethral occlusion pad:** Circle code 1 (Yes), if the patient was wearing a urethral occlusion pad during the day. Otherwise, circle code 2 (No).

f. **Some other reason:** Circle code 1 (Yes), if you classified a day invalid for some other reason and write the reason in the text field below.

Record the volume of all fluid intake for 1 or 2 complete days. We want 2 complete days of intake and output measurements abstracted from days the patient measured both her fluid intake and urine output. If the patient measured I&O for more than 2 days, abstract intake from the first 2 most complete days where both intake and output were measured. If the patient failed to measure intake for 2 complete days, abstract the intake from the most complete 1 or 2 days provided.

C5. **Record the date of the 1st day of fluid intake**: Record the date in the format of mm/dd/yyyy.

i. **Time of intake:** Use a 12-hour clock to record the time for every intake event. Indicate AM (code 1) or PM (code 2) by circling the corresponding **numeric** code. If the volume of intake is recorded but the time is not, do not prompt the patient to recall the time of the void. Write

'missing' or record negative nine (-9) in the data field to indicate the patient forgot to record time of intake.

ii. **Volume of Intake:** Record the volume of fluid intake in ounces. If the patient records volume in metric measure, convert it to ounces and record in ounces. If the time of intake is recorded but the volume is not, do not prompt the patient to recall the volume drank. Write 'missing' or negative nine (-9) in the data field to indicate the patient forget to record the volume of intake. Voided volume should be recorded as whole numbers. Round up for values equal to or greater than .5. Otherwise round down.

C6. **Record the date of the 2nd day of fluid intake**: Record the date in the format of mm/dd/yyyy.

i. **Time of intake:** Use a 12-hour clock to record the time for every intake event. Indicate AM (code 1) or PM (code 2) by circling the corresponding **numeric** code. If the volume of intake is recorded but the time is not, do not prompt the patient to recall the time of the void. Write 'missing' or record negative nine (-9) in the data field to indicate the patient forget to record the time of intake.

ii. **Volume of Intake:** Record the volume of fluid intake in ounces. If the patient records volume in metric measure, convert it to ounces and record in ounces. If the time of intake is recorded but the volume is not, do not prompt the patient to recall the volume drank. Write 'missing' or negative nine (-9) in the data field to indicate the patient forget to record the volume of intake. Voided volume should be recorded as whole numbers. Round up for values equal to or greater than .5. Otherwise round down.

Section D: Abstraction of Valid Diary Days

Start abstracting the Diary from the first valid day; record up to 7 valid Diary days.

D1. **First Valid Diary Day:** All data abstracted from the 1st valid Diary day should be recorded in D1.

D1a. **Date of this day:** Record the date in the format of mm/dd/yyyy.

D1b. **Record if the patient tracked output or rated urgency for this day**: Circle code 1 (Yes) or 2 (No) for both items.

a. **Did the patient measure any output today?** Circle code 1 (Yes) if the patient measured output for one or more voids for the day even if the patient did not measure intake. If code 1 (Yes) is circled, the DMS will expect an "Amount Voided" volume in column iv below for every void. Circle code 2 (No) if the patient did not measure any output for the day. NOTE: The patient is instructed to measure intake and output for 2 days, preferably Days 1 and 2.

b. **Did the patient rate any urgency today?** Circle code 1 (Yes) if the patient provided urgency ratings for one or more events in the day. Even if the patient only provided a rating for one event, circle code 1. If code 1 (Yes) is circled, the DMS will expect an urgency rating in column iii below for every event. Circle code 2 (No) if the patient did not record an urgency rating for any event for the day. NOTE: The patient is instructed to rate urgency for both voids and accidents on Day 1 and 7. The urgency column is not provided on the patient's Bladder Diary for Days 2-6.

D1c. **Detailed summary of voids and accidents on this day:** Abstract all void and accident data from the 1st valid day in this section. For each event record the following:

i. **Time of event:** Use a 12-hour clock to record the time for each event. Indicate AM (code 1) or PM (code 2) by circling the corresponding **numeric** code. If the time is missing but other credible information is recorded for the event, write 'missing' or negative nine (-9) for the time of event.

NOTE: Diary days begin at 12:00am and end at 11:59pm. Be sure to assign late night and early morning events to the correct day when completing F206. For example, if the patient records a midnight event as the last event at the end of a day, it should be abstracted as the 1st event on the next day.

ii. **Event type:** Patients are instructed to record the time of voids in the 1st output column, and time of accidents in the 2nd output column.

URINE OUTPUT					
Time of…		Urgency Rating† 0 1 2 3 (key at bottom)	Amount Voided (oz)	**Amount Leaked*** 1 2 3 (key at bottom)	**Reason for Accident**
Void	**Accident**				
	2:15 AM	*0*		*2*	***Coughed in bed, no urge***
3:00 AM		*3*	*7 oz*		
7:26 AM	*7:25 AM*	*3*	*6 oz*	*2*	***Woke up, strong urge***
	7:30 AM	*1*		*1*	***Took a shower, had to go***
9:00 AM		***2***	*6 oz*		
10:45 AM	*10:45 AM*	*0*	*4 oz*	*2*	***Sneezed, no urge***

Circle code 1: if the event was a **void**.
The 3:00am event in the Example Diary would be coded as a void.
If there is no time recorded in the Void column but there is a credible entry for Amount Voided, and no markings for Amount Leaked and no Reason for Accident, you can circle code 1 if the patient verifies the event was a void.

Circle code 2: if the event was an **accident**.
The 2:15am event in the Example Diary would be coded as an accident.
If there is no time recorded in the Accident column but there is a credible entry for Amount Leaked and / or a Reason for Accident, you can circle code 2 if there is no volume recorded for Amount Voided and the patient verifies the event was an accident.

Circle code 3: if the event was **both** a void and an accident.
The 10:45am event would be coded **both** for both an accident and a void. These are also called dual events.
Events that a patient records as occurring as separate events, even just one minute apart, should be coded as separate events, even if they are recorded on the same line in the patient's Diary. See the 7:25am and 7:26am events in the Example Diary above.
If there is no time recorded in either the Accident or Void columns but there are credible entries for Amount Voided and Amount Leaked and / or a Reason for

Accident, you can circle code 3 if the patient verifies the event was both a void and an accident.

IMPORTANT NOTE: Diary data should never be "created" during the Diary review. Illegible or ambiguous markings in the Diary may be clarified by the patient but the patient should not be asked to recall events, ratings or volumes where values or notes are completely missing. See the Procedures for the Evaluation Bladder Diary.

iii. **Urgency Rating:** Patients are asked to record an urgency rating for all events on Days 1 and 7. If the patient recorded any urgency ratings for the day [code yes (1) to D1bb], the DMS will expect a value for "Urgency Rating" for every event for the day. If the patient forgot to rate urgency for an event, do not prompt her to recall an urgency rating. Write the word 'missing' or code negative nine (-9) in the data field to indicate the patient forgot to rate urgency. If the patient records two separate events (i.e. a void and an accident at different times), on the same physical line of the diary, the one urgency rating noted for both events must be coded as "missing" for both events, as it is unclear to which event this rating corresponds. If the patient did not rate urgency for any event on the day [code no (2) to D1bb], no code for urgency rating is required. Therefore, you can leave the data field blank or put a strike mark through the box.

iv. **Amount voided**: Patients are asked to measure I&O for Days 1 and 2. If the patient measured output for the day [code yes (1) to D1ba], the DMS will expect a value for 'amount voided' for all void and dual events (event type=both). Record the volume of urine output in ounces. If the patient recorded voided volume in metric measure, convert it to ounces and record in ounces. Voided volume should be recorded as a whole number. Round up for values equal to or greater than .5, otherwise round down. If the event is not a void (event type=accident), no value for amount voided is required. Therefore, you can leave the data field blank, circle the code -2 (not a void), or put a strike mark through the box. If the patient forgot to record a voided volume, do not prompt her to recall a voided volume. Write the word 'missing' or code (-9) in the data field to indicate the patient forgot to record a voided volume.

v. **Amount leaked**: If the event was an accident, the DMS will expect a code for amount leaked. Record the amount leaked rating recorded by the patient from the Diary. If the event is not an accident, no value is required. Therefore, you can leave the data field blank, circle code -2 (not an accident), or put a strike mark through the box if the event type=void (code 1). If the patient forgot to rate the size of the accident, do not prompt her to recall the Amount Leaked. Write the word missing or (-9) in the data field to indicate the patient forget to rate the amount leaked.

vi. **Type of accident**: Review the patient's notes in the Reason for Accident column. Classify each accident as urge (code 1), stress (code 2) or other/indeterminate (code 3), based on the patient's description. Use the Type of Accident coding guide in Attachment A. If the event is not an accident, no value is required. Therefore, you can leave the data field blank, circle code -2 (not an accident), or put a strike mark through the box if the event type=void (code1). If the notes in the Reason for Accidents column are illegible or ambiguous such that you cannot classify the accident, query the patient to clarify her notes. If you still cannot classify the accident after the patient clarifies her note, circle code 3 (other/indeterminate). If the patient forgot to write a description of the accident in the Reason for Accident column, do not prompt her to recall a reason for the accident. Write the word missing or (-9) in the data field to indicate the patient forgot to write a reason for the accident.

D1d. **Wake Time / Bedtime / Pads used / diapers used**

i. **Wake time:** Use a 12-hour clock to record the wake time recorded by the patient in her Diary. Indicate AM (code 1) or PM (code 2) by circling the corresponding **numeric** code. If the time is missing, do not prompt the patient to recall her wake time. Write 'missing' or (-9) for wake time.

ii. **Bedtime**: Use a 12-hour clock to record the bedtime recorded by the patient in her Diary. Indicate AM (code 1) or PM (code 2) by circling the corresponding **numeric** code. If the time is missing, do not prompt the patient to recall her bedtime. Write 'missing' or (-9) for bedtime.

iii. **Pads used**: Record the # of pads used recorded by the patient in her Diary.

iv. **Diapers used**: Record the # of Diapers used by the patient recorded in her Diary.

If the patient forgot to record a number in the Pads Used or Diapers Used space, write 'missing' or (-9) in the data field. You can record zero (-0-) in the data field if the patient reports she never uses diapers, or never uses pads.

D1e. **Overall summary of accident data on this day:**

i. **Urge Accidents:** Record the total # of urge accidents on this day. Tally the total # of urge accidents from column vi (Type of Accident column).

ii. **Stress Accidents:** Record the total # of stress accidents on this day. Tally the total # of stress accidents from column vi (Type of Accident column).

iii. **Other Accidents:** Record the total # of 'other/indeterminate' type accidents on this day. Tally the total # of 'other/indeterminate' accidents from column vi (Type of Accident column).

iv. **Type Missing:** Record the total # of accidents that you could not classify, i.e. type missing, on this day. Tally the total # of missing (-9) accidents from column vi (Type of Accident column).

v. **Total All Accidents:** Record the sub-total of all accidents on this day. Double check your count multiple ways; i.e. add together the 4 totals across from D1e; count every event coded as an "accident" and "both" in column ii; count down all types of accidents recorded in D1c column vi (Type of Accidents column) including accidents you could not classify (i.e. code missing or (-9), and re-count all accidents from the day in question in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly.

D2-7. Record all data abstracted from subsequent valid Diary days in D2-7.

Section E: Eligibility Determination

Record the total # of accidents for all sub-types and the grand total.

E1. **Total # of Urge Accidents from all valid days:** Tally the total # of urge accidents from all days. Double check your count of all urge accidents multiple ways; i.e. add together the urge accidents from all Diary days; count down all urge accidents recorded in D1c-D7c column vi (Type of Accidents column); and re-count all urge accidents in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly.

E2. **Total # of Stress Accidents from all valid days:** Tally the total # of stress accidents from all days. Double check your count of all stress accidents multiple ways; i.e. add together the stress accidents from all Diary days; count down all stress accidents recorded in D1c-D7c column vi

(Type of Accidents column); and re-count all stress accident in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly.

E3. **Total # of Other Accidents from all valid days:** Tally the total # of 'other' type accidents from all days. Double check your count of all 'other' type accidents multiple ways; i.e. add together the 'other' type accidents from all Diary days; count down all 'other' type accidents recorded in D1c-D7c column vi (Type of Accidents column); and re-count all 'other' type accidents in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly.

E4. **Total # of Accidents you could not classify (Type Missing):** Tally the total # of accidents you could not classify, i.e. accident type coded as 'missing' (-9), from all days. Double check your count of all 'missing' accidents multiple ways; i.e. add together the unclassified accidents (type missing) from all Diary days; count down all 'missing' type accidents recorded in D1c-D7c column vi (Type of Accidents column); and re-count all 'missing' type accidents in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly

E5. **Grand total # of accidents:** Tally the total # of all accidents from all days. Double check your count multiple ways; i.e. add together the 4 totals in E1-E4; count every event coded as an "accident" and "both" in the "Event Type" column (ii), from all days; count all accidents recorded for all days in D1c-D7c column vi (Type of Accidents column), and re-count all accidents from all valid days in the Diary itself. Resolve any discrepancies. Accidents must be counted correctly.

E6. **Is E7 greater than or equal to 7?** If E7 is greater than or equal to 7, circle code 1 (Yes). If E7 is less than 7, circle code 2 (No).

E7. **Was the Bladder Diary completed per protocol?** We will track protocol deviations using E7. If the Diary is not completed per protocol circle code 2 (No) and complete E7a and E7b. Otherwise skip to E8.

E7a. **Was the deviation** a patient deviation, a staff deviation or some other type of deviation?

Circle code 1: if the deviation was a patient deviation.
Circle code 2: if the deviation was a staff deviation.
Circle code 3: if the deviation was some other type of deviation.

E7b. **Describe the deviation:** Provide a brief description of the deviation.

E8. **Please provide any information from the patient that may have affected the interpretation of the Bladder Diary data:** Write a brief description of any special circumstances that affected your interpretation of the Diary. This includes a summary of any clarifications that the patient may have provided about the Diary or any Diary day.

E9. **Is the patient eligible to continue with screening for the BE-DRI study?** Review your code for E6. If the patient is eligible to continue with screening, circle code 1 (Yes). If not, circle code 2 (No).

ATTACHMENT A

Bladder Diary Coding Criteria for Type of Accident

Code Accident "Stress" Type if:

It is associated with:

- Coughing
- Sneezing
- Brisk walking or jogging
- Lifting
- Bending
- Vacuuming
- Climbing Stairs
- Other clearly physical activity with no indication of urgency

Code Accident "Urge" Type if:

It is associated with:

- Urge sensation
- Sense of urgency
- Rushing to the bathroom
- Running water
- Drinking cold beverages
- Sudden exposure to cold weather or a cold draft
- Taking a shower
- Key in the door syndrome
- * Written note of "waited too long"

Leakage associated with walking, laughing, and standing up from sitting position can be either stress or urge accidents.

- Talk with the patient at the time of the Diary review and discuss these types of accidents to be sure you will be able to classify them as accurately as possible. Look for notes that indicate if urgency was present.
- If there is any note from the patient that urgency was present, score it as an urge accident.
- If the patient notes urgency was NOT present, score it as a stress accident.

If the patient's notes are ambiguous, inconclusive or uninformative, and you are unable to get more information from other recordings for the event in the Diary or clarification from the patient during a real-time diary review, code the accident as "other".

If the patient forgot to write a description of the accident in the Reason for Accident column, <u>do not prompt her to recall a reason for the accident</u>. Code the accident type as 'missing'. Write the word missing or negative nine (-9) in the data field to indicate the patient forgot to write a reason for the accident.

**** Revised 11/11/04***