

Patient number

Date of visit
month day year

BPH FORM E01.1

October, 1993

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FORM NUMBER = (FORM)
FORM VERSION = (VERS)

NIH - BPH CLINICAL TRIAL: PILOT STUDY

AUA SYMPTOM SCORE EVENT REPORT

This form should be completed if the patient experiences either event in Section C.

Part I / IDENTIFICATION

A. Patient Identification

1. Patient number (PATID)

clinic patient

2. Patient's initials (INITS)

first last

3. Patient's date of birth (DOB)

month day year

B. Initial Visit Information

1. Date of initial clinical event visit (AVSTDT)

month day year

2. Week of initial clinical event visit (AIVWK)

3. Type of visit (AIVTYP)

☐ Follow-up Visit

☐ Interim Visit

C. AUA Symptom Score Event Identification

1. Type of event (ASCEI) ☐ AUA symptom score 4 point event (Complete Part II)

☐ AUA symptom score 8 point event (Complete Part III)

Initials of person completing form (FORMIN)

first last

Date form completed

(FORMDT)

month day year

Signature _____

Patient number

Date of visit
month day year

Part II / AUA SYMPTOM SCORE 4 POINT EVENT

A. Initial 4 Point Event Visit

Complete this section if the AUA symptom score is 4 or more points greater than the baseline AUA symptom score (see label).

1. AUA symptom score (AI4SS)

2. Is the value in A.1 greater than or equal to 4 points more than the baseline symptom score (see label)? (AI4GRT)

YES	NO
<input type="text"/>	<input type="text"/>

If YES, CONTINUE.

If the patient was taking sinus medication, a new diuretic or has an infection, the clinic director should take corrective measures before continuing. After corrective measures have been taken, and not less than 2 weeks or greater than 4 weeks from the initial AUA symptom score 4 point event visit, the patient should be scheduled for a confirming

3. Are corrective measures necessary? (AI4CM)

YES	NO
<input type="text"/>	<input type="text"/>

If YES:

a. What is the reason for corrective measures? (Check only one) (AI4CMR)

- Sinus medication
 New diuretic
 Infection
 Other (Specify below)

If there is no need for corrective measures, schedule the patient for a confirming visit in not less than 2 weeks or greater than 4 weeks from the initial AUA symptom score 4 point event visit.

The Interim Visit Checklist should also be completed during this confirming visit.

B. Confirming 4 Point Event Visit

1. Date of visit (AC4DT)

<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
month	day	year

2. Week of visit (AC4WK)

Patient number

Date of visit
month day year

3. AUA symptom score (AC4SS)

4. Is the value in B.3 greater than or equal to 4 points more than the baseline symptom score (see label) ? (AC4GRT)

YES	NO
<input type="text"/> ¹	<input type="text"/> ²

If the symptom score in question B.3 is greater than or equal to 4 points more than the baseline AUA symptom score, this documents an AUA symptom score 4 point event. If the patient is on coded medication, DO NOT STOP CODED MEDICATION.

5. AUA symptom score 4 point event declared? (AC4DEC)

YES	NO
<input type="text"/> ¹	<input type="text"/> ²

Part III / AUA SYMPTOM SCORE 8 POINT EVENT

A. Initial 8 Point Event Visit

Complete this section if the AUA symptom score is 8 or more points greater than the baseline AUA symptom score (see label).

1. AUA symptom score (AI8SS)

2. Is the value in A.1 greater than or equal to 8 points more than the baseline symptom score (see label)? (AI8GRT)

YES	NO
<input type="text"/> ¹	<input type="text"/> ²

If YES, CONTINUE.

If the patient was taking sinus medication, a new diuretic or has an infection, the clinic director should take corrective measures before continuing. After corrective measures have been taken, and not less than 2 weeks or greater than 4 weeks from the initial AUA symptom score 8 point event visit, the patient should be scheduled for a confirming

3. Are corrective measures necessary? (AI8CM)

YES	NO
<input type="text"/> ¹	<input type="text"/> ²

If YES:

a. What is the reason for corrective measures? (Check only one) (AI8CMR)

- ¹ Sinus medication
 - ² New diuretic
 - ³ Infection
 - ⁴ Other (Specify below)
-

The Interim Visit Checklist should also be completed during this confirming visit.

month	day	year

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YES NO

1 2

YES NO

1 2

YES NO

1 2

month	day	year