



PVDOMICS STUDY

Clinical Center Participant Sleep

Initialization, Demonstration and Placement - Form #150

Instructions: This form is completed once per participant. Complete this form during initial evaluation of participant and demonstration of sleep monitoring device placement.

Note: Sleep studies using the PVDOMICS protocol can be completed up to 6 months after the end of 6-weeks post-enrollment study protocol period.

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1. Identification Number

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2. Alpha code

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3a. Date of initialization, demo and (if done on the same day) device placement: (mm/dd/yyyy)

3. b. Was a sleep study machine initialized and sent home with the participant? _____

0=No, continue to Q3c.

1=Yes, continue to Q4.

c. If not done, what was the reason? _____

1=Physician judgment/medical contraindication

2=Participant not approached to do sleep study (*protocol deviation*)

3=Logistics issue with clinical center (scheduling conflict, machine not functioning)

4=Logistics issue with participant

5=Participant refused

4. Username of PVDOMICS staff member initializing equipment and demonstrating proper device placement to participant _____

5. Were new AA batteries put in? (0=No, 1=Yes) _____

6. Are date and time correct on the device? (0=No, 1=Yes) _____

7. Sleep device unit identification number S _____

8. Number of minutes did it take to instruct and demonstrate the sleep monitoring unit: _____

9. What time does participant report going to bed (on average) (24-hour clock) (hh:mm) _____:_____

10. What time does participant report waking up (on average) (24-hour clock) (hh:mm) _____:_____

11. Participant baseline SaO₂ (%) _____

12. Does participant use O₂ during the night? (0=No, 1=Yes) _____

a. What is usual nighttime O₂ flow (l/min) _____

b. What type of O₂ delivery device used (1=Nasal cannula, 2=Mask, 3=Reservoir cannula) _____

c. Type of O₂ delivery (1=Continuous, 2=Pulse) _____

13. Does participant wear a positive airway pressure (PAP) device at night? (0=No, 1=Yes) _____

a. Continuous PAP (CPAP) device? (0=No, 1=Yes) _____

1. Pressure (cmH₂O) _____

b. Bilevel PAP (BiPAP) device? (0=No, 1=Yes).....

(Q 13b1 removed from form)

2. Back up rate (breaths per minute).....

3. IPAP Pressure (cmH₂O)(min) ____ - (max) ____4. EPAP Pressure (cmH₂O)(min) ____ - (max) ____

c. Auto PAP (APAP) device? (0=No, 1=Yes)

1. Pressure (cmH₂O)(min) ____ - (max) ____

d. Auto Bilevel PAP (autoBiPAP) device? (0=No, 1=Yes).....

(Q 13d1 removed from form)

2. Back up rate (breaths per minute).....

3. IPAP Pressure (cmH₂O)(min) ____ - (max) ____4. EPAP Pressure (cmH₂O)(min) ____ - (max) ____

e. Adaptive-ServoVentilation device? (0=No, 1=Yes)

(Q 13e1 removed from form)

2. Back up rate (breaths per minute).....

3. IPAP Pressure (cmH₂O)(min) ____ - (max) ____4. EPAP Pressure (cmH₂O)(min) ____ - (max) ____

5. Pressure support (PS)(min) ____ - (max) ____

14. Does participant wear nasal/oral appliance? (0=No, 1=Yes).....

a. What type of appliance used?

1=Provent

2=Dental appliance

3=Other: specify: _____)

200. Date form completed (mm/dd/yyyy)/...../.....

201. Username of person completing/reviewing completeness of this form.....

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy)/...../.....

Username of person entering this form.....