



L-PVDOMICS STUDY

Clinical Center Sleep Study/Nocturnal Oximetry Only

Initialization, Demonstration and Placement - Form #550

Instructions: This form is completed once per participant enrolled in **Level 1**. Complete this form during Level 1 visit and demonstrate sleep monitoring device and/or sole nocturnal oximetry device placement.

Note: Sleep studies using the L-PVDOMICS protocol can be completed up to 3 months after the end of the Level 1 visit.

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1. Identification Number

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2. Alpha code

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3a. Date of initialization (mm/dd/yyyy)

3. b. Was a sleep study monitor initialized and sent home with the participant for a standard sleep study or sole nocturnal oximetry recording?

0=No, continue to Q3c.

1=Yes, sleep study monitoring (*includes oximetry*), continue to Q4.

2=Yes, nocturnal oximetry monitoring only, continue to Q4.

c. If not, 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 monitor placement to participant

5. Were new AA batteries placed? (0=No, 1=Yes).....

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

7. a. Sleep device unit identification number S

b. Oximetry device identification number O

8. Number of minutes did it take to instruct and demonstrate the sleep equipment:

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 during sleep? (0=No, 1=Yes).....

If yes to Q13, review type of device(s) used for Q14-Q18:

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

a. Pressure (cmH₂O)

15. Bilevel PAP (BiPAP) device? (0=No, 1=Yes).....
a. Back up rate (breaths per minute)
b. IPAP Pressure (cmH₂O).....(min) ____ - (max) ____
c. EPAP Pressure (cmH₂O)(min) ____ - (max) ____
16. Auto PAP (APAP) device? (0=No, 1=Yes)
a. Pressure (cmH₂O).....(min) ____ - (max) ____
17. Auto Bilevel PAP (autoBiPAP) device? (0=No, 1=Yes).....
a. Back up rate (breaths per minute)
b. IPAP Pressure (cmH₂O).....(min) ____ - (max) ____
c. EPAP Pressure (cmH₂O)(min) ____ - (max) ____
18. Adaptive-ServoVentilation device? (0=No, 1=Yes)
a. Back up rate (breaths per minute)
b. IPAP Pressure (cmH₂O).....(min) ____ - (max) ____
c. EPAP Pressure (cmH₂O)(min) ____ - (max) ____
d. Pressure support (PS).....(min) ____ - (max) ____
19. How many hours, on average, does the participant use the treatment if indicated as 'Yes' for Questions 14-18? (hh:mm).....: ____
20. Does participant wear nasal/oral appliance for sleep apnea treatment? (0=No, 1=Yes).....
If yes to Q19, identify what type(s) – use 0=No, 1=Yes for each:
a. Nasal end expiratory pressure (e.g. Theavent, Provent).....
b. Oral appliance (e.g. mandibular advancement device, tongue retaining device).....
c. Hypoglossal nerve stimulation (e.g., Inspire).....
d. 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 _____