



INSTRUCTIONS FOR THE SLEEP EQUIPMENT FORM (SEF)

I. General Instructions

The Sleep Equipment Form (SEF) is administered by ARIC field center staff for all participants at Visit 11. It is recommended that this form is filled out after completing the other sleep questionnaires, the Epworth Sleepiness Scale and the Jenkins Sleep Evaluation Questionnaire, and after staff have introduced the sleep study to participants.

The SEF form should be opened and completed for all participants. If the participant declines participation in the study or is ineligible due to the adhesive allergy exclusion as indicated in the Participant Snapshot report, you should enter items 0a, 0b, and 0c, then save and close the form.

The Participant Snapshot report should be viewed prior to administering the form to determine eligibility. **Participants with an adhesive allergy are ineligible for the sleep monitoring study. Participants with a pacemaker or other implanted device are ineligible for the WatchPAT device only.**

Sections A-C are completed at the clinic visit when the devices are dispensed to the participant. Sections D-F are completed when the devices and Sleep Diary are returned to the clinic.

II. Detailed Instructions for Each Item

0a. Enter the date the form was completed.

0b. Enter the staff ID of the person who completed this form.

0c-0c1. Record whether the participant is interested in participating in the sleep monitoring study. If the participant is interested but ineligible for both devices due to the adhesive allergy exclusion as indicated in the Participant Snapshot report, select No and record this reason in 0c1. If the participant indicates they are not interested in participating, record the reason why not in 0c1.

A. SLEEP DEVICE EXCLUSION INFORMATION

1. Record whether the participant has a sleep apnea device. If the participant has a CPAP without a mask that covers the forehead, an oral appliance or mandibular advancement device, or other sleep apnea device (recorded in 1a), select these options, but note that none of these are exclusionary – these answers are for informational purposes only and assist in data analysis. A CPAP with a mask that covers the forehead is an exclusion for the Sleep Profiler device, and an Inspire implanted device is an exclusion for the WatchPAT device.

2. This question will only be answered if the participant is not excluded from the Sleep Profiler due to having a CPAP with a mask that covers the forehead. Record whether the participant has a facial irritation or head injury that would prevent them from wearing the Sleep Profiler. If they do, then they are ineligible for the Sleep Profiler and should not be dispensed this device.

3. This question will only be answered if the participant is not excluded from the WatchPAT due to having an Inspire implanted device. Record whether the participant has an injury on their hands or wrists, or other reason why they would be unable to wear the WatchPAT. Answering Yes to this question is an exclusion for the WatchPAT.

B. SLEEP PROFILER INITIATION

This section is only completed for participants who are eligible to receive the Sleep Profiler device – i.e., they do not have an adhesive allergy, a CPAP with a mask that covers the forehead, or a facial irritation or head injury.

4. Record if the participant received the Sleep Profiler.

5. Record the Sleep Profiler serial number. The serial number is 9 numbers and can be found on the back of device by lifting the right side of the strip (what the electrodes attach to), next to the letters SN. Do not record the dash in CDART; record the numbers only.



6. Record the date of the visit when the Sleep Profiler was dispensed to the participant.

7. Record the Staff ID of the technician who introduced and dispensed the Sleep Profiler to the participant.

C. WATCHPAT INITIATION

This section is only completed for participants who are eligible to receive the WatchPAT device – i.e., they do not have an adhesive allergy, a pacemaker or other implanted device, an Inspire implanted sleep apnea device, or an injury on their hands or wrists.

8. Record if the participant received the Sleep Profiler.

9. Record the WatchPAT serial number. The serial number is 6 numbers and can be found on the back of the watch face next to the letters SN.



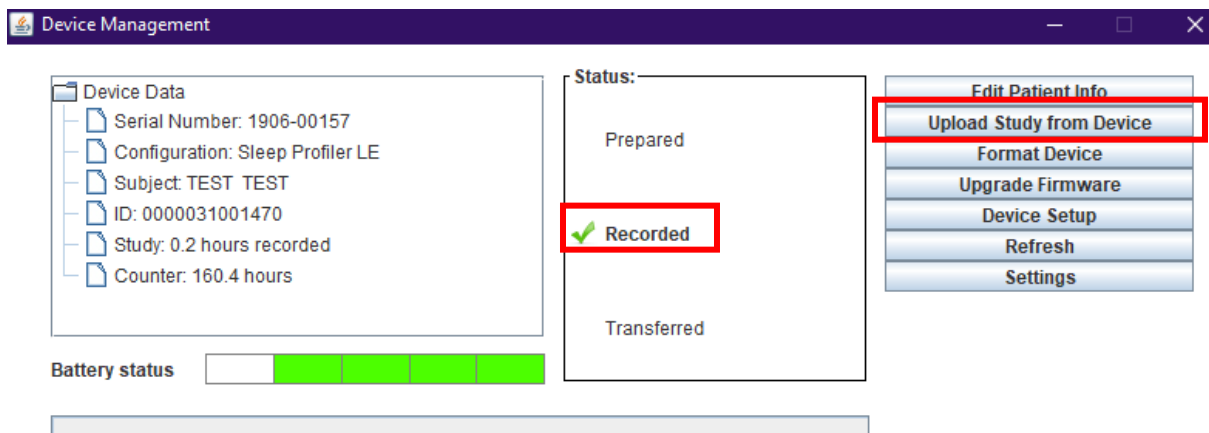
10. Record the date of the visit when the WatchPAT was dispensed to the participant.

11. Record the Staff ID of the technician who introduced and dispensed the WatchPAT to the participant.

D. SLEEP PROFILER COMPLETION

12. Record whether the Sleep Profiler was returned to the clinic.

13. Record the Staff ID of the technician who uploaded the data from the Sleep Profiler device. To upload the data, connect the device to the computer and navigate to the Sleep Profiler portal at <https://cportal.b-alert.com/sleep-profiler/login>. After logging in, go the Device Management, then select "Upload Study from Device".



14. Record the date the Sleep Profiler was returned to the clinic.

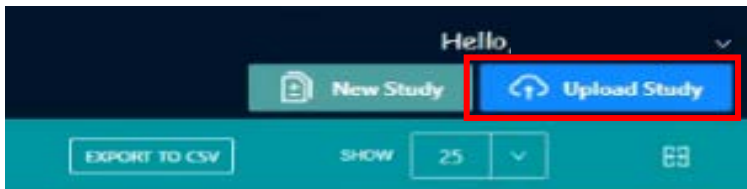
15. Record the date the data from the Sleep Profiler was uploaded. This should be done the day the equipment is returned, if possible.

15a. Record whether the data was successfully uploaded from the device.

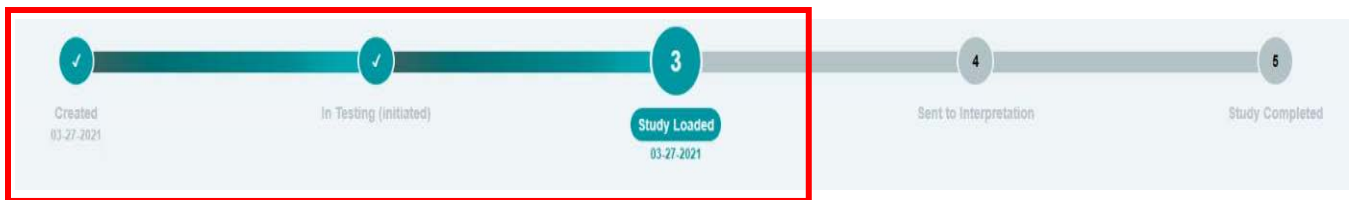
E. WATCHPAT COMPLETION

16. Record whether the WatchPAT was returned to the clinic.

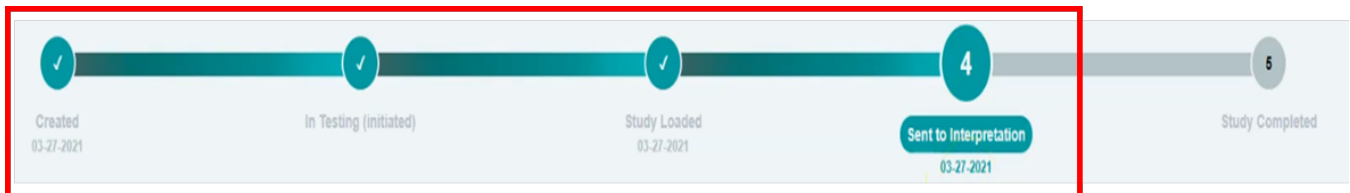
17. Record the Staff ID of the technician who uploaded the data from the WatchPAT device. To upload data from the WatchPAT, connect the device to the computer and navigate to CloudPAT at <https://cloudpat.itamar-medical.com/>. After logging in, select “Upload Study”, and then “Proceed with Upload” in the pop up window.



The tracker at the top of the screen will move to “Study Loaded”.



Click on the pencil next to the study and select “Lucey Lab” as an interpreter, then hit the checkmark.



18. Record the date the WatchPAT was returned to the clinic.

19. Record the date the data from the WatchPAT was uploaded to CloudPAT. This should be done the day the equipment is returned, if possible.

19a. Record whether the data was successfully uploaded from the device.

F. OTHER RETURN INFORMATION

20. Record whether the Sleep Diary was returned to the clinic. If the Sleep Diary was returned to the clinic, the Participant Sleep Diary (PSD) form should be completed in CDART using the information in the paper form from the participant. The PSD form is located in the V11 Accelerometry form group.

21. Record whether the participant wore the WatchPAT on their non-dominant wrist. This information is recorded in the paper Sleep Diary. All other information from the paper Sleep Diary is recorded in the PSD form in CDART.

22. Include any additional information that may be helpful for the Sleep Processing Center. This could include anything the participant wrote in the margins of the Sleep Diary, troubleshooting issues that occurred, early removal of equipment, participant wore equipment during time change, or other comments from the participant or site.