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Multi-modal home sleep monitoring in older adults --Manuscript Draft--

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1 TITLE: 2 Multi-Modal Home Sleep Monitoring in Older Adults 3 4 **AUTHORS & AFFILIATIONS:** Cristina D. Toedebusch^{1*}, Jennifer S. McLeland^{1*}, Claire M. Schaibley¹, Ian R. Banks¹, Jill Boyd¹, 5 John C. Morris^{1,2,3}, David M. Holtzman^{1,2,3}, Brendan P. Lucey^{1,2} 6 7 8 ¹Department of Neurology, Washington University School of Medicine, St Louis, MO 9 ²Hope Center for Neurological Disorders, Washington University School of Medicine, St Louis, 10 ³Knight Alzheimer's Disease Research Center, Washington University School of Medicine, St 11 12 Louis, MO 13 14 *These authors contributed equally 15 16 Corresponding Author: 17 Brendan P. Lucey (luceyb@wustl.edu) 18 19 Co-Authors: 20 Cristina Toedebusch (toedebuschc@wustl.edu) 21 Jennifer McLeland (mclelandj@wustl.edu) 22 Claire Schaibley (cschaibley@wustl.edu) 23 Ian Banks (ian.banks@wustl.edu) 24 Jill Boyd (boyd.j@wustl.edu) 25 John Morris (jcmorris@wustl.edu) 26 David Holtzman (holtzman@wustl.edu) 27 28 **KEYWORDS:** 29 Sleep, home sleep testing, single-channel EEG, actigraphy, sleep logs, obstructive sleep apnea, 30 continuous positive airway pressure 31 32 **SUMMARY:** 33 Here, we present a protocol to improve the quality of data from home sleep testing by 34 providing a method to enhance instructions through a structured participant visit. This protocol 35 includes the implementation of a step-by-step educational manual with photos to ensure 36 proper placement of equipment. 37

ABSTRACT:

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The gold standard for sleep monitoring is attended in-lab polysomnography; however, this method may be cost-prohibitive and inconvenient for patients and research participants. Home sleep testing has gained momentum in the field of sleep medicine due to its convenience and lower cost, as well as being more naturalistic. The accuracy and quality of home sleep testing, however, may be variable because studies are not monitored by sleep technologists. There has

been some success in improving the accuracy of home sleep studies by having trained sleep

technicians assist participants inside their homes with putting on the devices, but this can be intrusive and time-consuming for those involved. In this protocol, participants undergo at-home sleep monitoring with multiple devices: 1) a single-channel EEG device; 2) a home sleep test for sleep-disordered breathing and periodic limb movements; 3) actigraphy; and 4) sleep logs. A major challenge of this study is obtaining high-quality sleep monitoring data on the first attempt in order to minimize participant burden. This protocol describes the implementation of educational manuals with step-by-step instructions and photos. The goal is to improve the quality of home sleep testing.

INTRODUCTION:

The relationship between sleep and Alzheimer's disease (AD) is a growing area of research with sleep disturbances hypothesized to have a role in both AD pathogenesis and as a biomarker for AD pathology¹,². In order to study the relationship between sleep and AD biomarkers, cognitively normal or very mildly impaired participants aged ≥65 years old are recruited from a longitudinal study of aging at the Knight Alzheimer's Disease Research Center (ADRC) at Washington University School of Medicine. Although this study was focused on AD research, the methods presented here have broad applicability to home sleep testing in older adults. Attended in-lab polysomnography is the gold standard for sleep monitoring³, but such monitoring can be cost-prohibitive and inconvenient for participants. An alternative is home sleep testing. The accuracy of home sleep studies may be improved by having trained sleep technicians assist participants inside their homes with device placement, but this can also be intrusive and time-consuming⁴. Therefore, this protocol was developed to instruct the participants how to set up sleep monitoring devices at home and still collect reliable data.

Participants were asked to wear a home sleep test (HST) for measuring sleep-disordered breathing (e.g., obstructive sleep apnea) and periodic leg movements. Following HST recording, participants wore a single-channel EEG device for 6 nights to monitor brain waves for EEG-based sleep staging. Previous findings indicate that the single-channel EEG device has a high level of agreement with polysomnography for multiple sleep parameters⁵. Throughout the single-channel EEG and HST monitoring period, participants completed a sleep log and were asked to wear actigraphy on their nondominant wrist for the entire duration of the sleep study to track activity. Studies were defined as acceptable if there were at least 2 nights recorded by the single-channel EEG device with <10% artifact and at least 1 night recorded on the HST with ≥4 hours of scorable data. Initially, the failure rate due to poor data quality was ~40−50%. Repeat monitoring for participants with poor data quality was deemed too burdensome, therefore, this protocol was developed.

Previous work found that many elderly persons have difficulty adjusting to technological interventions⁶⁻⁹. This impacts numerous fields from geriatrics to education and is particularly relevant to medical studies in which older adults must use or interact with unfamiliar technologies. In order to reduce in-home study failure rates, education manuals were created that provided pictures and step-by-step directions to set up the HST and single-channel EEG devices. The education manuals were derived from the device user manuals^{10,11}. Additionally, a 24-hour helpline was provided to participants, so they could reach a member of the study team

at any time with any questions or concerns.

To analyze the impact of this protocol, a retrospective review was conducted on the success and failure rates for acceptable data quality from the at-home sleep monitoring before and after implementation of the education manuals. The data sources were successful recordings and participant calls to research study staff with questions. Participants were asked to come into the sleep center to learn about the sleep monitoring equipment. During the 2-hour visit, a study team member educated each participant about the equipment using the manuals, which provided step-by-step instructions for device usage. After reviewing the manuals in the office and being guided through the application and use of the devices, participants were given the opportunity to independently practice applying the home sleep monitoring devices using the manuals as a guide. Feedback was provided to participants during the visit and they were given the opportunity to ask questions in addition to reapplying the equipment as needed. Participants then took the equipment home, put the ambulatory equipment on themselves at night, and were encouraged to call a study team member at any time, day or night, for assistance troubleshooting any questions or problems.

All single-channel EEG studies were scored manually by registered sleep technologists who were validated, gold-standard scorers using modified American Academy of Sleep Medicine (AASM) scoring criteria⁵. HST recordings included airflow measured by nasal pressure transducer and thermistor, respiratory effort measured by thoracic and abdominal respiratory inductance plethysmograph belts, body position, pulse oximetry, and leg electromyogram (EMG) using the optional electrocardiogram (ECG) yoke. Lights off and lights on were determined by the time that each participant pressed the event button on the HST device and/or entry in a sleep log. A registered sleep technologist manually scored the HST studies and then a board-certified sleep physician performed an epoch-by-epoch review of each study.

Following the introduction of this protocol, the failure rate was reduced to 19% and reliable data was obtained. The protocol represents a novel, low-cost, and effective way to increase the success rate of at-home sleep studies. While the HST device has been used in some studies, it is primarily used as a diagnostic tool and not for scientific studies^{12,13}. This protocol also provides a method that allows participants to easily use a Positive Airway Pressure (PAP) machine while they are wearing either the HST or single-channel EEG device. The use of the HST and single-channel EEG devices with education manuals is a particularly useful research tool that could be more widely utilized using the method shown in this protocol.

PROTOCOL:

This protocol was approved by the Washington University Human Research Protection Office. Instructions were written specific to commercially available devices and their related software for data collection (see Table of Materials).

1. Set up of the sleep monitoring devices prior to the participant visit

- 133 1.1. Connect a fully charged actigraphy device to the docking station and open the
- actigraphy software. Initialize actigraphy device to record for the desired timeframe¹⁴. Use the
- 135 following parameters.

- 137 1.1.1. Select the 30 second epoch length from the drop-down menu for epoch duration. This
- allows for comparison to 30 second epochs on the single-channel EEG and HST recordings.

139

1.1.2. Select activity and light logging mode from the drop-down menu for logging mode. The light logging mode allows measurement of light exposure at night.

142

143 1.1.3. Collect actigraphy data for the duration of HST and single-channel EEG device recordings. Measure actigraphy for approximately one week for this protocol.

145

1.2. Connect a charged, single-channel EEG device to computer. Open device software and select data management and edit patient data prior to the start of the recording 15.

148

1.3. For home sleep testing, insert batteries and data card into the HST device. Connect HST device to computer and power the device on.

151

1.3.1. Open device software and select **Device Configuration** from the menu. Choose the appropriate study montage¹⁰.

154

1.3.2. Select **Auto Start**. Enter times for auto start and stop beginning 2 hours prior to and ending 2 hours after the participant's habitual bedtime to ensure the entire sleep period is recorded.

158

159 1.3.3. Choose the option to automatically record for 2 consecutive nights. Click on the good study indicator tab and choose 6 hours.

161

1.3.4. Use a Positive Airway Pressure (PAP) adapter kit in place of the thermistor and pressure transducer to monitor airflow if the participant wears PAP.

164 165

2. Participant visit for instruction on wearing the sleep monitoring devices

166

167 2.1. Instruct participant to wear the actigraphy device on the non-dominant wrist for the duration of the study with the exception of bathing or swimming.

169

2.1.1. Ask the participant to press the event button at the bedtime and wake time to set a lights-out and lights-on marker on the actogram.

172

- 173 2.1.2. Complete the sleep log every morning upon awakening. Instruct the participant to
- 174 document the following:
- 175 Bedtime and wake-up time;
- 176 How long it took to fall asleep;

- 177 Number of nighttime awakenings;
- 178 Occurrence of unusual events that may impact sleep.

180 2.1.3. Place the device on the participant's wrist during the visit and provide detailed written181 instructions to the participant.

182

183 2.2. Instruct the participant regarding the Home Sleep Test Device (HST) and review the education manual.

185

NOTE: Following the educational session, participants were given the opportunity to independently apply the device using the manual and then receive verbal feedback from a study team member.

189

2.2.1. Position the blue belt with the holster around the chest directly under armpits with the
 buckle almost centered.

192

2.2.1.1. Center holster on the chest and tighten the belt until it is snug enough so that the holster will stay in the center of chest when moving during the night. Point the arrow on the belt buckle facing down.

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198

2.2.1.2. Place the black lanyard strap around the neck and tighten until it is comfortably snug. Place the other blue belt around the waist and tighten the belt until it is snug enough that it does not slide when moving during the night. Point the arrow on the belt buckle facing down.

199 200 201

2.2.1.3. Snap the white box into the holster on the chest belt. Ensure that there are 2 clicks as the box goes into the holster. Orient the label of the HST device outward.

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2.2.2. Open the device by sliding the button at the top of the device. Refrain from pressing the power button since the device is set to auto start and stop. Look at the device window.

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NOTE: All the sensors will stop flashing when they are either plugged into the device or placed on the body.

209

210 2.2.3. Instruct participant that the line connected to the mouth (purple rectangle) will flash the entire time if used with PAP.

212

- 2.2.4. Plug the chest (thoracic) wires into the ports on the bottom of the chest belt buckle.
- 214 Repeat this step and plug abdominal wires into the ports on the bottom of the abdominal belt 215 buckle.

216

217 2.2.5. If PAP is worn, skip steps the following sub-steps.

218

219 2.2.5.1. Place the prongs of the white wire (thermistor) in the nose and wrap the wire 220 around ears. Pull the plastic piece up toward the neck to secure.

222 2.2.5.2. Position the second set of prongs (clear nasal cannula) in nostrils and wrap
223 tubing around ears. Ensure that the two prongs from the cannula fit just inside the nose and
224 position the longer prong in front of the mouth, trim to fit area by mouth opening.

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2.2.5.3. Slide up the plastic piece toward the neck to secure. Use a small piece of tape to affix both sets of tubing to each cheek.

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229 2.2.6. Run the long red and white leg wires through each pant leg along the side to avoid them getting tangled during the night. Use sticky patches to attach a red and white wire to each leg.

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2.2.7. Place a hand on the shin and flex one foot up and down to locate the anterior tibialis muscle on the outside (lateral front) of the lower leg and place patches directly on the muscle at least 2 finger widths apart from one another.

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233

2.2.8. Apply tape over each sticky patch sufficient to cover patch, wire, and skin to secure.
 With knee bent (to give plenty of slack in the wires), tape the wire above each knee to prevent the wires from getting tangled.

239

240 2.2.9. Use an oximeter to measure oxygen levels throughout the night.

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2.2.9.1. Pinch the top of the oximeter to open the clip. Match up the picture of a fingernail on the outside of the clip to the fingernail of middle or index finger and place the oximeter on index or middle finger.

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2.2.9.2. Wrap tape around the outside of the oximeter clip to secure. Place a piece of tape over the oximeter wire to attach it to hand just above the wrist. Tuck the extra oximeter cable in the chest belt to avoid getting tangled in the wire.

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2.2.10. Look at the man on the display screen and confirm that no signals are flashing. Once all sensors are on properly and lines are solid (unless using PAP), close the device.

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2.2.11. Instruct the participant that if the yellow light on the outside of the device starts flashing during the night, the device has lost a signal. If this happens, open up the device to check the display window to determine which signal has been lost. Once identified, reattach the sensor(s) that has come off.

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2.2.12. Press the circular event button on the outside of the device at lights out and again at lights on. Open the device and check the good study indicator circle.

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NOTE: Participants are asked to call the study team in the morning if the good study indicator does not display a complete study. The device is set to record a second night for this reason. If the participant is willing to wear the device a second night, then discuss troubleshooting measures over the phone and encourage the participant to call again at night with any 265 questions or concerns.

2.2.13. After waking up in the morning for the last time, make an entry in the sleep log.

2.3. If participant wears PAP, attach a PAP titration kit to the device to measure PAP flow. Do this by twisting it into the connector designated for the nasal cannula. Ask the participant to attach the PAP mask to one side of the titration kit adaptor and the hose to the other side of the adapter. Provide a picture to the participant and demonstrate this during the office visit. Inform the participant that all masks and hoses are universal and will fit the provided kit.

NOTE: If the hose does not fit in the adapter, ask participants to feel the end of the hose for a hard-plastic piece. If the mask adapter is still in the hose, the PAP kit adapter will not fit until it is removed.

2.4. Instruct participant regarding single-channel EEG device¹¹ and review the education manual.

282 2.4.1. Place the device over the participant's head to demonstrate proper placement. Instruct
283 the participant on how to adjust the headgear for proper fit and where to affix the electrodes
284 on the forehead for accurate placement.

2.4.2. Provide charging instructions and a demonstration in the office.

288 2.4.3. Provide extra electrodes to participant in case they are needed.

290 2.4.4. Ask participant wearing PAP to bring his current mask to the visit as a mask fitting may 291 be required.

2.4.4.1. Check PAP masks for a forehead component. If present, provide a loaner mask for the duration of the study to ensure proper fit of the single-channel EEG device.

2.4.4.2. Educate the participant about the application of the mask and headgear. Allow participant to apply the mask and adjust the headgear as needed. Instruct participant to apply the device before the mask at night. This will allow removal of mask without dislodging the device.

NOTE: Hard-of-hearing participants are encouraged to call the helpline when attaching the single-channel EEG so that the research coordinator can confirm the single-channel EEG is properly initialized.

3. Data Download and Processing

307 3.1. Place the actigraphy device on the docking station to connect to computer for download.

309
 310 3.1.1. Open software and retrieve data¹⁴. End the recording and put watch to sleep until next
 311 use.

312

3.1.2. Launch actogram to view recording. Use a previously described protocol for reviewing and scoring actigraphy device and sleep log data¹⁶.

315

3.1.2.1. Remove all automatically scored intervals and manually score sleep interval using sleep log bedtime and wake time¹⁷.

318

3.1.2.2. If the reported times are misaligned with actigraphy by more than 30 min and the event marker button was pressed within 30 min of activity changes, score the sleep interval using the event markers.

322

323 3.1.3. Set the following data processing parameters prior to generating reports.

324

325 3.1.3.1. Set **Wake Threshold** to low with a value of 20.

326

327 3.1.3.2. Set **Immobile Minutes** for sleep onset and sleep end to 10.

328

329 3.1.3.3. Generate a clinician's report and convert data to analysis software (e.g., Excel) 330 for further analysis.

331

332 3.2. Connect the single-channel EEG device to computer, open portal and select data 333 management to upload study¹⁵.

334

3.2.1. Convert the study to a European Data Format (EDF) files in the portal. Select **Record**, click on **Actions and Reports** and choose **Export EDF File**. Download EDF file to computer. If needed, use a split EDF tool to timestamp and split multiple studies on a saved file.

338

3.2.2. Set sleep tags using the sleep log bedtimes and wake times.

340

3.2.3. Score EDF study using AASM scoring criteria⁵ and generate a report using any sleep system software.

343

3.3. Connect the HST device to computer, open software, click on **File** and **Import** to upload study to database.

346

3.3.1. Visually inspect the data after download to ensure that there are at least 4 hours of scorable data.

349

3.3.2. Score study in the HST database using AASM scoring criteria¹⁸. To generate a report, click on **Report** and choose **Generate PSG Report**.

352

4. Quality assurance procedures

NOTE: All recordings are reviewed by a registered sleep technologist and a board-certified sleep physician. Specific markers of quality assurance are reviewed as follows:

- 358 4.1. Review the actograms to ensure the lights out and lights on times are set accurately to the sleep log times or the event markers per protocol.
 - 4.2. Review the single-channel EEG recording while referencing the sleep log and actigraphy. Recordings are rejected for the following reasons: there is >10% artifact present in the single-channel EEG recording and movement on actogram does not align with artifact; or the EEG recording started 30 minutes late or ended 30 minutes early in comparison to the actogram.
 - 4.3. Reject HST recordings if there is <4 hours of scorable data. A board-certified sleep physician reviews each study epoch by epoch to ensure accuracy of scoring.

REPRESENTATIVE RESULTS:

Single-channel EEG

At the start of the study, an acceptable overnight recording with the single-channel EEG device was defined as 1) aligning with the sleep period defined by sleep log and/or actigraphy device, and 2) <10% of the recording unscorable due to movement, myogenic, electrode, or other artifacts. Each participant needed at least 2 nights meeting these criteria. Prior to the implementation of the single-channel EEG manual, 14 participants wore the single-channel EEG device. Of those 14 participants, 42% (6) needed to repeat testing due to inadequate collection of acceptable data as defined above. After implementing the protocol with the instruction manual, only 2 of 15 (13%) participants needed to repeat monitoring with the single-channel EEG device due to poor data quality (**Table 1**). Example hypnograms of an acceptable good and unacceptable poor single-channel EEG recording are shown (**Figure 1**).

Home Sleep Test

For the HST, an acceptable recording was defined as 4 or more hours of data scorable for respiratory events and periodic leg movements. Poor data quality is usually due to one or more of the sensors failing to record, such as from artifacts or losing contact. In this study, one common indication of unscorable data was breaks in the SpO_2 channel. Prior to using the HST instruction manual, 3 of 7 (42%) participants failed to meet this standard for one HST recording. 16 participants wore the HST over 2 months after implementing the instruction manual with only 3 (19%) participants failing to meet the acceptable "good" recording standard (**Table 1**). Example hypnograms of an acceptable good and unacceptable poor HST recordings are shown and the SpO_2 channel is highlighted (**Figure 2**).

FIGURE AND TABLE LEGENDS:

Table 1. Participants with Acceptable Sleep Studies Pre- and Post-Protocol Implementation.
 Before implementing this study protocol, fourteen participants wore the single-channel EEG

device and seven participants wore the home sleep test (HST). For the single-channel EEG and the HST, 43% of participants had an unacceptable study. After implementation of the protocol, this was reduced to 13% of participants with unacceptable single-channel EEG studies and 19% of participants with unacceptable HSTs. Neither of these differences were significant.

Figure 1. Acceptable and unacceptable hypnograms from 1-night recording on the single-channel EEG device. (A) A single-channel EEG hypnogram showing artifact-free data collection. This figure shows data for one night of single-channel EEG recording on an hour-by-hour basis. The x-axis indicates the number of hours starting from the beginning (lights-off) to the ending (lights-on) of the recording. The y-axis indicates sleep stages. Movement (MT) indicates artifact during the recording from movement, muscle, electrodes, or other sources. Artifact-free data was recorded throughout the study (shown in green) and were scored for different sleep stages. (B) A single-channel EEG hypnogram showing unscorable data due to artifact. This figure shows data for one night of single-channel EEG recording on an hour-by-hour basis with the same x-axis and y-axis as in (A). This data represents a hypnogram in during which the single-channel EEG recorded artifact indicated by MT (shown in red). The sensors on the single-channel EEG were unable to record brain wave activity that were scored for during different sleep stages during these time periods. W: wake; R: rapid eye movement sleep; N1: non-rapid eye movement (NREM) stage 1; N2: NREM stage 2; N3: NREM stage 3.

Figure 2. Acceptable and unacceptable hypnograms from 1-night recording on the home sleep test. (A) A home sleep test (HST) hypnogram showing artifact-free data collection over one night. The x-axis indicates the time in hours that the recording was taken, and the y-axis indicates heart rate, oxygen saturation, sleep-disordered breathing, and body position. Note, there are no breaks in the SpO₂ channel (shown in green) indicative of data loss, artifact, or otherwise unscorable data. (B) A HST hypnogram showing an unacceptable "poor" recording over one night with a large proportion of artifact during the study. The x-axis and y-axis are the same as in (A). There are breaks or missing data in the SpO₂ channel (shown in red) indicative of unscorable data from artifact or other data loss. HR: heart rate; BPM: beats per minute; SpO₂: percent oxygen saturation; CA: central apnea; OA: obstructive apnea; MA: mixed apnea; HYPO: hypopnea; S: seconds; Pos: position; B: back; R: right; L: left.

Supplemental File. Selected pages from the Home Sleep Test education manual showing the step-by-step set-up instructions are provided as an example.

DISCUSSION:

This protocol is the novel application of instructional manuals in conjunction with participant education for in-home ambulatory sleep monitoring. Based on the results, the implementation of the protocol with instruction manuals improves the feasibility of in-home sleep testing in older adults. In-lab polysomnography remains the gold standard for sleep monitoring but may be limited by cost as well as disrupted sleep due to the new environment (i.e., the "first night" effect¹⁹). This protocol has shown that it is feasible to obtain high quality sleep monitoring at home in an elderly population with a single-channel EEG device for sleep staging and a HST to screen for sleep disorders such as obstructive sleep apnea. Additionally, this protocol provides a

method that enables participants to use a PAP machine in conjunction with both the single-channel EEG and HST system.

Participants were educated on the use of all the sleep monitoring devices during an in-person visit with a study team member. Additionally, written instructions were provided for the actigraphy device and sleep log and step-by-step instructional manuals are provided for the single- channel EEG and HST devices. The detailed instructions were tailored to the devices selected (see Table of Materials) and may vary with alternative equipment. The HST instructions were broken down in step-by-step instructions and pictures were inserted to provide a reference for proper sensor placement (Supplemental File).

During the study visit, participants were given the opportunity to apply all study equipment to get feedback on sensor placement and ensure all questions were answered prior to departure. Participants were provided a 24-hour helpline to call with any questions or concerns should they arise during testing. Study team members noted that utilization of the helpline appeared to vary by age, cognitive ability, and participant support system (e.g., if a spouse or partner attended the visit and was available to assist with the devices). Finally, participants were asked to apply the devices at home without a study team member being present.

A strength of the protocol are the novel solutions developed to solve specific problems with home sleep monitoring in older adults. One example is that the HST device has multiple sensors that need to be applied by the participant and this can seem overwhelming initially. Breaking the instructions down into step-by-step directions with pictures and eliminating steps when possible helps to simplify the procedure. For instance, sending participants home with the holster attached to the chest belt eliminates the risk that the participant may open the battery compartment and dislodge the memory card. The protocol is designed to educate the participant about the HST at the office visit by following the steps of the manual while placing the equipment on the participant's body. Afterwards, the HST is removed and participants are given the opportunity to put on the HST unassisted while using the manual. The practice session helps to clarify any steps that the participant does not understand. In addition, the study team member provides feedback about the participant's HST self-hook up afterwards.

All participants were provided a 24-hour contact number to call with any questions. They were encouraged to call as soon as an issue was identified to avoid frustration with the equipment. Participants called for a variety of reasons, but it was common for participants to call for assistance troubleshooting the equipment prior to bedtime. Some participants needed extra guidance with sensor application and others called when a light remained flashing on the HST device after all of the sensors were on the body. The study team member on call would ask questions and walk the participant through any steps needed to resolve the issue. At times, the answers were in the manual and at other times additional information was needed to troubleshoot the problem. If participants had difficulty applying sensors at the office visit, the study team offered to talk through the entire hookup process over the phone at night. The participant was asked to call when ready to apply the sensors and the study team member would talk through each step of the manual as the participant placed each wire on the body.

Participants were asked to call in the morning if the HST device did not display a complete study. Any issues that arose during the night were discussed and participants were asked if they were willing to wear the device a second night. Troubleshooting measures were reviewed as needed and the participants were encouraged to call with any questions during the hookup process or during the night. It was also common for participants to call in the morning with questions about the button on the actigraphy device. The button does not make a noise when pressed and participants had concerns about inadvertently powering the device off. Participants were reassured that the equipment was recording, and they were following the study protocol.

Another novel aspect is the success in having participants who use PAP to treat obstructive sleep apnea wear both the HST and the single-channel EEG device. This requires an adapter to measure air flow on the HST. For participants using a PAP mask with a forehead attachment, a loaner mask was provided if the participant agreed. Using this protocol allowed for assessment of participants using PAP under their normal sleep conditions both in terms of sleep staging with the single-channel EEG and obstructive sleep apnea severity with the HST.

A major limitation of the protocol is application in the clinical setting. Participant visits to review the equipment, instruction manuals, and practice runs setting up the devices take $^{\sim}2$ hours. In addition, participants are able to call a sleep technologist at night to troubleshoot problems they may experience. It would be challenging to implement this protocol in a clinical setting due to these constraints.

This protocol provides a method to successful use multiple in-home sleep monitoring devices, including a single-channel EEG and HST in older adults. To date, >300 research participants have completed this protocol. While these devices are validated, cost-effective tools, they are not a replacement for attended polysomnography. This protocol does demonstrate that a simple and low-tech introduction of instruction manuals and education can improve the success of inhome sleep studies. This same protocol can be adapted for use with other types of technology and demonstrates the importance of communication and availability for encouraging use of technological research tools in studies, particularly those involving the elderly. This also answers the increasing need for diagnostic tools to address sleep disorders and improve sleep in the general population²⁰. However, this study only considered elderly individuals and was limited to three types of sleep monitoring devices. Further protocol revisions may be needed with different in-home ambulatory equipment are needed.

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DISCLOSURES:

533 CDT, JSM, CMS, IRB, JB, and BPL: Authors have nothing to disclose.

534

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- Neither Dr. Morris nor his family owns stock or has equity interest (outside of mutual funds or other externally directed accounts) in any pharmaceutical or biotechnology company. Dr.
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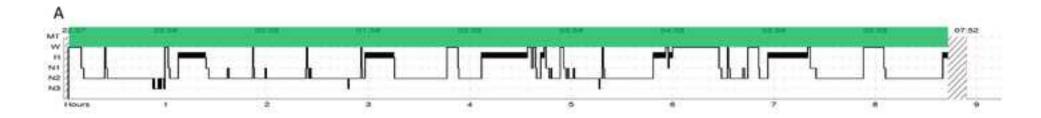
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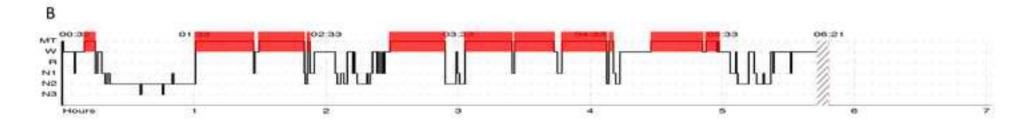
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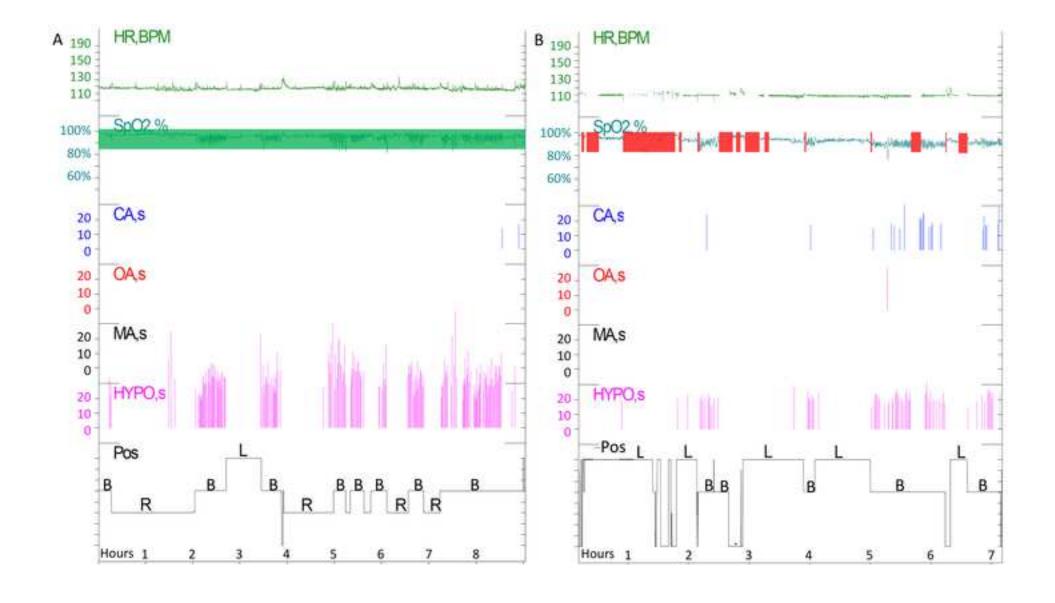


Table 1: Participants with Acceptable Sleep Studies Pre- and Post-Protocol Implementation

	Single-Channel EEG		Home Sleep Test	
	Acceptable	Unacceptable	Acceptable	Unacceptable
Pre-protocol	8	6	4	3
Post-protocol	13	2	13	3

Single-channel EEG: Fisher's exact test, p=0.11 Home sleep test: Fisher's exact test, p=0.32

Name of Material/ Equipment	Company	Catalog Number
Actigraph	Phillips Respironics	1048090
Actiware site license	Phillips Respironics	1114828
Actigraphy docking station	Phillips Respironics	1048092
Home Sleep Test (HST)	Phillips Respironics	1043941
Sleepware G3 software	Phillips Respironics	1082462
CPAP titration kit	Pro-tech	P1391
3-foot SpO2 Extension Cable (Nonin)	Phillips Respironics	927-3
SpO2 Sensor (Nonin)	Phillips Respironics	936
SD Card Reader	Phillips Respironics	1047300
EXG yoke	Phillips Respironics	1040808
Dual Snap Leg Lead Wires	MVAP	TLC0048
Small Foam Electrodes	MVAP	5000ZT
Thermistor Airflow Sensor	Pro-tech	P1388
Oral/Nasal Air flow Pressure Cannula	Saltar Labs	5760-7
Zrip DuraBelt kit	Phillips Respironics	P1837

Single-channel EEG	Advanced Brain Monitoring	SP40-1001
SP Sensor EEG kit	Advanced Brain Monitoring	SP40-4225.1
CPAP masks	Resmed	62925, 63504, 63506, 63507, 63445, 63446, 63447

Comments/Description
Actiwatch 2
Actigraphy software
Actiwatch charger
Alice PDX device
Alice PDX software
Connects PAP to HST
Oximeter cable for HST
Oximeter finger clip for HST
card reader for HST
HST cable for leg leads
leg leads for HST
electrodes for leg leads
HST thermoistor
Pressure Transducer
HST Thoracic and Abdominal belt kit

Sleep Profiler device
Sleep Profiler electrodes



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Author(s):	
, tatilot (3).	Costina D. Toedebusch, Jennith S. Mcleland, Claire M. Schaibley
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CORRESPONDING AUTHOR

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Title:	Assistant Professor
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October 29, 2018

Dr. Vineeta Bajaj:

We are pleased to resubmit our revised manuscript, "Multi-modal home sleep monitoring in older adults", for publication in the <u>Journal of Visualized Experiments</u>. We appreciate the opportunity to revise our manuscript and thank the editor and reviewers for their helpful comments. We think that the revisions have substantially improved the paper.

Please see the manuscript for our replies to the editorial comments. There are a few comments I wanted to briefly discuss.

- 1. There is no citation in the literature for the Healthy Aging and Senile Dementia project. This is an on-going program project grant that has been continuously funded since 1984. Our sleep project was added to the grant in 2014.
- 2. Regarding the question in the Representative Results section (page 10), this paragraph was deleted because it reviewed observations of the co-first authors. Unfortunately, data was not collected during the nightly phone calls from participants that would allow us to demonstrate this statistically.
- 3. Figures 1 and 2 were modified from the sleep study reports generated from the Alice PDX software. Since we purchased an Alice PDX to use in this project, we obtained a license to use the software including generating reports. We attached an email from our Phillips Respironics representative stating that we do not need further permission to publish images generated by this software.

Thank you for consideration of our work. Please contact us if there are any questions.

Sincerely,

Brendan P. Lucey, MD, MSCI
Assistant Professor of Neurology
Washington University School of Medicine
St Louis, Missouri
Email: luceyb@wustl.edu

Setting up the Alice PDX for Home Sleep Testing

Participant Instruction Book

- Position blue belt with holster around your chest under your armpits with the buckle almost centered.
- Holster should be in the center of your chest
- Belt should be snug enough that the holster will stay in the center of your chest when you toss and turn during the night.
- The arrow on belt buckle should point down.

See picture on next page





Place lanyard around your neck and adjust as needed

- Place the other blue belt around your waist.
 Belt should be snug enough that it does not slide when you toss and turn.
- Arrow on belt buckle should point down.





 Snap white box into the holster on the chest belt. You will hear 2 clicks as the box goes into

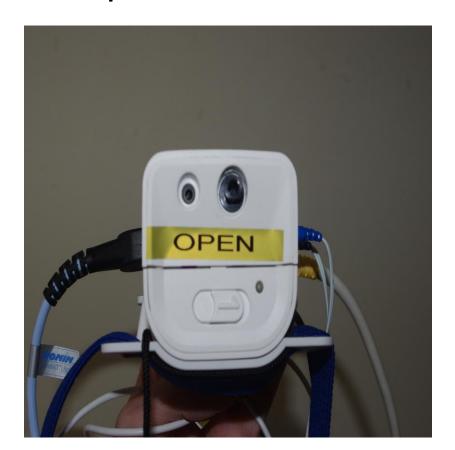
the holster.

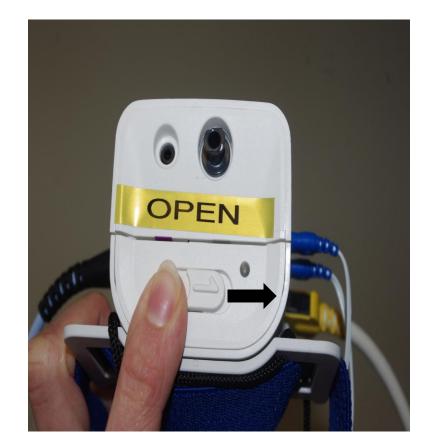
ut RESPIRONICS

"Respironics" label faces out



 Open the device by sliding the button at the top of the device





The device is already powered on. DO NOT press the power button.

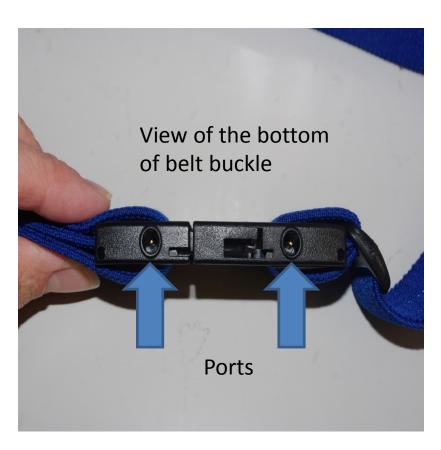


 You will see a picture of a man in the device window. All of the sensors will stop flashing when they are either plugged into the device or placed on the body.



 Plug chest (thoracic) wires into the ports on the bottom of the belt buckle.



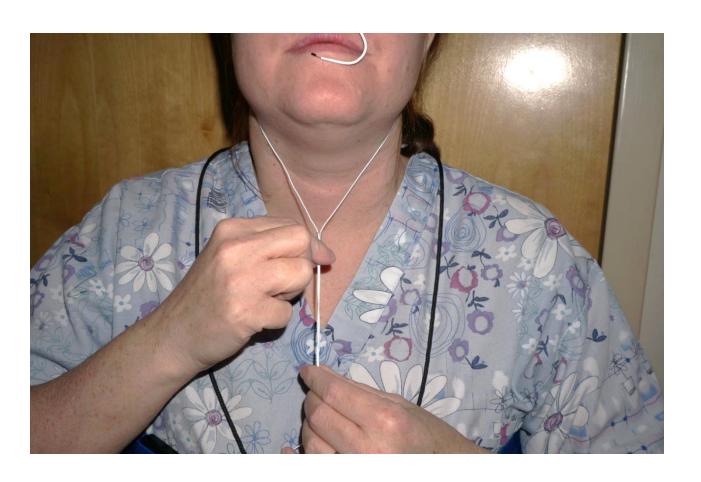




A. Place the prongs of the white wire in your nose and wrap wire around your ears.



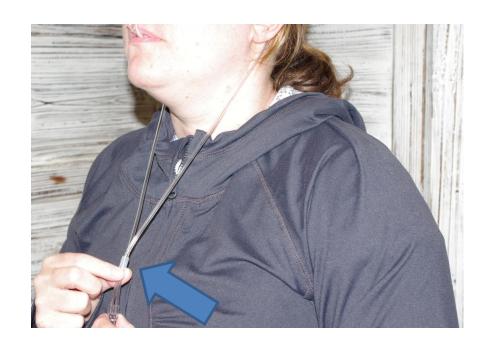
B. Pull plastic piece up by neck to secure



A. Position second set of prongs in nostrils and wrap tubing around ears. 2 prongs fit just inside the nose and 1 near the mouth.



B. Slide up plastic piece toward neck to secure





A. Run the long red and white leg wires through each pant leg to avoid getting tangled during the night

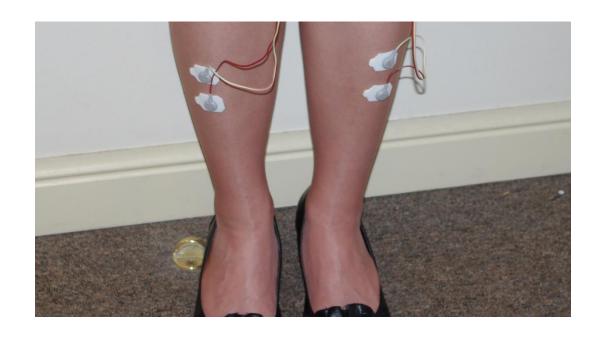
B. Use sticky patches to attach a red and white wire to each leg.

C. Flex your leg up and down to locate the muscle on the outside of your lower leg. Place patches directly on muscle. Place one patch directly above the other, at least 2 finger widths apart

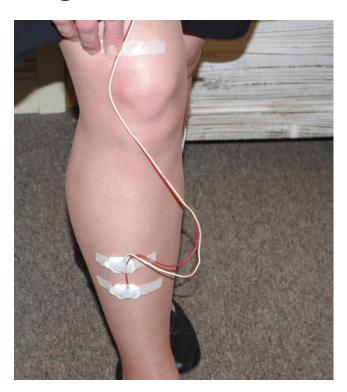
from one another.



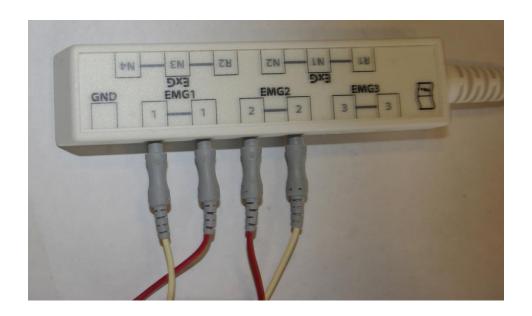
When both sets of leg electrodes are attached, it should look like this:



 Apply tape to each electrode to secure. With your knee bent (to give yourself plenty of slack in the wires) tape wire above each knee to prevent you from getting tangled in the wires.



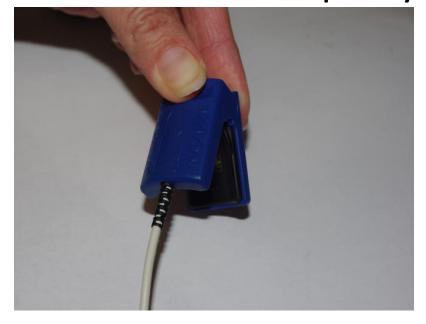
 The opposite end of the red and white leg wires should already be plugged into the accessory box



 A clip style oximeter will be used to measure your oxygen levels throughout the night.



- A. Pinch the top of the oximeter to open the clip
- B. Place the oximeter on index or middle finger
- C. Match up the picture of a fingernail on the outside of the clip to your fingernail





Wrap tape around the oximeter clip to secure



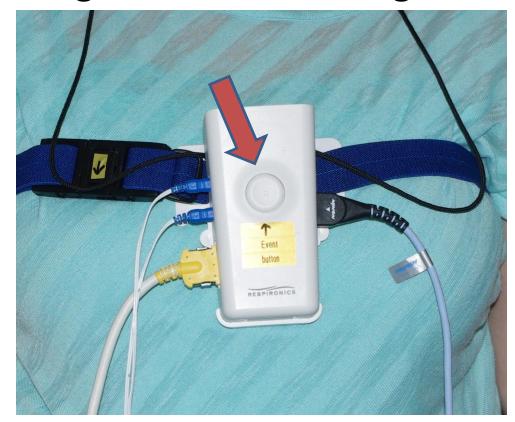
 You can tape the oximeter wire to your hand and arm. Tuck the cable in the chest belt to avoid getting tangled in the wire.

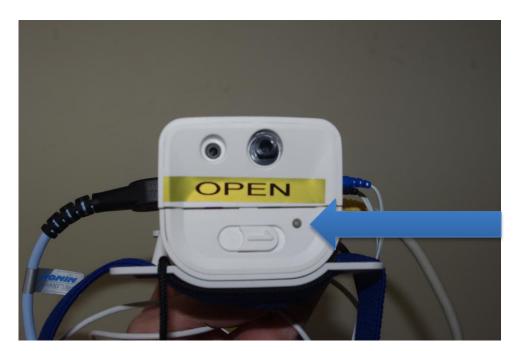


- Look at the man on the screen. No signals should be flashing.
- If any signals are still flashing, please call the research team for troubleshooting instructions.
- Once all sensors are on properly, close the device.

Press the event button on the outside of the device at lights out and again in the morning

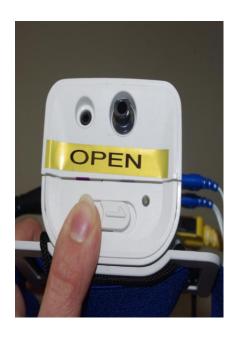
before you remove the device.



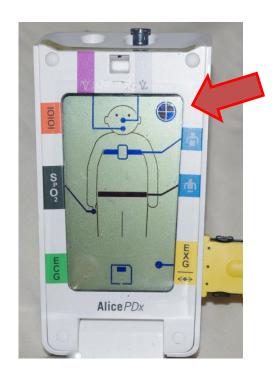


The yellow flashing light indicates that either a signal has been lost or that there is a loose connection. Open up the device to check the display. The flashing line will indicate which signal needs to be fixed. The flashing light will turn off after the issue has been fixed.

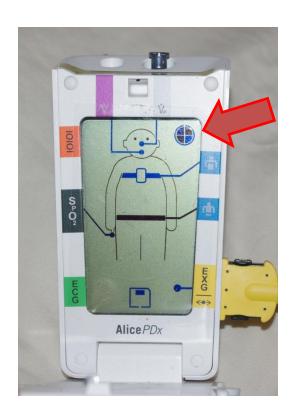
Open the device and check the good study indicator circle







All four quadrants will be solid if it was a complete study





Determine recording quality below



– Study recorded the entire night. Good recording! $\ensuremath{\mathfrak{G}}$



Study recorded ¼ of the night.



Study was incomplete the entire night.

Thursday, October 25, 2018 at 1:44:24 PM Central Daylight Time

Subject: FW: question for manuscript

Date: Thursday, October 25, 2018 at 1:12:19 PM Central Daylight Time

From: Toedebusch, CristinaTo: Lucey, BrendanCC: McLeland, Jennifer

See below

Cristina Toedebusch CCRC, RPSGT Clinical Research Coordinator ASTEP Technical Director Washington University Sleep Medicine Center (314) 747-0646 phone (314) 747-3814 fax

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From: Crabtree, Todd [mailto:todd.crabtree@philips.com]

Sent: Wednesday, October 24, 2018 6:57 PM

To: McLeland, Jennifer **Cc:** Toedebusch, Cristina

Subject: Re: question for manuscript

Hi Jenny,

With your purchase, you have rights on the software and can use images from studies as needed.

Todd Crabtree, BS CRT Senior Clinical Specialist Philips Respironics Cell: (816) 519-3811

Email: todd.crabtree@philips.com

On Oct 24, 2018, at 5:56 PM, McLeland, Jennifer < mclelandj@wustl.edu > wrote:

Todd-

I have a bit of a random question. We are preparing a manuscript for publication which includes an image of the PDX hypnogram that shows oximetry. Does Respironics have a policy regarding the use of images from the PDX report in publications? I'm unsure if we need permission to use the image.

Thanks! Jenny

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