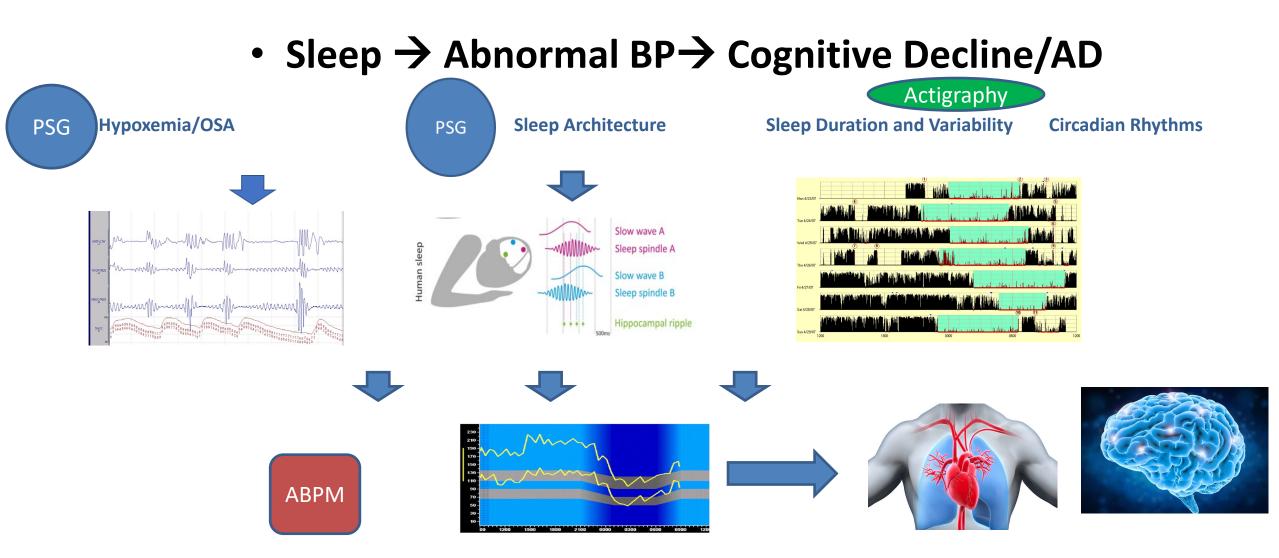
MESA Sleep Exam 7 Training Wrist Actigraphy, ABPM, and Neck



Goals for Today

- Overview of Actigraphy, Neck Circum, Sleep Diary, and ABPM – Overview of protocol, equipment, participant interaction
- Initial certification
 - Understanding of equipment, set up, ppt interaction->ABPM, Neck
 Circum
- To be covered later
 - Actigraphy
 - Initialization/download/transfer
 - Polysomnography

MESA-MIND-Sleep: Rationale



MESA-MIND-Sleep: Rationale

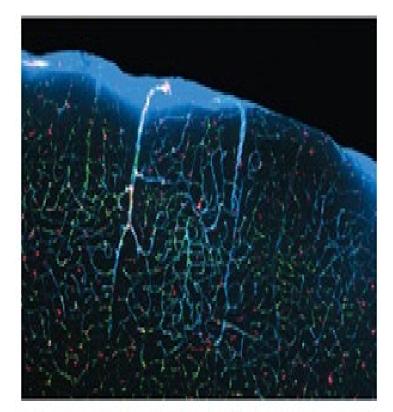
Impaired drainage in the glymphatic system, oxidative stress, inflammation, vascular stiffness, nocturnal surges in BP, altered cerebral blood flow, circadian misalignment



Accumulation of toxins (*Aß, tau*) Neurodegeneration, reduced brain volumes, disturbed anatomic microstructure, and impaired synaptic plasticity



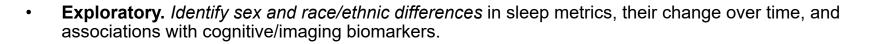
Cognitive impairment, cognitive decline, AD/ADRD

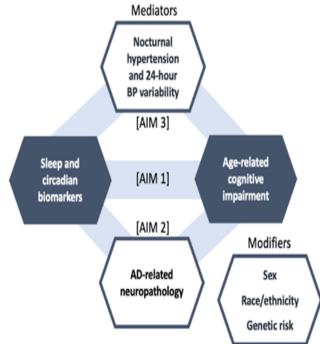


Cerebrospinal fluid (blue) flows through the brain and clears out toxins through a series of channels that expand during sleep. *Maiken Nedergaard*

Specific Aims

- Aim 1. How do sleep and rhythms change over 10 years (Exams 5 and 7) and do those changes predict cognitive decline and incident AD/ADRD?
- Aim 2. Which aspects of sleep associate with Alzheimer's Disease brain imaging markers and do they lead to cognitive deficits?
- Aim 3. Role of overnight blood pressure as a mechanism for sleep-related cognitive impairment?



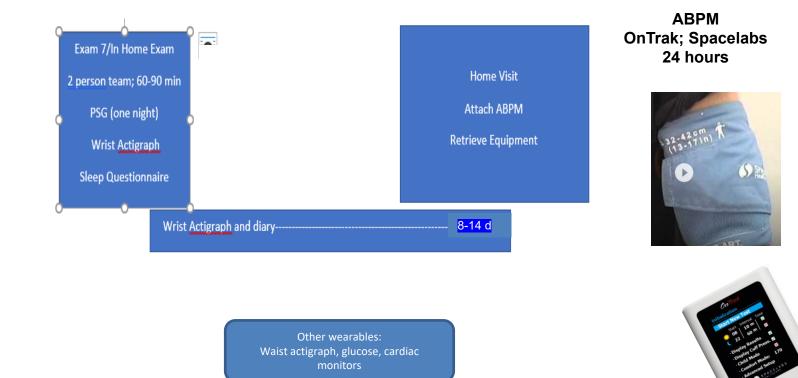


Protocol

• Targeting n=1800 Exam 7 (3-4 ppts/week per site)/No exclusions

NOX A1 PSG System (Overnight*1)





GeneActiv Wrist Actigraph 8-9 d



Sleep Questionnaire/Diary

Covid-19 Contingencies

 Self-applied mailed PSG



Wrist Actigraphy

- GENEActiv[®] actigraph
- Wrist-worn: wake-sleep patterns estimation
- 24h measurement of activity, light and temperature



- Data downloaded to computers
- Algorithms convert average movement to sleep wake "epochs"

Wrist Actigraphy

- Can be worn for days to weeks
- Aim in MESA: wear for 8-9 consecutive days

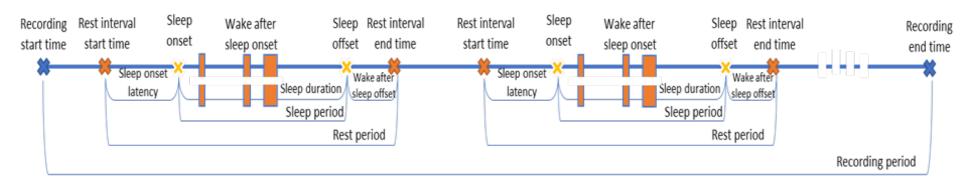
 Optimally coincides with both PSG night and 24 ABPM
- Waterproof

 \odot Instruct participant to try to keep skin dry

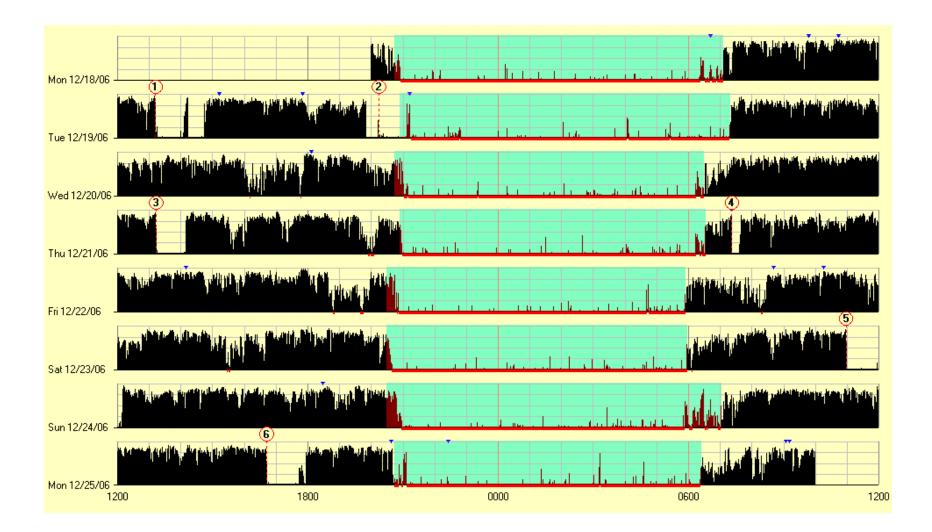
- Light (lux) data collected
 3 wavelengths
- Time off wrist identified

Wrist Actigraphy

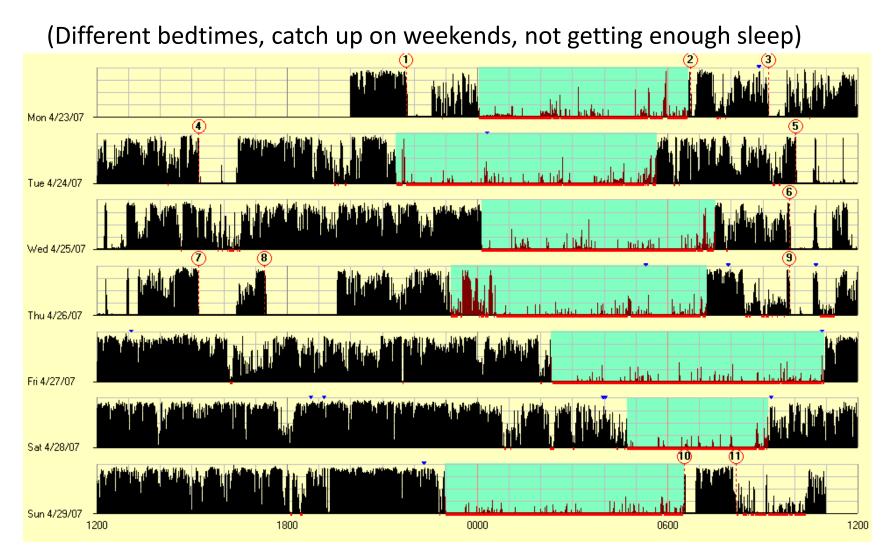
- Each "epoch" (time interval) has an activity measure
- Epochs that exceed thresholds-> wake
 - $\,\circ\,$ Total Sleep Time
 - $\,\circ\,$ Sleep efficiency % time in bed asleep
 - \circ Wake After Sleep Onset (WASO)
 - \circ Napping
- Provides complementary information to PSG
 - **Reliable** estimate of usual sleep patterns



Normal Sleep Wake Pattern- Actigraphy



Poor Sleep Hygiene



MESA Wrist Actigraphy: Set Up At Field Site (Pre-Visit)

- Ensure device is fully charged
- \circ Set the Measurement Frequency (60 HZ) and Measurement Period (12 days)
- Select "Local PC Time"
- Select "At Future Time" and enter date and time of visit
- Enter participant MESA ID and study date in the "Subject Code" field (no other identifier)
- $\circ~$ Select the appropriate GENEActiv device in the "Devices" field
- Click the button "Erase and Configure"
- o If configuration was successful, remove device from charging cradle
- Complete Wrist Actigraph Device Completion Form (p. 3)
 - $\circ~$ Shared document with 24H-ACT ~



MESA Wrist Actigraphy: Home Visit

- Explain purpose of the actigraph (no GPS)
- Explain how to wear it (non-dominant wrist)
 - $\circ~$ May help ppt find most comfortable fit
- Stress need to remove only for specific circumstance (Ptt. Instructions)
- $\circ~$ Explain how to use the "Event Marker"
- \circ Keep watch exposed to light
- \circ No heavy clothing under watch
- $\circ~$ Explain concurrent sleep diary. Fill out Day 1 with participant
- $\circ~$ Wear from set up until scheduled for return
- $\circ~$ Explain how to return the device and sleep diary



Wrist Actigraph Information & Instructions

> What is an actigraph?

This small device records information about body movement during everyday activities such as walking and sleeping. The actigraph is safe and uses a battery similar to a watch battery for power. It is **not** a GPS tracking device, nor does it record heart rate.



> What am I supposed to do with the actigraph?

The actigraph will start recording data today and will continue to record 24 hours a day for 8 to 9 days.

1. We ask that you wear the monitor for the full 8 days, all day and night. It is worn on the **non-dominant wrist** like a watch and should fit snugly around your wrist.

2. The monitor is water-resistant so it can be worn when taking a bath, shower, or swimming. If the monitor and wrist strap get wet, you may blot them dry with a towel and dry the skin under the monitor.

3. If you must take the actigraph off for any reason, remember to put it back on the same wrist as soon as possible.

If the actigraph is removed, please keep it away from small children and pets to avoid accidents.

5. Please firmly press the hidden event marker button under the six-digit number when you are trying to fall asleep and at your final awakening.



> Who do I contact if I have questions?

If you have any questions about the monitor, please call the sleep study project coordinator.

MESA Wrist Actigraphy: After Data Collection

• Retrieval

- $\circ~$ Site specific- mailing, courier, direct retrieval
- Coordinate across home-based ancillary studies
- Get the device back as soon as possible

Download and transmit data

- $\circ~$ First create a folder for each participant
- Name the folder using the Participant ID and study date (YYYYMMDD)
- $\circ~$ Download and store .bin file in the folder
- Transmit folder to the CC
- Complete the Wrist Actigraph Device Complete Form (p.4)
- After the SRC confirms, can initialize for next ppts

Clean actigraph

- Wipe with cavi-wipe or similar disinfectant
- Maintain actigraph tracking log (serial numbers)

Certification Requirements

- 1. Obtain Training by SRC Staff (or local staff trained by SRC Staff)
- 2. Read the Sleep Manual of Operations/ View Video
- 3. Successfully demonstrate how to:
 - Initiate the GENEActiv device for recording
 - \circ $\,$ Explain to participant instructions on device use
 - \circ $\,$ Explain to participant how to complete Sleep Diary
 - Collect at least 24 h of data in a non-participant volunteer
 - Download GENEActiv device data
 - Transmit GENEActiv data to the CC

Potential Problems

• Participant Errors

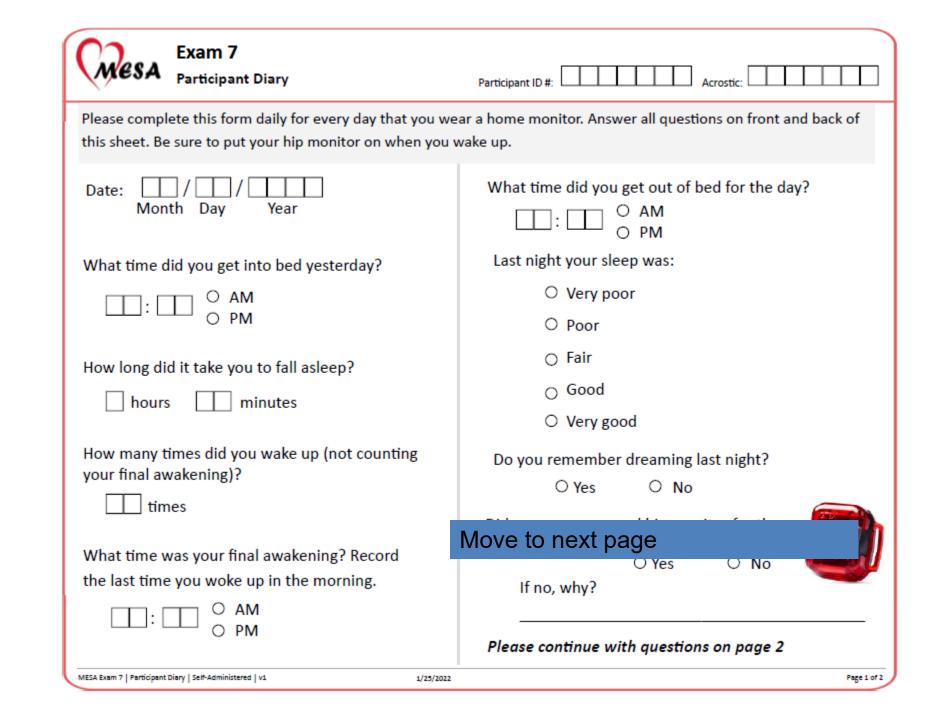
- \circ Removed watch in the evening
- $\,\circ\,$ Removed watch and forgot to reapplied it
- If collection is < 5 nights, ask participant to re-wear

• Technician Errors

- $\,\circ\,$ Not selecting correct measurement frequency
- Not creating database for each participant
- Watch Failures
 - \circ Wrong Time
 - \circ Failure to record
 - Battery not charged

MESA Exam 7 Training Participant Diary

BWH Sleep Reading Center January 2022



While wearing the watch, we ask you to complete a Participant Diary, indicating the times you went to bed, woke up, sleep quality, and whether you had dreams.

Beware of midnight!

Exam 7 Participant Diary	Participant ID #:	Acrostic:					
Instructions: Complete this form daily. Answer all questions on front and back of this sheet.							
Did you take a nap today?	What time did you	ı eat today?					
⊖ Yes ⊖ No ↓	Breakfast:	: . O AM O PM					
Nap 1:	Lunch:	: . O AM O PM					
Start time End time Image: I	Dinner:	:					
Nap 2:	Snack 1:	□ : □ ○ AM ○ PM					
Start time End time :	Snack 2:	: . O AM O PM					
Nap 3: End time Start time \bigcirc AM \square : \bigcirc PM	Snack 3:	:					
	Snack 4:	:					
MESA Exam 7 Participant Diary Self-Administered v1 1/23/2022			Page 2 of 2				

MESA Exam 7 Training Neck Measurement

BWH Sleep Reading Center January 2022

Neck Circumference Protocol

Purpose:

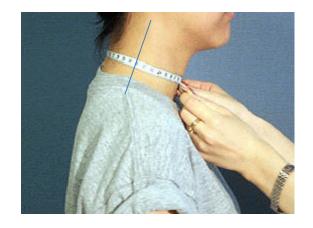
To obtain neck circumference

Method:

- 1. Have Participant stand or sit with the head in the Frankfort horizontal plane.
- Measure neck around the neck at the point below the 2. Adam's apple (thyroid prominence). Hold tape perpendicular to long axis of neck
- In women, use a point mid way along the neck. 3.
- Take the neck circumference three times and record 4 each.
- 5. Round the measurement to the nearest 0.1 centimeter.

Horizontal plane

Frankfort

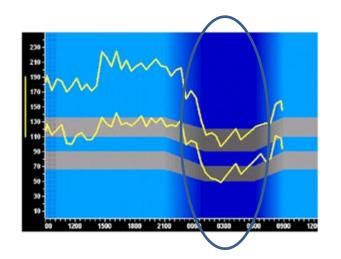


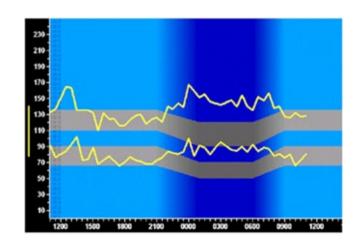
MESA Exam 7 Training 24 ABPM



Why 24 hour BP?

- Reduces "white coat" HTN
- Multiple measures- more reliable than clinic
- Can identify abnormal patterns—non-dipping
 - Less than 10% reduction during sleep





Recruiting to ABPM

We invite you to participate in a substudy called the MESA Sleep Study. [If appropriate: As you may recall, you participated in the MESA Sleep study a few years ago]. This part of the MESA Sleep study investigates the effects of blood pressure patterns on heart disease and brain health. Blood pressure may vary a lot of the day and night therefore a single blood pressure measurement in clinic alone may not tell us all we need to know about the level of blood pressure over the day and night. Measuring blood pressure multiple times during the day and night may help us understand which people are at most risk for problems related to high blood pressure, such as stroke. Identifying differences between night and day blood pressure also may help us understand how sleep problems influence blood pressure. If you agree to participate, we will schedule a home visit that will take about 30 minutes to attach the blood pressure device. This blood pressure monitor measures your blood pressure every 20 minutes over the day and every 30 minutes overnight. You also will be asked to use the wrist actigraph and complete a Diary. You will wear a light blood pressure cuff and carry a small box on your waist for 24 hours, including sleep. You will take it off to bathe or shower. The blood pressure monitor could be uncomfortable, and the blood pressure cuff will cause pressure when it inflates on your arm like what you feel when your blood pressure is checked in clinic. Very rarely, the blood pressure cuff can cause bruising in the arm. You will fill out a form to record your sleep times. After you return the blood pressure monitor, we will reimburse you \$50 for this part of the study. We ask that you don't exercise heavily or go swimming the day of monitoring. After the blood pressure information is analyzed, we will provide you a report that you -and if you wish- your doctor can use to understand your day and night blood pressure.

MESA ABPM: Pre-Home Visit

• Prepare the ABPM device prior to home visit:

- Ensure **two new AA batteries** are inserted into the OnTrak device
- Check prior arm circumference from clinic exam, record on form
- Configure OnTrak monitor for data collection using Sentinel software
 - Create a participant record via the "Patients" menu
 - Configure monitor with correct MESA Sleep collection protocol settings

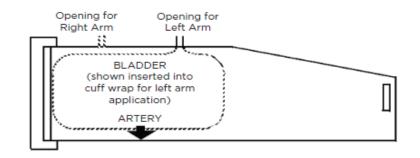
MESA ABPM: At Home Visit

- At home visit:
 - Explain purpose of the 24 h ABPM

This visit will take between [30 and 45] minutes. We will first review the use of an ambulatory blood pressure monitor and how information collected from it is used. We may recheck your arm size to select the blood pressure cuff that fits you best. We then will fit the ABPM cuff on your arm and check two blood pressure readings- to make sure the device is working correctly. If needed, we will adjust the cuff and repeat the blood pressure check. We will show you how to remove the cuff and device and stop recording if needed. We will show you how to carry it and sleep comfortably with it. We will talk about how to return it.

MESA ABPM: At Home Visit

- At home visit:
 - Explain purpose of the 24 h ABPM
 - Ascertain which arm to use for the ABPM
 - Measure (or check prior) arm circumference
 - Select the appropriate cuff size (ABPM Home Tracking & Alert form)
 - Check that the bladder is inserted correctly into the cuff wrap
 - Identify the pulse maxima of the brachial artery and draw a dot
 - Place appropriately sized cuff cover on the arm
 - Apply the selected cuff over the cover (arrow printed on the cuff must point at the dot)





MESA ABPM: At Home Visit

- At home visit (*continued*):
 - Place cuff about 2 cm above the crease in the elbow, with tubing going up toward the shoulder
 - Offer participant a belt or a strap to carry the device
 - Explain how to turn on/off and remove device, and how to replace the device and turn on to resume BP readings
 - \circ $\;$ Explain how to power off device and return the device to study site
- At the home visit (*after OnTrak has been placed on participant*):
 - \circ $\,$ Connect the cuff tubing to the port on the top of the OnTrak monitor
 - Power **ON** the monitor by pressing and holding the **Action button** for 3 seconds
 - Device will be powered on in "Office Check" mode
 - Obtain two manual BP readings before the 24-hour data collection begins
 - Record first and second manual reading from the OnTrak on the ABPM Home Tracking & Alert form
 - Take the device out of "Office Check" mode to start the 24-hour recording by pressing the Action button to start a third reading, and then pressing the Action button again to interrupt the reading.





The ABPM will begin measuring blood pressure after the blood pressure cuff is placed and the unit is powered on and will continue recording for the next 24 hours. You should carry the ABPM with you all day and night for this time period.

Before the machine starts to inflate for daytime readings, there will be a beep. Please sit down if possible and don't cross your legs, place your arm at the level of your chest, and rest (if you can't sit, please stay still standing). Please do not talk, eat, or drink while the cuff is inflating and try to stay still for the few minutes that it takes for the machine to take your BP. When the cuff gets tight and/or the tone sounds, <u>STAY STILL and KEEP YOUR ARM STILL</u> until the cuff is loose again. For nighttime readings, the monitor will not beep before the cuff inflates to measure blood pressure.

When you go to bed, please remove the monitor from its pouch and place on a folded towel on your mattress. Then put a small pillow (or another towel) over the monitor to muffle the sound. When you wake up, please put the monitor back in its pouch and attach the pouch to the belt or strap. Continue wearing the monitor until XXX. You can then take it off and place it in the box to pick up or mail back. Please put all supplies- belt, strap, monitor- in the box.

If the cuff does not deflate, remove the cuff, turn off the device, let the cuff deflate, reattach the cuff, and turn the device back on by pressing the Action button for 3 seconds. If at any time the cuff becomes uncomfortable while it is inflating, press the Action button to stop the blood pressure reading. The cuff should deflate until the next scheduled reading time. Follow the instructions for powering off the device if you need to temporarily suspend blood pressure readings to take a bath or shower. After your bath or shower, replace the cuff and then press the Action button for 3 seconds to turn the monitor back on and resume readings. If you have problems replacing the cuff or it does not seem to be working, please call your clinic staff number.

While wearing the monitor, check that the tubing from the cuff is not twisted or bent.

Please, treat the equipment gently. Please, no hard knocks, bumps, or drops. And please do not bathe or shower with the device attached to you.

24 Hour Blood Pressure Home Monitoring Instructions

To understand your day and night blood pressure patterns, we ask that you wear a blood pressure cuff for approximately 24 hours- from the time it is placed until one day later. Please don't remove the cuff until _____. The cuff will inflate about every 20 minutes during the day and every 30 minutes at night.

Some tips while wearing the monitor:

- During the day, before the monitor starts to inflate, there will be a beep. Please sit down and don't cross your legs (if standing), place your arm at the level of your chest, and rest (don't talk during cuff inflation). At night, there will not be a beep before the monitor start to inflate.
- When the cuff gets tight and/or the tone sounds, <u>STAY STILL and KEEP YOUR ARM</u> <u>STILL</u> until the cuff is loose again.
- 3. While wearing the monitor, check that the tubing from the cuff is not twisted or bent.
- 4. Treat the equipment gently. Please, no hard knocks, bumps, or drops.
- 5. Keep the equipment dry. Remove the cuff when showering or bathing.
- 6. Try not do to do heavy physical activity during the day you wear the monitor.
- During sleep, take the monitor out of its pouch, place on a folded towel, and cover the monitor with a pillow or towel (to muffle the sound). You may place the monitor under a pillow or at the side of the bed.

Stopping a Reading or Pausing Readings:

If at any time the cuff does not deflate or becomes uncomfortable, press the Action button to stop the blood pressure reading. The cuff should deflate until the next scheduled reading time. If the cuff does not deflate, remove the cuff, and follow the instructions below to power off the monitor. The following steps should also be used if you need to temporarily suspend blood pressure readings for the purposes of taking a bath or shower.

To Power Off:

- 1. Press and hold the Action button for 3 seconds.
- A message will appear on the monitor display asking you to confirm your decision to power the unit off.
- 3. Press the Down arrow button once to highlight the "Yes" option.
- Press the Action button once to confirm the selection, and the unit will shut down. Wait for the cuff to deflate.

To Power On and Resume Readings:

 Put the cuff back on your arm as described below in "Replacing the Blood Pressure Cuff."



MESA ABPM PPT INSTRUCTION SHEET

- Press and hold the action button for 3 seconds to turn the unit back on. An audible beep will confirm the unit has powered on.
- Wait approximately 10 seconds and then press the action button. The cuff will inflate, and the monitor will take a blood pressure reading.
- 4. The unit will automatically resume readings.
- If the unit did not power on or would not take a blood pressure reading, please contact a study staff member for instructions.

Replacing the Blood Pressure Cuff after removing it:

- 1. Hold your arm out with your palm facing up.
- The cuff will be inside a soft cover and should not be removed from the cover. Wrap the cuff around your arm with tubing pointing up towards the shoulder.
- Point the arrow on the cuff toward the center of your arm near the bend inside of your elbow as shown in the image (and over the spot that the MESA research assistant showed you). Tighten the cuff so that it is snug and stays in place but is not uncomfortably tight.
- Bring the tubing behind your neck and down the other side of the front of your body toward the waist.



- Hold down the round Action button located on the front of the monitor for 3 seconds until a beep is heard. The monitor will switch on within 7 seconds.
- 6. Push the round Action button to inflate the cuff and start readings

Remember: We want **awake and asleep** blood pressures, so it is important to wear the monitor for 24 hours. <u>HOWEVER, do not wear the unit into the bath or shower. Follow the instructions for suspending readings, and please remember to put the monitor back on after your bath or shower.</u>

When you are finished wearing the monitor, take the monitor off and follow the instructions to power off the monitor. Follow the instructions provided by the study staff to return the monitor.

FAQs: ABPM

• Do I need to do anything different because I'm being tested? No. Because the test is being carried out to find out what your normal daily blood pressure is, please continue your normal routines. However, you should avoid heavy exercise such as going to the gym or running.

• What clothes should I wear for the appointment? You should wear loose clothing, preferably a short-sleeved top. The monitor will be fitted underneath your top. You may wear loose bed clothes with short sleeves if you don't plan to go out after the visit.

• Do I have to sleep with the monitor on? Yes, this will help us understand what your blood pressure is doing while you are sleeping. However, the recorder can be placed next to you on the mattress or a bedside table while you are sleeping.

• May I take a bath/shower whilst undergoing monitoring? It is best not to shower or bathe during the day that the blood pressure monitor is used. If you take a bath or a shower you will need to take off the monitor and cuff as these are not waterproof and you must not get them wet.

• M

• ay I exercise with the monitor on? *Please try not go to the gym or exercise heavily while the monitor is attached. A gentle or brisk walk is fine.*

MESA ABPM: After Data Collection

Retrieval

- Site specific- mailing, courier, direct retrieval
- Coordinate across home-based ancillary studies
- $\circ~$ Get the device back as soon as possible

Clean ABPM and inspect for damage

- Wipe with warm water/soap solution to remove visible soil
- Wipe with a PDI Sani-Cloth wipe or similar disinfectant
- Belts and bladder covers can be washed in water/soap solution

Download and transmit data

- Log into Sentinel software
- Connect ABPM device to computer
- Follow MOP instructions for ending test and downloading ABPM data
- Export the recording from Sentinel software
- Locate exported recording and transmit to CC
- Maintain ABPM tracking log (serial numbers)



Spacelabs H	lealthcare - Sentinel: ABP Downlo	ad $ imes$	
	Do you want to download the recording into the following test?		
64	Organization:	Brigham and Women's Hospital	
	Patient ID:	9012345	
	Name:		
	Date of birth:		
	National ID:		
	Hookup technician:	BWHStaff001	
	Download status:	Not downloaded	
	Recording details		
	Security ID:	112e55ac67964638b814e3f66a1becec	
	Measurements:	5	
	% Valid:	80%	
	Total duration:	00:42:00	
	Recorder details		
	Recorder:	Spacelabs Healthcare OnTrak	
	Serial number:	227-014190	
	Firmware version:	1.10-4.33-1.30	
	Battery status:	ОК	
	Manually identify	OK Cancel	

24 h ABPM Tracking and Alert Form

	icipant ID #:			
Form	chnician ID: Date:/// Month Day Year			
1. Record date and time at Attachment	2. Record date and time at Removal			
Date: Month Day / Year	Date: Month / Day / Year			
Time: O AM O PM	Time: O AM O PM			
3. Arm circumference:	4. Cuff size: Small adult (17 - 26 cm) Adult (24 - 32 cm) Large adult (32 - 42 cm) Extra large (38 - 50 cm)			
5. ABPM reading at attachment (check the arm used for final attachment): Select one: O Right arm O Left arm 1 st reading SBP DBP Pulse SBP DBP Pulse Note: The ABPM monitor will inflate the cuff twice at attachment. Record first and second reading. Use the 2nd reading to determine alert in next section.				
6. Alerts and Referrals 6.1. Manual Blood Pressure using ABPM device (awake, seated, 2nd reading) Blood Pressure Values Action				
1. Systolic blood pressure > 210 mmHg	Immediate referral to the PI or a health care provider?			
-OR- Diastolic blood pressure > 120 mmHg	O Yes → Date: ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓			
2. Systolic blood pressure 180-210 mmHg -OR- Diastolic blood pressure of 110-120 mmHg	Was the participant notified? O Yes \longrightarrow Date: O No \longrightarrow No \longrightarrow N/A Month Day Year			
Comment of action taken:				

Mesa	Exam 7 24h ABPM Home Tracking and Alert Form	
Was an alert receiv	e using ABPM device (average 24 ed from the Reading Center? • Date alert was received:	h BP)
-OR-	ystolic blood pressure ≥ 180 iiastolic blood pressure ≥ 110	Action Was the participant notified? ○ Yes → Date: Month Day / Year ○ No Year
		ninistered v1 1/20/2022 Page

Participant Feedback/Medical Alerts

- Studies scored within 2 business days of receipt.
- Similar to Exam 5, ppts will receive a feedback letter summarizing key results of their sleep studies, and now ABPM results, including an explanation of typical ranges and general health recommendations.
- Urgent Alert notifications will be e-mailed to the FC study coordinator (cc FC PI). The FC PI reviews this information, including information on known conditions and treatment, and then contacts the participant (and their physician) as indicated to expedite referral.

Potential Problems

• Participant Errors

- Removed ABPM
- Reapplied it in wrong position
- o If incomplete data, ask participant to re-wear

• Technician Errors

- Participant record not created correctly
- ABPM device not initialized correctly per protocol
- \circ $\,$ New batteries not inserted prior to data collection $\,$
- Data download not performed properly
- Data not exported correctly to proper file format
- Batteries not inserted into device prior to data collection
- $\circ~$ Data not successfully transmitted to CC

• ABPM Failures

- \circ Wrong Time
- $\circ~$ Failure to record

Certification Requirements

- 1. Obtain Training by SRC Staff (or local staff trained by SRC Staff)
- 2. Read the Sleep Manual of Operations/ View Video
- 3. Complete a practical and a written exam
- 4. Successfully demonstrate how to:
 - Initiate the ABPM device for recording
 - Explain to participant instructions on device use
 - Collect at least 24 h of data in a non-participant volunteer
 - Download ABPM device data
 - Transmit ABPM data to the CC

Participant Feedback/Medical Alerts

Key medical alerts:

- PSG:
 - AHI > 50 (and not currently being treated for OSA)
 - > 10 % of the recording time at an oxygen saturation < 85%
 - > 2 continuous minutes in which heart rate is < 30 or > 150 BPM
 - Atrial fibrillation of any rate not previously noted or known atrial fibrillation with ventricular rates <50 or > 120; second or third degree AV block
- ABPM:
 - 24 hour SBP <u>></u> 180/110 -> Urgent
 - At placement: If >180/>110, BP will be rechecked after 15 mins (assuming asymptomatic). If still elevated but < 210/<120 the ppt will be advised to call their physician within the next 24 hrs (if none, referred for the ER). If >210/120 or symptomatic, contact site PI/MD- advise ppt immediately contact their physician or go to the ER.

MESA Exam 7 Training NOX PSG

BWH Sleep Reading Center January 2022

PSG Training Plans

- Install Software
- Arrange video training
- Pilot studies/certification



Questions and Feedback?

Many thanks to the entire MESA "family"!!!

