

ACTIVITY MONITOR

1. Background and Rationale

The equipment that will be used for this study, the Body Monitoring System by Body Media, includes an activity based device called the SenseWear armband which measures energy expenditure. The armband is a small comfortable device worn on the back of the upper arm and monitors various physiological and movement parameter. The activity monitor will be worn for at least 5 24-hour periods on the participant's upper right arm against the skin (at tricep level). In order to ensure the device is worn for this length of time, the participant will stop wearing the armband on the 7th day. The device utilizes a unique combination of sensors that continuously gather the following data: movement, heat flow, skin temperature, ambient temperature and galvanic skin response. Total energy expenditure (TEE), active energy expenditure (AEE), METs, total number of steps, physical activity duration (PAA), sleep duration, and lying down, can all be calculated from the data the sensors gather. The Body Monitoring System and the SenseWear armband have been scientifically-validated and has been used successfully by clinical and research departments worldwide.

To allow for longitudinal comparisons, the same equipment and protocol that was used at Visit 3 will be used at Visit 4. Both those participants who return to the clinic for Visit 4 and the SAQ onlys should be asked to wear the activity monitor.

2. Equipment and Supplies (per box)

- **One Monitor SenseWear armband**
- **Two adjustable straps (normal and large) with velcro tabs (extra straps can be ordered)**
- **One USB cable**
- **Two AAA batteries (1 per unit)**
- **InnerView software (used for initializing the armband and downloading data)**

3. Copying InnerView Software to computer

The software can be found on the PSG IVE site <http://ive2.sfccc-cpmc.net/mros> under the site specific MROSAccel Activity Monitor folder. You must be an authorized user to have access to this site. Click on InnerView 5.1, then click on Innerview5.1.exe and click on run. This will download the program to your C: drive. Once files are downloaded click on the InnerView.exe icon to open the program.

4. Armband Initialization Procedures

Participant's current height, weight, handedness, smoking status and subject ID are required to initialize the activity monitor. If height is measured using the MrOS stadiometer and the 1st and 2nd measurements are within < 4mm apart, please use the 1st height measurement for initializing the armband. If the 1st and the 2nd measurements are 4

mm or more apart, then measure height two more times, per MrOS Visit 4 Height Protocol, and use either the 1st or 2nd height measurement that is closest to these measures to initialize the armband.

For initializing the armband, height can be measured with any stadiometer; however, if the height measured is off by 4 mm or more compared to both the 1st and the 2nd height measurement made by the MrOS stadiometer, then the armband will need to be reinitialized using the measurement from the MrOS stadiometer (see above paragraph on which measurement to use).

For those doing SAQ only who agree to wear the monitor, height and weight will be self-reported over the phone and filled in on the Activity Monitor Checklist form. If the participant does not know their height and weight, but is able to provide it at a later date, then they can still wear the armband; however, the information will need to be entered in when the data is retrieved from the armband and sent to the Coordinating Center. If the parameters for the armband (height, weight, handedness and smoking) cannot be collected from the participant, then they should not wear the armband.

For smoking status and handedness, all participants wearing the armband should answer Questions 3, 4, and 5 on the Activity Monitor Checklist form. If a participant answers yes to either question 3 or 4, then they should be considered a smoker. For handedness, please use the hand they predominantly use for writing.

The following procedures should be followed for optimal armband use and output:

- 1) Prior to initialization, verify that the AAA battery in the armband is new. A new battery should be placed in the device for each participant. It is ok to use rechargeable batteries.
- 2) Clean the device sensors with a soft cloth dampened with 70% isopropyl alcohol. Allow to dry for 5-10 minutes before wearing.
- 3) The adjustable straps should be hand-washed with mild soap and water and air dried.
- 4) Connect one end of USB cord to device and the other end to the computer. You should hear a beep which confirms a connection. If you do not hear a beep press the button on the front of the device once.
- 5) Open InnerView program and check the box "Via USB Cable" (this should be the default).
- 6) Click on Configure SenseWear and then Retrieve Configuration.
- 7) SenseWear Parameters will pop up and possibly a warning that states the computer clock is out of sync with the armband clock. Confirm that computer clock is correct and then click Apply to update the clock.
- 8) Check that both Battery Life and Memory Available are 100%. If they are not at 100%, replace battery and clear the data and patient information from Sensewear armband. This can be done by clicking on "Clear Data & Subject Info" on the SenseWear Maintenance drop down list.
- 9) Reboot armband by clicking on SenseWear Maintenance tab and then on Reboot SenseWear.

- 10) Write down Serial Number on the Activity Monitor check list form. The serial number can also be placed on the front of the armband using a removable sticker (this will be a clinic based decision).
- 11) Click on Subject Info tab and enter participant's information. Participant ID + ACROSTIC should go in the Subject field (e.g. PO1010ABCD).
- 12) Click Apply and OK to finish initializing the device.
- 13) Check to make sure initialization took place by retrieving configuration and confirming participant information, date and time are all correct

Things to note:

- **We recommend the armband be checked at least once prior to being used for the first time. This means initializing and wearing the armband for approximately ½ hour and then retrieving the data to ensure the device is collecting data. The device should be cleared after being checked.**
- **The initialization procedure for the participant should take place as close as possible to the time the armband is given to the participant (within at least five hours).**

5. Wearing the Armband (Data Collection)

1. The participant will be instructed to wear the armband for 7 days, removing it on the morning of the 7th day. Each participant should be oriented to procedures for wearing the activity device. The devices will be distributed at the patient's clinic visit.

At the visit the participant will receive:

- SenseWear Armband
- Adjustable strap
- Information Sheet
- Activity Diary forms. The day # and dates for the diary should be filled out by the clinic staff prior to giving to the participant. The day # fields should be filled in as day 1 to day 7. For SAQ onlys just the day #s will be filled in by clinic staff and the participant will fill in the dates.
- Mailing supplies to return the armband (if clinic is not picking up the armbands)

Before scheduling the participant to wear the armband make sure they know that the week in which they are being monitored should be a **“typical”** week with respect to their activity level. They should not be going on vacation or engaging in atypical levels of activity, either more sedentary or more active than usual.

If a participant is unable to wear the monitor at the time of the clinic visit due to upcoming unusual activity they should plan on wearing it within 30 days of the visit.

If participant has a disability in their right arm (i.e. paralysis, amputation) or if he or anyone in his household uses oxygen then the participant can not wear the armband. No data will be collected. Please fill out the Activity Monitor Checklist accordingly. If oxygen is being used within the same facility as the participant (i.e. retirement home/assisted living) it is fine for them to wear the activity monitor as long as the participant is not sharing a room with the oxygen user. Participants using CPAP can safely use the activity monitor.

Participants with pacemakers/defibrillators/implant devices from the following manufacturers can safely wear the activity monitor: Medtronic, Guidant and St. Jude. This information can be found on the participant's implant identification card. If your participant has an implant device that is not from one of these three places, please email Stephanie Harrison at the Coordinating Center the name of the manufacturer, the serial # and the product # so we can look into it (again this information can be found on the participant's implant identification card). If there is any uncertainty about the safety of wearing the activity monitor with the participant's implanted device then they should be excluded from wearing the monitor. Please see the Appendix for written confirmation from Medtronic, Guidant and St. Jude regarding device compatibility.

The procedure for wearing the activity monitor and the data collection forms (Activity Diary pages) should be explained to the participant while they are in the clinic or over the phone (for SAQ only) and any questions should be answered at that time. Items to be explained to the participant include:

- 1) Wearing the armband - The armband should be worn on the back of the upper **right** arm (the tricep muscle), touching the skin. The skin should be clean. The Timestamp button is located near the top of the device and should be facing up when positioned on the arm. Clinics are welcome to add a sticker to the device to make it easier to remember which way is up. Adjust the straps so that it fits on the arm comfortably, and then secure the oval pull-tab. Ensure that the sensors maintain continuous contact with your skin at all times and that the armband does not slide off the arm. Be careful not to secure it too tightly. Once it fits comfortably you will not need to readjust the strap. The armband should be worn at **all** times except when bathing or performing water sports. If the participant absolutely refuses to wear it while sleeping have them continue wearing it while awake.
- 2) Making sure the armband is on and working- There is no on/off button on your armband. When the device makes secure contact with the arm, it automatically performs a "turning on" sequence. This may take up to 5 minutes for some people.

The sequence is as follows:

- Welcome: Four distinct notes descending in tone (do-de-do-deet). This sound indicates the armband has made contact with the skin.
- Warming Up: Two second vibration. The participant will feel a series of light vibrations as it settles to the body.

- Ready: Three notes (de-de-deet). This sound indicates that the armband is collecting data.
 - In order to check if the armband is working properly, press and hold the Time-stamp button until you here the three note sound (de-de-deet). This means the device is working properly.
 - Once activated, the device will start collecting data while on the participant's arm and will only stop collecting data when removed. Once put back on the participant's arm the device will resume collecting data.
- 3) While wearing the armband- If the armband beeps and vibrates occasionally the participant should not worry about it, however, if it beeps and vibrates often the armband should be tightened a bit.
 - 4) Removing the armband- The armband can be simply slid on and off (again no need to adjust the band). The device should be removed when bathing and/or during water sports (such as swimming or water aerobics). This is to avoid damaging the device and to prevent shock hazard. It is also advised to remove the armband one hour for every 24 hours worn. Make sure both your arm and the sensors are cleaned daily, especially after vigorous exercise. To clean the sensors wipe with a soft damp cloth. If a rash develops where the armband comes into contact with the skin, participant should immediately discontinue use.
 - 5) Things to note:
 - If the "memory" light on the armband is red this means the memory is full. The data should be retrieved.
 - If the "battery" light on the armband is red this means the battery is low. Battery should be replaced immediately. Removal of the battery to install a new one should take no more than 30 seconds or data will be lost.
 - 6) Completing Activity Monitor Checklist – The date and time the armband was initialized should be the date/time patient information was entered into the system. The time the device was activated can be taken from the time stamp on the report that tells what time the device began collecting data. The number of days the activity monitor was collecting data ideally should correspond to the number of diary days. The day the participant puts on the armband will be counted as one day and the day the participant removes the armband will be counted as one day. If a participant wears the device according to protocol this field (#8 on the Activity Monitor Checklist) should be 7 days.
 - 7) Completing Activity Diary - the Activity Diary should be explained to the participant while they are in the clinic or over the phone (for SAQ onlys). Each participant will be provided with a diary to record their wearing of the armband. For the clinic participants the date and day # for each page should be filled out by the clinic staff to aid in correct completion of the diary. For the SAQ only participants the clinic staff should just fill out day # and the participant will fill in

the dates. The form number at the top of the activity diary supplement page corresponds to day. The first supplement page should be form number 2, the second is form number 3, and so on. The first page of the diary is considered to be page 1 and starts the day the armband is put on the participant. The last page of the diary should be filled out the morning the participant removes the armband (the 7th day). If the participant refuses to complete the diary they should still be given an accelerometer to wear and should be encouraged to fill in as much data as possible.

A summary of the above information with critical points should be provided to the participant. An example of an information sheet can be found in the Appendix. The information sheet should be reviewed with the participant before they take it home with them or on the phone with the SAQ only participants. The sheet will provide them with a phone number to call should they have further questions.

2. The participant should begin to wear the armband the day of the clinic visit or in the case SAQ only the day they receive it in the mail.
3. The participant will start using the activity diary on the day of their clinic visit, or for those with SAQ only, the first day they put on the monitor. The last page of the diary should be completed on the morning of the 7th day.

| Armband Start Day | Activity Diary and Data Collection Begins | Armband Data Collection Ends | Activity Diary Ends | Armband Returned |
|-------------------|---|------------------------------|---------------------|------------------|
| Monday | Monday | Sunday Morning | Sunday Morning | Monday |
| Tuesday | Tuesday | Monday Morning | Monday Morning | Monday |
| Wednesday | Wednesday | Tuesday Morning | Tuesday Morning | Tuesday |
| Thursday | Thursday | Wednesday Morning | Wednesday Morning | Wednesday |
| Friday | Friday | Thursday Morning | Thursday Morning | Thursday |

The participant should be instructed on when to begin filling in information using the Activity Diary. They should also be told when it is ok to stop wearing the armband (the morning of the 7th day).

All armbands should be returned either by mail in the provided envelope or drop off or pick up with clinic should be arranged. If possible the armband should be returned within 24 hours from the time the armband was removed on the 7th day.

6. Retrieving Data from the Armband

When an armband is returned after a participant has worn it for the specified time, the data needs to be downloaded from the device to the clinic computer.

If the monitor did not collect data a message will pop up when trying to retrieve the data that states no data was collected. If this occurs the armband needs to be checked to see if working properly. A staff member can wear the armband for ½ hour to see if data is being collected. If the monitor does not seem to be working, please contact Stephanie Harrison at the Coordinating Center.

If the armband collected any data, then it needs to be sent as a .swd file to the Coordinating Center for analysis (this is the default extension).

To Retrieve Data:

- 1) Connect armband to the computer using the USB cable (similar to what was done when initializing the device).
- 2) Double click on the armband icon on your desktop to open InnerView software.
- 3) Click “Retrieve SenseWear Data”. Click “Via USB Cable”. Click “Retrieve”.
- 4) **Unclick the box “Clear SenseWear for next use.” We want to be sure the data is correct and saved properly before we clear the device.**
- 5) Name and save file as “MrOSIDAcroscopic” (using the ID and Acroscopic of the participant who most recently wore the armband, e.g. 10001ABCD). **Save with the extension .swd.**

Once data is saved a screen will appear that summarizes the activity monitor information. Look at this file and make sure the participant ID and Acroscopic are correct (matches the participant who wore the armband), that the number of days are correct, that the armband collected data (if data was not collected a message will pop up), and that the start and end times are correct (check against diary). You can then generate a report by clicking on the Generate Report tab at the bottom of the screen. This report can be given to the participant for their own information.

Once the data file has been saved the armband can be cleared by going to the drop down list at the top of the screen under SenseWear Maintenance and clicking on Clear Data & Subject Info.

7. Sending the Data to Coordinating Center

Please send all data files to the Coordinating Center regardless of the amount of data collected. We will decide if there is a sufficient amount of data or if the participant will have to re-wear the device. If a participant claims to have had ‘atypical’ activity (i.e. hospital stay, travel, etc.) while wearing the armband, please let the Coordinating Center know and we will decide if there are enough ‘typical’ activity days worth of data. If necessary, we will alert the sites to ask the participant to re-wear the monitor. If no data at all was collected the clinic should ask the participant to re-wear the monitor.

Transfer of data will occur via the Coordinating Center's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Authorized users will be given a login id and password.

- Log onto our secure website (<http://ive2.sfcc-cpmc.net/mros>)
- Click on the site specific MROS Accel Activity Monitor folder
- Click on Upload File
- Browse for the file you wish to upload and then click “Upload”

Retain a copy of the file on the clinic computer hard drive until you receive notification from the Coordinating Center that it is ok to delete the file.

If the wrong ID and/or Acrostic were used in the Subject Field (when initializing the device) or when naming the file, please email Stephanie Harrison at the Coordinating Center to let her know this happened and she will take care of it.

The activity diary pages should be kept at the clinic in participant’s chart. The original diary from the participant may need to be transcribed onto a new teleform if the writing will not fax in well. They should be faxed into the Coordinating Center data system.

8. Maintaining an Activity Monitor Log

A log should be maintained at the clinic so that the location of the armbands is known at all times. An example log is included in the Appendix, it can be modified as individual clinics see necessary. A serial number for each armband can be found when initializing the device. This should be used as the Armband ID.

9. Quality Assurance for the Armband

Each interviewer charged with the responsibility of initializing, downloading or any other handling of the Armband will be required to meet performance standards that indicate an understanding of the InnerView software, the SenseWear armbands function, and cautions related to the armband’s sensitive inner workings. Only personnel who meet these standards will be certified and approved to handle the armbands and instruct the participants.

Personnel will be required to attend a training session, or undergo local training by a certified technician. Training will consist of:

1. Overview of Operating Manual
2. Hands-on training for initializing, wearing of the armband and downloading/saving of files. Transfer of the armband data file to CC will also be shown but may not be required for each personnel (this requires a secure web site with limited access.) Each personnel involved with the activity monitor, will be required to wear an armband for one over-night period. They will be required to download/save the file and print out the activity report, and discuss results. There will be a discussion of some common questions from participants, armband problems, battery problems, and other situations that may occur. Monthly activity monitor conference calls are suggested.

3. Besides completing the requirements in the Activity Monitor Certification form, each personnel needs to successfully complete 5 initializations, downloading, file checking, saving to the assigned folder, uploading to the Coordinating Center.

Appendix

SenseWear Armband Information Sheet

Thank you for agreeing to participate in the MrOS Visit 4 Study.

You will be wearing the armband for a number of days and nights in order for us to monitor your activity. Please make sure this week is a “typical” week for you in regards to your activity level.

Things to Remember About Wearing the Armband:

- The armband measures data, such as calories burned, duration and level of physical activity, and sleep/wake states. It will tell us how active you are during the day and how much you sleep at night.
- Appearance of the armband: It is a slim design that minimizes interference with day-to-day activity. It can be worn discreetly under clothing and can be comfortably worn while sleeping, exercising, or during daily activities.
- Wearing the armband: The armband will go on your **right** upper arm held in place by an adjustable Velcro strap. Adjust the straps so that it fits on the arm comfortably, and then secure the oval pull-tab. Ensure that the sensors maintain continuous contact with your skin at all times and that the armband does not slide off the arm. Be careful not to secure it too tightly. Once the straps fits your arm comfortably there is no need to readjust, simply slide it on and off your arm. The armband sensors should maintain continuous contact with your skin when being worn. The armband should be worn at **all** times, except when bathing, participating in water sports, or removing for one hour a day. It should be cleaned daily, especially after exercise, with a soft damp cloth. Make sure arm is clean and free of lotion or other products during this time.
- Do not use the armband in water for this can result in shock hazard.
- The armband will activate when in contact with your arm. This activation may take up to 5 minutes. You will know it is on when you here four beeps, feel a two second vibration, and then hear another three beeps. The device will stop collecting data when removed and start up again this same way when placed back on your arm.
- Do not worry if armband beeps and vibrates occasionally, however, if this happens often then the armband should be tightened a bit.
- Please do not open the tab on the front of the armband.
- You will wear the armband home from the clinic or the day you receive the armband in the mail and start recording the information in your Activity Diary that day.
- Take your armband off in the morning of the last day. Make sure that your Activity Diary information is complete.

- Return of the armband and Activity Diary: We will give you information on when the clinic staff will pick the armband up at your home, or information on returning by mail.
- **Contact Information:** If you have questions about wearing the armband or about filling out the diary, please call:

Appendix

Log for SenseWear Armband _____

| Armband ID | Date Initialized | Initialized By | ID/Acrostic | Date Downloaded | Downloaded By | Date Cleared | Cleared By |
|------------|------------------|----------------|-------------|-----------------|---------------|--------------|------------|
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Appendix

It has been recently confirmed, regarding the below information, that there have been no changes since the last visit.

Email responses from implant device manufacturers regarding the safety of using the SenseWear Activity Monitor.Guidant:

From: Fetter, Patricia (STP) [Patricia.Fetter@guidant.com]

Sent: Friday, April 13, 2007 1:50 PM

To: Harrison, Stephanie Litwack

Subject: RE: SenseWear Armband by Body Media

Importance: High

Hi, Stephanie

Please forgive me for not getting back to you sooner. I just received a notice from our EMI engineer that the Sensewear armband is not contraindicated for our pacemaker and ICD patients. No issues. Therefore, it is safe to be used with patients with Guidant implants.

Best regards,

Pat

St. Jude:

From: McIntyre, Craig [mailto:CMcIntyre@sjm.com]

Sent: Monday, April 02, 2007 10:51 AM

To: Fullman, Robin

Subject: FW: compatibility with pacemakers

Hello Robin,

I have your response below.

Please do feel free to contact me with any additional questions or comments that you may have.

Best regards,

Craig McIntyre

Technical Support Engineer I

Phone: 1-800-722-3774

Fax: 1-800-756-7223

cmcintyre@sjm.com

From: Hamilton, James (R&D)

Sent: Monday, April 02, 2007 10:45 AM

To: Davis, Daryel; McIntyre, Craig

Subject: FW: compatibility with pacemakers

This Bodymedia SenseWear Pro3 armband should not interfere with our devices.

Regards,

James Hamilton

Activity Monitor

Principal Eng.

From: Customer Service
Sent: Monday, April 02, 2007 10:32 AM
To: Customer Service; Hamilton, James (R&D)
Subject: RE: compatibility with pacemakers

Hi James - I just spoke with the director of hardware here and questioned him as you asked - the armband runs on DC so there is no frequency, and the voltage is 1 volt. please let me know if this is sufficient information, or if additional information is required. Thank you!

Susan

Medtronic:

From: Samsel, Tim [tim.samsel@medtronic.com]
Sent: Monday, April 02, 2007 9:07 AM
To: Harrison, Stephanie Litwack
Subject: RE: BodyMedia IEC 60601-01 compliance

Stephanie -- Yes, that should not be a problem. We always recommend that any EMI source be kept as far away from the implant as possible which is why I mentioned using the arm opposite the implant, but based on the Bodymedia device specs there should not be any concern about interference with the implanted device.

Tim

From: Harrison, Stephanie Litwack [mailto:SLitwack@sfcc-cpmc.net]
Sent: Monday, April 02, 2007 10:43 AM
To: Samsel, Tim
Subject: RE: BodyMedia IEC 60601-01 compliance

Hi Tim. thank you somuch for your response. Unfortunately the device can only be worn on the right arm. Do you think this is still ok?
Thank you again for your response.

Stephanie

-----Original Message-----

From: Samsel, Tim [mailto:tim.samsel@medtronic.com]
Sent: Monday, April 02, 2007 7:47 AM
To: Harrison, Stephanie Litwack
Subject: RE: BodyMedia IEC 60601-01 compliance

Stephanie -- I had our EMC expert review the manual you sent me . The BodyMedia device operates with very low power and therefore should not affect Medtronic pacemakers and ICDs. We would recommend that that if possible the armband be worn on the arm opposite to the implant.

Let me know if you have any further questions or concerns.

Regards,

Tim