Version	Who	Date	What changed
1.0	Yasmin	5/10/2017, to v1.1	- Screening section removed (original section 3.4.2) - Two enrollment options included: in-person and via mail were split into two separate sections (new sections 3.4.1 and 3.4.2) - The informed consent could be done via phone when done in mail format (added to section 3.4.2) - Actical figures updated with more current actical software display and entries (section 7.6 and 7.8).
1.1	Yasmin	3/5/2018, to v2.0	- Actical calibration updates to reflect after 5 uses/wears instead of 4 (section 7.11).

NHLBI grant: Ancillary to HCHS/SOL: Cardiometabolic Outcomes in Multi-ethnic Physical Activity & Sedentary Behavior Study (R01 HL136266; Y Mossavar-Rahmani, RC Kaplan, & V Ramachandran)

COMPASS

Study of Latinos – Cardiometabolic Outcomes in Multi-ethnic Physical Activity & Sedentary Behavior Study
HCHS/SOL COMPASS

Field Center Manual of Procedures
(adapted from SOL CASAS Manual)

Version 2.0, February 2018

Study of Latinos – Cardiometabolic Outcomes in Multi-ethnic Physical Activity & Sedentary Behavior Study
HCHS/SOL COMPASS

Table of Contents

1. FOREWORD

This is the manual of operations for the Study of Latinos – Cardiometabolic Outcomes in Multi-ethnic Physical Activity & Sedentary Behavior Study (SOL COMPASS). This manual provides an overview of the study and the interviews conducted as part of the field center study visit, including appendices of forms and question-by-question (QxQ) instructions for questionnaire administration. Table 1 lists the main components of the SOL COMPASS study visit.

Because high quality of data and strict standardization of the study visit and interview techniques among each of the interviewers are essential, it is important that SOL COMPASS personnel be familiar with this manual of procedures. To meet our scientific goals and to make this study a success, all SOL COMPASS personnel must be fully trained and certified in the procedures described in this manual, and must remain standardized through the data collection phase.

To the degree that this is applicable, the description of each interview/exam component in this manual includes a brief rationale for its use, operational procedures, an overview of training requirements and certification criteria, routine quality assurance measures, and data collection procedures.

2. STUDY OVERVIEW

2.1 Objectives

The scientific aims of the SOL COMPASS ancillary study to the HCHS/SOL are to determine whether sedentary behavior & physical activity patterns are associated with 6-year changes in metabolic health and onset of diabetes in HCHS/SOL participants and participants in the Framingham Heart Study (FHS) Third Generation & Omni Gen 2 (FHS Gen3/Omini2) cohorts. Specifically we will: 1) identify physical activity and sedentary behavior patterns associated with conversion to diabetes; 2) identify the relationship between moderate-to-vigorous physical activity, light physical activity and sedentary behavior with incident cardiovascular events and mortality, in order to define the magnitude of risks and dose-response for duration, intensity and bout length; 3) investigate demographic and psychosocial correlates associated with six year changes in patterns of physical activity and sedentary behavior in Hispanic/Latinos & non-Hispanics/Latinos with prediabetes.

2.2 Background

SOL COMPASS is an ancillary study of participants from all four sites (San Diego, CA, Chicago, IL, Miami, FL, and Bronx, NY). From March 2008 to June 2011 (Visit 1, "baseline"), the HCHS/SOL enrolled 16,425 male and female adult participants between the ages of 18 and 74 years from four field centers located across the U.S. The purpose of the parent study is to determine the prevalence and incidence of cardiovascular disease and other chronic conditions, and to identify risk factors playing a protective or harmful role in these conditions, in Hispanics/Latinos. Participants eligible for SOL COMPASS include those who participated in the HCHS/SOL Visit 1 who are returning to complete the HCHS/SOL Visit 2 or have completed Visit 2. All should have accelerometry data considered adherent from visit 1.

Table 1. Outline of SOL COMPASS Study Visit, with Reference to the Corresponding Study Form Codes

Visit Components	Form Code
Pre-visit screening (eligibility)	CEP
Informed consent	ICT
Interviews:	
Physical Activity	PAE/PAS
Accelerometry	
Actical Physical Activity Device	
Activity Feedback Form	CFE/CFS

3. RECRUITMENT

3.1 Overview

SOL COMPASS is a study of Hispanic/Latino adults participating in HCHS/SOL and is funded by the National Heart Lung & Blood Institute (NHLBI).

3.2 SOL COMPASS Study Sample

The study aims to recruit 4,760 Hispanic/Latino adults who completed the HCHS/SOL clinic Visit 1 and are completing Visit 2 at all HCHS/SOL sites and who self-report at SOL COMPASS screening that they do not have diabetes.

3.3 Recruitment Plan

Recruitment for SOL COMPASS will coincide with recruitment for Visit 2 of the HCHS/SOL parent study starting in February 2017 until September 2017. Afterwards, COMPASS will continue until February 2020. The recruitment plan is discussed further in the Recruitment Steps section.

3.3.1 Monitoring and Mid-course Corrections

The SOL COMPASS recruitment period is 36 months in duration. The study will monitor the recruitment rates on an ongoing basis. Adjustments to the recruitment procedures may occur as a result of this monitoring and are referred to as mid-course corrections.

3.4 Recruitment Steps

3.4.1 Visit approach

Participants can be approached at visit 2 at the clinic for participation. Interested participants will be administered Section 1 of the Eligibility/Participation Checklist (refer to COMPASS study web site) to determine eligibility. Once it is determined that an individual is eligible to participate in SOL COMPASS, he/she will be invited to participate. Eligible participants who agree to participate will be given the option of enrolling in SOL COMPASS and starting study activities on the same day after completion of the HCHS/SOL Visit 2 or at a separate visit.

3.4.2 Mail approach

Staff will mail the SOL COMPASS invitation letter as well as informed consent forms to participants who have completed visit 2. The invitation letter provides information about the SOL COMPASS study to the HCHS/SOL participant, including the study site address and phone number to visit or call if they are interested. (See SOL COMPASS web-site for these materials and phone recruitment script.) Once enrolled in the study, the actical will be mailed to them along with a pre-addressed stamped mailer to use to return the actical.

For these participants, informed consent will be administered over the phone.

3.4.3 Phone Calls

Phone call attempts will be made in conjunction with HCHS/SOL Visit 2 scheduling phone call attempts. Each call attempt should be noted in the SOL COMPASS CDART database. If a HCHS/SOL participant wishes to be contacted about SOL COMPASS at a later time, the recruiter should note the best day and time to reach him/her. The participant should be contacted again on the day and time specified. If the individual does not respond at that time, it should be noted, so that a SOL COMPASS research assistant could follow up with him/her during Visit 2.

3.4.4 Reporting Screening Outcomes

Recruitment staff is responsible for completing page one of the Eligibility/Participant Checklist (CEP) prior to when the individual arrives at the SOL COMPASS site for his/her HCHS/SOL Visit 2. If a HCHS/SOL participant is undecided about participation in SOL COMPASS, a note should be made in the notes section of the CEP and a SOL COMPASS staff member should follow up with the participant the day he/she completes the HCHS/SOL Visit 2.

The information on the CEP form should be entered into the SOL COMPASS CDART 2 data management system live or within 48-72 hours after data collection. Data entry for this form is important for coordination between the SOL COMPASS sites, and the Coordinating Center; the latter will use these data to monitor the recruitment process.

3.5 Forms

3.5.1 Eligibility/Participation Checklist (CEP)

The Individual Eligibility/Participation Checklist (CEP) includes the script for determining a participant's eligibility. The participant's eligibility and participation status are recorded in sections 1 and 2 of the form. Sections 3 and 4 are completed the day of the SOL COMPASS study visit. Recruiters are responsible for verifying that all individuals meet the eligibility criteria for inclusion in the study. Refer to the CEP QxQ (refer to COMPASS study web site) for further instructions on how to complete the form.

3.6 Eligibility Criteria

A HCHS/SOL participant is considered eligible to participate in SOL COMPASS if he/she has completed HCHS/SOL Visit ,1considered adherent with respect to accelerometry data) has completed the HCHS/SOL Visit 2, is not diabetic and can walk one block without help. Refer to the CEP QxQ for further clarification on the type of assistance that would determine an individual ineligible for participation in SOL COMPASS.

3.7 Recruiters

3.7.1 Overview

Recruiters will be knowledgeable of the HCHS/SOL and the SOL COMPASS ancillary study. Recruiters must have the ability to develop and maintain a positive demeanor with the participant, should be non-judgmental, and be able to establish trust. It is important that the recruiter always maintain a professional and friendly demeanor. Recruiters are required to read the study manual of operations and review all pertinent recruitment materials. They also need to review and understand the recruitment flow chart and understand the reasons for ineligibility. In addition, recruiters will be expected to maintain their IRB certificate current and be able to demonstrate knowledge of the IRB regulations.

3.7.2 Training

All recruitment staff will be provided with adequate training prior to their first contact with potential SOL COMPASS study participants. The following are the certifications that the SOL COMPASS study recruitment staff needs to complete.

- Human Subjects Protection
    - Overview of principles, regulations, and policies which affect research involving human subjects in research
- General Interview Techniques
    - Overview of questionnaire administration and interviewing techniques

- Recruitment and Screening
    - Overview of recruitment and screening process for the SOL COMPASS study
- Web-based Data Management System
    - Overview of the CDART2, data entry, and training on the use of SOL COMPASS study forms

3.7.3 Privacy and Confidentiality

Confidentiality in research means keeping the information that the participant provides during the study private. It is very important that recruiters remind participants that all information collected is confidential and protecting their privacy is a priority to the study.

Because of the risks involved with a breach of confidentiality, it is very important to implement appropriate confidentiality procedures to protect information collected from participants in research studies. Adherence to general protocol guidelines helps to protect the confidentiality of information provided by participants during a research study. These include:

- Carefully store research materials in locked filing cabinets and do not leave them unattended on desktops or in unlocked filing cabinets.
- Use password protection, log off, and shut down your computers when leaving your workstation for any length of time.
- When referring to participants, use their study ID number.
- When transporting study materials (completed forms), remove the materials from car as soon as possible to avoid loss, theft or damage.
- When working with participants from the community, do not discuss their participation in the study with family and friends or other members of your community.
- Remove any information that will identify the participant when study materials are stored for future analysis.

3.7.4 Professional Ethics and Participants' Rights

As a recruiter, there is a professional responsibility to adhere to the highest possible standards of ethical practices and to protect the rights of the participant. Each recruiter is responsible for taking and passing the required Human Subjects Protection course through his/her institution. As a professional it is important for the recruiter to make sure that individuals understand what is involved when participating in a study and are able to ask questions before and during their voluntary participation. Any study participant has the right to autonomy, privacy, and the freedom of action.

3.7.5 Using Scripts

A script is provided for uniformity and standardization during the screening process. The script needs to be followed in order to maintain consistency. Deviations to the script may occur when potential participants ask questions about the study.

4. RECEPTION

All participants will be received in the main HCHS/SOL Visit 2 reception area. Participants will be received according to the procedures outlined for the HCHS/SOL Visit 2. If a HCHS/SOL participant expressed an interest in participating in SOL COMPASS or expressed uncertainty towards participating in SOL COMPASS, his/her information will be transferred to the Eligibility-Participation Checklist (refer to COMPASS study web site). Throughout the participant's HCHS/SOL Visit 2 examination, he/she will be presented with opportunities to hear more about SOL COMPASS and talk to a SOL COMPASS research assistant about any questions he/she may have. If the participant agrees to participate, the HCHS/SOL Visit 2 staff will work together with the SOL COMPASS staff to coordinate the completion of the SOL COMPASS informed consent and study visit components. If a participant is uncertain about participating in SOL COMPASS, he/she will be provided with a copy of the informed consent and a follow up phone call will be made to see it the participant has additional questions about participating in SOL COMPASS.

5. INFORMED CONSENT

Informed Consent is the first data collection form administered during the SOL COMPASS visit. The informed consent and its content meet the requirements of the respective Institutional Review Boards.

The primary objective of administering informed consent is to inform the individual of the SOL COMPASS visit procedures, protect the rights of the study participants, and meet local Institutional Review Board requirements. The informed consent makes the study participants aware of their right to withdraw from the study or to decline to answer question(s) without penalty.

5.1 Administration

The purpose of the study activities should be reviewed with participants. Informed consent forms are available in Spanish and English, and bilingual SOL COMPASS personnel should be available to review and administer the forms.

After introducing the informed consent form to the participant in a private area, the SOL COMPASS study personnel will ask whether the participant prefers to read the informed consent form or to have it ready by SOL COMPASS study personnel. Study personnel will review the informed consent with the study participant in great detail. Questions are encouraged and time will be allowed for the participant to read and sign the informed consent document in the presence of SOL COMPASS personnel serving as witness. Inform consent must be obtained before all other SOL COMPASS study visit components can take place.

The original informed consent document is filed in the participant's study folder. A copy of the informed consent is given to the participant before he/she leaves the clinic.

6. INTERVIEWS

Interviewing is a collaboration between the SOL COMPASS staff and the study participant to collect study data using standardized techniques. This section presents a general description of interviewing for SOL COMPASS.

Interviews in SOL COMPASS are administered in English or Spanish, at the preference of the study participant, by trained and certified personnel who are bilingual. Interviewers are administered using the SOL COMPASS CDART 2 Data Management System, which provides quality assurance features such as missing fields checks. The most important factors that tend to influence both the participant's satisfaction and the quality of the interview data are the interviewer, his/her interviewing skills and overall adherence to the study protocol.

6.1 Characteristics of a Good Interview

Interviews tend to be friendly but businesslike. At the beginning of each encounter the interviewer makes introductions and verifies the participant's name. Participants are always thanked at the conclusion of the interview session. Interview areas should be as quiet and private as possible.

Interviews are the structured, one-sided transfer of information, not a conversation. The pacing of questions is based on the comfort and comprehension of the participant with each interview; it may vary as the content, complexity or period of recall of the person or subject matter changes. During an interview, questions from the participant are answered with neutral, nonjudgmental responses and questions to the participant are limited to probes to clarify or resolve incomplete, ambiguous or inconsistent responses. Repeating a question is most appropriate when the participant does not appear to understand the intent or meaning of the question. Gently stressing the portion of the question that was not understood when the question is repeated is often more efficacious than re-reading it in exactly the same manner.

6.2 Characteristics of a Good Interviewer

Interviewers are responsible for being fully familiar with the questions, response categories, and skip patterns of each interview. At the beginning of an interview the study participants may wish to be reassured of the confidentiality of each response/measurement. Interviewers use a conversational tone and establish a pace consistent with the engagement and comprehension of the participant. A good interviewer projects the importance of the interview to the participant and attempts to gain his/her confidence, while remaining impartial and nonjudgmental. For example, a verbal response (or body language when the interview is being conducted in person) that indicates positive feedback is inappropriate.

6.3 Communication Traps and Obstacles to Standardization

Communication traps include: (1) anticipating or answering questions directed to the participant with the interviewer's own thoughts; (2) hearing what one expects to hear; or (3) being drawn into a conversation. Questions thought to be "sensitive" should be asked in a neutral manner that does not differ from the normal professional flow of the interview.

The most frequent obstacles to the administration of a standardized interview are: (1) a perceived conflict by the interviewer between the need to standardize the question with the desire to obtain the truth; (2) a conflict between the interviewer's desire to achieve rapport with the participant and adherence to standardization; (3) inadequate training of the interviewer; and (4) inadequate "training" of the respondent.

6.4 Interviewer Bias

The use of standardized interviewing techniques is employed to reduce one of the many potential sources of misclassification; i.e., interview bias, a *systematic* difference between responses obtained by different interviewers. Although introductory scripts may be modified to respond to

different situations an interviewer may encounter, administration of each question exactly as written and use of standardized definitions or explanations are critically important to avoid bias.

6.5 Conducting the Interview

Interviewers must keep in mind that the interviewee is not familiar with the questions, their sequence and response categories. Many interviews require the interviewer to "train" the respondent, mostly using verbal instructions and at times using response cards handed to the study participant. For example, responses may follow a series of patterned questions, e.g., a doctor diagnosed condition, age at onset, and age at treatment during the participant's lifetime or may require the selection of the most appropriate category from a series of descriptors, e.g., almost never, sometimes, often and almost always. Unless a response card is used, these instructions should be repeated until it is clear that the respondent understands them, and then subsequently offered only as needed. When the pattern of questions in a form changes to another repeated sequence of responses the interviewer should assist the study participant in making this transition.

The most important technique for conducting a rigorously standardized interview is to read the question in the exact words and in the exact sequence as printed in the questionnaire. With experience the interviewer can memorize specific questions. This helps in maintaining eye contact with the study participant, but care must be taken to avoid changing the wording of the question(s) that are not being read. The review of taped interviews assists in maintaining standardization in that it can alert interviewers who inadvertently change the wording of a question. Every question must be asked, even if the participant appears to have provided the information in the answer to another question. If based on a previous answer a question is asked out of the printed sequence, a skip pattern instruction presented on the monitor screen (or printed on the form).

Reading the transition statements exactly as they are worded is equally important in maintaining standardization. The transition statements are designed to inform the participant about the nature of a question or a series of questions, to define a term, establish a time frame or describe what is being asked in the question.

Response styles of an interviewer influence the willingness of the participant to respond to questions and the quality of the response. Inappropriate styles include those that are evaluative or judgmental, interpretive, or pedantic. Interrupting responses for reasons other than to focus or channel the participant's answer should be avoided.

Appropriate styles of interviewing include providing neutral utterances to reassure, pacify or reduce the intensity of the respondent's feelings. Examples include an understanding murmur, as well as nondirective or understanding statements such as a repetition of what the respondent has just said (in contrast to paraphrasing). These behaviors are intended to reassure the participant or show interest without intruding on the flow of the response.

Probing is appropriate to seek further information, provoke further discussion along a certain line of thought or explanation, or to present a question to the respondent. In general, and unless specifically countermanded in the QxQ instructions of the interview, probing is appropriate when an answer is unclear, incomplete, inconsistent or no response is given. The best and most frequently employed probe is silence. In a silent probe, the interviewer pauses or hesitates and looks to the participant for an answer. What appears to be dead time to the interviewer may allow the participant to review a lifetime of events.

Other types of probing include repetition of the original question, channeling ("tell me more about..."), clarification ("when did your doctor tell you that?"), elaboration/ continuation ("what happened next?"), encouragement ("I see, um, uh-uh") and completion ("anything else?"; "can you tell me anything more about that?").

The most effective, spoken probes are neutral, such as:

"How do you mean that?", instead of "Why?"

"Can you tell me more about this?"

"Can you give me an example?" or "Can you explain that in a little more detail?"

"How are you using that term?"

"If you had to choose, which would you say?"

"What else can you tell me about that?" instead of "Anything else?"

The cautions in using probes are similar to those for the other interviewing techniques: do not interrupt; do not give the impression you are not listening; do not paraphrase the respondent's words; do not change the question; and do not suggest an answer.

6.6 Quality Assurance

6.6.1 Interview Observations

All SOL COMPASS interviewers will be observed once a year to ensure interviewing techniques are in accordance with the study protocol except for the first month when they will be observed twice. The SOL COMPASS interviewer will ask the participant for permission before the observation, being sure to stress that the observation is for quality control purposes only. After the first observation, the interviewer will be given feedback that includes strengths and improvement areas that will be an area of focus for the second observation. If the interviewer does not show improvement at the second observation, the quality assurance observer will track the staff member for additional observations until improvement is made.

7. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

7.1 Rationale

Study participants will wear a portable motion sensor (i.e., accelerometer) to measure the frequency, duration, and intensity of physical activity over 7 days. The accelerometer provides an objective measure of physical activity that will supplement the interviews for self-reported regular physical activity. SOL COMPASS staff will give each participant the instructions for wearing the device near the end of the SOL COMPASS study visit and provide each participant with instructions on how the device should be returned to the SOL COMPASS sites.

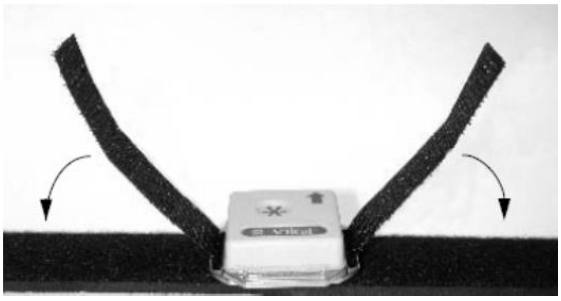
7.2 Technical Information about the ActiCal Accelerometer

The ActiCalTM (MiniMiter Respironics®, Bend, OR) accelerometer (model 198-0302-00) is a small, lightweight motion sensor that is attached to a belt and worn on the body. The Actical device measures the occurrence and intensity of motion in all directions by generating an electrical signal proportional to the force of the displacement. A microprocessor inside the accelerometer digitizes the signals, sums and stores them as "activity counts" over a user-defined time interval that can be as short as 1 second. Data can be collected and stored for approximately 6 weeks before being downloaded for data analysis. In addition to the activity counts per unit of time, the average time spent in light, moderate, and vigorous activity can be estimated.

7.3 Protocol

SOL COMPASS staff will give the participant an accelerometer following the administration of study visit questionnaires. Study staff will select the appropriate size waist strap for the participant. The waist strap should be about 2-3 inches greater than the participant's waist.

Thread the Actical unit onto the waist strap as pictured below. With the belt loop on the right, the orientation of the arrow on the monitor should be facing up.

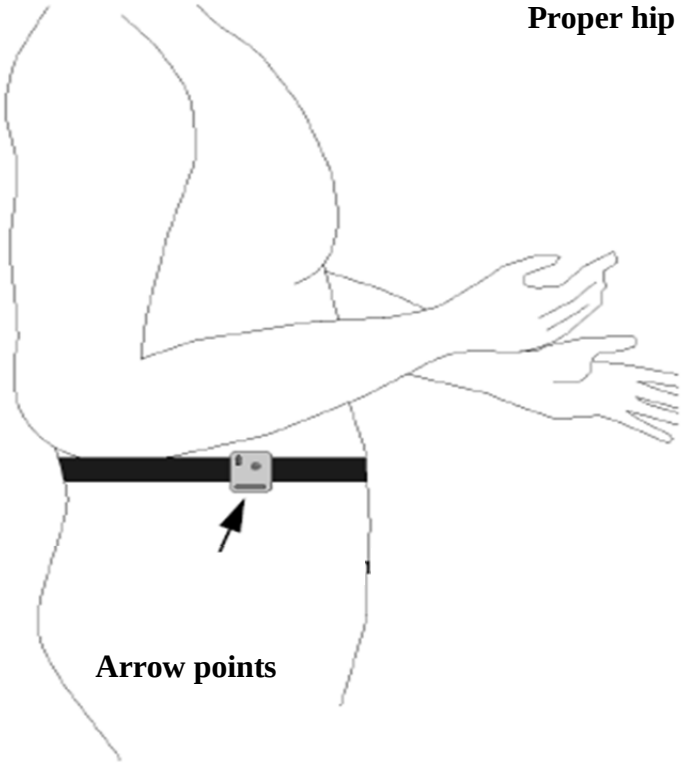


Study staff will briefly describe the purpose of physical activity monitoring (please see COMPASS study web site for a sample script) and ask participants to undertake their normal activities for the week while wearing the monitor. Staff will emphasize that participants should <u>not</u> engage in activities that they ordinarily would not engage in, specifically because they are wearing activity monitors.

Staff will demonstrate how the device is worn, and specify that it is worn over the right hip on the waist strap. The belt should be mounted on the body so that the device rests on the iliac crest (the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis) of the hip with the arrow pointed up (toward the head). The Actical should be snug against the body (but not tight) so that it does not bounce around. The unit can be worn underneath or on top of clothing, whichever is most comfortable to participants. During the SOL COMPASS study visit, participants will practice putting the monitor on properly with study staff present to provide feedback.

Generally, based on best research practices recommendations, we will measure 7 days of recording so that we can capture intra-individual variability in total, moderate and vigorous activity and increase the likelihood of capturing at least four days of activity—the length at which reliability is at least 0.80. Participants are asked to wear the accelerometer continuously over 7-days and to remove it only for swimming, showering, and sleeping.

Figure 1: Proper placement of the Actical



Participants are told that a staff member will call them two times during the week to answer any questions or concerns about the device and to make sure that the instructions are clear. The phone call also provides staff with the opportunity to remind participants to wear the monitor continuously. Before leaving the SOL COMPASS study visit, staff will give participants a brochure (refer to COMPASS study web site) with instructions for using the Actical. This pamphlet will also include the date indicating when the participant should stop wearing the device. Participants will be given the option of returning the Actical device to the SOL COMPASS sites or having a staff pick up the device from their home. Staff will call participants again two weeks after completion of the recording period if their accelerometer has not been returned to the examination clinic.

Please see COMPASS study web site frequently asked questions about the accelerometer device.

A sample Actogram will be showed to participants the day of the study visit when they are

being fitted with the device. This sample Actogram will help research staff convey to the participants the type of data the device will be collecting as well as the importance of adherence. During the study visit, participants are told that they can request a copy of the actogram when they return the device after the seven days.

7.4 Equipment and Supplies

The following items are needed to conduct the accelerometry portion of SOL COMPASS:

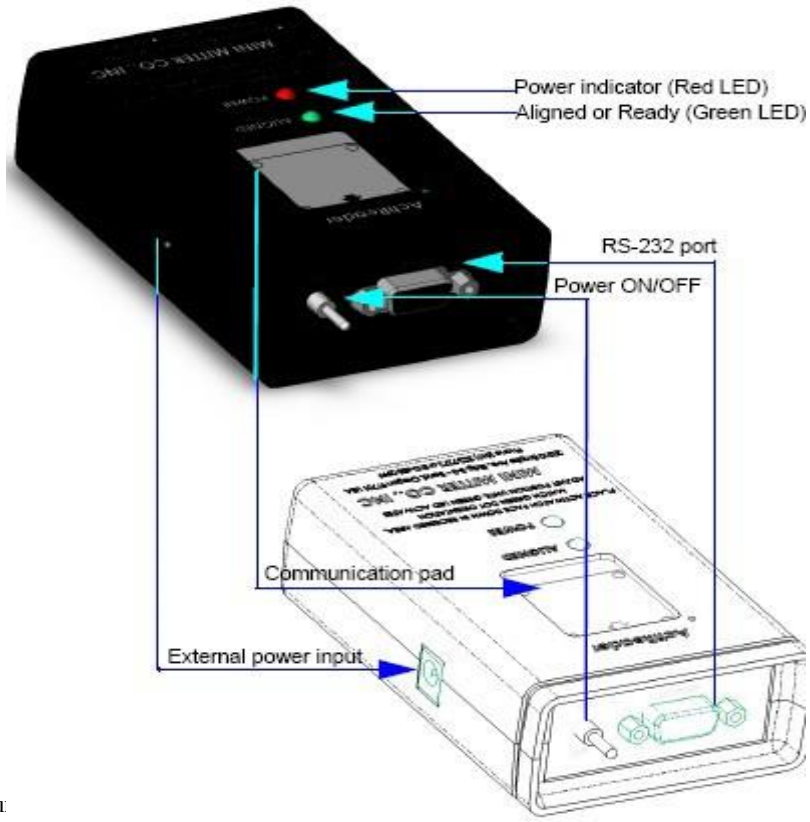
- Actical devices
- Waist straps of varying sizes
- 1 ActiReader units
- Cables with USB adapter for connecting the ActiReaders to the computer
- Actical software v2.12 to load onto the study computer
- User's manual for the Actical
- "O-rings" (to be checked when replacing batters)
- CR2025 lithium coin cell ion batteries

The ActiReader will be connected to the study computer. The computer does not need to be dedicated to collecting the accelerometry data; however, it should be available whenever units are returned so that data can be downloaded and stored when the units are received.

7.5 Initial Hardware and Software Set-up

Actical software must be installed on each PC (laptop or desktop) that will be used for initializing and reading Actical data. Detailed installation instructions are provided in the Actical User's Manual found online. A hard copy should be present at each field center and the coordinating center.

Figure 2: The ActiReader Device



1. Install the Actical software by loading the installation CD into your drive and follow software installation instructions.
2. Connect one end of the serial communication cable to a USB COM Port on the PC and the other end to the ActiReader (Figure 2). As soon as the reader is plugged into the PC, a window should pop up saying which COM Port you are connected to (e.g., COM 2).
3. When you first open the Actical 2.12 software, go to Reader > COM Port and select the appropriate port number (e.g., COM 2)

4. Test the ActiReader set by selecting: Reader > Test Reader. Follow the prompts through the test procedure. If the test fails, follow the prompts to correct the problem.
5. If the Belkin adapter cable is not recognized and you are using a 64-bit Windows 7 system, you may need to download a special driver).

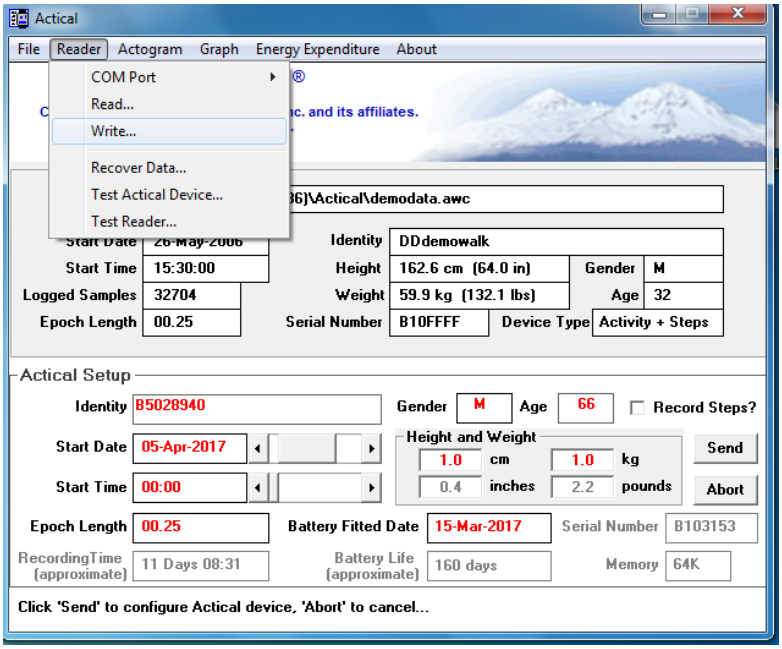
This procedure should be repeated for each computer/ActiReader used in the study.

7.6 Initializing the Actical Device

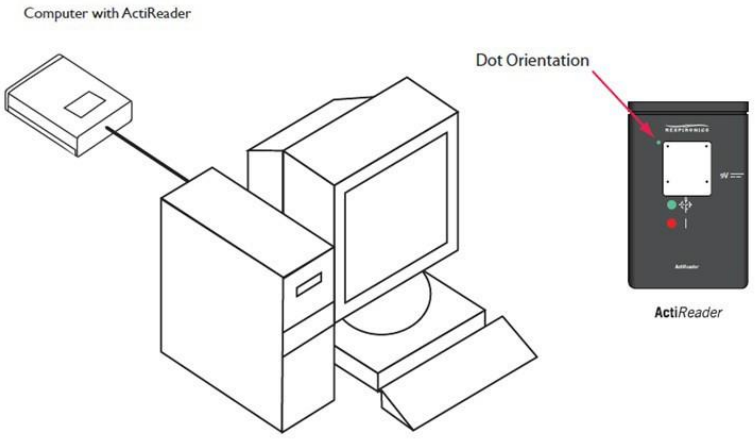
Initialization of the Actical device should not take place before the participant arrives to the SOL COMPASS sites. Once the participant arrives, the study staff should select an Actical and record the monitor serial number and participant ID in the accelerometry tracking log. Then the study staff should initialize the accelerometer using the following steps:

Each Actical device must be uploaded with set-up information (initialization) prior to collecting data. This is done within the Actical 2.12 software and then loaded onto the Actical device using the ActiReader.

1. Open the Actical main window and select Reader > Configure Actical, and follow the prompts that alert you that setting up a device will erase previously stored data.

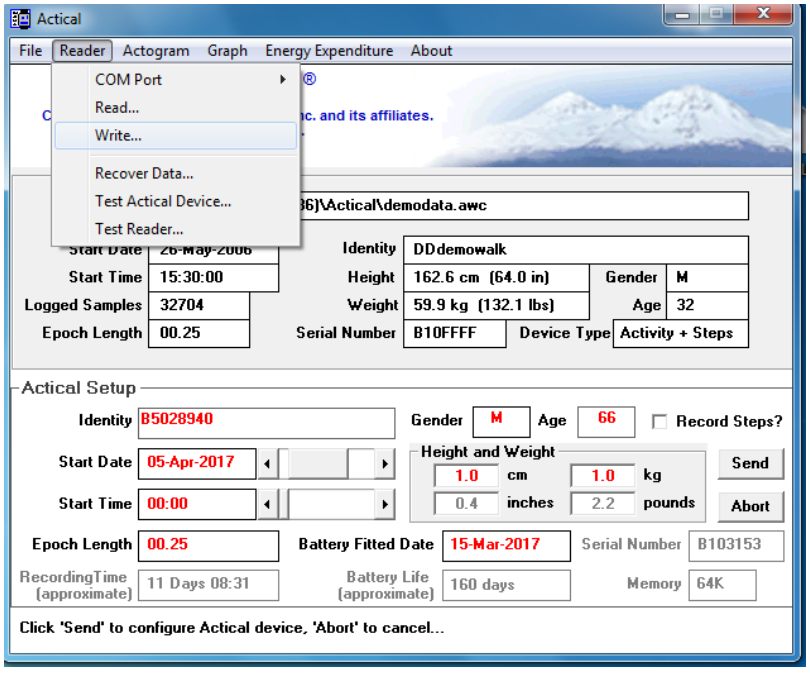


2. Click “Yes” in response to the question “Do you want to continue?”
3. Place the Actical device on the ActiReader by aligning the green dot in the metal back of the communication pad, the green LED will light up. The “communication” bar at the bottom of the screen will demonstrate a connection.



4. Click “Okay”.
5. Check the battery life displayed under the battery fitted date. If the value is less than 5 days, then replace the battery even if the battery was not scheduled to be replaced.
6. Under “Identify”, enter the participant ID number. Enter gender and age as appropriate. The start date should be the next day’s date and the start time should be entered as 00:00 (midnight). Epoch length should be set to 0.25 (which is 15 seconds). Enter 1.0 for height and weight because these values will not be used for SOL COMPASS.

    - The participant should leave the study visit wearing the actical device even though the device will not be recording any data until midnight of the day of the visit. This is so that staff can observe that the participant is wearing the device correctly and to ensure that data will be collected in the event that the participant is still awake and moving about when midnight approaches. The participant should not be told that the device is not collecting data when they put it on.
    - For example, if a participant arrives and completes the study visit on 4/5/2017, the start date and time would be set as follows:



7. When all the information has been entered, click “Send”. The information will be sent to the Actical device.
8. The initialization progress will be shown by the red bar at the bottom of the window. Remove the device from the reader, put it back in the plastic case, and label the case with the participant ID number. The case should then be stored with the participant chart until the time of the COMPASS study visit.
9. During the study visit, staff will place the Actical device on a belt for the participant to wear. The participant should start wearing the device during the visit. The staff should demonstrate to the participant how to put on, wear, and remove the belt as outlined in the brochure (refer to COMPASS study web site).
10. Arrangements for the return of the accelerometer should established at this time.

7.7 Instructions for using the Accelerometer

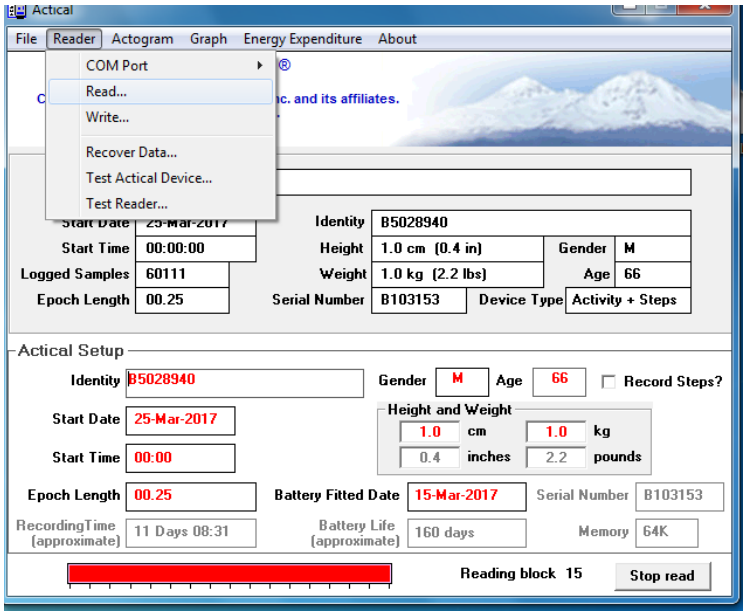
A brochure (refer to COMPASS study web site) with instructions for the use and return of the accelerometer should be given to the participant before he or she leave the SOL COMPASS sites and should include the following points:

1. What the accelerometer is and what it records;
2. Importance of wearing it every day, all day;
3. Proper placement of the accelerometer;
4. Importance of returning the accelerometer promptly;
5. Expect telephone calls two times during the week following the clinic visit to make sure the participant is wearing the accelerometer and understands the instructions;
6. Expect telephone call to check up on the return of the accelerometer if it is not received back within two weeks of completing the protocol.

7.8 Downloading the Data

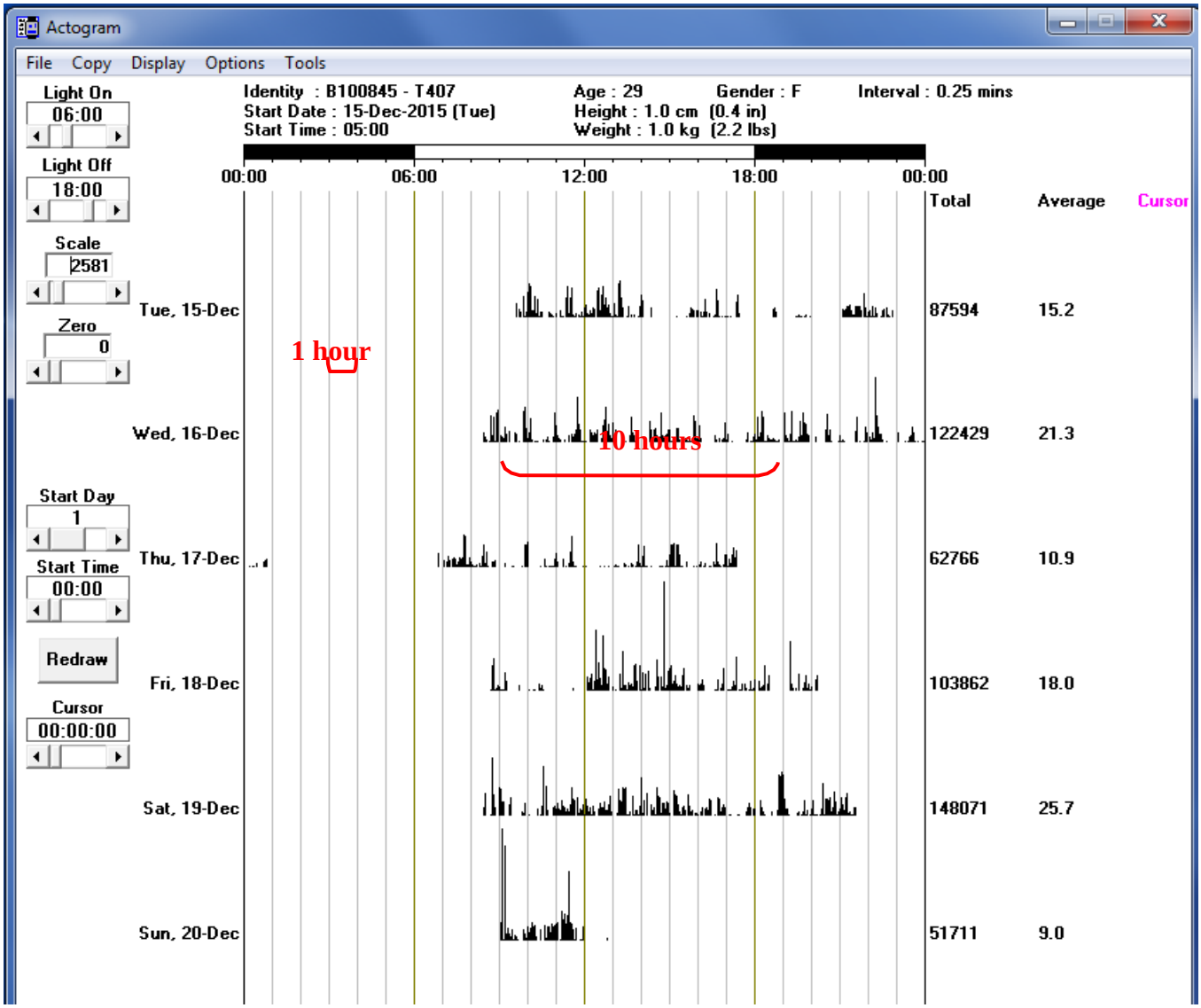
As soon as the accelerometer is returned, download the data. This should be done on the same computer on which the accelerometer was initialized.

1. Place the device into the ActiReader and open the Actical 2.12 software.
2. Click on Reader > Retrieve Data from Actical. The data download will be shown by the red progress bars at the bottom of the window. A prompt will tell you when the download is complete.



Once the download is complete, a window will appear stating "Actical Data Read Successfully". Click "Save Data Now", assure that the file name is appropriate (select the default name, but remove the "list" part. Therefore, the file name is the participant ID and will have the extension awc). Select the appropriate location (shown below) to save the file to. After saving, navigate to the folder to assure the .AWC file was saved appropriately.

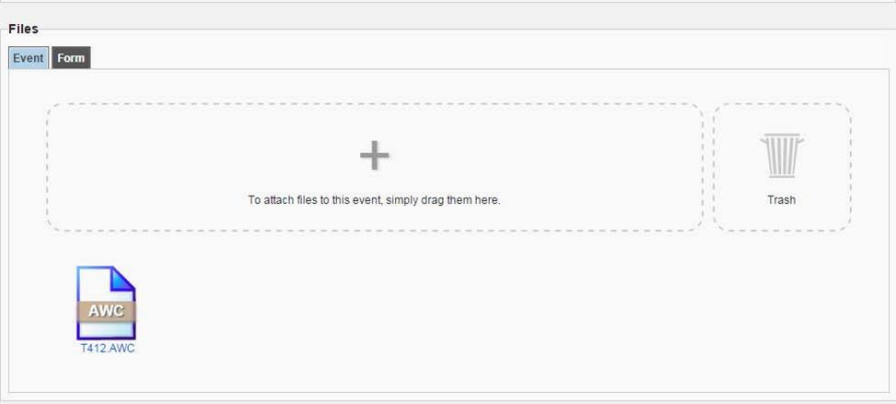
3. Next, check to assure that the participant wore the device for the required minimum wear time of at least 4 days with at least 10 hours per day.
    a. Click on Tools > Actogram.
    b. Count how many days have at least 10 hours of wear time. Each vertical grey line that extends from the top to the bottom of the window represents 1 hour. The vertical black lines within each day show movement and indicate the times when the device was worn. When there are no vertical black lines, it means the participant was not wearing the device. In general, you should identify, for each day, where the black lines start and end, and calculate the time frame (i.e., number of hours) between those start and end points. The only exception to this method of calculating wear time is that gaps of over 120 minutes of non-wear (i.e., no lines) in the middle of the day should be excluded from the total wear time calculation.
    c. If the participant has not worn the device for at least 10 hours per day on at least 4 days, they should be asked to rewear the device for 7 more days. Note that a new device will need to be initialized to collect data again. So you will need to initialize another device and give it to the participant before he or she leaves the field center.


Actogram
File Copy Display Options Tools
Light On
06:00
Light Off
18:00
Scale
2581
Zero
0
Start Day
1
Start Time
00:00
Redraw
Cursor
00:00:00
Identity : B100845 - T407
Start Date : 15-Dec-2015 (Tue)
Start Time : 05:00
Age : 29
Height : 1.0 cm (0.4 in)
Weight : 1.0 kg (2.2 lbs)
Gender : F
Interval : 0.25 mins
00:00
06:00
12:00
18:00
00:00
Total
Average
Cursor
Tue, 15-Dec
87594
15.2
1 hour
Wed, 16-Dec
122429
21.3
10 hours
Thu, 17-Dec
62766
10.9
Fri, 18-Dec
103862
18.0
Sat, 19-Dec
148071
25.7
Sun, 20-Dec
51711
9.0

7.9 Transmitting Data to the Coordinating Center

Actical files will be sent to the Coordinating Center by uploading the files to CDART.

1. Go to the CDART website and log in: https://cdart2.cscc.unc.edu/CDART2/login.jsp.
2. Use the search box to find Subject's ID. Click on the subject's ID to open the forms.
3. Click on "edit form" (the red pencil icon) for the (CEP) COMPASS Eligibility form.
4. Click and drag your chosen file from the Actical Data folder to the event area.
    a. Once the file is uploaded, it will appear below this area.
    b. To discard this attached file, simply drag it to the defined "Trash" area.
5. Click on save when the chosen file is uploaded to the appropriate subject's COMPASS Eligibility form.



7.10 Equipment Maintenance

7.10.1 Cleaning

The Actical devices should be disinfected after each participant use by wiping the surface with a non-alcohol based germicide such as Lysol disinfectant wipes. Cleaning should only be carried out when the battery cover is in place and fully sealed.

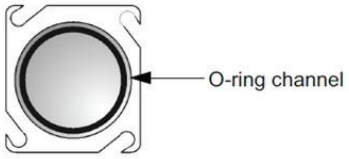
Waist straps should be rinsed in a cleansing solution such as Tide and hang to dry after each use.

7.10.2 Battery Replacement

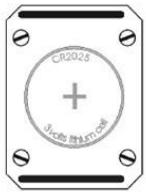
The Actical unit runs on a CR2025, 3-volt, 220-m-Amp-hour Lithium Manganese cell battery. The battery is required for data collection, reading, and writing. Although stored data are not lost after the battery has run down, it is important to change the batteries after every other use. A battery indicator light on the reading device will display a green light when the battery is charged. A log of battery changes should be kept for each Actical device.

The steps are as follows:

1. Remove the strap from the watch and use the flathead screwdriver to loosen and remove the 4 screws on the slots in the battery cover of the device.
2. Turn the cover clockwise to display the battery (if the screws are loosened). Life the cover off if the screws are removed.
3. Remove the battery and discard.
4. Clean the O-ring channel with a dry, lint-free cloth (DO NOT USE ALCOHOL).

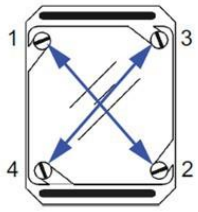


5. Place the clean O-ring into the channel on the back cover by pre-stretching the O-ring by gently flexing it in several directions. Be sure that it is properly sealed in the channel and is not twisted or deformed.
6. Place a new battery into the Actical case, positive (+) side up.



7. With the green dot in the upper-left corner and the back cover upright to the able to read the wording, rotate the back cover counterclockwise until the slots in the back are firmly sealed around the screws and the back is square with the case (or replace the cover and screw it firmly back on).
8. Tighten all 4 screws in an "X" pattern until snug.

CAUTION! DO NOT over-tighten the screws. They can be stripped easily.



9. Test the Actical battery by placing it on the ActiReader. A green LED light indicates successful battery placement and installation.
10. Record the Battery Fitted Date in the ActiCal set up.

For any technical questions or product support, please contact Philips Respironics at 1-800-685-2999.

7.11 Quality Control

It is important that each Actical unit not be worn more than 5 times since the quality of data collected can diminish after 5+ uses. The number of times an Actical unit is used will also be tracked in the Inventory log to ensure it does not exceed 5 uses. After 5 wears, remove the Actical from circulation by placing it in the box labeled "Acticals used 5 times in SOL COMPASS".

8. EXIT INTERVIEW

The end of visit debriefing provides an opportunity to ask for feedback about the visit and to identify aspects that the participant may have perceived as stressful or unpleasant. It also provides an opportunity to further develop rapport with the study participant and to seek commitment for a long-term association with SOL. The participant is reminded of the follow-up call (in about 3 days) and the call can be scheduled at that time. The participant will also be asked if he/she prefers to bring the device back to the SOL COMPASS sites or mail back the device in the mailer.